Volume 4, Issue 2 Fall 2010

Health Law & Policy Brief

American University
Washington College of Law

Health Law & Policy is printed in accordance with the standards established by the Forest Stewardship Council (FSC) that are designed to eliminate habitat destruction, water pollution, displacement of indigenous peoples and violence against people and wildlife that often accompanies logging. Achieving FSC Certification requires that every step of the printing process, from lumber gathering to transportation to printing to paper sorting, must comply with the chain of custody established by the FSC which runs a strict auditing system to maintain the integrity of their certification process.

Currently, FSC Certification is one of four methods a publisher can employ to ensure its publications are being produced using the best responsible practices. It is also the method practiced by our printer, HBP, Inc. (FSC Chain-of-Custody Certification: SW-COC-002553). *Health Law & Policy* is printed using vegetable based inks, formulated to reduce use of petroleum distillates and volatile organic compounds (VOCs).

FSC
Mixed Sources
Product group from well-managed forests, controlled sources and recycled wood or fiber
Cert no. SW-COC-002553
www.fsc.org
© 1996 Forest Stewardship Council

Health Law & Policy Brief
2010-2011

Health Law & Policy (HLP) is a publication of American University Washington College of Law (WCL) and the Health Law Project LL.M. Program on Law & Government.

Letter from the Editors

Dear Reader:

On behalf of the Editorial Board and staff, we proudly present Volume 4, Issue 2 of the *Health Law & Policy Brief*. The eighth issue of our publication features the annual Washington College of Law Health Law Symposium and several timely articles addressing a broad range of health law topics.

The 2010 Health Law Symposium focused on health disparities, which are increasingly evident today. The Symposium featured a number of prolific panelists and we are very pleased to share their memorable talks with you. Four distinct panels addressed: 1) language and race-based health disparities; 2) health disparities for the aging and people with disabilities; 3) international health disparities; and 4) federal and state approaches to ending health disparities. A true highlight of the Symposium was the keynote address delivered by Councilman David Catania, the District of Columbia Council At-Large Member and Chairman of the Council's Committee on Health. We hope you will benefit from his insights into addressing health disparities in Washington, D.C. and beyond.

In addition to the Symposium, this issue includes three timely student articles. Ashley Goren addresses the right to health care in the domestic forum based on international treaty law. Jocelyn Sweet compares the use and regulation of assisted reproductive technology in the United States with that of the United Kingdom. Patrick Manders discusses the future of charitable status for tax-exempt health care providers. Finally, we present brief columns on several recent health law developments.

We extend our sincere gratitude to our incredibly talented staff and our dedicated advisor, Professor Corrine Parver, Esq. Thank you for your readership and we look forward to bringing you more health law scholarship in the future.

Sincerely,

Walakewon Blegay

Kathryn Coniglio

Colin Rettammel

Co-Editors-in-Chief

Symposium on Health Disparities

Spring Health Law Symposium

February 17, 2010

Panel I: Language and Racial Disparities

Julia Pierce, *Department of Health and Human Services, Public Health Division, Indian Health Services*
Leonard Rubenstein, *Johns Hopkins University Bloomberg School of Public Health*
Gina Wood, *Joint Center for Political and Economic Studies*
Mara Youdelman, *National Health Law Program*

Panel II: State and Federal Perspectives on Health Care Disparities

Ken Johnson, *Department of Health and Human Services, Office of Civil Rights*
Carlessia Hussein, *Maryland Department of Health, Office of Minority Health and Health Disparities*
Hilary Frierson Keeley, *Department of Health and Human Services, Public Health Division, Indian Health Services*

Keynote Address: Councilman David Catania, *Council of the District of Columbia*

Panel III: Aging and Disability Disparities

Ahaviah Glaser, *AARP, Adjunct Professor, American University Washington College of Law*
Chris Harmon, *National Association of Social Workers*
Daniela Kraiem, *Associate Director, Women and the Law Program, American University Washington College of Law*

Panel IV: International Disparities

Margaret Farrell, *American University Washington College of Law*
Sean Flynn, *Associate Director, Program on Information Justice and Intellectual Property American University Washington College of Law,*
Mark Green, *Malaria No More*

Language and Racial Disparities

MARA YOUDELMAN:* I will address language access issues as they relate to health disparities. First, I will briefly tell you about my organization because we do a lot more than language access. I will then walk you through some of the issues surrounding language access and then I will talk about some of the work we were doing on health reform to remedy language access issues.

The National Health Law Program (NHeLP) is a national nonprofit law firm. Our overriding mission is to work on behalf of low and limited income individuals to improve access to and quality of care. I do a lot of work on civil and human rights issues and that is where our health disparities work comes in. I have been working on language access issues ever since I got involved with NHeLP about nine and a half years ago.

For about seven years now we have been receiving funding from the California Endowment for our language access work. In large part, this supports a broad national coalition of stakeholders who work together in areas of consensus to improve language access. It has brought together the folks who used to be at many of the health care provider associations—the advocates, the health care accrediting organizations, interpreting associations, companies that provide interpreters and translated materials, and others—to work together to raise awareness at the federal level and improve policies related to language access.

In terms of the demographics, in the United States over fifty-five million people speak a language other than English at home. In the health care field, we say that if you speak English less than very well, you are considered limited English proficient (LEP) and you are likely going to need assistance communicating with health care providers. Those who are LEP might need a provider who is bilingual, or they might need an interpreter who can translate conversations between providers and patients. They also need help understanding written materials. There is a lot of material that needs to be translated for these folks. About nine percent of the population is LEP for health care purposes.

In the health care provider setting this means that about eighty percent hospitals see LEP patients at least monthly. These statistics are derived from national surveys that NHeLP funded along with partners in the national coalition. This problem does not just affect the big states where lots of immigrants are. It is no longer just Illinois, California, New York, and New Jersey where the traditional pockets of immigrants have been. The same statistic holds true for small practices of general internal medicine physicians. We conducted a study with community health centers and the results indicated that eight-four percent of these clinics are providing daily care to patients with limited English proficiency. This is a widespread national issue that is really overlooked in a lot of ways.

There is a lot of documented research on the problems that people face when they have a limited English proficiency. One such problem was very well documented in a lawsuit out of Florida, which resulted in a $71 million settlement for a young man who was left quadriplegic after being misinterpreted in the health care setting. There are lots of other horrible stories. For example, a six-week-old infant was admitted for a barbiturate overdose, which was caused by a dosing error when a LEP mother did not understand the medication instructions that were given by the doctor. The instructions were only available in English and they were not translated. Lots of issues, lots of stories, lots of horrible consequences.

Right now, NHeLP is doing research on malpractice and language access, which has always been of interest to us. We are frequently asked: Are there more lawsuits? Can we see more evidence about the consequences of poor language access? We have been

* **Mara Youdelman** has worked with the National Health Law Program since August 2000 on issues including Medicaid, language access, racial and ethnic disparities and data collection. She is the Director of the National Language Access Advocacy Project funded by the California Endowment to increase awareness of language access issues at the federal level.

She coordinates a national coalition to develop a consensus driven agenda to improve policies and funding for individuals with limited English proficiencies. She authored numerous publications on language access issues. Ms. Youdelman also chairs the Certification Commission for Health Care Interpreters whose mission is to develop and administer a national, valid, vendor-neutral certification program for health care interpreters. Prior to working with the National Health Law Program, she completed a teaching fellowship at Georgetown University Law Federal Legislation Clinic. She earned her J.D. with the Boston University School of Law and her LL.M. in advocacy from Georgetown University Law Center.

working with a malpractice insurer in California to review through their closed claims. Soon we will releasing an issue brief that documents a lot of malpractice cases where language barriers were at least one piece of the puzzle. In addition to sharing stories about the horrible effects of language barriers on health, NHeLP is really trying to build a legal case to make a change.

On the legal side, we have a strong case for requiring language services. Since 1964 Title VI of the U.S. Code has said that anyone who receives federal funds cannot discriminate on the basis of race, color or national origin. The Supreme Court and federal agencies like the Department of Health and Human Services (HHS) have said language can be a proxy for national origin. Therefore, if you receive federal dollars, you cannot discriminate based on language, meaning you should be providing meaningful language access to all patients in federally funded locations. Virtually every single health care provider is receiving some federal funding. They participate in Medicaid, the Children's Health Insurance Program (CHIP) or Medicare. They accept research funds from the Centers for Disease Control and Prevention (CDC) or the National Institutes of Health (NIH). Federal dollars touch virtually all aspects of health care. There really is, then, an expectation that health care providers provide language access. They should be providing interpreters and they should be translating materials. Still, the vast majority of providers are not doing that and as a result we still have significant health disparities.

In addition to federal law, there are many state laws affecting this issue. NHeLP conducted a national survey a couple of years ago looking at all fifty states and identifying statutes and regulations that address language access in health care. Every single state has at least two laws on point. Some states have extremely comprehensive laws and some have just minor provisions here and there. We also saw some recent trends. There is starting to be more attention at the state level to issues of language access. We have seen new educational requirements on cultural competency and language access for health profession students and continuing education for health care providers.

We have also observed that some states are developing standards for health care interpreters. Many providers do not understand that utilizing a family member to interpret between patient and provider is not the best way to go. Family members, children of patients in particular, often say that they are bilingual, but when they begin interpreting they face difficulties. Even if this individual is bilingual, he might not know how to translate medical terminology, or confidentiality explanations. On a related note, some states are starting to look at the issues of confidentiality certification standards for interpreters. Although private insurers who do not receive federal funds are not subject to federal non-discrimination laws, some states, such as California, are requiring private insurers to ensure that all network providers provide language access.

We have talked about some statistics, but who is considered LEP? Basically, anyone who cannot speak, read, write or understand English at a level that permits effective interaction with health and social service agencies is LEP. A physician friend once reminded me that in the health care field you are not just dealing with English and Spanish, for example, but you are adding on two more languages: medical English and medical Spanish. That is why many people need assistance in interacting in English in the health care setting even if they effectively interact in English in other settings.

What has NHeLP been doing? We work extensively to improve language access through health reform. Although health reform is stalled, we still are optimistic. There were three main acts that members of our national coalition developed. We are trying to influence and address disparities through federal legislation. The first idea was to give states more money to provide interpreters through Medicaid and CHIP, the two public health programs that primarily are for low income individuals and children. Many states do not provide interpreters because it costs about fifty cents for every dollar earned. We wanted to increase federal payments to states to incentivize language access programs in public health care.

The second piece was to address language access through Medicare. Medicare serves the elderly and people with disabilities and does not pay for language services. We realized that Medicare could not support the estimated $2.5 billion cost of providing language services. Instead we wanted to get the ball rolling by doing a one-year study to examine how Medicare could pay for language services and a three-year demonstration program to gather data and fund in-practice trials. The third piece was to work with health care exchanges—where people who do not get insurance through a public health program or their employers can buy private health insurance. We wanted to put requirements on plans participating in the exchange to provide culturally and linguistically appropriate services.

In the Senate, we were not able to get funding on these three ideas through Medicare or Medicaid. In the House of Representatives we were much more effective. The House allocated some of the increased Medicaid funds to hospitals to be used to pay for translation and interpreters. The House also had a number of provisions that would have required culturally and linguistically appropriate services by plans in the exchanges. The House was also going to require health care plans to use plain language in their communications, which really improves literacy for LEP patients. It is much easier to translate and understand plain English communications.

We are really trying to get the federal government, particularly the Centers for Medicare and Medicaid Services, which oversee the programs, to step up. We would like Medicare, for example, to translate forms so that providers across the country do not have to do it themselves. We would like to see these programs create a clearing house for materials to assist providers and insert requirements for language access in related regulations. Our next step is to await developments in health reform. In the meantime, we are looking at other legislation and administrative opportunities to advance language access in health care. We will continue to research and document needs and disparities to improve the likelihood that policy makers respond to this issue.

JULIA PIERCE:* At the Indian Health Service (IHS) we also face language barrier problems, but we are dealing with 564 different languages. IHS provides health services to the 564 federally recognized tribes in America. IHS serves 1.9 million of the nation's estimated 3.3 million Indian people. Many of those people live in Alaska in tiny villages that are ordinarily remote and isolated. IHS strives for maximum tribal involvement in the health services we provide, but there are budget limitations that make that challenging. Federal tribal relations are considered a political relationship, not a racial relationship, which allows a lot of the work IHS does and a lot of hiring to escape the Title VI Affirmative Action Laws. IHS actually has a preferential hiring policy that is established by statute. Many years ago, Congress found that Indian people related better to other Indian people who they felt had a better understanding of where they were from and the challenges they were facing.

IHS finds a basic problem between the federal and state relationship. Often the states think of tribes as separate states within states. States often believe that tribal people are not eligible for state-sponsored programs, but in reality the federal government is funding these programs and, of course, Indian people are citizens of their states as well as of their individual tribes. Indian people are eligible for state-sponsored programs just as anybody else is. It is a challenge we have to overcome.

Indian people have long experienced lower health status than other racial populations in America. On average, the life expectancy of Indian people is about four and a half years shorter than other races in the United States. American Indians and Alaskan natives die at a higher rate than other Americans from tuberculosis—about 750 percent higher; alcoholism—550 percent higher; diabetes—190 percent higher; unintentional injuries—150 percent higher; and homicide—100 percent higher. There are reasons for these disparities, many of which we have been examining for years.

When you really start looking at why there are such health care disparities, you have to look to history. Many Indian people are located in remote locations where there is no economic opportunity. Up until recently, these people did not have the same educational opportunities. Even Indian people who obtain their education away from their tribes have to deal with the ramifications of not being able to find a job in their field when they return to their reservations. All of this leads to health care disparities because health care is not just about the services available. IHS takes a holistic approach in native communities. Am I able to have the emotional well-being and intellectual stimulation to allow me to feel worthwhile? If I come back to my community, am I able to sustain myself? If I do not come back to my community, do I lose part of my culture? These are things that IHS considers in its provision of services. We also support native medicines. We are a federal agency that supports alternative medicine. In some of our contracts with native peoples we are intentionally vague about the medicine and techniques provided to tribal members. In these cases it would be sacrosanct to the Indian people to reveal their medicinal traditions.

While many Indian people are in rural communities, they are not the same rural communities that some of us grew up in. They are rural in the most extreme sense where many people do not have sanitation and running water. We are looking at disproportionate poverty and often discrimination in the delivery of the health care that is available. In these places, Indians are not revered as they often are on television or the movies. There is a lot of racial discrimination, a lot of cultural misunderstandings and a lot of ridicule for people who prefer to stay true to their cultural and traditional practices. These are the sorts of things that lead to disparities in health care that are not really openly discussed unless you set up a forum and that is what IHS, and in larger part, HHS, tries to do.

We have a policy of consultation with tribes on basically everything that we can afford to consult on. We are not an entitlement program hence there is not a never-ending well of funding under the department. We are able to provide the services that tribal people in the country deserve. We have a $4 billion budget to serve about 1.9 million people in very remote locations. We are working to build hospitals and clinics because about fifty-seven percent of the Indian population is being served by basically forty-five hospitals and 600 clinics. We are providing health services either directly in places where tribes are not able to provide them for themselves or in places where tribes have gotten a bit savvier and have expertise, through the Indian Self Determination Act Contracts. This means that a tribe takes the funding the government would have spent and they provide the services for themselves. For us, that is a win. That is when we can actually see the

* **Julia Pierce** represents the Department of Health and Human Services, Office of General Counsel, Public Health Division, Indian Health Service Branch. She served as a licensed radiologic technologist at the Navy Hospital in the Navy Reserves from 1988 to 1996. Ms. Pierce worked as a radiologic technologist at the Medical College of Virginia in a community hospital while attending college and law school.

While attending the University Of Virginia School Of Law, she served as the president of the Native American Student Union. After graduating in 1998, she joined the Indian Health Service Branch of the Office of General Counsel where she served as team leader negotiating consistency among teens that negotiated the Indian Self Determination and Education Assistance Act contracts with Indian tribes. She was instrumental in transferring over $2 billion a year from the federal government to tribes annually.

She has been involved with litigation at every level of the federal court system including the Supreme Court. She has also served on the team that developed the regulations required by Title V of the Indian Self-Determination and Education Assistant Act traveling throughout the country for over a year to meet various tribes for a consultation. Last year she completed the Department of Health and Human Services eighteen-month Senior Executive Service Candidate Development Program and was certified as an SES member in 2009.

> A tribe can decide to let the government run its own health care operation. That is as much a statement of self-governance as the tribe running the operation itself.

good work that IHS is doing and continue a government-to-government relationship.

If you have had an Indian law course, you are familiar with the *Worcester v. Georgia*[1] case, which established native tribes as dependent domestic nations. That is an interesting title. It sets up a guardian-ward relationship, which in its own way is a bit paternalistic. But, if you look at it in terms of a situation where the government is attempting to pay back a debt that is owed, it is not as paternalistic. We are sincerely trying to bring tribes to a level where self-determination is for everybody. A tribe can decide to let the government run its own health care operation. That is as much a statement of self-governance as the tribe running the operation itself.

As I said, we are under-funded. Four billion dollars seems like a lot but it is not when you are in health care. What we have done to try to make up for some of this disparity is to look into partnerships with not only other agencies within our department, but other departments at large. The Department of Housing has an Indian housing program. They are also responsible for sanitation in houses. The Department of Justice has real justice programs, which provide many of things that one would not necessarily think of as health care-related, like who provides guards for the hospital. IHS does not have the funding to address these health-related issues. We try to work with the Bureau of Indian Affairs. They provide Indian people with social programs.

We have set up partnerships not only throughout the government, but with private entities. Many of you may not know that Nike has designed a shoe for Indian people. Admittedly, it looks like a huge, hideous block, but many Indian people who have diabetes are also large. The size of these individuals is due to poverty and the food that the government gave Indian people on reservations. Nike has, in conjunction with IHS, provided a shoe that accommodates the wider, larger foot of Indian people. The purpose of entering into such a partnership is not only to get specifically designed shoe wear, but also to encourage exercise and to encourage care among private organizations about health on reservations. It has a secondary effect. Besides being able to supplement our budget it shows Indian people that there are people who care about them. The rest of the world has not forgotten that Indian people exist. We are trying to enter as many partnerships as possible. We have been encouraged to do this by the highest levels of government. President Obama has recently reissued the Executive Order on consultation, saying that if there is anything the federal government is going to do that affects Indian people, they need to consult with Indian people.

IHS is a very interesting place to work because we not only deal with a section of society that most people know very little about, but we deal with a section of society that most people, if they really read history, would agree have not been treated particularly fairly. Amends need to be made.

LEONARD RUBENSTEIN:* We need to distinguish at least three kinds of disparities. One health disparity is disparities in access. The health care access debate in this country has been in the forefront for the last year. We know that not only do we have tens of millions of uninsured people, but that African Americans and other minorities are disproportionately uninsured. The second disparity is disparities in health status. We have supposedly had a national effort to eliminate health disparities by 2010. The third disparity is quality. I will discuss data about the last two types of disparities.

Just recently, the *American Journal of Public Health* published a report on how we are doing at addressing health disparities. For example, African-Americans have died from all causes at a younger age thirty-five percent more than Whites. The only outcome where Whites fair worse than African-Americans is deaths by suicide. Regarding tuberculosis, there is a 600 to 700 percent difference in deaths between African-Americans and Whites. Despite the supposedly enormous national effort to eliminate health disparities, at least half of the indicators have gotten worse since 1990 when measured by mortality indicators. We still have a stunning problem in disparities in health status. It is a very sobering set of data considering the decades of discussion and commitment, or supposed commitment, to reducing health disparities based on race.

People talk about quality of care even less frequently, because we assume that everybody gets the same quality of care. There are now numerous studies in peer-reviewed journals showing that African Americans and other ethnic minorities get worse quality of care than Whites. There are fewer referrals for renal transplants,

* **Leonard Rubenstein** is a renowned advocate for human rights and medical ethics. He is currently a visiting scholar at the John Hopkins Bloomberg School of Public Health, Center for Public Health and Human Rights and Center for a Livable Future. He is the former executive director of Physicians for Human Rights and was recently a senior fellow at the United States Institute of Peace. He coauthored a report on the disparities and quality of care and application of international human rights law and brought the issues to the U.N. Racism Conference in 2001.

less adequate pain medication for cancer, poorer HIV care, and fewer admissions to cardiac care units. You might think that this inequality is attributable to access to health insurance. But, if you look at the Medicare population where everyone has the same access, across indicators, across type of care, African Americans got worse care.

For a long time there have been efforts to address this problem through the Office of Minority Health. These efforts have not been very successful. It has been many years since a concerted effort was made to provide disparities data to the communities. For almost 10 years, legislation has not made it through Congress to require that. In the health care reform bills, there are provisions to assure that we collect data so that people can observe disparities on a national level and the community level. People would know what is going on in their communities and can organize around that. As of yet, we do not yet have that disaggregated data.

The second problem is how we think about disparities. In our legal system, we have had wonderful civil rights laws that are all written in basically the same way. They say if you are discriminated against, you may have a claim. If you have your rights violated, you can sue. However, international human rights law takes a very different approach to the concept. Discrimination does not create an automatic right to sue. Rather, the state has a responsibility to eliminate discrimination. In our system, civil rights are individual claim-based and create no responsibility to eliminate discrimination.

The United States is infamous for not adhering to or ratifying Human Rights Treaties. We have not ratified the Women's Convention. We have not ratified the Convention on the Rights of the Child. We have not ratified the Mine Ban Treaty. We have not ratified the Cluster Munitions Treaty. But, we have ratified the International Convention on the Elimination of All Forms of Racial Discrimination. This is not like all human rights treaties in the U.S. in that is not self-executed—you cannot sue based on this. In human rights, we are often without remedies. In fact, one of my colleagues says the reason the human rights movement exists is because of the failure of law.

Human rights law may not provide a remedy in court, but there is a lot we can do with it. We can go to Congress with it. We can go to the public with it. We can go to our communities with it. It is incumbent upon us to learn about human rights law and how it applies, because as we have seen from the statistics, just talking about disparities is not sufficient. We have to think seriously about new ways to eliminate disparities.

GINA E. WOOD:* I would like to highlight some of the work of the Joint Center for Political and Economic Studies on the status of health and equity affecting African Americans and other people of color, as well as possibilities for eliminating these inequities through the health reform bill. The Joint Center released a study entitled *The Economic Burden of Health Inequalities in the United States*.[2] We released it during a health reform briefing at the National Press Club which featured HHS Secretary Kathleen Sebelius. The study used data from existing federal health surveys and found that between 2003 and 2006, health inequalities in the U.S. for people of color costs more than $50 billion a year. The direct medical cost over the four year period of the study amounts to a total of $229.4

> Despite the supposedly enormous national effort to eliminate health disparities, at least half of the indicators have gotten worse since 1990 when measured by mortality indicators.

* **Gina E. Wood** is Deputy Director of the Health Policy Institute at Joint Center for Political and Economic Studies. She is the team leader supporting the implementation strategy for health policy institute programs, public and private sector partnerships, communication, research and policy analysis and resource development. Miss Wood has an exemplary public service background spanning 20 years in the state and federal level positions.

In light of her prior experience in a legislative and executive branches of Oregon State Government, the then Governor Jim Hodges of South Carolina asked her to join his cabinet as Director of the Department of Juvenile Justice. Subsequently she was confirmed as Director by the South Carolina State Senate. At the federal level, she served as Staff Director of the Coordinating Council on Juvenile Justice and Delinquency Prevention chaired by then Attorney General Janet Reno and comprised of leaders of key federal agencies. During her ten years, she led major interagency initiatives which garnered the support of the United States Congress and a number of foundations.

Ms. Wood is currently affiliated with the Women of Color Policy Network at the Robert F. Wagner School of Public Service in New York University and serves on the Board of Directors at Crittenton Services of Greater Washington. She is also the member of the Advocacy Committee of the Juvenile Justice for the Commonwealth of Virginia. In addition, she serves as the trustee on two national boards, the Coalition of Juvenile Justice where she chairs the Ethics and Cultural Diversity Committee and the National Crittenton Foundation. Miss Wood holds a bachelor's degree in communications from the University of Missouri.

billion. The price tag of $230 billion between 2003 and 2006 reflects only the *excess* cost associated with health inequalities. If we were to eradicate health inequalities, these excess costs would disappear.

For African-Americans alone, the direct medical expenditures due to health inequalities over the four year period was $135.9 billion. A great deal of these direct medical expenditures due to health inequalities over the four year period were for hospital costs. It is important to remember that because low income people of color are disproportionately more likely to lack coverage they are also more likely to delay or forego health care visits. By the time such vulnerable patients end up in a hospital setting, their respective health conditions have worsened to the point of requiring far more rigorous medical interventions and treatment regimens. This may help explain some of the soaring health based medical care costs for African Americans and people of color. To reverse this trend, we need comprehensive health care reform that is actually designed to eliminate health inequalities. At the Joint Center we focus more on health inequities versus disparities. In short, eliminating health inequalities for African Americans, and certainly other people of color, is not only the just and moral thing to do, it is also the most cost-effective thing to do to restore the nation's physical health.

> "It is important to remember that because low income people of color are disproportionately more likely to lack coverage they are also more likely to delay or forego health care visits."

Let me say a few words about the indirect costs that result from health inequalities. Indirect costs include the loss of productivity, wages, absenteeism, use of family leave for avoidable illnesses and lowered quality of life due to illness, as well as premature deaths, which cause loss of wages, tax revenues, benefits and services for families of the deceased, and lower quality of life for family survivors. Researchers have calculated that the indirect costs of health inequalities added up to more than a trillion dollars from 2003 to 2006. When you add the direct and indirect costs of health inequalities together, the grand total is more than $1.24 trillion in a four year period—more than the annual gross domestic product of India, the world's twelfth largest economy. You might ask who is paying this $1.24 trillion bill. The answer is simple: all of us, through federal, state and local taxes, as well as increased costs for doctor visits, prescription drugs and medical procedures. Yet, eliminating racial health inequalities will do more than put the nation's fiscal house in order. It will also improve health status outcomes for people of color from cradle to grave.

We especially need to improve health status and outcomes for African Americans. Seventeen years ago the Joint Center published what was at the time a pioneering document entitled *A Health Assessment of Black Americans*, which included noteworthy findings on African-American men and women's health. Although it is hard to believe, it was not until 1985 that HHS published an official report on African-American and minority health. The Office of Minority Health at HHS was established the following year, in 1986. Moreover the National Institutes of Health (NIH) did not adopt a policy that urged the inclusion of people of color and women in its clinical health research trials until two years later, in 1987. Three years later, in 1990, the NIH established the first Office of Research on Women's Health. We are still trying to understand the importance of women and communities of color to health outcomes.

Congress did not mandate the inclusion of people of color and women in all NIH supported clinical research until 1993. NIH is still attempting to overcome barriers to include more people of color and women in clinical research trials. One of the most pressing of such barriers is the continued lack of racial and ethnic diversity among health researchers and practitioners. We have an initiative that we have been working on with former HHS Secretary Dr. Louis Sullivan, who has made it his lifetime commitment to ensure that we have diversity within the health care profession.

I would also like to bring attention to heart disease in the U.S. and the implications for cardiac-related data on health disparities. According to a study reported in the September 16, 2009 issue of the *Journal of American Medical Association*, African-American patients who suffer cardiac arrest in a hospital setting are much less likely to survive than White patients. Although survival after having a cardiac arrest in a hospital setting is historically low, survival rates for blacks were significantly lower at twenty-five percent versus thirty-seven percent for Whites. This amounts to about a twelve percent absolute difference in survival rates. According to lead researcher, Dr. Paul S. Chan, a cardiologist at St. Luke's Mid-America Heart Institute in Kansas City, this twelve percent absolute difference in survival is the largest survival disparity for any medical condition. Much of this disparity is believed to result from the quality of hospital in which black patients receive care. Also, thirty-two percent of African-Americans have high blood pressure or hypertension, a leading risk factor for heart disease, compared to 22.5 percent of Whites in 2007. African-American men are thirty percent more likely to die from heart disease than their White non-Hispanic males according to 2005 data from the Office of Minority Affairs website.

The disturbing disparity between heart-related death rates for African-American males and White males of this country is not only stubbornly persistent, it also applies to females. Since 1997, the Joint Center has published the *Women of Color Health Data Book*. Our third edition of the *Women's Health Data Book* was released in 2007. As highlighted in this latest data book, African-American women are more likely to be obese and more likely to have sedentary lifestyles. Fifty-five percent of African-American women reported they had sedentary lifestyles between 1999 and 2001, which means they did not engage in light physical activity for ten minutes at a time in this period. They are more likely they have elevated levels of lead in blood, which is associated again with high blood pressure. They are more likely to die of heart disease, more likely to die of diabetes related causes and more likely to have a shorter life expectancy. Equally alarming are some of the health indicators for African-American adolescent females as well. I will not go into all the details, but you can draw the conclusions. Health reform legislation is absolutely imperative if we are to truly eliminate the current health inequalities facing African-Americans and other people of color.

Inequalities are now well-documented by the premature death and disease rates among African-Americans. When Secretary Sebelius joined us at the press conference, she called these higher rates of premature death and diseases among African-Americans "quite stunning and shocking." She was very eloquent when she emphasized that, although we have become better at measuring these inequalities, we have made little progress in reducing them. She also pledged her personal commitment as well as that of the administration to eliminate such health disparities. These inequalities are serious and significant financial barriers that prevent access to quality health care services for the time sensitive treatment options to preventative care that are aimed at a wide range of chronic and debilitating illness.

QUESTION: I sit on the board of directors of Holy Cross hospital in Silver Spring, Maryland, part of the Trinity Health System. It is a non-profit hospital. Because of their tax-exempt status, not-for-profit hospitals are required to have community benefit programs. I know there are ninety different languages that are spoken by patients in Holy Cross Hospitals. I do not know that there are translators for all of those languages, but I do know that the commitment of the hospital and the health system is significant in providing as many translators as possible. Can we not use the traditional community benefit required by the IRS to coerce not-for-profit hospitals to provide these services as part of their commitment to community?

JULIA PIERCE: There are a number of laws like community benefit and Title VI, but the problem really is enforcement. Title VI, for example, is mostly enforced by the HHS Office for Civil Rights (OCR). We lack the resources to do what we need to do. To enforce community benefit, folks would have to bring challenges to the IRS when hospitals fail to meet community obligations.

QUESTION: One of my areas of interest is traditional health beliefs. In certain ethnic groups, there are traditional medicine beliefs that really affect receptivity to Western medicine. Is there any emphasis on that in your programs? And how is that being addressed?

JULIA PIERCE: There certainly is in the IHS program. I would have to restate that the majority of people working for IHS are Native Americans. There is a huge respect for native medicines. Each individual tribe has its own specific traditional medicine practices, ranging from sweat lodges to specific herbal remedies to practices that are completely unfamiliar to us. When we negotiate Indian Self-Determination Act contracts with the tribes to transfer the funding that IHS will spend, almost all of the contracts have a traditional medicine paragraph. This is something that we fought with the Department of Justice on for years, because the Department of Justice is very conscientious about litigation risks. It is the right thing to do to support people in their traditional practices.

MARA YOUDELMAN: This is a broad issue. You hear about cultural competency and trying to help educate health care providers about different cultural issues that come into play. I think it is more important to develop what is called cultural sensitivity or humility. We are never going to get providers to understand all of the different cultural issues of all the patients that they treat. Rather, they have to be understanding and receptive to talking with their patients about what those beliefs are and what those complementary alternative medicine practices are and how it may affect the patient's understanding of their diagnosis and decision about treatment, etc.

Language is one piece of the puzzle of cultural awareness, but it is certainly a much broader issue and it does affect disparities. Many patients will not follow through with a treatment plan because they do not understand it or is not explained to them in a way that they can be reconciled with their cultural beliefs.

JULIA PIERCE: Additionally, it is important to know that traditional medicine is not the same as complementary alternative medicine. They are usually grouped together. They are not grouped together at the IHS.

QUESTION: There has been a lot of discussion surrounding immigration in the US, specifically illegal immigration. There has been an assumption that illegal immigrants are using up the system. Then there are many who have said that this is not the case. What does the research say?

MARA YOUDELMAN: There has actually been research in a number of settings that showed immigrants are actually using less health care, costing less to the health care system, and are on average healthier.

QUESTION: There is an association between language issues and immigration. How do you deal with that politically? If you want more funding or if you want legislation, how are you going to go against the anti-immigration political wall that I would think exists even if the Democrats are in power?

MARA YOUDELMAN: It has been interesting. We have been very cautious about how we talk about language access. We do not talk about immigrant issues and language access in the same Capitol Hill visit or policy discussion, because it does get tainted. As much as we want to advance immigrants rights, we realize if we are going to advance language access we have to be careful. But, we also can show based on the demographics and census data that there are lots of citizens, both nationalized citizens and U.S.-born citizens who are limited English proficient. This also applies to

> There is a real absence of a voice in this country that says human rights and human dignity cannot be distinguished by status of documents.

many assylees and refugees who come into this country. We have been able to make the case that this is about access quality.

I was able to crunch some basic census numbers to find that about two thirds of LEPs are actually here as citizens or documented immigrants. We are not really talking about a huge proportion of undocumented immigrants. It is something in the arsenal that we can use to help make our case.

LEONARD RUBENSTEIN: You are raising the larger question of the poverty of our debate. During the presidential election, President Obama famously said that health care is a right. But, President Obama also went out of his way in a joint session of a Congress to say that undocumented people would not be in his health care plan. Everybody who is working pragmatically to get health care reform has to buy into the notion that we are going to exclude undocumented people. There needs to be another voice. There is a real absence of a voice in this country that says human rights and human dignity cannot be distinguished by status of documents.

MARA YOUDELMAN: My organization has been trying to make that voice heard and we just keep getting deaf ears. We are having some success in states to get laws or amendments declaring health as a human right. If you buy into health as a human right, you do not have to talk about the immigrant issue. We are just meeting a lot of resistance from the policy-makers. We need louder voices from folks in higher positions whose voices will be heard.

[1] 31 U.S. (6 Pet.) 515 (1832).
[2] *Available at* www.jointcenter.org.

State and Federal Perspectives on Health Care Disparities

DR. CARLESSIA A. HUSSEIN:* One of the interesting things that we have done in the Maryland Office of Minority Health and Health Disparities, which started in 2004, was to begin to look closely at health data by race and ethnicity. There is plenty of data at the national, federal, state and city levels. But what is interesting is that the data often are not asked questions about race and ethnicity. We have made projections, based on 2008 data on the number of minorities that reside in each of the twenty-three jurisdictions in Maryland and Baltimore City. There are thirty percent minorities in eight of the twenty-four jurisdictions. This is important information because it provides knowledge that differentiates people and enables program interventions to be tailored. For example, when we looked at the vital statistics data in the state of Maryland and the published reports, we saw that there was very little information about minorities. The data were primarily listed by Black and White. That was not sufficient to identify diseases that affected the different population groups in the State. Our office, with the charge to promote programs that reduce health disparities, needed data on the four major minority groups: African-American, Hispanic/Latino, Asian American, and Native American. These groups historically have been medically underserved and experience poor health status in the state of Maryland.

Comparing the racial and ethnic distribution of physicians against the 2007 population data reveals that there is decreasing representation in the health workforce of African-American and Hispanic physicians. We also see that there is an under-representation in the matriculation for African-Americans, Hispanics/Latinos, and Native Americans for the periods 2005 to 2006 and 2008 to 2009. This is critical because we know that the minorities in the health professions are declining due to aging and minorities are entering health professions at lower numbers. The policy implications are clear, reduced diversity in the health workforce diminishes the compatibility of the health worker with the patient. The health care delivery system becomes less efficient and more costly.

To improve minority matriculation in the health professions, we have to improve student capabilities in math and science, create mentoring programs in middle and high schools, and identify achievers among minority populations. These goals are really difficult when we have a tendency to put all students who look similar in the same box and make the same assumptions because the pants hang down on all of them, the caps turn back on all of them, they all speak bizarre languages, and are just talking on the cell phone. But they are different one from the other. We, as teachers and mentors, have a responsibility to learn to identify these differences and make opportunities for those, in spite of how they are dressed. Financial aid is an important issue that must be addressed with the growing costs of university admission. Along with financial aid, the availability of mentors and adequate academic support is necessary for students.

Now I will take a minute to talk about a program that I worked while I was the Associate Dean at the University of California, School of Public Health at Berkeley. I started a Minority Recruitment Program back in the '70s. I located funding on campus that supported travel and recruitment to the Navaho Indian Reservation to explain the program to the elders. Nurses applied and were admitted to the school to obtain a Masters in Public Health. Hispanic/Latino students were also recruited and admitted. The African-American community learned that a minority was in the School and handling admissions, so applications flooded in with anticipation that they would get fair consideration. This debunked the myth that traditional

> "Comparing the racial and ethnic distribution of physicians against the 2007 population data reveals that there is decreasing representation in the health workforce of African-American and Hispanic physicians."

* **Dr. Carlessia A. Hussein** has served as the Director of the Maryland Office of Minority Health and Health Disparities since 2004, and the Director of the Cigarette Restitution Fund Program since 2000. Her professional education began as a registered nurse and continued in completion of a Public Health Doctorate at the University of California in Berkeley School of Public Health.

She has served in many professional capacities, including Associate Dean at UC Berkeley School of Public Health, Chair of the Nursing MPH Program at the UC Berkeley School of Public Health, Senior Health Planner for the California State Hypertension Program, and Deputy Health Director of the Los Angeles County Forestry and Fire Department.

Dr. Hussein's accomplishments include establishing a Minority Health Network, managing a Minority OB Program that worked with local health departments and community AIDS groups to reduce the black all-cause cancer mortality disparity by 50.5 percent from 2000 to 2005 in Maryland, and engaging health professional schools and community hospitals to strive for workforce diversity in cultural and neolistic competency in their institutions.

> To improve minority matriculation in the health professions, we have to improve student capabilities in math and science, create mentoring programs in middle and high schools, and identify achievers among minority populations.

White institutions often say that they cannot find 'qualified' minority people. If the presentation of the institution seems welcoming and sincere, minorities will come forth and apply. So with this Program, we were able to raise the admission rates in the School of Public Health up to well over forty-six percent, and the School and I were very pleased.

In addition, with funds from the Chancellor's office, we provided a Summer Preparatory Program, where readiness courses in statistics were offered. As the fall semester got underway and relationships developed with the students, it became apparent that mentoring and on-going support was needed to help the students navigate the university. The support was essential to build and maintain an environment in which the students felt welcomed and that people wanted them to succeed. At that time, I was Associate Dean of Student Admissions and fell into a "Mom" role with all of them. I encouraged the faculty and others to develop stronger mentoring and supportive relationships with the students.

Next, I will briefly discuss workforce diversity and cultural competency. Our Maryland office has a five-year Health Partnership grant with HHS, Office of Minority Health that began in 2005. One objective of our grant was to help increase recruitment and matriculation of minority students in medical, nursing, dental and pharmacy schools in Maryland. One activity with the schools was to lay the ground work for establishing a health alliance in the state of Maryland. The purpose of the alliance would be to encourage the schools to work together, along with our historical black colleges and universities and community colleges to attract and graduate more minorities to enter the health fields. We have been working on the project with Dr. Louis Sullivan, the former HHS Secretary.

Expanding eligibility for the safety net will enable more of the uninsured in Maryland to receive needed health care services. As people have commented, healthcare reform is very important to get through in some reasonable form. So we all pray and wait. We have to resolve issues of chronic high unemployment, which is a big issue now with the down turn of the economy. We need to improve the proportion of employers who offer health insurance to their employees, which health reform would assist if passed.

There is a very important relationship between healthcare and prenatal care. In the state of Maryland, the Black and Hispanic groups experience high rates of late or no prenatal care. This data has policy implications, as well as implications regarding preventing infant mortality, geographic disparities, health insurance disparities, and linguistic and cultural competency sensitivity and respect.

There are two minority health programs I want to discuss. One is the Minority Outreach and Technical Assistance Program (MOTA). It is funded by monies received from the national Tobacco Settlement Program. We use a portion of the monies to fund minority groups and minority-serving groups, such as Holy Cross Hospital, in the jurisdictions with the highest proportion of minorities in the state of Maryland. And we very much appreciate Holy Cross and Montgomery County because they present a community partnership model that works to serve a diverse community. They received funds to address tobacco and cancer control and passed grants to Hispanic, African-American, and Asian groups at the community level. Thus resources got through to the people at the ground level, empowering them to participate in reducing health disparities. So we are very proud of Montgomery County and the Holy Cross Hospital partnership.

The second program on this particular slide is the Minority Infant Mortality Reduction Project. Our office was able to receive monies in the 2009 Budget that we used to fund minority reduction demonstrate grants to reduce minority infant mortality. The African-American infant mortality rate is twice that of Whites. What we did was to fund two jurisdictions. One was Prince George's County, where the minority infant mortality rate is very high. The second is Montgomery County, and everyone's surprised that we selected this county…. "Oh they're wealthy and healthy." But oh no…when you dig down into the data and look at the African-American and Hispanic groups in Montgomery County, they have unacceptable high rates in terms of a number of diseases.

We have a cancer success story. The tobacco settlement monies that came to Maryland funded a program to control cancer in the State. Maryland's share of the Tobacco Settlement was 4.4 billion dollars starting in 2000 for twenty-five years plus. The Cigarette

Restitution Fund Program was launched in 2000. A portion of the funds supported the Minority Outreach and Technical Assistance program (MOTA) that increased awareness and recruited individuals to seek cancer screening and adopt cancer prevention behaviors. MOTA, working with local health departments and community-based organizations was able to significantly increase the number of minorities screened for various cancers. The new and targeted strategy contributed to a 50.5 percent reduction in the all-cause cancer mortality disparity between Blacks and Whites in Maryland from the year 2000 to the year 2005.

Since then things are not going as well. This trend of decreasing disparity has leveled off and is beginning to rise. The Cigarette Restitution Fund monies have not increased with inflation and the cost of cancer screening and treatment services are rising. But the important thing to note is that it is possible to reduce and to eliminate health disparities if we target, focus, and use innovative interventions that are culturally sensitive and culturally competent in trying to work with specific affected groups.

By now you get the point. In Maryland, as in other parts of the country, the White/Black death rates are one to six times higher, depending on which disease you look at.

Improving data collection, doing the proper analysis, asking the data the right questions, and then recording it are all very important. We have published a Maryland Health Disparities Chart Book. And we are publishing the second edition that has data by race and ethnicity and in some cases by small jurisdictions or by counties. In too many cases, we produce data reports by "Black versus White." The reason for this is that, for most racial and ethnic groups, their numbers in the State are too small to complete reliable analyses or the data are not collected for each ethnic and racial group. On the other hand, the African-American population is larger and the data have been collected by race for a number of years. We are very concerned about the Hispanic/Latino population. Although for minority infant mortality, the largest percent of minorities who were Hispanics are in two jurisdictions: Montgomery County and Prince George's County. So we have directed programs and funds there. We strive to improve the collection of data by race and ethnicity within each jurisdiction.

I mentioned that we were working with the various health professional schools, but we are also working with community hospitals, where the community hospital's medical director and president are interested in increasing the cultural competency, sensitivity, and performance of physicians, nurses, and the staff throughout the hospital. So they are undertaking programs to begin to move their facilities in that direction.

Another important program is the Minority Infant Mortality Project. In Maryland, the infant mortality rate compared to Whites was 2.6 times higher for African-Americans and 1.8 times higher for American Indians or Alaskan Natives between 2004 to 2008. For Blacks, the highest number of deaths was in Prince George's County at 116 in 2008. For Hispanics, the highest number of deaths was in Montgomery County at fifteen in 2008. Again, these numbers are the reason we were focusing on those two areas.

I want to try to demonstrate the different aspects of our model to reduce and eliminate minority health disparities. The first part is called "perinatal navigators," which addresses infant mortality. We recruit and train individuals who are living in the communities with the at-risk populations because they have credibility, understanding, and trust. They can serve as effective ambassadors or emissaries to communicate between the healthcare system and the individuals in those communities. We train them to help bring pregnant women in earlier so that they are showing up for prenatal care at an earlier date.

The second part of our logic model is Community Health Coalitions. We funded a coalition and are getting the health departments to pull together elected officials, private care providers, and others in the community, who have been working in isolation and passing each other. Prior to the coalition, there had not been a venue or the stimulus to bring them together collectively. But now, they are talking and sharing, and able to make a greater indent on the problem.

The third part of the model is to enhance clinical services and increase the number of opportunities for prenatal care. We brought in a primary care practitioner to help.

The fourth part of our model is community outreach and education. Our perinatal navigators literally went to the office of every obstetrician in the county, introduced the program, and offered to be of assistance to individuals who might be some of their clients and who may not come to the health department. They tried to make this a seamless program within the community.

And then finally, we promoted inter-jurisdictional partnerships. In our request for application to both counties, Montgomery and Prince George's, we required the applicant to work in partnership with the neighboring county. Because what we knew from looking at the data is that pregnant women cross the boundaries to seek better care and better services. But the providers were not sharing and talking about the fact that individuals were moving back and forth. So now they are sharing, there are economies of scale that they already see by working together.

And finally, I will close by saying that we worked with the H1N1 (Swine) Flu Campaign in Maryland and assisted in setting up a statewide Community Education and Outreach Program whose purpose was to educate and encourage residents to take the H1N1 flu vaccine and practice preventive behaviors. We built this Outreach Program on the existing MOTA program that was focused on tobacco and cancer control.

This Program was supported by the CDC funds sent to state to address H1N1. A network of community health workers were placed in each jurisdiction. The health workers collaborated with the local health department to distribute information on immunization to the entire minority, rural and other, communities in those counties. Their work enabled individuals to better understand immunizations and informed them of the location of H1N1 vaccine clinics.

So that has been a new strategy for our state. We have been asked by CDC to come and present how we developed the Outreach Program because there have not been many examples of this type of true community-based work around the nation. This kind of outreach is different because it takes services to the people instead of saying "Here's my health facility. We're open from 8:00am to 4:00pm. Come on certain days for services and information."

> The Tribal Consultation Policy established minimum standards for the involvement of tribal leaders in the development of policies that affect Native Americans and Alaskan Natives.

HILARY FRIERSON KEELEY:* I am a Senior Attorney in the HHS Public Health Division. I am going to discuss the 2006 HHS report on Barriers to Access in Healthcare for Native Americans and Alaskan Natives. It was a barrier study that polled both HHS program officials and tribal leaders on what they perceived to be the barriers to access of HHS grant programs. Since the report has been released, the three major findings that the Department discovered were that: 1) tribal leaders felt that they lacked the ability to find funding opportunities, 2) they lacked the skills or the training to apply for the funding opportunities, and 3) they felt that smaller or rural tribes lacked the ability to compete alongside both larger, more sophisticated tribes, as well as other minorities applicants in the funding process. So, since 2006 the Department has enacted several initiatives to try and combat those three things.

I will also discuss the initiatives that were enacted before 2006; primarily, the role of the IHS within the Department. Finally, I will discuss the changes to the Department's Office of Intergovernmental Affairs and the creation of the Interdepartmental Council on Native American Affairs.

The IHS is the primary federal agency that is responsible for providing healthcare to Native Americans and Alaskan Natives that are members of federally recognized tribes. The IHS provides care to 564 federally recognized tribes in thirty-four states. So naturally when there are issues that involve Native Americans and Alaskan Natives, the senior staff at the Department looks to the IHS in order to formulate policies and for technical assistance.

The IHS has been addressing barriers in Indian country since its inception as a federal agency. In 1975, President Ford signed a piece of legislation called the Indian Self-Determination and Education Assistance Act (ISDEAA), which spoke to two things. First, it recognized the government-to-government relationship between the federal government and tribal leaders. Second, it recognized that tribal leaders are the best suited to make decisions for their members and their communities. It encouraged the use of Indian Self-Determination Act contracting to allow for the transfer of federal management of programs to tribal management. And that is the role that I take on as OGC. I work with a team of regional attorneys throughout the country that provide legal advice to our 12 area office in IHS as we contract for the transfer of federal programs to tribal control.

As of February 2009, the IHS has negotiated seventy-five Title V Self-Governance compacts representing 328 tribes, and there is an additional 249 tribes that operate under Title I Self-Determination Act contracts. To put this into numbers, this means that federally recognized tribes control about 1.15 billion dollars of the IHS's annual appropriation, over thirty-two percent. So when you are dealing with tribal government, controlling thirty-two percent of our IHS appropriation, IHS has really been innovative in the ways that it makes sure that dollars are being used for programs that meet individual needs and also that the tribal governments have a say in the way that federal funds are being utilized.

One of the ways that this is done is through the ISDEAA negotiation process and with the Title V and Title I contracting process. Each year IHS sits government-to-government with tribal leaders and negotiates an annual funding agreement to transfer the funds to operate the programs. Going back to the Barrier Study, one of the things that the Department found out was that tribes felt like they were not competitive or lacked an advantage in competing for federal funds. IHS recognized that a long time ago. And one of the ways that we encourage smaller tribes or less economically established tribes to participate in the self-governance process is through our technical assistance in planning and tribal management grants.

IHS's Office of Tribal Programs and our Office of Tribal Self-Governance offers planning grants to allow tribes to hire financial consultants and to hire legal teams to help them to assess their ability to take on federally managed programs in a way that they are going to succeed. Grants also help create a plan for the transfer of programs, for example if you have a tribe that does not take 100 percent at once, if their financial infrastructure or their management infrastructure would only support perhaps a 5 percent takeover. And so the planning and management grants allow tribes to decide for themselves, but with the assistance of the federal government to make sure that they have the infrastructures in place so that they will ultimately succeed in their self-determination.

Second, the IHS was really innovative in 1997 when the IHS Director implemented the first Tribal Consultation

* **Hilary Frierson Keeley** a Senior Attorney in the Department of Health and Human Services Public Health Division. She serves as the team leader for national Indian Self-Determination and Education Assistance Act (ISDEAA). She also serves as a Regional Attorney for the Nashville Area Indian Health Service and advises the Nashville area on all the legal issues raised as to contracting and in compacting. She advises ISDEAA headquarters on various issues, including grants management, emergency preparedness, and EIA, Europe Indian Affairs, related education and detention center issues. Miss Keeley is a graduate of the University of Florida and the George Washington University School of Law.

Policy in the federal government. The Tribal Consultation Policy established minimum standards for the involvement of tribal leaders in the development of policies that affect Native Americans and Alaskan Natives. In 2000, President Clinton signed the first executive order requiring federal agencies to establish Tribal Consultation Policies. This has also been reaffirmed recently by President Obama. Since 2000, IHS has already revised its Tribal Consultation Policy twice. It will likely happen again soon because IHS is constantly looking for ways to make the most of both tribal and IHS resources and make sure that the policies that are made in Washington have the best effect that they can have on the ground.

One of the ways that Tribal Consultation has really proved beneficial within IHS is that the Director and senior staff at IHS have used Tribal Consultation, as well as the 638 Negotiation Process, to establish initiatives. When there are limited resources Tribal Consultation has helped the Director to see where limited resources best fit on the ground and in the field. Currently the Director's initiatives are for behavioral health; including suicide, substance abuse, and Methamphetamine abuse prevention. IHS has also have health promotion and disease prevention initiatives and a chronic fair management initiative.

The latter two include IHS's largest grant program, which is the Special Diabetes Program for Indians. Native Americans have the largest rate of Type II Diabetes in the United States. Under the Special Diabetes Program for Indians, Congress has appropriated 150 million dollars per year through fiscal year 2011 to help to remedy the disparities. The funding right now is being used to fund 336 community-based diabetes programs focused entirely on prevention and treatment, and then also sixty-five demonstration projects which will be used to establish best practices, not only for IHS and the Department but that can be used in the private setting as well to address Native American diabetes needs.

There are also a lot of things that have been going on at the Department level, both prior to the 2006 Barrier Report as well as a result of the report. The Office of Governmental Affairs is an office under the Secretary which serves as the primary liaison between state, local, and tribal officials. As a result of Tribal Consultation a permanent position was established under the Office of Tribal Affairs that will be the liaison for tribal issues.

The Office of Governmental Affairs is the office within the Department that is responsible for Tribal Consultation, Departmental level, and this is done in several different ways. The largest effort for Tribal Consultation is the Department's annual budget consultation process and that will be held the first week in March. It is a two-day process where all agencies within the Department that have funding available for Native Americans and Alaskan Natives meet with tribal leaders in Washington and go through their budget proposal and see how much they feel that they are using their budget to meet the needs of the Native Americans. And in turn, tribal leaders are able to propose their own budget initiatives with how they would foresee those same dollars being spent, and hopefully there are concessions made that result in a budget proposal that meets the needs in the field, as well as the needs of Washington.

One of the things that came out of the Barrier Report was that tribes were not aware of funding opportunities. So the Office of Governmental Affairs held a 1-day fair, sort of a tabling fair, a day before the two-day budget consultation process. During the fair, tribal leaders, who are already in town, would have the opportunity to meet with Department agencies and speak to them one-on-one about funding opportunities that will come available in the year, as well as for the preliminary idea of when funding announcements will come out, when they will be due, and if there are specific things that the tribe can be doing to be prepared to be competitive in those types of funding opportunities.

Another thing that came out of the Barrier Study was that Tribal Consultation that always occurs in Washington is not feasible for tribes. Large, wealthy tribes were able to come to Washington, leaving small, less wealthy tribes at home unable to afford the airfare to Washington or unable to leave their tribal affairs behind. One of the ways the Department found to combat those issues was to bring consultation to the tribes in a regional effort. Now, the Department conducts regional consultations throughout the country where multiple agencies combine their efforts together. Substance Abuse and Mental Health Service Administration (SAMHSA), Centers for Disease Control and Prevention (CDC), National Institute of Health (NIH), and Centers for Medicaid and Medicare (CMS) do five regional consultations rather that one consultation in Washington. Those are also coordinated through the Office of Governmental Affairs.

Finally, something that is very innovative and just started happening within the last ten years are things called Tribal Technical Advisory Groups (TTAGs). Currently, SAMHSA, CDC, NIH, and a combination technical advisory group are Federal Advisory Committee Act (FACA) exempt, meaning that they do not require publication under the FACA. Typically when the federal government seeks advice from advisory committees, it requires publication so that all interested parties can participate in the meetings. There is an exemption to the FACA requirements for meetings between federal government and tribal officials. To take advantage of the opportunity to learn from the expertise of tribal leaders, the Department has created these advisory groups that allow the federal government to sit down and actually talk about the way that policy would implicate actions on the reservation if enacted, prior to actually enacting the legislation. And so the TTAG has proved instrumental to CMS in flushing out agency policy before it actually is implemented.

Finally, Congress authorized the creation of the Interdepartmental Council of Native American Affairs. This council meets twice a year. Each agency within the Department has a representative and a technical liaison. They meet to discuss HHS by-polices and how they'll have implications in Indian country and to American Indians and Alaskan Natives. It ensures coordination and also consultation on all of the HHS issues that may have an effect.

> Cancer goes back historically to when we had mines in the North, the waterways that come South, and the weather systems that come south from Pittsburgh and other places.

KENNETH D. JOHNSON*: When my son Jay was about one year old, he went off to enroll in a swimming class at our local Fairfax County Recreation Center. When we arrived at that class, I was the only dad. They should have called it "Mommy and Me." I decided to press on and the reason why I decided to press on was that the Centers for Disease Control and Prevention has reported that Black children are four to five times more likely to suffer an accidental death by drowning than White children. I tell that story because I think it illustrates an important distinction in this discussion.

The different rates of accidental death, the different rates of disease incidents and the different rates of mortality are all examples of health disparities, but what the Office for Civil Rights focuses on is health care disparities. Health disparity is the problem and there are a number of interventions that we can use to address the problem. For example, on the swimming issue, one intervention might be a public education campaign to increase the number of African-American families who enroll their children in swimming lessons. Another intervention might be to increase the number of publicly available swimming facilities that African-American families could use. A third intervention might be, and as law students you've probably heard this argument before, to eliminate the vestiges of the dual system.

For some time in America, African-American families were legally barred from using city or county swimming pools. The attitudes that were shaped in that era exist today and we need to overcome those attitudes. Another example might be the health care intervention. Many pediatricians give their patients a book at the end of each year. What would happen if they really talked to the parents about swimming lessons? Would that intervention work?

The important focus that I want you to think about is the health care disparity in terms of a county agency that has a series of health centers all over the county. The way we do the analysis is to think about a hypothetical county agency located in the majority census tract—

the all white neighborhood. This county agency has urgent care hours from 5:00 p.m. to midnight. But if you look at the health center in the minority census tract—the black neighborhood—there is no urgent care. That is an example of the health care disparity. That black child with asthma has no urgent care center to go to. That has an impact on the health outcome. Keep that distinction in mind.

I will talk about three things that we do at the Office of Civil Rights (OCR). First, we have traditional civil rights enforcement that is primarily complaint driven. Second, we have an effective communication national initiative with the American Hospital Association. Third, we have a national initiative focused on Title VI education in medical schools.

To file a complaint, someone has to go to their local OCR office, or contact them by e-mail or letter. An example of a complaint is when the individual goes to a hospital and requests language assistance or a translator. The hospital might say no or it might say "It is $100.00 an hour." The hospital might say, "Can't your

* **Kenneth D. Johnson** is the Chief of Section Three in the Civil Rights Division Office for Civil Rights at the U.S. Department of Health and Human Services. He supervises a team of civil right analysts and equal opportunity specialists focusing on health disparities of the Temporary Assistant Screening Families Botanic (ph) Programs, the Children's Health and Insurance Program (CHIP), HIV/AIDS Treatment and Services, Program and Physical Accessibility for Individuals with Disabilities, and Civil Rights Review of Medicare Providers. Prior to joining the Office of Civil Rights, Mr. Johnson spent nine years litigating housing, fair lending, education, and disability discrimination cases in the Civil Rights Division at the U.S. Department of Justice. As a Senior Trial Attorney in the Housing and Civil Enforcement Section, he worked closely with the Regional Offices of the United States Department of Housing and Urban Development and served as lead counsel on several pattern of practice cases brought under the Fair Housing Act to oppose discrimination on the basis of disability, race, or national origin. Prior to joining the DOJ, Mr. Johnson practiced at Washington, D.C. and Los Angeles-based law firms. He also served as a law clerk to the Honorable Damon J. Keith of the U.S. Court of Appeals for the Sixth Circuit. Mr. Johnson earned his B.A. Degree in Political Science with honors from California State University Fullerton in 1983, and his J.D. Degree from Harvard Law in 1988.

son or daughter interpret for you?" Those are all inappropriate and illegal responses under Title VI, which prohibits national origin discrimination and requires hospitals receiving federal financial assistance to provide meaningful access to individuals with limited English proficiency. Once that complaint is filed, our regional office investigators go out and investigate the complaint. They interview the complainant, the people who were with the complainant, such as family members or friends, as well as the hospital staff who was involved. Oftentimes complaints are filed not only by an individual consumer, but also by an advocacy organization. Sometimes we have complainants who are represented by counsel.

After a complaint is investigated, the regional office decides how the complaint could be resolved. One option might be to find a violation and issue a letter of finding. If OCR finds a violation and issues a letter of finding, then under Title VI the hospital has a certain period of time in which to come into voluntary compliance. Usually, because we have an emphasis on voluntary compliance, we would work with the hospital to get to that point. In an ideal situation we would negotiate a settlement agreement, where the hospital would institute a language assistance services program. That is essentially the best-case scenario. If the hospital is unwilling to negotiate a language assistance program or implement that type of program, then we would have to proceed with enforcement. Our civil rights attorneys in the Office of General Counsel would go to our HHS Departmental Appeals Board and file an action. The goal would be to terminate federal financial assistance to the hospital—basically, Medicare and Medicaid funding. This occurs rarely because usually hospitals or nursing homes would like to settle with us before we get to that point.

Earlier today my colleague talked about the limits of our civil rights enforcement efforts. We need you, as consumers and advocates, to bring complaints to us. The area of limited English proficiency is certainly one where it is very important to have advocates involved. At OCR, the complainant does not have to be the affected party. If you have a client or a colleague or a friend who has a complaint against a hospital, they do not necessarily have to file themselves. You or an advocacy organization can file on their behalf, which would lead to us to investigate that complaint.

Title VI prohibits discrimination on the grounds of race, color, or national origin in settings receiving federal financial assistance. HHS enforces Title VI against those entities that receive federal financial assistance from HHS. Medco is a recent case that we resolved where I do think that we made a splash on the Title VI arena. Medco is the largest national pharmacy benefit company in the nation. It doles out over 100 million prescriptions a year through the mail. In that case, a Spanish speaker filed a complaint with us. She wanted to use the mail-order pharmacy, but none of the documents were in Spanish. Medco did not have support staff on their 800 line to speak with her in Spanish.

Following the investigation, we negotiated with Medco. The company agreed to implement a critical language access plan with a number of different components. One was to use telephonic interpreters, which are now available 150 languages, including Spanish. Medco also agreed to revise its systems by enhancing the ability to route Spanish speakers to those who can actually answer their questions in their native language. A critical outcome of this settlement is that Medco's computer systems will now flag language preference on an ongoing basis. When someone orders prescriptions from Medco for the first time, the system will flag that the person wants to speak with a Spanish-speaking benefits counselor. That request will be in their file for the foreseeable future.

Another example of a Title VI case was a dispute with the state of Hawaii on the limited English proficiency issue. Hawaii's Department of Human Services has a 1.7 billion annual budget. The state covers programs including Temporary Assistance for Needy Families (TANF), Child Care, Child and Adult Protective Services, Vocational Rehab, and the state's Medicaid budget. This is such an important case because it's just critical for people who qualify for Medicaid, which is basically our safety net and the insurer of last resort, to have access to that program in their native language. Hawaii agreed to take reasonable steps to provide meaningful access to its programs for LEP persons who are eligible to receive services and benefits. We entered into a voluntary agreement with Hawaii's governor to maintain her administration's commitment to improving services for people with limited English proficiency. She has required all state and state funded programs to develop plans for providing interpretation services and translated documents.

This illustrates the limits of our litigation. We do not set the benefit standards. CMS does that. CMS is going to determine who qualifies for Medicaid. What OCR can do is enforce Title VI prohibition against national origin discrimination. We can make sure those services are delivered in a way that people with limited English proficiency have meaningful access. For the present moment, the enforcement of Title VI has been primarily in the area of limited English proficiency, but I do want to talk for a moment about a more traditional Title VI enforcement, which we have done in the past.

Traditional Title VI enforcement is much like traditional Title VII enforcement in that there are two legal frameworks, one being disparate treatment, the other being disparate impact. Under Title VI, much like Title VII, you can proceed with disparate treatment, which is intentional discrimination. Disparate impact is a more difficult case because does not require proof of intentional discrimination. It does require that a class of persons be treated differently. Disparate impact claims arise from allegations that a recipient of federal financial assistance is violating Title VI by utilizing a neutral policy or practice that has the affect of disproportionately excluding or adversely affecting members of a protected class.

As a real example, one county health department had both health centers in minority communities and in majority communities. The clinic located in a majority community provided evening appointments, but the clinic located in a predominately black area did not provide evening appointments. The problem with that policy is that it precluded black residents who worked during the day from access to care. The policy, while allegedly not race based, resulted in a disproportionate adverse impact upon African-Americans.

The county had a number of reasons for this policy, and principal among them was safety. They said their county workers did not want to be in this community late at night, and that was their kind of whole defense. However, once we establish an adverse impact we have to look at whether that county can articulate a legitimate non-discriminatory reason. If so, OCR will determine if the alleged non-discriminatory reason is a mere pretext for discrimination, and if there are equally effective alternatives

that would result in a lesser discriminatory affect. Here, the safety concern was not necessarily a legitimate non-discriminatory reason in that that safety concern could be addressed by security personnel. It also could be addressed by alternating the evening hours. For example, they county could have had evening hours at the health center in the Black community on Tuesday night, and they could have evening hours at the health center in the White community on Thursday night. That would have addressed the concern of staff costs. The practice of never offering evening appointments at the health clinic in the black area violated Title VI.

The questions we consider in looking at these cases include: Is there a facially neutral policy or practice? Does the policy or practice have a disproportion adverse impact based on race? Is there a legitimate non-discriminatory reason for the policy or practice? If a legitimate non-discriminatory reason is presented, are there equally affective alternatives to the policy?

Recently Martin Luther King Hospital in California closed. One of the reasons for the closure was serious safety issues. Throughout the country, especially in this time period where we are having an economic downturn and where state and local governments are strapped for cash, we are already starting to see hospital closures. We receive resultant complaints that the hospital closure is racially motivated. We did a big case related to this issue in Wilmington, Pennsylvania several years ago. OCR investigated a allegation that racial segregation would be the result of a hospital corporation's plans to modernize one hospital in an urban black area, close two hospitals in urban black areas, and build a new hospital in a suburban white area. The complainants alleged that as a result of these plans, the suburban hospital would be racially segregated.

In that case, we negotiated a voluntary settlement agreement around the primary issue of transportation. The case resolved much like the 1960's cases where we resolved school desegregation with busing. The hospital corporation agreed to provide transportation from the black community to the suburban hospital and from the suburban area to the one remaining black hospital. In this way, everyone would have access to care and to the specialists at both facilities.

QUESTION: I have questions about Maryland. I am from the Eastern Shore originally. Is there any difference in the success of resolving disparities between the city or metropolitan-type counties and the more rural counties, such as on the Eastern Shore or in Western Maryland?

DR. CARLESSIA A. HUSSEIN: There are differences and it depends on a couple of factors. For example, we are very concerned about some of the Eastern Shore counties because their statistics look very poor, not just for African-Americans but for the whites also.

And our concern- and we repeat this all the time- we are not just racial oriented. We are oriented to the entire population. So whichever group has the worst statistics is where we want to focus services. So we are seeing the differences and what we're trying to do is to give that information to the local health department with some recommendations of how they need to focus. Because often times the local health department does not know it, they just have the county total, they do not have the information by the Native American group here and the African-American group and the others.

QUESTION: Are the county health departments more responsive to what you are saying in more urban areas or in more rural areas, or is it the same? I am speaking more about success I guess.

DR. CARLESSIA A. HUSSEIN: It is a mixed bag. Of course, for some people it takes a while to understand that to offer health services in a way that are effective and has results, you have to offer it differently to different people. So, for example, sometimes the African-American rural areas of the Eastern Shore are not receptive. They do not go to the health department, do not feel they are welcome, and cannot visit the department during its open hours because they are times when they are trying to work and make a living. So for other health departments, they are more receptive and understanding and beginning to have late hours.

Some of them offered the H1N1 Swine Flu on a Saturday. Some of them left the health department and went to a church to kind of put things on. So that is why we are trying to get the health officers, their staff, other providers, and hospitals to be more targeted and focused on people. We also have moved heavily in terms of translating materials. We literally dug into the census data by small census tract for the counties to see what languages we needed to translate the H1N1 materials into because people really didn't have that level of detail. They are just generalizing about that population.

I know I do not have a good answer for you, but I am talking about what the effort is. We are beginning to get more people to understand that they need to know the small groups within the county to really organize services to really target people.

QUESTION: Just one other question about Maryland: Is there a role that geographic disparities plays within the broader scheme? I do not know if it is true anymore, but the Eastern Shore had an extraordinarily high cancer rate compared to other areas in Maryland.

DR. CARLESSIA A. HUSSEIN: Cancer is a very interesting concept not just for the Eastern Shore, but also for the Eastern part of the U.S. Cancer goes back historically to when we had mines in the North, the waterways that come South, and the weather systems that come south from Pittsburgh and other places.

There is not accurate data on this to point. The theory is that factories and industries that were developed in the East coast had an effect on the Eastern Shore area. I think that it is because that area is near the waterways. In terms of EPA and other related issues, we are now becoming more knowledgeable about the environment and what is impacting the health of all the people.

QUESTION: I have a question relating to Native American issues. I know that there was an issue with tribes wanting to gain recognition as a tribe. I have heard about that mostly within the context of gambling and casinos, but how does that play within the broader framework of healthcare and whether they are recognized as a tribe by the federal government or not, even though they might be Native Americans?

HILARY FRIERSON KEELEY: There are two agencies in the federal government that deal with Native American issues, one is the Bureau of Indian Affairs, and one is the IHS. We used to all be one part, one agency. Through the Transfer Act, healthcare was segregated and sent to HHS. The Bureau of Indian Affairs determines federal recognition, and it is done

through a two-part process. You can either be recognized by the Bureau of Indian Affairs, or you can be recognized through an act of Congress. If you are recognized as a federally recognized tribe then you are part of a political class, which are federally recognized tribes verses Native American as a racial category.

If you are a federally recognized tribe, you are then eligible for IHS benefits. If you are a member of a state recognized tribe, you are not eligible for IHS benefits, generally. There are some programs that state recognized tribes are eligible for. There is the Urban Indian Programs, which are programs for Indians in urban areas, and state recognized tribes can receive benefits there. There are also some grant programs in the Department that extend to state recognized tribes, but those mostly have met the strict scrutiny requirement that they are geared towards health disparities based upon race, not because of political class.

And so often our office is called upon. There are different agencies that would like to extend grants to tribes or to Native Americans, and so they always call us and say, "We would like to extend the grant but what can you tell us?" And we have to advise them that there is different case law, it is the *Morton v. Mancari Standard*[1] or the *Adarand Constructors, Inc. v. Peña*.[2] Standard. If you have met the political classifications, then you do not have to follow their strict scrutiny. But if you are in a racial classification, then you have to fall under strict scrutiny.

A lot of times when you have grantees that are extending their grants to state recognized tribes, and also to Native Hawaiians and Native Samoans, there are underlying reasons that will withstand strict scrutiny. And we work very closely with our OCR in cases like that to make sure that whenever grants go out that the agency understands the difference between what the IHS does, because our appropriation is only for federally recognized tribes, verses some of the granting authorities that would extend beyond this.

QUESTION: One other point I wanted to question is about the islands along Chesapeake Bay, Smith Island, St. Helena Island. From what I know, there are some disparity issues because of the isolation. What is being done in that regard for the populations on those remote islands within the Chesapeake Bay?

DR. CARLESSIA A. HUSSEIN: Not enough…I will just start there. There have been discussions about trying to have better transportation that is easier to get back and forth from the mainland to those islands but the issue of power and politics come into play and so it has not been sufficient. More needs to be done.

And just a comment on the recognition issue; in Maryland there are no state recognized tribes. So this is a big issue. Our office cannot do much other than just express sympathy, but we are certainly trying to talk to them. But it gets complicated because there are issues about ownership of the land, to the state verses to the tribe, and what is on the land and what is in the land. There are really many issues that have not been able to be pulled apart by the state of Maryland, which is unfortunate.

QUESTION: The descriptions about the negotiations with Native Americans appear to be sweeping generalizations that I find a little bit difficult to accept. Because I know there is a big difference between the Iroquois, who live up in New York, and groups down in the Southwest. Certainly the Southwest groups do not have any sense of what a business contract is all about.

HILARY FRIERSON KEELEY: The IHS is organized in the twelve areas that are geographic. Our Area Directors are primarily all appointed by the Director of IHS, but through Tribal Consultation with the affected tribes in those areas. When you are talking about the Albuquerque area, which represents the Pueblo, you have an Area Director who always has expertise and experience dealing with the Pueblo, which are very traditional tribes. For example. the Pueblo are different from the East Coast tribes who for the most part are more assimilated and may have more expertise in business transactions. When choosing Area Directors, the IHS looks for individuals that understand the unique needs of the tribes it represents.

I think that the IHS has really done well in this area. I do a lot of traveling and second chairing with regional attorneys throughout the country. Every negotiation that you go to, whether it's in the Oklahoma area where you are dealing with tribes with no land base with checkerboard reservations or you are dealing with Alaska in the remote villages, you have IHS leadership in place in the areas. The IHS leadership is very in tuned to the specific needs and knows how to negotiate government-to-government. That is something that our office takes great pride in.

I chair a monthly call with a negotiation consistency group with all of the regional attorneys that advise the different areas. Without fail, the Alaska area is probably the most unique because of their geographic location, and the fact that it is difficult to get supplies and to transport patients. Because of the way that IHS is structured and the way that the leadership is appointed, IHS deals with things in a much different way. It is not one size fits all by any means.

[1] 417 U.S. 535 (1974).
[2] 515 U.S. 200 (1995).

Keynote Address

> The undeniable truth is, though, if you are white in the District of Columbia you have the longest life expectancy in this country. If you are African-American, you have the shortest.

Councilman David Catania:* Often we get together and we sometimes celebrate our defeats in the parade of horrible, but there are a lot of good news stories about what is going on here in the District of Columbia. Specifically, with respect to our health care safety net we are moving the health care ball forward. Health care has been a focus of mine since I joined the Council in 1997. Early in my tenure on the Council, I was struck by the incredible disconnect between the amount of money that the District would spend on health care and our deliverables. There are enormous life expectancy disparities in Washington, DC based on class and color. I was given the opportunity to chair the newly organized Committee on Health. For those of you who are not aware, the Council is a unique legislature. We are the state, county, and city government. The committee chairmen have quite a lot of influence in deciding the direction of policy within the respective committee. Within weeks of assuming the new committee chairmanship, a steady stream of bad news flowed into my office.

Those of you who have been in DC for a while are aware some of the things we have not done exactly well with respect to HIV/AIDS. At the time, I took over the chairmanship in January 2005, I had vendors who had not been paid for in as long as nine months. You can imagine that under-resourced non-profits were essentially funding the government's operation while trying to meet their own overhead. Going nine months without being paid obviously puts quite a damper on operations. At the same time, our Board of Medicine ranked dead last in the country. The Board of Medicine polices your doctors. If you are at all concerned about having high quality care, you want a rigorous Board of Medicine to police doctors and root the bad ones out.

* David Catania is a member of the Council of the District of Columbia. He was first elected as an at-large city council member in 1997 in a special election and he has been elected for four terms. He chairs the Committee on Health and serves on Finance and Reviews, Libraries, Parks, and Recreation and Government Operations and the Environment Committees.

Councilman Catania received his bachelor's degree from Georgetown University's School of Foreign Service and his law degree from Georgetown University Law Center and is very often in the news as a true public servant.

Regardless of what the catastrophe de jour was at the time, there was one thing that was undeniable: no one was in charge of health care here. To hear the government's side of the story, you would believe that there was not enough money to provide the kind of high quality access to care that we are all entitled to. The truth is, at that time and today, the District has one of the highest per capita expenditures on health care in the nation. To this day, notwithstanding the progress that we are making, we still have a long way to go. The undeniable truth is, though, if you are white in the District of Columbia you have the longest life expectancy in this country. If you are African-American, you have the shortest. That is the simple truth. It is not as if we do not have the capacity or the services or the wherewithal to produce a long life expectancy. There are very real issues of race and class and income that are dividing these outcomes.

To me it was bad to see pubic officials simply wringing their hands and complaining without actually doing anything about it. I took it upon myself to begin chairing the committee in a different way. I started by reviewing every expenditure starting in January 2005. About 28 percent of the city's budget is spent on health care. That is an enormous amount of money. We have the largest percentage of the treasury of any of the nine standing committees. The fact of the matter is no one had actually looked at how we were spending the money. I will be honest with you. Over time people simply have ladled on one expenditure after another. They never actually go back and make sure we are getting what we are paying for. I took a fairly rigorous and proactive approach. We began looking at every expenditure of our two million plus dollars, right down to the phone bills. I want to share with you a couple of things that we found.

We hear the refrain of "waste, fraud and abuse" all the time. How many of you believe that it exists? How many of you think it is a tired excuse? It really does exist and it exists in a galling, maddening way. Let me give you a couple of examples. Two million dollars is a lot of money to go one line item at a time with a staff of five, but we actually took the old approach of "trust but verify." We found that the Department of Health leased over twenty pieces of property across the city. These leases originated in the late 1990's. Most of them lacked certain terms and conditions that you might find

interesting, like the number of square feet to be leased, or price per square foot. It would not surprise you that the people who were able to obtain these leases were individuals politically connected to our then mayor. To this day we are still extracting ourselves from some of these leases.

At the time I started this in 2005, we were paying as much as sixty-six per cent of the appraised value of the property in rent per year. For class-A office space downtown we pay eight to nine per cent of appraised value. These politically-connected individuals, with their friend's help, were able to simply steal money. I do not know how else to put it. We leased properties that were poorly equipped to serve the functions we needed. Some even lacked handicap accessibility. We "bought" these properties several times over. Our health outcomes did not happen by accident. We have been poorly served by five generation of leaders who allowed their friends to enrich themselves while at the same time crying a river about health outcomes. It took some doing to extract these bottom-feeders from their leases. There is no other way to describe them really. They are stealing money that is not intended for their pockets, but rather is intended to provide health care—high-quality, successful health care—for our residents. It took a lot to extract these bottom feeders, but I am pleased to say we have been fairly successful.

Another area that caught my attention through our focus on every expenditure was a telecommunications audit. Every local, county and federal government should conduct a telecommunications audit because they will find some eye opening things. I found that the Department of Health was paying for about 4,000 land lines to serve the Department. This did not in itself seem shocking, except we only had 1,300 employees. That did not include, mind you, city-owned cell phones. I am a believer in physics and even giving every employee one phone for each ear, we obviously still had more phones than we needed. We were able to dramatically beat that back as well.

One other example: Medicaid transportation. There are a whole host of people who make their money off of poor people. You have to be careful because they are usually the most clever advocates for poor people. If you are Medicaid eligible you are entitled to emergency and non-emergency transportation. The government will pick you up at your house and take you to medical appointments and back as many times as you need it. Washington, DC has the most highly developed public transportation structure of any state in the country, but our per person cost would rival that of Alaska, where patients are transported to doctor's appointments by plane.

We had a number of individuals who would bill the District seven figures and we could only find 3,000 dollars or less in actual services rendered. No one ever asked, "where is the money?" No one ever said, "where are the bills?" The amount these vendors were paid was self-determined. It was the most ridiculous honor system. It would not surprise any of you to understand that these Medicaid contracts were given to friends of public officials. This is important because of what you will hear later on about what we have done with dental benefits. We were able to save enough money by organizing a rational Medicaid transportation plan to provide dental benefits for 60,000 people. Let us just be nice and say there was *enough* waste in transporting people in non-emergency Medicaid plans. Today we still pay for Medicaid beneficiaries to get to the doctor. We simply took out the waste and we were able to provide a comprehensive dental plan for 60,000 people.

In the four years since I became chairman of the health committee, we have cut the number of uninsured in our city from about thirteen and a half per cent to roughly eight or eight and a half percent. Our uninsurance rate has recently jettisoned back up from seven percent because the economy has gone south and not everyone is availing themselves of COBRA. Still, this rate places the District in the top tier nationally with the lowest rates of uninsured. In terms of real numbers, it means about 35,000 more people that are insured today, even in this economy, than were five years ago. That equates to about half a ward.

With respect to children in this area, I am very proud. We rank with Massachusetts as having the lowest percentage of uninsured children in the country. That is the result of a very sensible policy to increase Medicaid coverage to 300 percent of the poverty level and then to have an alliance program that covers every child, regardless of immigration status, up to 300 per cent. That is something I am very proud of.

With regards to dental benefits, five years ago we ranked dead last (with Virginia and Maryland) in adult dental benefits. Misery loves company and our friends to the north and south, Virginia and Maryland, were ranked last with us so nobody made anybody look too bad. There was a perversion there, though. For example, we would pay for emergency tooth extraction—as many as you have teeth in your mouth—at local emergency room. Each extraction costs eight to twelve thousand dollars. It adds up. We thought it was a more appropriate public policy to deny care until emergency services were required. This practice caused pain and suffering and cost the tax payer. Rather, now we invest in expansive primary care dental benefits. Now we rank first in the nation in dental care reimbursement.

I receive routine calls from Medicaid and alliance managed care organizations complaining that we are too generous and are busting their budgets. Two of our managed care organizations actually lost money last year because the dental benefits have been so widely used. They asked if we could make an arrangement for them to get more money. I explained the notion of capitalism and risk-based contracting. They do not get to keep profits if they make them and also get reimbursed if they lose. They are supposed to be organized in such a fashion that they win if they do it right and fail if they do not.

Since April 2007, we have had over 30,000 unique dental visits by adults. We have invested well in excess of 60 million dollars. It really is a powerful thing to see people who really have been marginalized: the adult Medicaid population. These are poor people, most of whom work for a living. As poor adults age their teeth deteriorate,—as all of ours would if we did not take care of them,— it takes its toll on dignity and their ability to find employment. It is hard to show up for a job interview when you have no teeth. I actually had a woman testify at my appropriations hearing last year with her new teeth. It was an extraordinary moment and I felt that the city had actually delivered what it should to its residents. She explained how her teeth helped her manage her diabetes. It is not just opportunistic infections, viruses and the diminished life expectancy that come with poor oral hygiene, there are also issues associated with morbid health conditions.

What did we do with the rest of the money? As we extracted government waste we reinvested back into health care. Although colleagues of mine have been criticized for practices with respect to earmarks, I will tell you the other side. Earmarks can work if there is proper oversight and proper public participation. I will give you a few examples. One example is a set of earmarks I have given to Children's National Medical Center. In 2005, 37 percent of our schools had full-time nurses. Full time nurses are important, not just for ice and aspirin, but for a whole host of reasons. School nurses test body mass index and help to manage special education kids.

Part of the reason we have to send kids out of our system is because we cannot manage their special needs and health-related issues at the school. It actually saves us money to have nurses present at schools. Ninety-six percent of Washington, DC schools have full time nurses. Policy makers are coming from as far as Dubai to learn about DC's integrated electronic medical record central system. We have doubled the number of professionals in our school heath program.

> "DC is the only jurisdiction to ever have made substantial progress in preschool immunization, going from 72% to 93% of immunized preschoolers."

We were the only jurisdiction last year to receive the highest child immunization award of distinction from the Centers for Disease Control and Prevention. DC is the only jurisdiction to ever have made substantial progress in preschool immunization, going from 72 percent to 93 percent of immunized preschoolers. These are all investments in our future.

Additionally, the District has a number of receiverships, including special education and services for the developmentally disabled. We created these receiverships because of the way in which we organize Medicaid reimbursements. When a plan's reimbursement rate is low, not many professionals will accept that plan. In 2009, the District's reimbursement rates for Medicaid fee-for-service were one half that of Medicare. There was a long history of underfunding Medicaid reimbursements which had the effect of forcing physicians out of service. When the fee-for-service Medicaid population—the most vulnerable seniors, the most developmentally disabled, the most mentally ill—cannot get access to care and die in care homes, it becomes front page news in the Washington Post. There is a lot of outrage. The solution is as elementary as raising reimbursement rates to attract physicians to treat the aging and disabled. It does not require a Manhattan Project. Last year, I was able to facilitate near-doubling the tax on cigarettes. We now reimburse 100 percent on Medicaid and Medicare. We are one of the few jurisdictions that offer 100 percent reimbursement. We hope to attract more Medicaid fee-for-service providers.

Later today, I am heading to United Medical Center. The urban safety net hospitals are dying because of the loss of third-party paid insurance, which cross-subsidized Medicaid and Medicare. Medicare and Medicaid do not come close to reimbursing costs, so we must rely upon a fair mix of third-party insurance payment.

When you have a hospital like United Medical Center, where about 10 percent of the people are third-party paid and everyone else is government paid, when a hospital loses 22 to 35 cents on every dollar of service it cannot make that up with volume alone. United Medical Center was owned by a company called Doctors Community Health Care Corporation. A gentleman by the name of Paul Tuff was the CEO. I have said many times that he was one of the few people I ever met who could get out of a trash can without taking the lid off. While the city shoveled millions of dollars at him and he put the hospital not through one but two bankruptcies, he formed a small company called the Redman Tuff. He took six and a half million

dollars out of Redman Tuff for his private airplane. The year before he put the hospital into bankruptcy, he took three million dollars as salary.

The company served as an employment center for the Tuff family: brothers, aunts, uncles, kids, stepchildren. It was a larcenist cabal that is now bankrupt. He bought United Medical Center, then called Greater Southeast, in 1998, a year before he bought Michael Reese Hospital in Chicago. Michael Reese, like Greater Southeast, was a 450-bed hospital that served as safety net for a largely African-American community. I am going over to United Medical Center today to see the progress that we are making on our new 11 million dollar pediatric emergency room that will be run by Children's National Medical Center. I will see the 30 million dollars in capital investment including the first ever MRI and a fully restored radiology department including cardiac catheterization equipment. Today, Michael Reese Hospital has a crew on site in Chicago, but it is a demolition crew. This shows the struggles that we have in urban health care, whether there is the will within a community to make the gap up left by under-reimbursement of a publicly funded system in the absence of third-party payment.

For those of you who live in different jurisdictions, it is important to advocate for safety net hospitals because it is in your own interest. It is more expensive to not have them than to have them. If you allow safety net hospitals in the urban core to close, uninsured patients will seek care at local hospitals. It puts a pressure on the entire system.

If we had allowed the former Greater Southeast to close, we would have added 50,000 emergency room visits to hospitals already tight on capacity, putting a further strain on the existing infrastructure. You simply cannot escape the care. Individuals who need care will find a hospital near you and they will often tax your hospital's infrastructure beyond its physical capacity.

In Washington, DC, we have had quite a struggle with the HIV/AIDS epidemic. I want to provide a greater context for this discussion. You all have undoubtedly heard the stories about three percent of the District's population having HIV/AIDS. How many of you heard the references to third world countries? There is a different perspective. To be sure, the District has not always done its best, but I can provide context. For those who live in this region who are HIV positive there is a general policy. I do not mean to offend any Virginians, but if you are poor or in need of medical care, the accepted policy is to move to Washington, DC. There is no safety net in Virginia. Therefore, if you are HIV positive in neighboring Northern Virginia you move to the District, where every resident between zero and 200 percent of poverty is given access to a 100 percent publicly financed primary, specialty, and acute care insurance model. This practice adds to Washington, DC's HIV/AIDS numbers.

If you are from Maryland, you are slightly more evolved but not much. Coverage rates are higher than in Virginia, but not for single, childless, or immigrant individuals. If you are a Marylander with HIV who is struggling financially, you move to the District. If you are in need of primary or specialty care, none of the suburban hospitals have acute care capacity in HIV treatment. The same goes for Spanish-speaking capabilities. If you are LGBT or African-American, the suburban hospitals simply do not have the capacity to finance or the infrastructure to treat you. We wind up being the focal point for a region of four million people. Numerous people come here and it makes our HIV/AIDS numbers look bigger. Our numbers are also bigger because we are vigorous with respect to our treatment of HIV/AIDS. There is no waiting list to receive treatment. We have HIV/AIDS drugs assistance programs and there is no co-pay or deductible. By virtue of keeping people alive longer, the number of people with HIV in DC grows.

We will be releasing an epidemiology report that shows we have cut our new HIV infections in half, which is good news. Our HIV/AIDS drug adherence is up by 50 percent, which is good news. We still have a long way to go. The District government falling apart did contribute to this epidemic.

When I became chairman, we had no Epidemiology Department, no data to research. If you do not know how an epidemic is being transmitted, if you do not know the populations being affected and infected, you do not know how to organize your limited prevention dollars. You do not know how to build primary care and a care capacity for the populations affected. We used one budgetary earmark to contract with George Washington University School of Public Health. We worked with them to build our data research department within the HIV administration. It is evident that we have the finest urban data in the country now.

Communities today look very different than communities did ten or fifteen years ago. We are going into communities and providing a boot camp on everything from how to organize a board, how to apply for grants and how to properly administer grants, to how to make sure you file your 990's. We intend to prevent a disorganized or underperforming infrastructure as we go forward.

"If you allow safety net hospitals in the urban core to close, uninsured patients will seek care at local hospitals. It puts a pressure on the entire system."

Finally, I would like to talk about long-term care. Our long-term care infrastructure speaks about who we are as a community. At present, we have nineteen nursing homes in the city. A third of those are excellent with four or five star ratings. We have another third that are not so good. Our efforts are to improve the quality of care and expand care options.

Assuming you reach a certain age, you will need long-term care. At that point, you will probably rather stay in your own home than to go to a nursing home. Thus, we have made a huge investment in home, community-based care. We provide a Medicaid waiver that gives enrollees the same quality of health care in the home as they would receive in a nursing home.

I realize that people may eventually find their way into nursing homes. We recently passed a measure that organizes our skilled nursing facilities in a way to provide the highest quality care. The District is one of the first jurisdictions to require a physician in every nursing home. Other federal rules require a relationship with, not a presence of, a physician. The policy developed based on the needs of rural nursing homes where there were not a lot of doctors to have on staff. We have a lot of doctors in the city, however. We now have the first-ever requirement of 0.2 hours of physician time per patient per week.

The city has also advanced with respect to discharge planning. Often, at nursing homes, once you check in, there is no incentive to send you home because you generate revenue. To combat this, the District builds in a discharge planning regiment to help people make the decisions that are best for them. We are also licensing personnel administrators and geriatric specialty training for those who work in nursing homes.

Those are just a few things that we are doing here in the District. It is a great time to be involved with health care in Washington, DC. We have really made some progress. We have a lot further to go, but we are a rich jurisdiction and we have a lot of talent here.

Participant: I am wondering what became of Paul Tuff. Is there any litigation in progress?

Councilman Catania: You can hide behind corporate shields in this country and get away with crimes. That is what Paul Tuff did. There were no criminal consequences for his actions and frankly, very few financial consequences for his actions. He developed a model that worked for him. He would take reimbursements from insurance companies, third-parties and the government. He would pocket the money. He made his money off the backs of the doctors and providers. He simply would not pay those who provided goods and services. He would let the accounts payable stack up. At some point, you know the adage: If you owe the bank fifty dollars, you have a problem. If you owe the bank fifty million, the bank has a problem. The system is now bankrupt.

There were actions that a federal prosecuting authority could have looked at. The only thing D.C. could do was to use our efforts to extract him. I could go into detail about the actions that the committee took along with Chairman Vincent Gray to ensure that Paul Tuff would sell his D.C. hospital. The city used its tobacco settlement money to buy the hospital for seventy-nine million dollars. Thirty million dollars were allocated for new equipment, twenty million dollars for two years of operating capital, and twenty-nine million dollars to buy the facility. I was adamant that Paul Tuff walk away without a penny. Even though we paid twenty-nine million dollars for the hospital, the money went to vendors who had not been paid. We paid for goods and services needed to keep the hospital open. In the end, he did not get a cent. I acknowledge that he had already been paid many times over through his own fraud, but it really was not in my capacity as Chairman of the Legislative Committee to prosecute him.

Going forward, I am very excited about this facility because we have added 120 employees at the hospital. We have added two floors of skilled nursing facilities. We have added an entire floor of long term acute care. We have doubled our residential mental health capacity. We have added equipment, such as an MRI. I am a patient of the hospital, by the way, for a shoulder injury. I ask others to have confidence in the institution and I get treated there too. I am very excited about everything from new hyperbaric wound chambers for diabetes patients to the Children's National Medical Center partnership in a new pediatric emergency room. Many of the District's kids live in wards seven and eight and deserve access to the highest quality emergency pediatric services.

Participant: In the news you had some sort of a fight with pharmaceutical companies about payments to doctors. Has there been any progress?

Councilman Catania: Two years ago I was named the pharmaceutical industry's number one enemy—second to the Attorney General in New Jersey. We have taken a number of actions that have angered the industry; everything from a preferred drug list, supplemental rebates, and pharmacy benefit management legislation. Most recently, we put the kibosh on therapeutic interchanges without patient consent. Pharmaceutical companies conspire with pharmacies to switch your drugs without telling you or your doctor. This practice is now illegal in the District. We also oversee the licensure of pharmaceutical representatives.

We are the only jurisdiction in the country that has a code of ethics and the ability to extract pharmaceuticals representatives for violating them. Representatives who engage in off-label prescribing or who provide false or misleading information are denied a license. There is now an association of pharmaceutical representatives who are now trying to adopt their own code of ethics.

Participant: Is there anything that can be done as far as regulation of nursing homes?

Councilman Catania: We have a couple of homes where I am not thrilled with the current management. We have always had the means to seize the license of a nursing home but we have not had a way until now to pull the operator's license. We have never really seized the license of a nursing home administrator to the performance of her or his nursing home until now. We have also expanded the way in which we can actually seize control of a nursing home away from either the management or the owner. What it comes down to is providing the Department of Health with greater tools to increase performance. You can really tell the quality of the nursing home by the number of EMS calls to the nursing home. When you have the same nursing home making multiple 911 calls a day it will tell you that patients are not seeing a physician routinely. No one on the premises tending to patient needs. We estimate that we are spending about twenty-one million dollars a year in preventable hospitalization that originated out of this poor health care infrastructure.

It is not all about money, but I spend a lot of time focused on money because I have to cut about 400 million dollars out of our budget next year. We must be mindful about how money is being spent and make the greatest use of it.

A smarter system has physicians at the nursing home, treating patients where they live. We have also expanded the types of services that we now require nursing homes be able to provide, to include dialysis. We have long transported people back and forth to dialysis. This causes transport trauma and added expense. At larger size nursing homes, you ought to be able to provide certain services on site. The same is true for mental health, substance abuse, or rehabilitative services. We have given the Department of Health the flexibility to make these determinations. Increasingly, we are going to put pressure on the nursing homes to provide the services once they reach a critical mass. Right now, nursing homes call the ambulance to essentially force costs off onto emergency rooms and hospitals. We are trying to reconfigure this.

I have one home in particular that I have got my eye on. It is called Grant Park. I believe in letting them know that we are coming. It is the largest and only nursing home in ward seven and they are poor performers. If I have my way, the current owners will not be in business very much longer.

Aging and Disability Disparities

> For people who have Medicare, their out-of-pocket costs are on average six times greater than the out-of-pocket costs for someone with employer-sponsored coverage.

Professor Ahaviah Glaser:* I am going to talk broadly about health care disparities and older Americans. One of the things that I find most interesting is that as I told people that I was coming to give a talk on health disparities in aging populations I heard, "Well, what are you talking about? Older Americans are the subject of health care disparities?" My jaw dropped because I was having these conversations with very experienced policymakers, staffers, and lawyers who work on health care issues. I thought, "What do you mean?" What do you mean that older Americans do not face health care disparities? By and large these individuals said, "Older Americans have Medicare. They are taken care of." Therefore, a lot of what I want to talk to you about today is the fact that, unfortunately, although Medicare is a fabulous program, having Medicare does not mean that you have been taken care of.

It also does not take away the other health disparities that have been discussed here today. As soon as you turn sixty-five years old, you do not suddenly stop facing issues with linguistic and cultural competency, for example. You do not stop being affected by the number of physicians serving your community, so on and so forth. Those are sort of the big picture things that I want to look at. The other issue is too often people think of older Americans just as the sixty-five plus age group. In reality, older Americans, at least from the AARP perspective, are fifty years or older. What about fifty to sixty-four-year-olds, who are not old enough to be a part of Medicare unless they have certain qualifying disabilities? How do they get their coverage? These factors unfortunately really do indicate that older Americans are in fact subject to a variety of the health care disparities.

First, I will talk a little bit about Medicare. Here is the shocker: for people who have Medicare, their out-of-pocket costs are on average six times greater than the out-of-pocket costs for someone with employer-sponsored coverage. That figure is calculated as a percentage of income, but regardless, this is a shocking statistic. Part of the problem is unlike most employer-sponsored coverage and other coverage in the private market, there is no out-of-pocket cap in Medicare. If you have had a serious medical incident on Medicare you will not reach a point over the course of the year where out-of-pocket expenses cease and insurance coverage kicks in. Medicare has no out-of-pocket cap at all. Also, under Medicare prescription drugs are paid for using what is called co-insurance, rather than co-payment.

I am fortunate enough to have health care insurance coverage. I also have coverage that includes pharmaceuticals. In the last five or six plans I have had, when I go to the pharmacy there is a co-pay. Co-pays are tiered: five dollars for certain generics, maybe ten or fifteen dollars for another generic, twenty-five dollars for a brand name. I know that month after month with my insurance it is going to cost me five or ten dollars for me to pick up that prescription. People on Medicare pay twenty percent of prescription drug costs. If the cost of a drug goes up over the course of the year, Medicare enrollees pay for that. If a Medicare patient fills a 100 dollar prescription, he or she pays twenty dollars. If it is a 500 dollar prescription they pay 100 dollars. These high costs are not uncommon. I would encourage you to take a look at your local CVS clinical cost. You are only paying a tiered co-pay, but people on Medicare would pay a percentage. The same rule applies to fees at the doctor's office. I pay a twenty-five dollar co-pay when I go to the doctor, but it could be much, much higher if you are on Medicare paying a percentage of the actual cost. By and large, percentage of income has traditionally been a good way to look at health care costs. For example, at AARP we suggest that no one should spend more than ten percent of their annual income on health care costs. Under Medicare, the average beneficiary spends a minimum of thirty percent of their income on health care expenses. The oldest and poorest of Medicare beneficiaries spend more than half of their annual income each year on health care.

Medicare, although it is very important and very well thought of in a lot of different ways, does not cover costs such as eyeglasses, hearing aids, dental care, or preventive services, not to mention, most long-term care services. If a Medicare beneficiary needs to be in a nursing facility for longer than 100 days, Medicare will not contribute to those costs. There is

* Ahaviah Glaser is an Adjunct Professor at the Washington College of Law, and is a member of the AARP Health and Long-Term Care team where she focuses, among other things, on Medicare and pharmaceutical issues. She is a graduate of University of Michigan Law School. She has had a number of positions such as head of the Prescription Access Litigation Project. A community catalyst, she has been honored by the National Women's Law Center.

also an enormous coverage gap in the Medicare Part D prescription drug coverage benefit. The good news is that under Part D, Medicare now does cover prescription drugs other than those drugs that you get in your doctor's office. The bad news is that there is currently a 2,500 dollar gap in which enrollees get no assistance with drug costs. That 2,500 dollar gap will be a 6,000 dollar gap in another two short years. You can imagine what a 6,000 dollar gap in prescription drug coverage could mean for those with significant pharmaceutical needs; especially given that fifty percent of all seniors in the U.S. make 20,000 dollars a year or less. A lot of people who rely on Medicare and even Medicare with supplemental coverage are stuck with enormous costs that sometimes result in not getting the coverage they need.

Although others today have talked about racial disparity issues, there is a racially-related access issue in terms of finding a doctor near your home that takes your policy. Although lots of doctors do accept Medicare, there are simply not enough who do, particularly to support the aging baby boomer population. Many doctors are concerned with Medicare reimbursement rates for physicians. There is disagreement about this and I am not going to get into that today, but absent Congressional action, Medicare doctors are going to face a twenty-one percent decrease on March 1st and one can imagine that would only exacerbate this particular problem.

The last thing I want to mention, in terms of Medicare not necessarily being everything it should be for seniors, is financial assistance programs within Medicare are severely limited. Financial assistance programs under Medicare really only help those just above the poverty level (for those of you who have studied federal poverty issues, the poverty level is quite low and quite understated). The program is designed to punish those who have even a small amount of assets. If an individual has saved at all for retirement, if he owns the property where he lives, if he receives a small, even 1,000 dollars, insurance benefit when his spouse dies, he may become ineligible for Medicare's financial assistance programs.

The fifty to sixty-four year-old age group is a really interesting group because if they have employer-sponsored insurance, they are just as fine as anyone else might be. However, there are many people in this age group, about nine million Americans at the last count, who do not have employer-sponsored coverage. They are up a creek without an oar because depending on where these individuals live, there will be one of two results. There are parts of the country where there is literally not a single policy available for sale or application if you are in the fifty to sixty-four age group. Insurers have decided that it is not a particularly profitable market and they stay out of it. Therefore, the first possibility is that even if a fifty to sixty-four years old wants insurance, there are no policies to apply for.

The other possible outcome, for those living in areas where they can apply for a policy, is cost prohibition. Non-employer-based policies for fifty to sixty-four years olds tend to be prohibitively expensive; usually at least double the cost of an employer-sponsored program. There are even states in this country where a person fifty to sixty-four years old pays fifteen to twenty times what a younger person would pay for an identical policy regardless of their health status. There is a fundamental access to health care issue here.

To top that off, very often these policies are not comprehensive. It brings to bear this question: will your insurance actually cover you when you need it? Very often the answer is no for people enrolled in these policies. To add insult to injury, seventeen to twenty-eight percent of all applicants in the fifty to sixty-four-year-old group are rejected when they apply for available policies. Typically, rejection is based on what is called a pre-existing condition.

Rejection of coverage based on pre-existing conditions has been the subject of much debate in health care reform in the last year or so—or the last thirty years depending on how you look at it. The end result is that people in this age group, who have been losing jobs at a much higher rate than younger Americans in this recession, are in a lot of trouble and rarely have access to good comprehensive care. Last but not least, other health disparities problems are simply compounded for senior citizens. The health disparity issues they might face due to race, gender, disability issues, sexual orientation and all of those things do not go away. When you turn fifty or sixty-five, these problems do not evaporate.

Seniors, in more set-upon populations, can really struggle paying for health care coverage. Thankfully, we have solutions for all of these problems. By and large, it is a matter of implementation. We need to put an out-of-pocket cap in place. We need to eliminate the asset tax for financial assistance in Medicare. We need to raise the physician reimbursement rate particularly for general practitioners and gerontologists to ensure that they get into all the communities that need their services. We need to close the coverage gap in the Medicare Part D prescription program.

In terms of insurance market issues, these are fairly straightforward. Ideally, all insurers should be required to use community rating, which is the true spreading of risk in the traditional sense of what it means to have insurance. All insurers should be required to offer policies with comprehensive benefits. It will ensure that whoever is purchasing a policy is actually getting something for her money. It will also allow consumers to compare apples to apples to determine what policy they want to purchase on the market. We also need to eliminate the pre-existing condition barrier to obtaining health care coverage. This is an issue that has a lot of support on both sides of the aisle in Congress, but we do not have time to discuss it here. It has been very difficult to actually end denial of coverage based on pre-existing conditions.

In terms of general health disparities issues and what we can do: first and foremost we need to continue to collect data about health disparities. The reality is we need to be able to find solutions and do things wisely. Governments will typically not move without an awful lot of information, so we need to develop that information. We also need to put resources into enforcing existing civil rights laws within the health care context. This is an area lacking in funding and resources and I really feel strongly that investment in civil rights issues could impact health disparities by addressing issues with cost and access.

I say, as a matter of regular course, all medical providers should receive at least some level of cultural competence training and foreign language translation services should be readily available at all health care facilities. This is an issue that seemed an unimaginable problem twenty years ago, but today we have the resources where at least telephonically, no matter where a patient is in the country, he or she should have access to a trained medical translator in any language. Last but not least, I think that it is important to

provide incentives to bring providers into underserved areas to work with underserved communities.

That concludes my overview. The headline, of course, is unfortunately, older Americans, in particular, suffer from health care disparities.

Chris Herman:* My name is Chris Herman and I have been with the National Association of Social Workers (NASW) for four years. To give you a sense of where I come from, before I worked in NASW, I had more than a decade of social work practice experience in aging and disability settings, such as hospice care. Most of my experience is here in the Metro-DC area in people's homes, and also sometimes in assisted living and nursing facilities, because you can actually get hospice in those settings. I have worked with adults with multiple sclerosis—people who were in their 20s, 30s, 40s, like some of us in this room—whose lives were changed instantly with the diagnosis that, for many people, is progressive and can be debilitating. I also practiced geriatric care management that tended to be with a lot of what are sometimes called "older adults"—people more than seventy-five or eighty-five years old—and many of them in their homes, struggling just to stay independent. Often times these older adults had very limited social support or had out of town family caregivers. This practice perspective really influences the work I have been doing on a more macro level in developing resources for social workers and other professionals around aging and disability issues.

I am really pleased to be here and to have a chance to collaborate with those from the legal discipline. It is essential that we work together as professionals both on a practice level and on a policy level to achieve some of the changes to which other panelists have alluded. I was asked to address challenges related to aging and long-term care or, as is more commonly coming to be known, long-term services and support. Just a brief word of explanation: "long-term services and support" is a term that is very common in the disability community. Aging advocacy organizations can certainly appreciate the perspective that the need is not always about care, but about getting the services and support that people need to maintain the greatest level of independence in whatever setting they live. This is not to say that "long-term care" is not an appropriate term to use, but you may start hearing both terms more and more.

Even though I am going to focus on challenges associated with aging, I think it is essential to preface my remarks by expressing two perspectives that are inherent in social work practice. One is a person in environment perspective. The key to this perspective is that we can only understand and help improve an older adult or any person by exploring and addressing the social context in which that person lives or has lived. This perspective assumes that racism, ageism, sexism, homophobia, and other biases underlie and perpetuate health disparities both on individual and societal levels.

* Chris Herman has a Masters in Social Work and is a Senior Practice Associate for Aging at the National Association of Social Workers (NASW) in Washington, DC. At the NASW, Chris develops resources for social workers that deal with aging, and analyzes and develops policies for this population. Chris states, "the psycho-social perspective continues to inform her work," whether she is analyzing or developing policies or education resources for social workers or older adults, or collaborating with others.

The second perspective is the strengths perspective. In the aging and disability context, this perspective focuses on the resources, abilities, and contributions to society, economically and otherwise of older adults and people with disabilities. This perspective is very important because although it is great that there is so much more attention now being given to the aging of baby boomers, there can tend to be a catastrophic tone to aging. There are pitfalls to looking at older adults as disadvantaged. Such a viewpoint can lead to perceiving older adults as a burden to society and long-term care systems. Although societal aging does present challenges that we have to deal with focusing only on the challenges creates the danger of blaming the problem on the people involved rather than on the system. The strengths perspective also emphasizes collaboration with older adults and people with disabilities, which is really critical if we are going to eliminate disparities. These populations know firsthand what their experiences are and often what the solutions need to be. Also, we need greater collaboration with family caregivers. It has been very rare in my experience to work with older adults, and to some degree with people with disabilities, without also interacting with family caregivers. I mean "family" in the broadest sense of the word; whoever is significant to that person and provides support in various ways (physical, economic, emotional).

First, I will talk about older adults as a cohort and how they perceive the differences between older adults and younger adults. Much of the data that I have is from the Administration on Aging which tends to focus on people sixty years and older. Older adults are more than twice as likely to be diagnosed with two or more chronic conditions as their younger counterparts. Having two or more chronic conditions is associated both with lower income and fair to poor self-reported mental health. Almost thirty percent take five or more prescription medications concurrently and about half of that group also uses over-the-counter medications and dietary supplements. This is not always addressed by older adults or health

care practitioners, but it can certainly complicate the picture. As a whole, older adults are more likely than other age groups to be living with serious health care conditions and taking a lot of medications to treat them. At the same time, older adults tend to have lower health literacy levels than younger adults. Also, the health care system is becoming increasingly complex to navigate for all of us regardless of age. Furthermore, the health care profession has struggled to retain qualified workforce to serve older adults.

A 2008 Institute of Medicine (IOM) report,[1] "Retooling for an Aging America, Building a Health Care Workforce," highlighted two critical needs. One is the need for more health care professionals, such as physicians, nurses and social workers that specialize in gerontology. There is a general need both for more Medicare providers and for providers with specific geriatric training. In social work, only about nine percent of our workforce specializes in aging, and that is much less than we need. Also, the report highlighted the need for more training in geriatrics and gerontology across providers regardless of setting. There are social workers, for example, working in child welfare who wind up interacting with the grandparent who is raising the child. The next thing you know, the social worker is facing aging issues he or she may not be familiar with. The grandparent may have his or her own health care concerns or social service needs. Even though we need specialists, none of us can afford to know nothing about aging. The IOM report also described the need for enhanced support of and training for family caregivers. It is encouraging to know that the IOM may do a report on the mental health workforce at some point. Mental health needs, which are great, are often left out in health care discussions. NASW and many other mental health advocacy organizations support such a report.

Lack of workforce is not the only challenge that older adults face in getting access to mental health services. There has been a lack of parity in reimbursement for mental health services. This has been the case in many commercial insurance plans as well. Specific to Medicare Part D, when it comes to outpatient psychotherapy services enrollees must pay fifteen percent of the cost of treatment. This makes mental health services a lot less affordable. Fortunately, in 2008 Medicare legislation was passed that reduced beneficiary cost sharing from fifty percent to twenty percent over a five year period. There is a decrease in the co-insurance rate each year. This will make mental health services much more affordable for older adults. It has been a long time coming. It is also important to know that Medicare mental health providers, such as clinical social workers and clinical psychologists, are affected by cuts to Part D benefits and reimbursements, which makes it harder for older adults to find practitioners who can provide mental health services under their insurance.

Shifting to disparities among older adults, I am going to talk briefly about women, LGBT individuals, families, and racial and ethnic minorities. For each group, there are economic challenges to accessing high-quality health and long-term care. Some studies have shown that assisted living communities—despite affordability initiatives and Medicaid waivers that cover a portion of services—continue to be disproportionately located in areas with higher wealth, higher educational attainment, and higher housing ownership.

There are also private-pay services that enable an individual to maintain independence at home. A Home health aide services often get very little coverage from Medicare, so many people have to pay out of pocket to get that type of care. Affordability of such service is a particular concern for women. Women constitute almost sixty percent of the population age sixty-five years and older. Women eighty-five years and older outnumber men by about two to one. In general, women have less money to meet their long-term care needs. The median annual income in 2008, for example, was $25,000 for older men and $15,000 for older women. It is no surprise then that older women are nearly twice as likely as older men to live in poverty. Older women are also more likely to live alone than older men, which increases their risk of poverty. Again, it comes as no surprise that older women constitute about three-quarters of nursing home residents sixty-five years and older. The poverty rates are especially high for African American and Hispanic Latina older women living alone. Economic security is related to lifetime history of wages and benefits such as pensions, Social Security benefits and other savings. Older women also tend to live longer than men. They are more likely to report at least one functional limitation in old age.

In terms of LGBT aging, lack of visibility ranges from lack of inclusion of health care forms and research and data collection and that invisibility is reinforced by lack of cultural competence among individual health and long-term care providers within the systems. These dynamics reinforce a sense of stigma that has keeps many LGBT individuals in the closet throughout their lifetimes. Especially in old age it is not uncommon for people who have been open about their sexual orientation all their lives and then move into a residential care setting to go back into the closet for fear of the reactions they are going to get from their peers and the providers in the setting. This invisibility

> "Older adults are more than twice as likely to be diagnosed with two or more chronic conditions as their younger counterparts."

> Especially in old age it is not uncommon for people who have been open about their sexual orientation all their lives and then move into a residential care setting to go back into the closet for fear of the reactions they are going to get from their peers and the providers in the setting.

and lack of respect extends to relationships. Some states limit hospital visitation and there is a lack of recognition for care giving relationships by partners or other family of choice under the Family Medical Leave Act. Workplace discrimination throughout the lifespan is especially rampant for LGBT people because of the lack of federal employment discrimination protections based on sexual orientation and gender identity. The Employment Non-Discrimination Act would change this.

There are some hopeful signs of progress. The Administration on Aging has designated funding to create a national LBGT aging resource center which is very exciting. The IOM is conducting a study on LGBT health issues and research. This study is not specific to aging, but hopefully, but will hopefully yield some information that is relevant to LBGT older adults.

I want to sum up my remarks with a couple of notes on race and ethnicity. Poverty is very rampant among older adults of color. African American and Latino older adults are about three times more likely to live in poverty than older White adults. Health outcomes and access to services are also lower for African Americans and Latino older adults. For example, research has shown that African Americans are more likely to live in lower quality nursing homes than Whites. In conclusion, we need action on policy and practice levels to address health disparities between older adults and other age groups. Cultural and linguistic competence is essential to reducing disparities among older adults. Finally, we cannot succeed in any of these efforts without engaging older adults and family caregivers.

Daniela Kraiem:* All of us know someone or are related to someone, or perhaps even are someone who requires long-term care or long-term supportive services. Two years ago, the federal government promulgated regulations which allow a new delivery system option for people who receive federally funded long-term care through the Medicaid program. This delivery system is called "Consumer Directed Care," or as it is more commonly known, "Cash and Counseling." It is not an entirely new idea, but it was previously available only in small pockets as an experimental program, or through funding by states or localities. The new regulations allow large scale federal funding of this delivery system for long-term care. My talk today is about some of the issues raised by these recent regulatory changes.

"Cash and Counseling" amounts to an individual account that a Medicaid recipient can use to purchase goods or services for their long-term care. This option is in lieu of having Medicaid pay for a person live in a long-term care facility like a nursing home or having Medicaid pay for long-term care through an "Agency" model system in which contracting providers send long-term care aides into people's homes.

What is new and different about "Cash and Counseling"? The cash part is a major change in policy. Medicaid will now provide an individual account that a Medicaid recipient can draw from to pay for a long term care worker of his choosing. Basically, this cuts out the middle man—the agency. Money (in the form of vouchers) will flow more or less directly to the beneficiary who then pays the home health care worker. The beneficiary can also buy some goods or services with these funds, although today I am going to focus on long-term care aides.

The counseling part of "Cash and Counseling" comes in the form of training or assistance in how to hire, fire or train a long-term care worker. Most people are not used to being employers and many require some assistance in figuring out what they need to age in place. Most of the states that have already implemented "Cash and Counseling" wound up serving as fiscal agents for the beneficiary. The state cuts the checks to the vendors and manages withholding and employment taxes, even though the consumer is the employer.

There are several reasons why states started to experiment with this program, and why the federal government is allowing its adoption on a larger scale. The first reason is that it increases the autonomy of the beneficiaries who choose their services, and hire, fire, and train their own aides. Instead of having an agency deliver care, people are going to choose and direct their own care. This pleases fiscal conservatives, who see this as part of the "ownership society" promoted during the presidency of George W. Bush. It also pleases members of the disability rights movement, who have righteously struggled for many years to assert the capacity of persons with disabilities to control their own lives. To be clear, I am not talking about theoretical questions of autonomy and self-determination, but very specific, extraordinarily intimate decisions. We are talking about being able to choose the person who comes into your home, perhaps helps you to dress, eat and prepare food, and who may assist you with the most intimate bodily needs.

* Daniela Kraiem is the Associate Director of the Women and the Law Program at WCL, and also a Practitioner-in-Residence. Among other things, she has taught or is teaching courses like "Gender Perspectives Across the World" and "Gender Equality and the State."

The second reason for consumer direction in Medicaid funded long-term care is that, as other panelists at today's symposium have suggested, there is a severe shortage of direct care workers—including in-home long-term care aides. There is a crucial shortage of these direct care workers already, even long before the members of the large baby boom generation starts to require long-term care in great numbers. Because beneficiaries hire their workers directly, consumer directed long-term care addresses the labor shortage by opening up new pools of workers: people who might be willing to care for a friend or relative for pay, but who are otherwise uninterested in long-term care work.

In the pilot programs, consumer direction had an interesting side effect, which I suggest must be considered part and parcel of the program. Under the original system, a family member was very unlikely to become a paid caregiver. You were not going to hire yourself out to an agency where you could be sent to any consumer, if what you intended was to care for your aging mother, mother-in-law, or spouse. Also, under the old rules, legally liable family members, such as spouses and parents, were not allowed to become paid caregivers under most circumstances. With "Cash and Counseling," aging adults or persons with disabilities can easily hire their own family member, including those in the same household, to care for them. In the pilot programs for "Cash and Counseling," somewhere between sixty and eighty percent of the people enrolled in the programs picked a family member to provide their care. I have no conceptual problem with that, and I certainly believe that all caregivers should be compensated or remunerated in some way, but I wonder what kind of transformations this could create in both family life and long-term care more generally.

My larger project is to analyze critically the shift in policy. I will give only a rough overview of some of these concerns today. While "Cash and Counseling" has some real benefits, it also carries with it hidden costs that we need to be cognizant of if we are going to move on a large scale towards this model. Briefly, my concerns can be categorized into three areas.

The first is the focus on autonomy. The autonomy discourse, transforms the Medicaid beneficiary, typically a lower income person with long-term care needs, into a "consumer." The "Cash and Counseling" pilot programs self-consciously do not call enrollees "recipients," or "beneficiaries" which is what they are typically called in Medicaid, but calls them consumers. For those of you in the health care field, this may reminiscent of the consumer directed model in health care. On a much larger, philosophical level, this starts to equate social citizenship with only the ability to consume.

Second, this emphasis on the autonomy of the individual emphasizes individual solutions in which each person is responsible for his or her own long-term care decisions. While that can be very beneficial in some cases, it hides some of the structural nature of problems faced by the elderly or by people with disabilities, particularly issues related to other biases, like race or gender. It hides the disparities in the health care system by making it seem like each person has the same resources to solve the challenges of long-term care—when in fact, we know that people arrive at the need for long-term care in very different situations, with different constraints, resources and abilities. The emphasis on individualism also blinds us to the possibility of creating solutions inside of our communities. One of the things that we know is that when you are assisting a person who wants to age in place, for example, you are very rarely dealing with just that individual. You have to take into account his family and community, as broadly construed. An emphasis on individual thinking leads us away from pooled or collective solutions to problems.

My third set of concerns centers on how consumer direction might reinforce disparities, not just within the health care system, but within society at large. I am most interested in the relationship between long-term care workers and the consumer or the beneficiary of the services, and what the legal and social ramifications of the transformation of the employment relationship away from an agency model to a consumer directed model might be.

Why are race, class and gender disparities important in this discussion? Long-term care workers are part of the low wage workforce. They are ninety percent female. They are disproportionately women of color. They work without the protection of federal minimum wage or maximum hour laws. They work with minimal, if any, OSH protection. They receive very

"It hides the disparities in the health care system by making it seem like each person has the same resources to solve the challenges of long-term care—when in fact, we know that people arrive at the need for long-term care in very different situations, with different constraints, resources and abilities."

> In particular, it places the dignity and self-determination of people with disabilities at the center of the discussion. It emphasizes that the elderly and persons with disabilities can and should exercise control over their own lives.

spotty Workers' Compensation coverage, which is especially disturbing given the very high rates of on the job injuries on people who do the very physical labor of caring for other bodies. They earn on average somewhere between eight and ten dollars an hour. They have extremely low rates of health insurance. Many live in families who are eligible for public assistance, which tells you a little bit about their economic status.

It is no wonder we have a labor shortage in this field, which is oddly immune to the laws of supply and demand. Wages do not increase in this field, notwithstanding the shortage of labor. There are a couple of reasons for this. There are non-regularized workers in this field. In the private market, this is largely immigrant labor, and to a degree that we are not exactly sure of, although we are certain that it exists, undocumented immigrant labor, which puts downward pressure on wages. The other reason, of course, is the unpaid care giving performed by family members, largely women. The approximate dollar value of unpaid care in the US is around three hundred sixty billion dollars.

My concern, which I am only touch on very briefly here, is that this program splinters the employer—an agency, a big entity—into many individual consumers. In doing so, we reduce the ability of long-term care workers to engage in collective action or bargaining, which has been effective in raising wages. We will have a pool of workers, whether they are family members or not, who are unlikely to band together to raise dismal wages and improve dismal working conditions in these programs. In addition, workers who are employed in private homes lose most of the even minimal labor and employment protections. Given that these workers are overwhelmingly low income women of color and/or female family members, we have to stop and question whether consumer direction in fact reinforces race, class and gender-based disparities, albeit unwittingly.

I want to be very clear that I believe that consumer direction has real virtues. In particular, it places the dignity and self-determination of people with disabilities at the center of the discussion. It emphasizes that the elderly and persons with disabilities can and should exercise control over their own lives. My cautions and concerns, however, are warning flags of ways in which consumer direction might reinforce disparities and inequalities in the low wage work for or in family life. However, I do not assume that this must be the case, and I hope to see more policies in the future which take into account the needs of caretakers as well as beneficiaries.

Participant: I found it fascinating learning about the "Cash and Counseling" program. I am concerned that we have older adults who do not have a family complex. Where a person is just an individual we would have to go to the physical agent model, which means we are back in the old system again.

Daniela Kraiem: The "Cash and Counseling" program is designed is to be an option. States that participate are required also retain the other model. It is very clear to me from the data of demonstration studies that your point is correct. If a person is not already embedded inside a care giving community, the odds of her being able to hire her own worker are close to zero. One of the big problems is where to find a worker. Agencies have this problem too. The "Cash and Counseling" program does allow people to find workers that the agency could not find. If you have access to family members, or are a member of a church community, for example, you may well have an easy time finding a worker. If you are not already embedded in a care giving community, this is not a program that is going to work for you. The creators of the program did recognize that and the agency model will continue to exist for those people

Participant: At one time I organized caregivers in the State of Maryland. The workers are so dispersed that nobody knows each other. It is easy to organize when people work together, know that they have the same needs, and can discuss issues amongst each other. The workers were not very invested in organizing because they do not really understand the need. What efforts are being made in this regard? Most of the people we worked with actually were not family members. They started in the field because they had family members that needed care givers, and then they realized they could make some side money working for others. Being a care giver was something on the side for multiple people. They would make sure to check on four different people, for example. What is being done to get states involved so they can provide a different work environment for this entire industry?

Daniela Kraiem: Organizing care workers of any sort—this is true in childcare as well—is difficult. It is one of those fields where you have a tendency to grow very attached to the people for whom you provide care. Organizing these workers is notoriously difficult. There have been some very successful efforts at organizing long-term care workers and childcare workers also, most notably in California. In that state actually, in-home supportive service workers have an option of joining a union and they took the strategy

of organizing worker centers to do exactly what you talked about, actually bring people together. They created workers' centers, a place where people would come to have meetings and to get training. This was done so that California long-term care workers would get to know one another and form a kind of a collective community. Once together, these workers could look at the fact that they were all making eight dollars an hour and trying to live on that in Los Angeles County, which is an expensive place, and agitate, in some cases very successfully, for increased wages and better working conditions. Workers have actually gone so far as to agitate for increased benefits for the people they work for.

In California, despite the state's fiscal crisis, the in-home supportive services workers union, which is quite active, have fought the governor on across the board cuts to long-term care services. This was done to keep members' jobs, but also on behalf of beneficiaries. I think "Cash and Counseling" actually undercuts that potential. Once you are working for an individual beneficiary, you cannot get more money in the pot. If an individual given a set benefit the worker cannot ask for more from their employer. The employer is a poor person *by definition*, because they are enrolled in the Medicaid program. When there was an agency, workers could lobby the state for additional funds for the system as a whole, which would then trickle down to them. Collective action was possible. With individual beneficiaries serving as employers, the workers lose the ability to organize, and what we are going to see is really bad wages and difficult working conditions frozen, with very little potential for improving them.

Participant: I have a quick question about the "Cash and Counseling" program when it comes to existing difficulties in establishing care in rural areas or in the mental health field where there is even less access to long-term care workers. Do you think that it is possible to address those issues under the current program?

Daniela Kraiem: The rural question is a really interesting one. Despite all of my reservations about "Cash and Counseling," I think that in the rural community it works quite well for some people. For example, in New Mexico, where I am from, few people live in the city and the rest of us all live out in the country. Particularly on the Native American reservations, there are huge distances between communities. A care worker could not serve three different clients because they all live eighty to ninety miles apart. Therefore, in rural communities, the ability to have a local worker, as well as bring some cash into what is probably a very cash-poor household through "Cash and Counseling" can be quite beneficial. For rural communities this kind of program can work very well.

On the mental health front, there is no one size fits all answer. While families are places of safety and refuge for a lot of us, for others they can be difficult spaces. With mental health issues those problems are often magnified, particularly if you are going to combine mental health and substance abuse in families. Keeping people ensconced within their family, may not be the best option for either the beneficiary or the family. On the other hand, it may be possible to meet the needs of a person with a mental illness through consumer directed care. One issue that bears watching is the question of consumer direction and dementia. Caregivers for patients with dementia report the highest levels of stress of all caregivers. Consumer direction may help some of these families, while it may create additional burdens for others. From the point of view of the families and the beneficiaries, choice about the type of delivery system and type of care are crucial.

[1] *Retooling for an Aging America: Building the Health Care Workforce*, INST. OF MED. (2008), *available at*, http://www.nap.edu/catalog/12089.html.

> The access to medicine movement addresses a basic problem: purchasing medicine can be very expensive, but it does not have to be because making medicines is often incredibly cheap.

Professor Sean Flynn:* I am the Associate Director of the Program on Information Justice and Intellectual Property program at Washington College of Law (PIJIP). One of PIJIP's activities is focused on public policy solutions to the problems created by the globalization of patents on pharmaceutical products, particularly in underdeveloped countries.

I want discuss access to medicine disparities in developing countries and the link between those disparities and the globalization of patents with the World Trade Organization. I will talk about what we call the "access to medicines movement," which is an international movement of global health advocates that is focused on the problems and policy solutions that lie at the intersection of intellectual property, trade policy and the right to health.

The access to medicine movement addresses a basic problem: purchasing medicine can be very expensive, but it does not have to be because making medicines is often incredibly cheap. The actual manufacturing process of creating a pill is very inexpensive. An individual pill often contains a very small dose of pharmaceutically active ingredients. The cost of the component chemicals is minor. What is costly is the research and development that goes into the initial invention of that drug.

So what we have in pharmaceuticals is an industry that presents very low marginal costs – the cost of making that next pill – but high fixed costs – the cost of inventing the pill and setting up the manufacturing infrastructure. That is the problem the patent system seeks to solve. If you let the market run free, then new producers will copy the original product and turn out equivalent products in competition with one another until prices approximate the marginal cost of production. That is great for promoting access to the drugs we have now. But why would you create a new drug (or other product) if marginal cost pricing is what you can expect from your research and development investment?

The patent law solution to the problem is to grant a monopoly right – what we used to call a franchise – to be the only seller of a new product for a limited time. That right to exclude competition allows the company to charge higher prices and corner all sales for a period, enabling the company to recoup research and development costs plus a potential profit premium. The lure of those supra-competitive profits drives investments in research and development.

Now, recall the important premise in patent law – the franchise is to be limited. To reach the optimum balance between consumer interests in innovation of new products and their interest in accessing affordable products now, the patent right must tailored to the context. No one I know proposes that patent rights should run forever in a given industry or be impervious to all forms of economic regulation that impacts the price patent holder demands. That would expose consumers to perpetual monopoly rents, which few if any economists would endorse as an efficient solution for consumers or the economy more generally.

Now for the second premise: patents pose pricing problems in all industries, but the problems (and therefore need for tailoring of patent rights) are particularly evident in markets for pharmaceuticals and other essential goods.

As we discussed at the onset, in a competitive market the introduction of new suppliers willing to sell at ever-lower above-cost prices will force prices down close to the marginal cost of producing the good. In other words, the restraint on prices in a well functioning competitive market is the cost of production.

* Professor Sean Flynn completed clerkships with Chief Justice Arthur Chaskalson on the Constitutional Court of South Africa and Judge Raymond Fisher on the U.S. Court of Appeals for the Ninth Circuit. He also represented consumers and local governments as a senior attorney for the Consumer Project on technology. He served on the policy team advising the Assistant Attorney General Deval Patrick. He also taught constitutional law at the University of Witwatersrand in South Africa.

Monopoly markets are different. With no additional competitors that can enter, the restraint on price will be a function of demand instead of cost. The monopolist will raise its price above cost until any additional increase, because of the resulting fall off in sales, will be unprofitable. Monopolists cannot profitably set any price. The maximum profitable price will be determined by the willingness and ability of the market to pay. In other words, the maximum profitable price will be a function of the shape and slope of the demand curve.

Patents on medicine can cause particular problems for two reasons. First, drug patents often effectively cover the entire product, rather than an input into a larger product (e.g. a widget in a machine). Where the medicine is truly innovative in the sense of doing something useful for a particular group of patients that no other drug can do, then the monopoly created by a drug patent can be particularly strong. There will be no substitutes consumers can shift to.

Second, needed medicines are essential goods. Access to medicines is necessary to enjoy the full scope of the right to health. Without needed medicines, people will live shorter and less fruitful lives to the disadvantage of themselves and the societies they live in.

This essential element has two implications, one economic and one moral. The economic point is that people will be willing to pay very high portions of their income to access essential products. Imagine how much you would be willing to pay for access to a life saving medicine. Or how about water or electricity in your home. In the latter cases, the essential good is often delivered by a monopoly as well. But we regulate the prices those monopolies can charge because otherwise they could exact very high prices for the services. Would you pay twice your current bill to have water in your home? Three times? Ten times? You might consume less at these prices, but there is really no substitute you can choose.

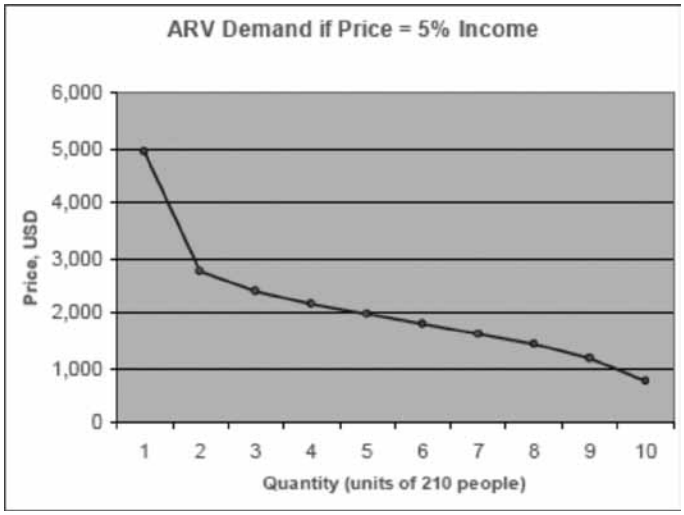
The essential aspect of medicines also brings to the fore a moral component of policy choices in this area. Where government policy is distributing access to goods and services needed to actualize human rights and basic welfare concerns, then equity concerns need to be paramount. If governments can produce a policy that leads to as much or more of the innovation of the necessity while increasing access then (morally) it should. And if it can purchase a good that will demonstrably increase lives and health, then human rights laws may require that.

Now we are ready for our third premise. The problems with pharmaceutical patents will be compounded in countries with high income inequality, which applies to most of what we call the Third World or the group of underdeveloped countries.

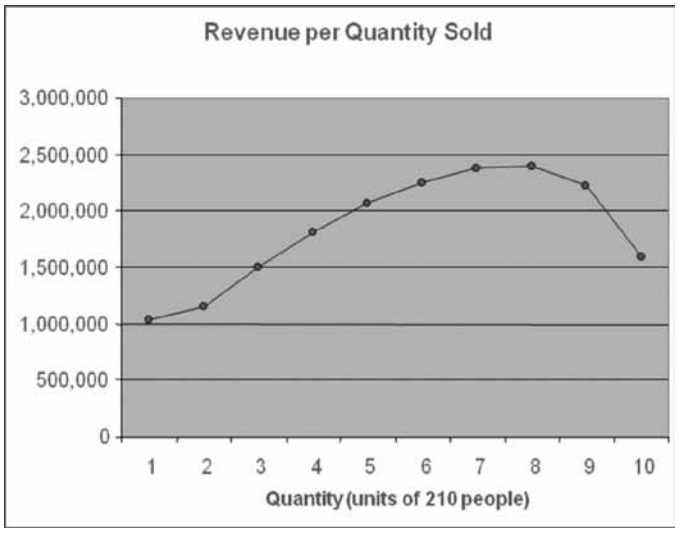
Recall that in the monopoly markets that patents create, price will be a function of the shape and slope of the demand curve. These factors are in turn impacted by the degree of income inequality in a market.

Compare two polar cases – Norway (with the greatest income equality) and South Africa (with the greatest income inequality).

If you assume that the demand curve for an essential good will be driven by ability rather than willingness to pay, then you can construct the shape of that curve based on distribution of income. The figure for Norway is included below.

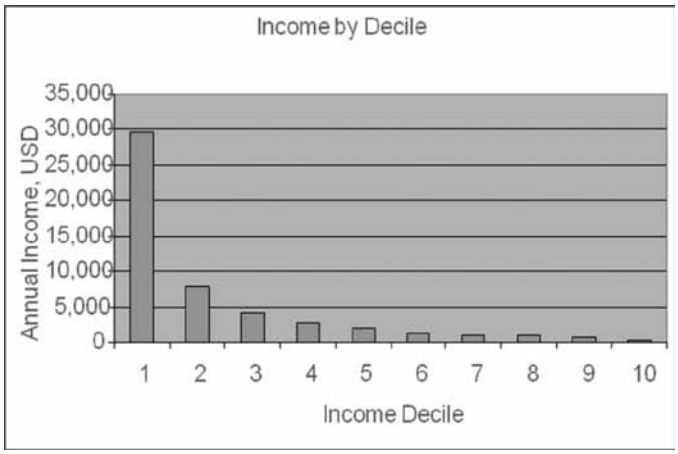


As demand curves go, that one is pretty flat. Small price decreases along the vertical axis will lead to relatively large increases in purchases along the horizontal axis. This creates a profit maximizing incentive for the monopolist to decrease prices to sell more units until about 80 to 90 percent of the population is served, leaving 10 to 20 percent of the consumers as deadweight loss. That fact can be represented in a second figure, which shows the number of sales at each price along the demand curve and the total revenue (along the vertical axis) for each price and quantity sold.



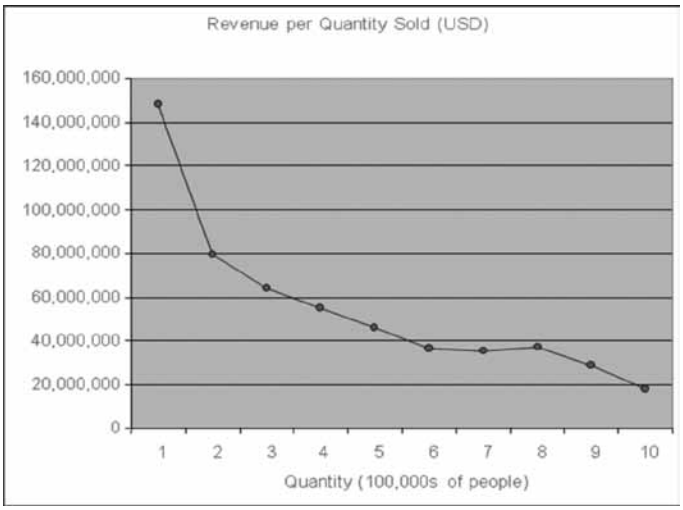
The model predicts that in Norway the social cost we will pay for the incentives to innovate from monopoly provision of the product will be about ten to twenty percent of the population prices out of the market and therefore dependent on social provision of some sort (if there is a right to the medicine in question). Of course in Norway, everyone receives social provision.

Now let us compare this outcome with a demand curve representative of a country with extremely high income inequality. In South Africa, the top ten percent of the people earn first world incomes. But after that, the amount of income in each decile of the population falls off pretty dramatically, creating along flat tail of the demand curve where people have very low incomes.



This creates very different pricing incentives for the monopolist. The demand curve is very steep at the richest segment of the population, meaning that even large price decreases will not lead to large numbers o increased sales. Look at the step between the first and second decile. If the company halves its price it will still be too expensive to reach the next segment of demand. The company would have to decrease its price to about 25% to double its sales – not a profitable choice.

The profit maximizing behavior of the company can be depicted in the chart below.



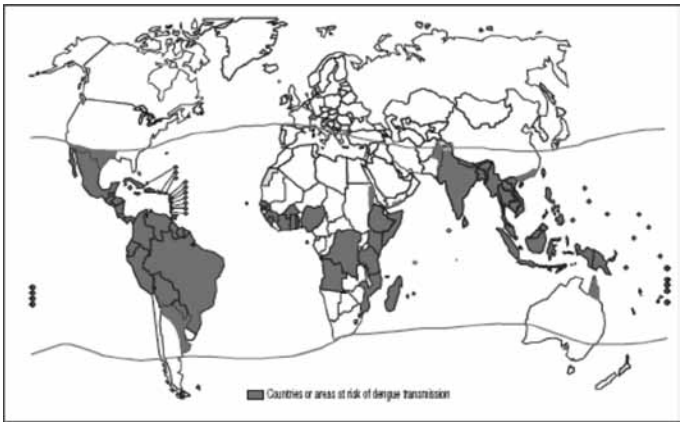
Essentially, every time the company decreases price to reach a larger segment of the population, it loses money. So the rational company, assuming it has no means to price discriminate between consumers, will set its price to serve the top 10 percent of the population and leave the rest as deadweight loss.

The last premise was that the price of patents in underdeveloped countries with high income inequality is likely to be very high. Correlatively, the contribution to incentives for innovation is likely to be quite low.

If you are choosing a market to innovate for and the reward for innovation is a monopoly, then who are you going to target – Norway or South Africa? Global income distribution essentially looks like the South Africa chart – with the small segment of national economies being very rich, and long tail of low income nations where the majority of the world's population lives.

This leads to the so-called 10/90 gap. The rough-hand trope is meant to convey that something like ninety percent of global research and development investment on medicines serves the needs of just ten percent of the world's population.

Consider the distribution of Dengue fever, which affects about a million people a year.[1]



Will a company invest in the development of a new treatment for that disease? What about tuberculosis, malaria, sleeping sickness, etc.

The premises outlined above lead to a modest conclusion. Because of the particularities of the impact of patents on pharmaceutical products and of the characteristics of demand in underdeveloped countries with high inequality of income, one-size-fits-all patent-based solutions to the problem of incentivizing innovation for medicines in underdeveloped countries are inappropriate. Patent rights on pharmaceuticals, to the extent they are granted at all, need to be highly tailored in underdeveloped country markets and alternative means of incentivizing research and development for conditions that primarily impact underdeveloped (especially tropical) countries need to be considered.

The international intellectual property law trend has been in exactly the opposite direction. The comparative history of protection of patents in the pharmaceutical industry is one of a myriad of policy tools used to tailor patent rights on pharmaceutical products:

- In Brazil, Argentina, Switzerland and Japan, pharmaceuticals were entirely exempted from patent laws until the 1970s or later.
- In the United Kingdom and Canada, there were special compulsory licensing provisions for pharmaceuticals that allowed governments to open up access to generic competition for pharmaceutical products.
- India created a patent regime that only protected the process of making pharmaceuticals, instead of the end product, which spun into the largest generic pharmaceutical industry in the world, where reverse engineering was used to bring competing products to market in India.

In the 1970s and 80s the pharmaceutical industry, largely based in the U.S. and Europe, led a policy drive to change this state of affairs and globalize patent laws, specifically for pharmaceuticals. The justification was that there was free riding by developing countries on the pharmaceutical research and development expenditures by the United States and other wealthy countries. Ultimately, that policy process led to the inclusion of a specific agreement on intellectual property in the 1994 World Trade Organization Agreement.

The WTO agreement on Trade Related Aspects of Intellectual Property (TRIPS) was the first international agreement setting global minimum substantive standards for intellectual property. All countries are now required to grant patents on products and processes. India's process system is out. No discrimination is allowed by field of technology — which means that pharmaceutical industry-specific measures will have to meet additional justificatory burdens.

Post-TRIPS free trade agreements narrowed the tailoring options and expanded patent rights further.

And now we have the Anti-counterfeiting Trade Agreement (ACTA) which may limit the ability of countries to limit remedies for patent enforcement (e.g. by doing away with injunctions) and may increase the rights of transit countries to seize drugs and other products at the border, thereby limiting the free trade in affordable medications.

We can pause and ask if this was a positive development. Theoretically, there are good aspects of the globalization of intellectual property. It addressed a real free-riding problem regarding what economists call a "global public good." Everyone benefits from a new invention, whether you pay for it or not. When one country pays for the invention of a new medicine, all countries benefit from it. But should poor countries who benefit little from intellectual property protection pay the same – or really more in deadweight loss terms – than the richest?

If your answer is no, which mine is, then you might join the campaign to expand "flexibility" in international IP law and work on thinking up other tools to meet the challenges of incentivizing innovation. This is the agenda of the access to medicines movement.

Professor Margaret Farrell:* I recently took a ten day trip to Cuba with twenty-seven other health care professionals. I count myself as a health care professional because I am a lawyer that works in health care. The rest of the group were doctors, nutritionists, social workers, psychiatrists, and mental health workers, among others. We had a packed itinerary of visiting health care facilities, hospitals and sanitariums and talking to professional involved in providing care in those institutions. I was reflecting on my remarks about health care disparities in Cuba and it called into question what health care disparities in Cuba really are. Is it disparities in access to care or disparities in outcomes and quality of care? Are we talking about disparities among Cubans—rich, poor, urban, rural, minorities? Does the topic include disparities between Cuban citizens receiving care in Cuba and foreign visitors receiving care in Cuba, so called medical tourists? The topic may also include disparities between Cuba and other countries in the world.

Cuba is geographically isolated–an island the size of Pennsylvania. It has eleven million people and most of the population lives in urban settings. The population is primarily made up of people of European decent. There is a small population of mixed races that were immigrants from Haiti—about ten percent of the population. The primary language is Spanish. Cuba's major exports are: nickel, sugar, tobacco, shellfish, coffee and interestingly, doctors. Cuba is a Communist country and it was overtaken in 1959 by Fidel Castro, who was then supported by the United States. At the time of the revolution, there were a fair number of doctors per capita, but the disparities were great. There were 6,000 doctors in the country before the revolution, but about half of them left for Miami after 1959. The Castro revolution left Cuba with essentially no health care system and the country was forced to develop a health care system in isolation.

> "Where government policy is distributing access to goods and services needed to actualize human rights and basic welfare concerns, then equity concerns need to be paramount."

* **Professor Margaret Farrell** attended University of Chicago and Yale University's Law School and has also been a post-doctoral fellow at John Hopkins University School of Hygiene and Public Health. Professor Farrell received a fellowship at the Federal Judicial Center in Washington, D.C, where she conducted research on scientific evidence and expert testimony. She has published articles on a wide range of topics and practice law as a partner at *Ennis*, *Friedman*, *Bersoff and Ewing* in Washington, D.C. and worked as a member of Governance and Legal Audit Committee of the White House Health Care Task Force. She is currently Special Master in the United States District Court for the District of Columbia on behalf of the mentally disabled. She studied public health in Cuba and served as a volunteer legal advisor to the Minister of Health and Social Welfare.

> That basic focus on community and social functioning makes the Cuban delivery system very different. The statistical outcomes of Cuba's health care system are truly impressive.

Cuba is also politically and economically isolated — partly by virtue of the U.S. embargo, although the U.S. embargo gets blamed for more of Cuba's economic problems than it should. As a result of its isolation, Cuba can be seen as a Petri dish experiment in how to create a health care system with few resources. The first thing that Cuba did after the revolution was establish medical schools. Most professors left Cuba after President Batista was overthrown, so students with little experience, who had just graduated from the country's only medical school, became the medical school faculty. Later, foreign doctors joined the faculty to teach in Havana. Eventually, Cuba developed a system of six year medical schools located in each province and an international medical school with 8,000 students — the Latin-American Medical School in Havana — which draws students from all over Latin America to train in western medicine.

A three-tier system for delivering health care was established. In Cuba, health care delivery system is focused on the family. At the bottom level there are neighborhood clinics that are staffed by a doctor and a nurse who are committed to work in the neighborhood for two years. The doctor lives above the clinic, so he or she really becomes a part of the community. They see most of their clinic patients in the mornings, and in the afternoon, clinic doctors make regular visits to families to assess their health care needs.. The family is the basic unit of health care delivery in Cuba. This differs from the U.S. individual-based health care system. Doctors visit each family at least once a year The medical diagnosis is tripartite—physical, mental, and social health. The doctor examines how well patients are functioning in their families and communities. That basic focus on community and social functioning makes the Cuban delivery system very different.

The statistical outcomes of Cuba's health care system are truly impressive. Life expectancy in Cuba is a little bit higher than it is in the U.S. Mortality of children under five is 6.5 deaths per thousand births in Cuba and 7.6 deaths per thousand in the U.S. In 2009, newborn deaths in Cuba were five per thousand births, whereas the number was six deaths per thousand in the U.S. Cuba also has the lowest incidence and prevalence of HIV/AIDS of any country in Latin America (and the highest literacy rate). In Cuba there is one doctor for every 170 people. In the U.S., we have one doctor for every 188 people. The World Health Organization (WHO) calculates Cuba's annual per capita health expenditure at $229 per person. The U.S. spends more than $6,000 per person on health care. Although differences in cost of living and average annual incomes make a comparison of health care expenditures in the two countries difficult, there is a vast difference in the amount of resources that go into Cuba's system.

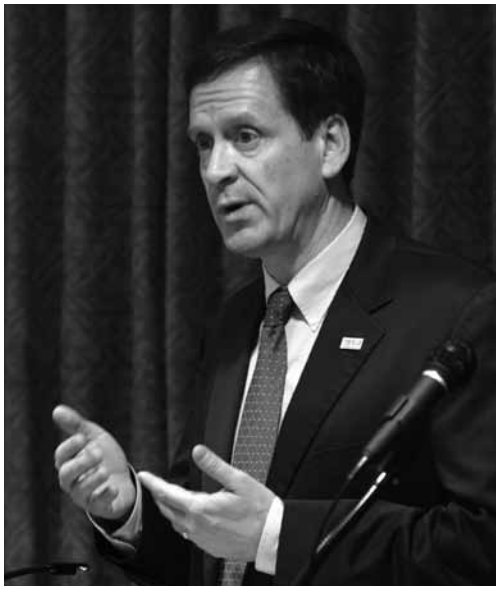
The neighborhood health system gets much of the credit. Cuba assumes responsibility for providing health care for its population. The Cuban Constitution, unlike the U.S. Constitution, was amended in 1976 to say that everyone has a right to health protection and care. Cuba guarantees this right by providing free medical and hospital care, offering medical service networks, providing clinics and hospitals with preventative and specialized treatment centers, and by providing health publicity campaigns, medication, regular medical exams, general vaccinations, and other measures to prevent disease.

Thus, in Cuba, health is a positive Constitutional right and the state has a corresponding obligation to provide medical care and treatment to its citizens. Cuba uses the $229 per person to concentrate on prevention, which results in the country's very favorable health outcomes. Doctors in the neighborhood clinics are activists. They talk in the schools on a regular basis about sanitation and hygiene, run vaccination campaigns and lead school children in campaigns to eliminate mosquitoes. In addition, since it is a Communist country, Cuba can require their citizens to do things that the U.S. would have to persuade people to do. For example, loss of life due to hurricanes is very low because citizens are required to participate in evacuation drills, are warned and are evacuated by police. Cuba's low infant and maternal mortality rates also result from a system of close monitoring, maternal residences for high risk mothers, and specialized hospitals. It does not rely on a mid-wife system since health clinics and hospitals are accessible even in rural areas. Cuban citizens seem to feel that they have a civic duty to be healthy and to use the benefits provided to them free by the State.

Mark Green*: What I would like to do is frame my comments around a true story. About a month ago, I had the chance to visit a small hospital on the islands of Zanzibar called Nizium Mojo. Literally translated

* Mark Green is the former United States Ambassador to the United Republic of Tanzania. As Ambassador, Mark worked tirelessly to create lasting relationships with the government and people of Tanzania to create economic growth and fight disease like malaria. Prior to serving as ambassador, Mark served four terms in the U.S. House of Representatives. He was a member of the House Judiciary and International Relations Committees, and served as an Assistant Majority Whip. From 1987-88 Mr. Green served as secondary school teachers in Kenya through WorldTeach Project, a development organization based at the Phillips Brooks House of Harvard University. Mr. Green attended the University of Wisconsin Eau-Claire and received his law degree at the University of Wisconsin-Madison.

Nizium Mojo means, one coconut tree. There was a terrible cyclone that swept over the islands of Zanzibar and wiped out all the trees but a single coconut tree and that is where they build the hospital. What is really interesting about Nizium Mojo is not the story of how people survived the terrible storm but how the people are surviving the storm of global health challenges each and every day on the islands of Zanzibar.



On the day that I was there, just a month ago, our guide was Dr. Mohammed who is an old friend of mine from my days as ambassador. Dr. Mohammed was also the Principal Secretary of the Ministry of Health and a licensed surgeon. He took us upstairs to the pediatric ward and as we were walking in I saw that there were about fifteen beds. Dr. Mohammed told us that just three or four years ago, there were three children for every single bed in that pediatric ward. On the day that we walked in, there were three children in the entire ward. The first child had what Dr. Mohammed called clinical malaria, not confirmed by a test. The second child was a truly pathetic sight—sickly thin arms, cheeks were drawn, eyes open, but unseemly. The child's eyes had been damaged by Vitamin A deficiency. The third child that we saw was an even more heart rendering sight. Her skin was so badly disfigured that as we were walking up to her, she looked like a burned man. She suffered from severe malnutrition: protein deficiency. Dr. Mohammed looked at the third child and said, "We can help her." This story drives home several important lessons about health disparities, global health challenges and opportunities for change that are out there.

The first lesson is that historic progress is being made right now on a number global health fronts. As Dr. Mohammed noted, not so long ago, there would have been three children to a bed—forty-five children per ward, not three. The good news is that because of the focus on improving interventions and improving medicines, we have an opportunity in front of us to conquer some of the diseases that were once believed to be inevitable. If you spend any time in Africa, you will meet person after person who will say "I am the oldest," "I was the third born," or "I was the fourth born," because his brothers and sisters died before him in childbirth. However, we are making extraordinary progress, particularly in the area of malaria. On the islands of Zanzibar, 40 percent were infected with malaria just a few years ago, but today that number is less than half a percent. Many actually believe that by 2015 malaria will be entirely eliminated from the islands of Zanzibar. In the area of neglected tropical diseases—lymphatic filariasis or elephantiasis disease—there are now elimination programs for this terrible disease in 44 of the 83 endemic countries. River blindness has already been eliminated from ten West African countries and there are plans to do so in many other countries on the continent. We should first feel good about the progress that has been made and the opportunities that lie ahead.

Secondly, the progress that we are making on diseases like malaria and river blindness and some of the neglected tropical diseases, free up resources to take on other global health challenges. Returning to my Zanzibar story, a drop from forty-five to three patients means that there are forty more children who are disease-free and able to help their parents, play ball in the streets, or, hopefully, learn in school. More pragmatically, it means is there are more beds and health care workers available to take on other challenges out there.

The third lesson is not to look at the challenges of global health through American eyes, as we often do when we talk about numbers. In most places in America, a child is generally either sick or they are healthy. This is not the case in the impoverished nations of the world. Children are never quite healthy in those countries. The child that survives malaria in its earliest days of life will very likely suffer life-long cognitive disabilities, or he or she may be weakened and made vulnerable to other diseases and illnesses. He or she is already likely to suffer from malnutrition and unsafe drinking water. The child may not be suffering from malaria symptoms, but neither is he strong and ready to learn.

On my first night as a volunteer teacher in Kenya some twenty years ago, the school's headmaster took me to the funeral of one-year-old twin boys who had died of measles. I could not believe that the children had died of measles. In Kenya, measles and other complicating factors such as malaria, malnutrition, and parasites cause children to die.

We talk about combating global health challenges, but we must realize that global health is not as black and white as we tend to assume. President Obama's administration has unveiled its global health initiative, designed to build upon the marvelous programs that are already there. We are trying to integrate the services that are provided in some of those programs so that we get stronger health systems to begin with. At Malaria No More, we think integration is a good idea, particularly in the areas of diagnostics and lab facilities. When we talk about health where people are most vulnerable—places like Africa—we cannot look at things in black and white, through American eyes.

We are living during pretty exciting times in global health. As I was getting ready to come here today, the story that broke that King Tut died of malaria. When examined, the mummy was discovered to have a number of afflictions and malaria was one of them. Some of our global health challenges have been with us for a long time. We cannot back down from any global challenge, be it malaria or HIV. Organizations that are devoted to global health must think of ways to expand programs to be most effect and that is what Malaria No More is trying to do.

Question: What is the reimbursement rate for physicians in Cuba?

Professor Farrell: You will not believe it, but it is $35 a month. Physicians really want to practice medicine. It is seen as an honor and patriotic duty to serve the communist government in that way. Nevertheless, the physicians we met complained about being over worked, as some of their colleagues had left to practice in other Latin American Countries.

Question: Does Cuba isolate those with HIV?

Professor Farrell: Yes and no. When AIDS was initially discovered in the 1980s Cuba confined people infected with HIV to sanitariums. When the mechanism of HIV transmission was discovered, those in sanitariums were allowed to leave, but many preferred to remain where the living conditions were better than in their communities. Today, it is voluntary. We visited these sanitariums which were quite adequate with good living conditions. Many people who decided to stay there now leave during the day to work in AIDS programs in the city.

Question: The population of Cuba is thirty times less than the U.S. population (11 million to 300 million). Is it not easier to manage the health of a small population, thus explaining Cuba's statistics?

Professor Farrell: That is absolutely right. Additionally, cultural ideologies and community differences play an important role.

[1] WHO 2010 report

Treating Health Care Under the Right to Health: Why the Public Option is the Only Way to Prevent Inequitable Access to Medications from Becoming Terminal

*Ashley Goren**

Introduction

In 2008, the late Senator Ted Kennedy (D-Mass) expressed an aspiration that the United States should recognize health care access as a right of all Americans.[1] He declared:

> [t]his is a season of hope—new hope for a justice and fair prosperity for the many, and not just for the few . . . new hope that we will break the old gridlock and guarantee every American—north, south, east, west, young, old—will have decent, quality health care as a fundamental right and not a privilege.[2]

Access to health care is not just a dream, however, but a legal right protected by customary international law.[3]

The "right to health" is a prominent legal doctrine that pervades international law.[4] President Franklin Roosevelt introduced a right to health care in his "four freedoms" speech, suggesting that Congress recognize "the right to adequate medical care and the opportunity to achieve and enjoy good health."[5] His speech influenced the content of the Universal Declaration of Human Rights ("UDHR"), one of the first international agreements to include the right to health.[6]

Despite ties between U.S. politicians and the growth of the right to health doctrine, however, the U.S. does not guarantee access to health care for many Americans.[7] The picture of the American health care system is dire.[8] Health problems create an immense economic burden on U.S. families, which can lead to the choice between health care and food.[9] Many U.S. citizens are unable to afford medications, and therefore must go without them.[10] Others go bankrupt as a result of the catastrophic financial strain imposed by illness.[11]

Change is now a necessity. However, discussions of health reform create great friction in the U.S.[12] The debate about whether to enact national health insurance began over seventy years ago.[13] Although Congress recently took great strides towards accomplishing this elusive goal, a governmental guarantee of universal health care access remains a distant ideal.[14]

This article argues that the U.S. must eventually establish universal health insurance coverage in order to comply with international standards of health care access imposed by the right to health doctrine. In particular, contrasting the ability of U.S. citizens to access medicines against the internationally accepted standards will expose the disparities between the two.[15] Part I surveys the evolution of the right to health and health care access within the U.S.[16] Part I additionally looks at customary international law and its importance in the field of human rights.[17] As the U.S. is not legally constrained by treaty law, it is only bound if the doctrine is a norm of customary international law. Part II concludes that the right to health is a part of customary international law and considers its definition and implications for the U.S.[18] Part III suggests steps American leaders can take to conform to the international standards of health care access.[19]

I. Background

The concept of the "right to health" has evolved substantially during its long history.[20] International organizations have long grappled with its meaning, but it is now prominently understood as a right to enjoy access to necessary components of health care.[21] The recent health reform debate provides a useful opportunity to evaluate the doctrine's meaning and authority in relation to U.S. health care.

A. The Evolution of the "Right to Health"

The international community first announced a "right to health" as a component of human rights in the Constitution to the World Health Organization ("WHO").[22] The preamble of the Constitution recognizes that the enjoyment of the highest attainable standard of health is a fundamental right.[23] It goes on to establish WHO to help all individuals attain this right.[24]

* **Ashley Goren** is a J.D. Candidate (2011) at American University Washington College of Law. She would like to thank Professor Corrine Parver for her guidance and encouragement. She would also like to thank her parents, Al and Sharon Goren, and her sisters, Stephanie and Jessica, for their love and support. She is grateful to Marc Gibson for all of his help and motivation.

Following WHO Constitution's initial proclamations, countries drafted myriad international treaties that recognize and formalize the right to health.[25] The Universal Declaration of Human Rights states in Article 25(1) that everyone has a right to health and security in the case of sickness or other "circumstances beyond [one's] control."[26] The International Covenant on Economic, Social, and Cultural Rights ("ICESCR") in Article 12(1) reaffirms this right[27] and further illustrates steps that state parties must take in Article 12(2).[28] International treaties with a more specific scope also reference the right to health, including the Convention on the Elimination of All Forms of Discrimination against Women, and the Convention of the Rights of the Child.[29] Increasingly, the international community espouses a common belief that access to the health system is an essential component of an equitable society.[30]

B. Defining the "Right to Health"

Despite its widespread use, "right to health" is a broad and ambiguous phrase.[31] It is difficult to conceptualize exactly what countries must do to comply with the requirements it establishes.[32] For this reason, documents subsequent to the original treaties clarify the broad terminology and delineate the right's obligations.[33]

WHO provided an initial interpretation of what "health" means and how it applies to the right to health.[34] The preamble to the WHO Constitution specifies that, "health is a state of complete physical, mental and social well-being and not the absence of disease or infirmity."[35] The Constitution asserts that "[g]overnments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures."[36]

In 1978, WHO supplemented this vague standard with a document commonly called the "Alma-Ata Declaration."[37] The Alma-Ata Declaration presented necessary components for primary health care, including health education, promoting the availability of food and water, immunizations against prominent infections, appropriate treatment for common diseases and injuries, and the provision of essential drugs.[38] WHO reaffirmed these principles in 1998 with a resolution entitled "Health for All in the Twenty-First Century."[39]

In defining the right to health, the U.N. did not adopt WHO's conception of health, but built upon the framework of the Alma-Ata Declaration.[40] The U.N. created the Committee on Economic, Social, and Cultural Rights ("CESCR") in 1985 to monitor and interpret the International Covenant on Economic, Social, and Cultural Rights.[41] The Committee defines the right to health as "a right to the enjoyment of a variety of facilities, goods, services and conditions necessary" for the realization of health.[42] General Comment No. 14 also establishes precise actions that states must take to ensure this enjoyment.[43]

C. Customary International Law

The growth of the right to health leads to the question of whether it now constitutes customary international law.[44] Customary international law is a significant source of codifying human rights norms.[45] According to the International Court of Justice ("ICJ"), a rule becomes customary international law when two conditions are met: it must be carried out frequently enough to constitute "settled practice" and states must follow it pursuant to *opinio juris*, a belief that the practice is obligatory.[46] Once a law meets the test, it is binding upon all nations.[47]

D. Health Care in the United States

Despite its widespread acceptance, the U.S. has a poor record of recognizing the right to health.[48] The U.S. largely declined to ratify the numerous treaties containing the right to health.[49] Additionally, unlike most developed nations, the U.S. does not provide universal access to health services, but relies heavily on private financing for health care.[50] Legal protections only ensure economic assistance to obtain health care for the poorest segments of the population and senior citizens.[51]

The cost of pharmaceuticals in the U.S. has dramatically increased since the 1990s.[52] Insurance companies redistribute these added costs to consumers by restricting benefits and increasing the expenses of the insured.[53] Studies show that the high prices of medications, and the insurance companies' subsequent practices, restrict accessibility.[54] Some patients who cannot afford the cost of prescribed medication forego complying with their medication regimen.[55] Medical experts refer to this as "cost-related prescription nonadherence" ("CRNA").[56]

In 2006, approximately twenty-three percent of patients in the U.S. did not comply with their prescriptions due to prohibitive medication costs.[57] Lack of health insurance coverage is closely linked to this phenomenon.[58] Additionally, CRNA is most common among marginalized populations, including individuals with lower incomes[59] and minorities.[60]

Current trends accentuate the likelihood that members of the U.S. population will not be able to afford pharmaceuticals.[61] The number of individuals without health care insurance is rapidly increasing.[62] Furthermore, an increasing number of U.S. citizens are underinsured, meaning their health insurance does not adequately protect them from high health care costs.[63] These ominous figures indicate that the public could experience significant deleterious effects if the situation does not improve.[64]

E. Health Care Legal Reforms in the United States

The government is taking action to change the dire health care situation in the U.S.[65] In 2009 the two houses of Congress each passed a bill to reform the health care system.[66] Both bills contained provisions to expand coverage to insure more individuals[67] and to lower costs.[68] They each additionally attempted to combat the problem of CRNA by requiring "essential

benefits" insurance companies must provide, including pharmaceutical coverage.[69]

Although the late Senator Kennedy championed health care reform throughout his life,[70] his death ended a Democratic supermajority in the Senate, threatening to end the push towards reform.[71] Therefore, on March 21, 2010, the House of Representatives abandoned the bill passed in the House, HR 3962, and instead adopted the bill approved by the Senate, HR 3590.[72] On March 23, 2010, President Obama signed the Patient Protection and Affordable Healthcare Act into law, making health care reform a reality.[73] Soon after, both houses passed a "budget reconciliation bill" altering several provisions of the Senate bill.[74]

The Patient Protection and Affordable Care Act requires most citizens and residents to obtain health insurance.[75] To ensure affordability, the law establishes state-based health care "exchanges" for consumers to purchase insurance coverage.[76] The "American Health Benefit Exchanges" will create forums that enable U.S. Citizens and legal immigrants to compare and select regulated health care plans.[77] It will have an online component to browse plans as well as a hotline for assistance.[78] The exchanges are intended to augment competition between plans and promote optimal coverage at minimal cost.[79] Although the plans within the exchanges will be regulated, existing health insurance plans will persist in the private market.[80]

Insurance plans within the exchange will provide coverage based on a tiered structure.[81] Through this system, insurance companies must cover at least 60% of total annual health care costs at the lowest tier and up to 90% at the highest tier of coverage.[82] Additionally, each plan must ensure essential benefits including prescription medication.[83]

The Act also enhances affordability through government assistance based on financial necessity. The Patient Protection an Affordable Care Act establishes government subsidies for families to reduce health care costs.[84] Families earning up to 400% of the federal poverty level will be eligible for assistance.[85]

Although these benefits will improve health care access and affordability, the House of Representatives bill, HR 3962, was best suited to ameliorate the problems addressed in this article.[86] HR 3962 would have established a public option, thereby creating universal coverage.[87] The government would have run the public insurance option to compete with private insurance and guarantee coverage to the public.[88] Without a public option, the government cannot ensure all individuals can obtain health care insurance. The Congressional Budget Office estimates that over twenty million non-elderly individuals will remain uninsured after the Act takes full effect.[89]

II. Analysis

The health care system within the U.S. creates a jungle in which all citizens must fend for themselves. As a result, a disturbing percentage of citizens cannot afford the materials necessary to protect their health.[90] This begs the question: does the U.S. comply with the legal obligations of the right to health doctrine? In order to determine the answer, one must first discern the doctrine's authority on the U.S., what it requires, and whether the U.S. meets these requirements.

A. The Right to Health Binds all Nations as Customary International Law

The right to health doctrine has ripened into a rule of customary international law.[91] As established above, to form customary international law, a norm must constitute "settled practice" and states must follow it pursuant to a belief that the practice is obligatory.[92] Evidence exists to meet both facets of this test.[93]

1. Implementation of the Right to Health is Accepted Practice

A practice need not be universal, but should reflect a general acceptance by relevant states to amount to accepted practice.[94] Evidence of human rights as state practice includes domestic constitutional protection of the right, decisions upholding it in regional and national courts, U.N. resolutions, and regional organization resolutions.[95] The evolution and increasing acceptance of the right to health doctrine resulted in a proliferation of such evidence to demonstrate the doctrine's status as customary international law.[96]

The right to health enjoys widespread international acceptance.[97] Almost every country in the world is a party to at least one treaty that recognizes the right to health.[98] Copious regional agreements also recognize the right.[99] Over one hundred nations include health care access in their national constitutions.[100] Of these nations, at least six mandate specific steps the government must take towards achieving a successful health care system that all citizens can access.[101] These countries thereby commit themselves to achieving quality health care that all citizens can afford.[102]

The requirement to uphold the right to health is also enforced by courts.[103] An array of cases before domestic and regional courts condemned actions that violated the states' duties to protect these rights.[104] Domestic courts have upheld obligations under the right to health doctrine in countries including South Africa, Canada, Argentina, Brazil, Colombia, Costa

"The health care system within the U.S. creates a jungle in which all citizens must fend for themselves."

Rica, Ecuador, India, and Venezuela.[105] Additionally, the Inter-American Court protects the same rights inherent in the right to health doctrine, but more commonly under the "right to life."[106] This shows that nations condemn violations of the right to health, accept the doctrine's obligatory nature, and are actively enforcing its provisions.[107]

Furthermore, state acceptance of the right to health doctrine goes beyond rhetoric.[108] All developed nations, except for the U.S., provide universal health care coverage.[109] Countries increasingly protect health care access as an integral right of citizenship.[110] Even nations that do not confer health rights within their constitution spend exorbitantly to ensure health care accessibility.[111] Based on the near universal recognition and implementation, protection of the right to health now constitutes accepted practice.[112]

2. States Follow the Right to Health Doctrine Pursuant to a Perceived Obligation

States implement the right to health doctrine based on a perceived obligation.[113] When states consent to international resolutions or enforce a legal doctrine in court, they accept the binding nature of the doctrine.[114] The international community has validated the obligations imposed by the right to health doctrine through numerous international declarations.[115] The members of the United Nations unanimously accepted the Universal Declaration of Human Rights, which heralded the right to health as a fundamental human right.[116] Nations also accepted the right to health doctrine through World Health Organization resolutions, such as the Alma-Ata Declaration and "Health for All in the Twenty-First Century."[117]

In addition to the international resolutions, widespread state participation in treaties recognizing the right to health supports the existence of *opinio juris* and establishes the right to health doctrine as customary law.[118] Rights crystallized in multilateral treaties become customary international law when widespread practice conforms.[119] Thus, the numerous international and regional treaties enforcing the doctrine lend additional credence to the doctrine's status as customary international law.[120] The right to health is enshrined in as many treaties as the right to be free from torture, another human right now accepted as customary law.[121] The myriad treaties protecting the right to health enjoy widespread ratification in addition to their prevalence.[122]

Upholding the right to health doctrine is general practice followed pursuant to the belief that it imposes an obligation and is, therefore, customary international law.[123] As such, the right to health doctrine binds all nations.[124] The doctrine thus holds authority over the U.S. under international law.[125]

"Upholding the right to health doctrine is general practice followed pursuant to the belief that it imposes an obligation and is, therefore, customary international law."

B. CESCR's General Comment No. 14 Defines the Term "The Right to Health" and Provides Guidance on Compliance

The term "right to health" may invoke any number of different concepts.[126] Since the relevant treaties provide scant guidance on what steps countries must take to comply, states and scholars look to the U.N. Committee on Economic, Social and Cultural Rights' General Comment No. 14 for guidance.[127] General Comment No. 14's description of the obligations under the right to health doctrine is widely accepted and is considered the most comprehensive and respected delineation of the concept.[128]

General Comment No. 14 contains the authoritative interpretation of the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), the core treaty establishing the right to health.[129] When a treaty provision is also customary international law, it binds non-treaty parties only to the extent that it reflects state practice.[130] General Comment No. 14, however, not only establishes ICESCR's scope, but also mirrors nations' current practice.[131] The obligations outlined by General Comment No. 14 frequently form the interpretation of the right, even outside of the U.N.[132] Both regional and domestic bodies employ the analysis contained within the General Comment.[133] It is the most commanding and frequently invoked interpretation of the right to health doctrine.[134] It therefore provides the proper scope through which to interpret the right to health doctrine in customary international law.[135]

C. The United States is in Breach of the Right to Health Doctrine as Defined in General Comment No. 14 because Medicine is Not Equitably Accessible Absent Discrimination

Pursuant to the requirements established by General Comment No. 14, the U.S. is in breach of the right to health doctrine under customary international law.[136] General Comment No. 14 reports that the right to health requires countries to ensure the availability, accessibility, acceptability, and quality of health care facilities, goods, and services.[137] However, prescription medications in the U.S. are not economically accessible to all citizens.[138]

The term "goods" refers to products necessary to protect health.[139] The Committee on Economic, Social, and Cultural Rights specifies that treatment for diseases and "essential" medicines are core health care goods.[140] Prescription medication, an important health

"good," can be crucial to the treatment, prevention, and control of diseases, and therefore is clearly protected by provisions guarding health goods.[141]

Although all aspects of the doctrine are crucial, the right to health predominantly focuses on individuals' ability to access health care.[142] Members of the population must be able to access health care equitably[143] and without discrimination.[144] States must ensure that socially disadvantaged groups can afford health care goods and services.[145]

Prohibitive costs create subpar access to health goods.[146] Nations must ensure that essential medications are available equitably to all citizens, despite their economic status.[147] CESCR explains that states have an affirmative duty to ameliorate accessibility inequalities, even if they arise unintentionally.[148] A state may need to implement policies that favor the disadvantaged or impoverished portions of the population.[149] The requirements of nondiscrimination and equitable access exist throughout international law, nullifying any argument that an alternative definition of the right to health doctrine could exclude these provisions.[150] Therefore, if essential medications are not equitably and indiscriminately available to all, and the government does not act to change this situation, the state violates the right to health.[151]

Despite these obligations, medications are not equally accessible to all members of the population within the U.S.[152] Medication accessibility is a significant problem.[153] In a study comparing the U.S. to four other developed nations, the country ranked last for patients' ability to afford prescriptions.[154] As of 2006, 23% of U.S. citizens could not afford to comply with prescriptions and medication inaccessibility is increasing.[155] Poorer individuals are disproportionately affected.[156] However, it is a systemic problem reaching beyond indigent portions of the population.[157] Unfortunately, the government is not acting sufficiently to assist economically disadvantaged groups.[158]

The situation is most dire for the marginalized populations the right to health doctrine expressly requires states to protect.[159] Troubling disparities currently exist in access based on income-level, gender, and ethnicity.[160] Low-income families are disproportionately unable to access medications, both due to lack of money and insufficient or nonexistent insurance coverage.[161] Ethnic minorities and women are more susceptible to the effects of prohibitive cost barriers than the rest of the population.[162] These facts reveal discriminatory medication accessibility.[163] This widespread inaccessibility of medications breaches the right to health doctrine under customary international law.[164]

1. The United States is Not Respecting, Protecting, and Fulfilling Medication Accessibility Pursuant to the Right to Health Doctrine's Obligations

Pursuant to General Comment No. 14, states must respect, protect, and fulfill the requirements of the right to health doctrine.[165] To respect the right to medicine accessibility as part of the right to health, countries must avoid any action or policy that hinders access.[166] To protect this right, governments must implement policies to safeguard access and prevent third parties from impeding accessibility.[167] To fulfill the requirements, states must establish all necessary policies to ensure medication accessibility.[168] Countries must ensure low pricing for medications, or insurance to compensate for high prices, such that all citizens can afford essential medications.[169]

The U.S. is not upholding the obligations to respect, protect, and fulfill the right to health doctrine.[170] Most notably, the United States violates the duties to protect and to fulfill medication accessibility.[171] To protect the entitlements under the doctrine, a state must prohibit third parties from preventing its fulfillment.[172] However, the government has not implemented sufficient laws to protect individuals in the U.S. from excessive pharmaceutical prices or predatory insurance tactics.[173] The only national protections currently in place focus exclusively on the most impoverished individuals, the disabled, and the elderly.[174] Therefore, the U.S. does not currently uphold the duty to protect medication accessibility under the right to health doctrine.

Pursuant to the obligation to fulfill the right to health, the government must establish a national health plan to ensure medications are affordable and accessible to all, without discrimination.[175] Some argue that the U.S. meets the duty to fulfill through the creation of Medicare and Medicaid programs.[176] However, this position ignores the fact that many individuals do not benefit from these systems and still cannot access medications.[177] Additionally, private insurance plans are currently insufficient.[178] Through inaction, the U.S. thus violates the obligation to fulfill the right to health doctrine in addition to the obligation to protect it.[179]

It is not yet clear how the Patient Protection and Affordable Care Act will affect pharmaceutical prices and affordability. However, pharmaceutical manufacturers preemptively increased prices to avoid decreased profits.[180] This signals that insurance and pharmaceutical companies may attempt to circumvent the efficacy of the reform act. Without a public insurance option, the government's efforts will likely prove insufficient to correct the accessibility predicament. This is illustrated by the Congressional Budget Office's expectation that twenty-three million nonelderly residents will be uninsured in 2019.[181] Illegal residents only account for two-thirds of this figure.[182] Thus, millions of legal residents will remain uninsured. Furthermore, the reform act may potentially exacerbate the problem of impoverished and unhealthy individuals shouldering a disproportionate burden of health care costs.[183] Only a public option could guarantee universal coverage and the lowest possible costs.[184]

2. The United States is Unwilling, Not Unable to Uphold the Obligations Imposed by the Right to Health Doctrine

Economic considerations play a role in implementing the doctrine.[185] Therefore, a state only violates its obligations when it is unwilling, not unable, to comply.[186] This suggests a balancing test to determine a reasonable level of action: weighing a nation's economic strength and ability against the measures it takes to ensure the public can access health care services.[187] If the state does not attempt to fulfill obligations to its full capacity, it violates the doctrine's mandates.[188]

In balancing the government's ability to enable medication access under the right to health doctrine against its efforts, the scales are tipped heavily against the U.S.[189] The violations of the doctrine established above are based on a lack of will, not inability, to eradicate these problems.[190] Based on World Bank indicators on governance, the United States ranks highly in governmental capability.[191] The nation's 2009 gross domestic product ("GDP") surpassed $14 trillion, just behind the GDP of the entire European Union and more than any other country in the world.[192] Additionally, the government currently spends more than any nation per capita on health

care.[193] Yet, nations that spend substantially less are able to ensure universal health care access.[194] It is therefore clear that the U.S. has the capability and resources to implement the measures necessary to ensure access to essential medicines.

While General Comment No. 14 predominantly discusses "essential" medicines, the U.S. likely must ensure citizens can afford most, if not all, prescribed medications.[195] The General Comment requires states to uphold health accessibility to their maximum capability.[196] Based on the economic strength of the U.S., the government must take significant action to ensure medication accessibility for all.[197] Balancing the economic strength and significant capability of the U.S. to implement the obligations under the right to health doctrine against the meager protections afforded, the U.S. clearly breaches the obligations set forth in General Comment No. 14 and customary international law.[198]

III. Recommendations

The most glaring problem in U.S. health care is that many individuals are uninsured and unable to afford medical necessities, such as prescription medication.[199] Thus, the first step to redeem the health care system is to create universal health care that incorporates prescription coverage. Additionally, the U.S. should ratify the International Covenant on Economic, Social, and Cultural Rights.

A. The United States Should Enact Reform Laws to Create A Public Health Care Option

In order for the U.S. to comply with the right to health doctrine, prescription medications must be equitably accessible without discrimination.[200] Prohibitive pricing and manipulative health insurance tactics cannot be allowed. The government must take action to enable all citizens to enjoy the right to health and the right to access medicines.

Health care reform laws can ensure these rights.[201] As previously addressed, high prices create an insurmountable obstacle prohibiting uninsured or underinsured individuals from accessing medicine.[202] This tragedy is intensified in the recessed economy and by practices insurance companies employ to ensure high profits and to restrict an insured party's benefits.[203]

The Patient Protection and Affordable Care Act is a step in the right direction, but of the two bills before Congress in 2009, H.R. 3962 would have best ensured pharmaceutical access to the entire population without discrimination or prohibitive cost.[204] A public insurance option is crucial to the eradication of access disparities.[205] It would address many of the underlying problems that create unequal access and ensure that all citizens could obtain coverage. Additionally, a public option would compete with private insurance to discourage unfavorable practices through market competition and could keep administrative costs to a minimum.[206] Although the Patient Protection and Affordable Care Act will make great strides toward greater medication accessibility, it will likely fail to eradicate inaccessibility entirely and fulfill the requirements of the right to health doctrine. For this reason, Congress should establish a public option to bring the U.S. in line with its obligations under international law.

B. The United States Should Ratify the International Covenant on Economic, Social and Cultural Rights

The U.S. should formally ratify the International Covenant on Economic, Social, and Cultural Rights in Congress. Ratifying the Covenant would formally acknowledge the U.S.'s acceptance of the right to health doctrine's binding obligations. Such a public legal commitment can prove crucial for reform. Debates about access to health care currently center on moral imperatives, not legal rights. If the U.S. became a party to ICESCR, these problems would be discussed under the discourse of legal violations. This discourse is more likely to encourage change.[207]

Furthermore, if the U.S. ratifies the International Covenant on Economic, Social, and Cultural Rights, it would encompass the country under the purview of the Committee on Economic, Social and Cultural Rights. The Committee could then analyze the situation within the U.S. and provide guidance on measures for the U.S. to follow in order to improve access to health care and prescription medications.

Conclusion

It is time to fulfill the dreams of the millions of Americans who require health care and cannot afford prescription medications. This article demonstrates that access to health care is a fundamental human right ensured by customary international law, but unprotected in the U.S. The Founding Fathers of the U.S. declared, "all men are created equal" and "are endowed... with certain unalienable rights" including "Life, Liberty, and the Pursuit of Happiness."[208] An individuals' health is integral to all three. A public option would neutralize systemic inequalities preventing their realization. As a nation that prides itself on being a beacon of hope and freedom, it is time to honor the memory of visionaries such as Theodore Roosevelt and Ted Kennedy. The United States should

"Although the Patient Protection and Affordable Care Act will make great strides toward greater medication accessibility, it will likely fail to eradicate inaccessibility entirely and fulfill the requirements of the right to health doctrine."

join the advanced countries of the world in providing universal health care access. As Senator Kennedy urged:

> It is the glory and the greatness of our tradition to speak for those who have no voice, to remember those who are forgotten, to respond to the frustrations and fulfill the aspirations of all Americans seeking a better life in a better land. We dare not forsake that tradition.[209]

[1] *See* Senator Edward Kennedy, Speech at the Democratic National Convention (Aug. 25, 2008) (transcript *available at* http://www.americanrhetoric.com/speeches/convention2008/tedkennedy2008dnc.htm) (praising Barack Obama's nomination as the presidential candidate for the Democratic party and highlighting the need to improve health care access in the U.S.).

[2] *Id.* (proclaiming that the introduction of health care reforms in the U.S. was the "cause of [his] life.").

[3] *See* discussion *infra* Part II.A (evaluating the prominence of the right to health and concluding that it binds all nations because it is customary international law).

[4] *See* discussion *infra* Part II.A.1 (establishing the prevalence of laws that mandate health care access internationally).

[5] *See*, *e.g.*, Jean Carmalt & Sarah Zaide, Center for Econ. and Soc. Rights, *The Right to Health in the U.S. of America What Does it Mean?*, at ii (Oct. 2004), http://www.cesr.org/article.php?list=type&type=5 (advocating for the inclusion of the right to health within policy discussions about health care in the U.S., as President Roosevelt intended, to focus the debate on human rights and not economic costs) (internal quotations omitted); Michael Kirby, *The Right to Health Fifty Years On: Still Skeptical?* 4(1) Health & Hum. Rts. 6, 8 (1999) (suggesting that the atrocities committed during World war II led President Roosevelt to fight for the protection of human rights).

[6] *See*, *e.g.*, The Universal Declaration of Human Rights: A Common Standard of Achievement xxvii (Gudmundar Alfredsson & Asbjorn Eide eds., Kluwer Law International 1999) (indicating that his influence may be due to the fact that his wife, Eleanor Roosevelt, chaired the Commission drafting the UDHR).

[7] *See* Senator Edward M. Kennedy, *Health Care as a Basic Human Right: Moving from Lip Service to Reality* 22 Harv. Hum. Rts. J. 165, 165 (2009) (acknowledging the fact that the U.S. government does not ensure health care access for all citizens although the international community has recognized the right to health for more than sixty years).

[8] *See, e.g.*, Eleanor D. Kinney, *Recognition of the International Human Right to Health and Health Care in the U.S.* 60 Rutgers L. Rev. 335, 368-70 (2008) (presenting indicators of the poor performance of U.S. health care including the fact that the U.S. population has a lower life expectancy than at least thirty other nations despite spending significantly more on health care than any other country).

[9] *See* Kennedy, *supra* note 7, at 166 (linking a shorter life expectancy to individuals being underinsured because of their tendency to avoid necessary care as a result of costs).

[10] *See* discussion *infra* Part I.D. (exploring the effects of prohibitive pricing and high rates of uninsured individuals on the population's ability to afford medications in the U.S.).

[11] *See* Kennedy, *supra* note 7, at 166 (relaying one study's findings that health care payments cause one-half of U.S. personal bankruptcies, and that every thirty seconds a family goes bankrupt for that reason).

[12] *See* Kinney, *supra* note 8, at 348-53 (tracing the history of the debate over national health care back to 1935, and noting that Presidents Truman, Nixon, Carter, and Clinton all advocated universal health care within the U.S. to no avail).

[13] *See* Kinney, *supra* note 8, at 348 (pinpointing the debate over the Social Security Act in 1935 as the beginning of deliberations on whether to provide national health insurance coverage).

[14] *Cf.* Allison K. Hoffman, *Oil and Water: Mixing Individual Mandates, Fragmented Markets, and Health Reform* 36 Am. J.L. &Med. 7,15 (2010) (concluding that the suggestion of a government-run health insurance plan is a "political lightening rod in the U.S." which provokes widespread backlash centering around allegations that such a plan would be tantamount to "socialized medicine.").

[15] *See* discussion *infra* Part II.C (demonstrating that the U.S. does not currently meet the legal requirement of equitable access for all without discrimination).

[16] *See* discussion *infra* Part I (laying out the high costs of medications within the U.S. and the subsequent effects on the population, as well as the reform bills proposed in 2009 to increase health care accessibility).

[17] *See* discussion *infra* Part I.C (introducing the definition of customary international law and the International Court of Justice's inclination to recognize human rights as customary international law).

[18] *See* discussion *infra* Part II (deducing that the right to health is binding on all nations as a part of customary international law and that it requires medication accessibility beyond the level obtained in the U.S.).

[19] *See* discussion *infra* Part III (offering the possibility of universal health insurance as an answer to the hurdles preventing medication accessibility in compliance with the right to health).

[20] *See* discussion *infra* Part I.A (explaining the progression of human rights provisions establishing the right to health).

[21] *See* discussion *infra* Part I.B (detailing the World Health Organization and United Nation's attempts to narrow the definition of "health" and the "right to health").

[22] *See generally* Constitution of the World Health Organization, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185 [hereinafter WHO Constitution] (stating that the parties to the Constitution recognize that health is basic to international harmonious relations and establishing the World Health Organization to promote the protection of health).

[23] *See* WHO Constitution pmbl. (specifying that countries should provide the right "without distinction of race, religion, political belief, economic or social condition").

[24] *See id.* pmbl. (declaring that the promotion of health in any nation benefits the entire international community).

[25] *See*, *e.g.*, International Covenant on Economic, Social, and Cultural Rights, *opened for signature* Dec. 16, 1966, 993 U.N.T.S. 3, art 12(1) [hereinafter ICESCR] (forming binding obligations for nations to recognize the right to health and adopt tools for its implementation); Universal Declaration of Human Rights, G.A. Res. 217A, U.N. Doc. A/810, art. 25(1) (Dec. 10, 1948) [hereinafter UDHR] (announcing a right to an adequate standard of living to support health and well-being as a human right).

[26] *See* UDHR, *supra* note 25, at art. 25(1). The UDHR's preamble proclaims a "recognition of the inherent dignity and . . . equal and inalienable rights of all members of the human family." Id. at preamble.

[27] *See* ICESCR, *supra* note 25, at art. 12(1). The ICESCR preamble asserts that U.N. members have "a responsibility to strive for the promotion and observance of the rights recognized in the present Covenant." Id. at preamble.

[28] *See* ICESCR, *supra* note 25, at art. 12(2) (including requirements for the signatory countries to takes steps to reduce stillbirth, decrease infant and child mortality rates, improve hygiene, and create conditions ensuring medical care to all).

[29] *See* World Health Organization, Fact Sheet: The Right to Health, http://www.who.int/mediacentre/factsheets/fs323_en.pdf [hereinafter WHO Fact Sheet] (displaying the extensive international acceptance of the right to health and noting that physical health and mental health are both protected).

[30] *See* Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights*, ¶ 12, *delivered to the General Assembly*, U.N. Doc. A/HRC/7/11 (Jan. 31, 2008) (by Paul Hunt) [hereinafter Promotion and Protection of All Human Rights] (elaborating that an effective health system is a "core institution" of government, just as a fair justice system is).

[31] *See* David P. Fidler, International Law and Public Health 302 (2000) (identifying difficulties in conceptualizing, implementing, and enforcing the right to health as main problems in the right's history).

[32] *Cf.* Eleanor D. Kinney, Lecture, *The International Human Right to Health: What Does This Mean for Our Nation and World?* 34 Ind. L. Rev. 1457, 1457 (2001) (contending that the seemingly vague nature of the right to health doctrine should not deter nations from attempting to comply, as it is no more obscure than other social and cultural human rights incorporated into international law).

[33] *Cf.* Alicia Ely Yamin, *The Right to Health Under International Law and Its Relevance to the U.S.* 95(7) Am. J. Pub. Health 1156, 1157-58 (July 2005)

(finding that a consensus has formed on what the right to health entails from international agreements).

[34] *See* WHO Constitution, *supra* note 22, pmbl. (providing an early attempt to define "health" which focused on the overall state of the body); *see also* Fidler, *supra* note 31, at 278 (arguing that this definition was beneficial in advancing a concept of health looking at overall "well-being" instead of a narrow, medical focus).

[35] WHO Constitution, *supra* note 22, pmbl. (denouncing a simplistic view of health and linking the definition to governments' obligations to protect the health of the members of society); *see also* Fidler, *supra* note 31, at 279 (observing that the definition contained within the WHO Constitution may be the broadest vision of health within the discourse of modern health law).

[36] WHO Constitution, *supra* note 22, pmbl. (advancing the argument that the enjoyment of health is a fundamental right which is principal to individuals' happiness and security).

[37] *See* Benjamin Mason Meier, J.D., LL.M., *Breathing Life into the Framework Convention on Tobacco Control: Smoking Cessation and the Right to Health*, 5 Yale J. Health Pol'y L. & Ethics 137, 157 (2005) (isolating the Alma-Ata Declaration as the beginning of a more encompassing view of the right to health).

[38] *See* International Conference on Primary Care, Alma-Ata, U.S.S.R., Sept. 6-12, 1978, *Declaration of Alma-Ata*, art. VII (calling the provision of primary health care "the key" for governments to protect the health of their populations).

[39] *See* Meier, *supra* note 37, at 157 (noting that both resolutions call for universal health care access).

[40] *See* U.N. Comm. on Econ., Soc., and Cultural Rights [CESCR], *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, ¶ 2, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000) [hereinafter *General Comment No. 14*] (rejecting the definitions suggested by WHO, reasoning that the history and wording of ICESCR Article 12(1) and 12(2) promote the inclusion of additional socio-economic factors as inherent in the right to health); *id.* ¶ 43 (naming the Alma-Ata Declaration as an instrument that helped to shape the specifications provided in the General Comment).

[41] *See* High Commissioner for Human Rights, *Review of the composition, organization and administrative arrangements of the Sessional Working Group of Governmental Experts on the Implementation of the International Covenant on Economic, Social and Cultural Rights*, E.S.C. Res. 1985/17, U.N. Doc. E/RES/1985/17 (May 28, 1985) (creating the Committee to be composed of eighteen human rights experts).

[42] *See General Comment No. 14*, *supra* note 40, ¶ 9 (accepting that no state can guarantee that citizens will be healthy, and focusing instead on enabling citizens to access health services).

[43] *See* discussion *infra* Part II.B (relaying the actions necessary to comply with medication accessibility under the right to health).

[44] *Cf.* Kinney, *supra* note 32, at 1464 (finding customary law "promising" to establish the right to health as an internationally binding norm).

[45] *See* Oscar Schachter, International Law in Theory and in Practice 335 (1991) (recognizing customary international law's influence on the field of human rights because it encompasses nations within the purview of human rights obligations that may not have signed the treaties that initially established the rights).

[46] *See* North Sea Continental Shelf (F.R.G./Den. v. F.R.G./Neth.), 1969 I.C.J. 4, 45 (Feb. 20) (readministering the test originally set forth by the Permanent Court of International Justice and denying that continental shelf delimitation had reached the point of customary international law at that time); *see also* Theodor Meron, Human Rights and Humanitarian Norms as Customary International Law 107 (1989) (commenting that the Continental Shelf Cases contains the classic definition of customary international law).

[47] *See* Fidler, *supra* note 31, at 48 (clarifying that if a country is a "persistent objector" when the law is forming, it is not bound by the customary international law).

[48] *Cf.* Kinney, *supra* note 8, at 364 (contrasting the vast international recognition of the right to health with the U.S.' "mixed" record of recognition by supporting the UDHR, ratifying CERD, but failing to ratify regional treaties).

[49] *See Kinney*, *supra* note 8, at 346-47 (suggesting the Cold War and racial tensions within the U.S. as reasons why the country did not join treaties during the height of the human rights movement).

[50] *See* Carmalt & Zaide, *supra* note 5, at 8-9 (arguing that the Medicare and Medicaid programs are the closest the American system comes to providing universal health care).

[51] *See* Carmalt & Zaide, *supra* note 5, at 9 (lamenting that the current framework excludes millions of Americans who cannot receive aid based on the eligibility requirements).

[52] *See* The Henry J. Kaiser Family Found., *Prescription Drug Trends* at 2 (Sept. 2008), www.kff.org/rxdrugs/upload/3057_07.pdf [hereinafter Kaiser] (illuminating that prices rose at an average rate of 6.9% per year between 1997 and 2007, over two and a half times the average annual inflation rate from this period and that the drug manufacturers ranked within the top five most profitable within the U.S. in that time).

[53] *See id.* at 4 (listing the techniques used by the insurance companies, such as excluding a greater number of medications from coverage, use of quality dispensing limit—such as only covering generic forms of a prescription—and increasing out-of-pocket copayments).

[54] *See e.g.*, Jae Kennedy, Ph.D. et al., *Drug Affordability and Prescription Noncompliance in the U.S.: 1997-2002*, 26(4) Clin. Ther. 607, 607-14 (2004) (attributing these trends to, *inter alia*, increased third-party payment plans, changes in the population, new and more effective drugs, pharmaceutical companies' direct marketing, and high pharmaceutical company profits).

[55] *See e.g.*, Becky A. Briesacher, Ph.D. et al., *Patients at Risk for Cost-Related Medication Nonadherence: A Review of the Literature* 22(6) J. Gen. Intern. Med. 864, 864 (June 2007) (reporting that as many as 32% of older adults decreased prescription drug use because of the cost).

[56] *See e.g.*, *id.* at 864 (referring to the phenomenon as cost-related nonadherence); Kennedy et al., *supra* note 55, at 607-14 (utilizing the abbreviation CRNA).

[57] *See* Jae Kennedy, Ph.D. & Steve Morgan, Ph.D., *Cost-Related Prescription Nonadherence in the U.S. and Canada: A System-Level Comparison Using the 2007 International Health Policy Survey in Seven Countries* 31(1) Clin. Ther. 213, 215 (2009) (insisting that medication non-adherence is an important public health problem and suggesting that, based on their findings, mandated universal drug coverage is the most effective solution).

[58] *Cf.* Briesacher et al., *supra* note 55, at 866 (establishing lack of drug coverage as a leading cause of noncompliance through a comparison of seventeen separate studies); Kennedy & Morgan, *supra* note 57, at 217 tbl.II (quantifying the connection by showing that uninsured individuals amount to over 43% of those who could not afford to fill prescriptions).

[59] *See* Briesacher et al., *supra* note 55, at 866 tbl.2 (correlating a "significant" increase in noncompliance with low income and financial pressures); *see also* Kennedy & Morgan, *supra* note 57, at 266 tbl.I (specifying that 34.4% of individuals reporting CRNA received a below average income).

[60] *Cf.* Kennedy et al., *supra* note 54, at 609 (elucidating that women reported 7.1% noncompliance compared to 4.7% of men, and African Americans reported 8.4% and Hispanics 6.6%, whereas Caucasians reported 5.5% noncompliance).

[61] *Cf.* Kennedy, *supra* note 7, at 165 (urging the population to support health care reform because the economic recession will exacerbate individuals' struggles to afford health care).

[62] *See* Sarah R. Collins, et al., *The Comprehensive Congressional Health Reform Bills of 2009: A Look at Health Insurance, Delivery System, and Financing Provisions*, at 3 (Dec. 18, 2009), http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2009/Oct/Congressional-Health-Reform-Bills.aspx (referring to a Census Bureau report released in September of 2009 that determined 46.3 million individuals in the U.S. did not have insurance in 2008, and that this figure increased by eight million people since 2000); *see also* Carmalt & Zaide, *supra* note 5, at 15 (revealing the alarming fact that 78% of uninsured Americans between 2002 and 2003 were employed).

[63] *See generally* Cathy Schoen et al., *How Many Are Underinsured? Trends Among U.S. Adults, 2003 and 2007* 27(4) Health Aff. w298, w298 (June 10, 2008),http://content.healthaffairs.org/cgi/content/abstract/27/4/w298 (showing that the population of underinsured individuals is encompassing a more affluent sector of U.S. citizens and thus more individuals are at risk of CRNA).

[64] *See* Robin A. Cohen, Ph.D. et al., *Health Insurance Coverage Trends,*

1959-2007: Estimates from the National Health Interview Survey, 17 Nat'l Health Stat. Rep., 1, 1 (July 1, 2009) (citing a recent report that found a "lack of health insurance coverage negatively affects both access to health care and health status"); *see also* Briesacher et al., *supra* note 55, at 869 (cautioning that such behavior prevents patients from receiving the full benefits of medications and creates health risks); Kennedy & Morgan, *supra* note 57, at 218 (decrying the fact that CRNA continues to pose an "important public health problem" despite the documented effectiveness of complying with prescriptions).

[65] *Cf.* Collins et al., *supra* note 62, at 1 (proclaiming that, "[t]his year, policymakers in Washington have risen to the challenge posed by the faltering U.S. health care system..").

[66] *See generally* Jennifer Haberkorn & S.A. Miller, *House OKs Health Reform Bill*, Wash. Times, Nov. 8, 2009 (announcing the ratification of H.R. 3962 in the House of Representative as a landmark in changing the U.S. health care system); Shailagh Murray and Lori Montgomery, *Senate Passes Health-Care Bill, Now Must Reconcile it With House*, Wash. Post, Dec. 25, 2009 (broadcasting the Senate's approval of its health care bill in the early morning of Dec. 24, 2009).

[67] *See generally* The Affordable Health Care for America Act, H.R. 3962, 111th Cong. (2009) (prohibiting the revocation of coverage unless the insured committed fraud on the company in § 103 and requiring plans to cover dependent children up to twenty-seven years of age in § 2703); The Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2009) (extending required covering to dependent children up to twenty-six years old); *see also* Collins et al., *supra* note 62, at 8 (sharing projections from the Congressional Budget Office that the number of uninsured would decrease by thirty-six million people through the provisions of H.R. 3962, and thirty million people through H.R. 3590).

[68] *See* Collins et al., *supra* note 62, at 4 (pointing out that the bills would attempt to lower costs through enabling the population to better compare and choose between plans, by providing government subsidies based on income for those in need, and establishing maximum out-of-pocket expenses insurance companies can charge).

[69] *See* H.R. 3962 (including hospitalization, outpatient hospital and clinic services, medical and surgical care, immunizations, maternity care, and prescription medications among the minimum required benefits); H.R. 3590 (incorporating ambulatory services, emergency services, hospitalization, maternity care, rehabilitation, behavioral health treatment, preventative and wellness care, and pediatric services).

[70] *See generally* Kennedy, *supra* note 1 (emphasizing the importance of the goal to reform the healthcare system so that all Americans can access health care).

[71] *See e.g.*, Jim Acosta, et al., *Brown Wins Massachusetts Senate Race*, CNN, Jan. 19, 2010, http://www.cnn.com/2010/POLITICS/01/19/massachusetts.senate/index.html (announcing that Republican Scott Brown was elected to hold Senator Kennedy's seat resulting in only 59 Democrats in the Senate, one fewer than necessary to defeat a filibuster).

[72] *See e.g.,* Robert Pear and David M. Herszenhorn, *Obama Hails Vote on Health Care as Answering the 'Call of History'*, N.Y. Times, Mar. 21, 2010, http://www.nytimes.com/2010/03/22/health/policy/22health.html (noting the deep-seated ideological difference among U.S. citizens on the issue of healthcare reform and the "epic political battle" that was necessary to enact the reforms).

[73] *See* Henry J. Kaiser Family Found., *Summary of New Health Reform Law* 1 (Apr. 21, 2010), http://www.kff.org/healthreform/upload/8061.pdf [hereinafter *New Health Reform Law*] (commenting that the law focuses on expanding coverage, restraining costs, and improving the efficiency of the health care system).

[74] *See* Jack Begg, *Budget Reconciliation*, N.Y. Times, Apr. 6, 2010, http://www.nytimes.com/info/budget-reconciliation-us-congress/?inline=nyt-classifier (explaining that the process of budget reconciliation allows Congress to alter fiscal provisions by a simple majority and without the possibility of filibuster in legislation where they are 'merely incidental' to the true intent of the legislation").

[75] *See New Health Reform Law*, *supra* note 73, at 1 (clarifying that individuals without health insurance coverage would be subject to a tax penalty of at least $695 per year up to a total of $2,085 beginning in January of 2016).

[76] *See* Patient Protection and Affordable Care Act, Pub. L. No 111-148 § 1311 (2010) (requiring states to create an exchange no later than January 1, 2014).

[77] *See e.g.*, Henry J. Kaiser Family Found., *Summary of Coverage Provisions in the Patient Protection and Affordable Care Act* 2 (Apr. 28, 2010), http://www.kff.org/healthreform/upload/8023-R.pdf (elaborating that the exchanges will be specific to different states but that there will be at least two multistate exchange plans available in each American Health Benefit Exchange); Karen Davis, Ph.D, The Commonwealth Fund, *A New Era in American Health Care: Realizing the Potential of Reform* 22-23 (June 2010), http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2010/Jun/A-New-Era-in-American-Health-Care.aspx (adding that experts expect the health insurance exchanges to lower consumer risk and reduce administrative costs and that at least one plan will be provided by a non-profit organization to further reduce prices).

[78] *See* Pub. L. No. 111-148 § 1311(c)(4) (laying out the minimum requirements for exchanges, including providing a rating for each insurance plan and using a standard format to display the plans to allow for easy comparison).

[79] Comm. on Educ. and Labor, 111st Cong., Press Release, *House Makes History on Health Reform*, Nov. 7, 2009, http://help.senate.gov/Press_releases.html (addressing the incentives for creating health insurance exchanges and claiming that health care reform will lead to affordable, quality health care coverage for eligible consumers).

[80] *See e.g.*, *New Health Reform Law*, *supra* note 73, at 6 (pointing out that current plans will continue, but the plans must cover dependant children up until the age of twenty-six and, beginning in 2014, cannot impose a monetary limit on lifetime coverage, nor rescind coverage for reasons other than fraud).

[81] *See e.g.*, *New Health Reform Law*, *supra* note 73, at 5 (laying out the benefits of the four tiers, which includes the bronze plan that will cover 60% of total health care expenses, the silver plan that will cover 70%, the gold plan that will cover 80%, and the platinum plan that will cover 90% of total expenses).

[82] *See* Davis, *supra* note 77, at 12 (noting that these plans will become available beginning in 2014 and that the tiered structure facilitates individuals' ability to understand the expenses each plan will cover).

[83] *See* Patient Protection and Affordable Care Act, Pub. L. No 111-148 §1302(b) (2010) (consisting of ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use services, prescription medication, rehabilitative services, laboratory services, preventative and wellness services, and pediatric services).

[84] *See New Health Reform Law*, *supra* note 73, at 2 (observing that the cost-sharing limits will decrease for individuals receiving such subsidies).

[85] *See* Henry J. Kaiser Family Found., *supra* note 77, at 2 (denoting that the federal poverty level as of 2009 would allow for assistance for a family of four that earned $88,200).

[86] *See* discussion *supra* Part I.D (confirming that lacking insurance coverage leads to CRNA and numerous individuals within the U.S. are uninsured); Kennedy & Morgan, *supra* note 57, at 218 (proving that the establishment of universal drug coverage lowers CRNA better than other insurance systems).

[87] *See* The Affordable Health Care for America Act, H.R. 3962 § 321(a) 111th Cong., (2009) (highlighting that the Secretary of Health and Human Services has a responsibility to structure the plan to ensure low costs but sustain quality).

[88] *See* H.R. 3962, § 322 (allowing for premiums to vary based on the location of the recipient).

[89] *See* Davis, *supra* note 77, at 8 exhibit 2 (predicting that twenty-six million non-elderly individuals will remain uninsured in 2015 and that the figure may decrease to twenty-one million individuals in 2016).

[90] *See* discussion *supra* Part I.D (containing statistical findings on the percentages of uninsured within the U.S. population and their subsequent inability to afford proper health care).

[91] *Cf.* Schachter, *supra* note 45, at 341 (suggesting that the right to "public assistance in matters of health" meets the two-part test of inclusion in national law and international recognition of its significance); *see also* Fidler, *supra* note 31, at 155 (conceding the likelihood that the right to health is customary international law but finding that enforcement of customary law is elusive); Eibe Riedel *The Human Right to Health: Conceptual Foundations*

in Realizing the Right to Health: Swiss Human Rights Book Volume 3 36-37 (Andrew Clapham et al., eds., Apr. 2009) (presuming that most states accept the right as a fundamental human right and thus enforce individuals' rights under the right to health doctrine in domestic law); Lisa Forman, *"Rights" and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines?* 10(2) Health & Hum. Rts. 37, 39 (2008) (insisting that the legal power of the right to health doctrine is escalating such that it is difficult to argue against its strength).

92 *See* North Sea Continental Shelf (F.R.G./Den. v. F.R.G./Neth.) 1969 I.C.J. 4, 45 (Feb. 20) (holding that the practice of defining continental shelf boundaries contained in Article 6 of the Geneva Conventions of 1958 did not yet amount to customary law because it failed this test).

93 *See* discussion *infra* notes 96-125 and accompanying text (listing specific evidence corroborating the right to health's widespread acceptance and binding nature).

94 *See* Peter Malanczuk, *Akehurtst's Modern Introduction to International Law*, *reprinted in* Harry J. Steiner & Philip Alston, International Human Rights in Context 72, 74 (2d ed., 2000) (reasoning that no exact formula exists and state practice may vary as long as there are no major inconsistencies).

95 *See* Schachter, *supra* note 45, at 336 (rationalizing that because the protection of human rights is generally a domestic concern and human rights violations rarely affect nationals of other countries, states do not usually protest these violations, ergo national proclamations that the laws protecting human rights create binding obligations, or similar evidence that states follow the human rights norms based on perceived obligations, are rare); *see also* Restatement (Third) of Foreign Relations Law § 103 (1987) (stating that substantial weight should be given to the opinions of international courts, domestic courts, scholarly writings, and state declarations as evidence of international law); *see also* Malanczuk, *supra* note 94, at 73 (speculating that most of the material that would verify state practice and intent, such as diplomatic correspondence and the opinions of legal advisors, are not published and therefore unavailable).

96 *See* Kinney, *supra* note 32, at 1464-67 (contending that proper evidence supports considering the right to health doctrine as customary international law).

97 *See e.g.*, Promotion and Protection of All Human Rights, *supra* note 30, ¶ 12 (pointing out that the broad implementation of the right to health has demonstrated its importance as "a fundamental building block of sustainable development, poverty reduction and economic prosperity").

98 *Compare* WHO Fact Sheet, *supra* note 29, at 1 (suggesting that the concept is internationally relevant because *all* countries have ratified at least one international treaty recognizing the right to health); *and* Gunilla Backman et al., *Health Systems and the Right to Health: An Assessment of 194 Countries*, 372 Lancet 2047, 2047 (Dec. 13, 2008), *available at* http://www.who.int/pmnch/topics/health_systems/en/ (agreeing that all states have ratified at least one binding treaty that includes the right to health and adding that one such treaty, the Convention on the Rights of the Child, is signed by all but two nations); *with* Kinney, *supra* note 8, at 364 (determining that a *majority* of nations recognize the right to health and showing the fact that the U.S. is not bound as a treaty party is unique).

99 *See* WHO Fact Sheet, *supra* note 29, at 10 (naming The African Charter on Human and Peoples' Rights, the Additional Protocol of the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, the European Social Charter, the American Convention on Human Rights, and the European Convention for the Protection of Human Rights and Fundamental Freedoms as regional agreements that include the right to health).

100 *See* Kinney, *supra* note 32, at 1461 (noting that the growth in accepting human rights was largely a result of nations reacting to the offences committed during World War II); *see also* Stephen P. Marks, *Access to Essential Medicines as a Component of the Right to Health*, *in* Realizing the Right to Health, *supra* note 91, at 182 (quoting a United Nations task force finding that one hundred and thirty-five nations recognize health care as a fundamental right in their constitutions).

101 *See* WHO Fact Sheet, *supra* note 29, at 10 (including a state duty to develop health services or implement a budget for health care as examples of constitutional requirements); *see also* Puneet K. Sandhu, Comment, *A Legal Right to Health Care: What Can the U.S. Learn from Foreign Models of Health Rights Jurisprudence?* 95 Cal. L. Rev. 1151, 1175 (2007) (explaining that the South African Constitution in particular requires the government to provide health care access to all citizens and refrain from denying emergency medical care).

102 *See* Eleanor D. Kinney & Brian Alexander Clark, *Provisions for Health Care in Constitutions of the Countries of the World* 37 Cornell Int'l L.J. 285, 286-87 (2004) (adding that these constitutions augment obligations imposed by legislation and administrative actions).

103 *See generally* Hans v. Hogerzeil et al., *Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable Through Courts?* 368 Lancet 305 (July 22, 2006) (conducting a study to determine if the right to health is enforceable through domestic courts and finding fifty-nine cases of successful claims).

104 *See supra* notes 107-08 (describing numerous cases before both domestic and regional courts enforcing health care access as a right); *see also* Forman, *supra* note 91, at 39 (discovering a trend among domestic courts upholding the rights contained within the right to health both directly, in countries such as South Africa and many Latin American nations, and under the purview of the right to life).

105 *See* Horgezil et al., *supra* note 103, at 307-10 (finding success through the justice system is most likely where the country recognized the right to health in its constitution); Sandhu, *supra* note 101, at 1174-82 (detailing the cases of *Minister of Health v. Treatment Action Campaign* in South Africa in which the Court found that denying access to drugs to prevent mother-to-child HIV transmission violated the constitution, and the Canadian case of *Eldridge v. British Columbia* where the court held that the government violated the constitution by failing to provide equal access in health services).

106 *See generally* Steven R. Keener & Javier Vasquez, *A Life Worth Living: Enforcement of the Right to Health Through the Right to Life in the Inter-American Court of Human Rights* 40 Colum. Hum. Rts. L. Rev. 595 (Spring 2009) (indicating that recent cases before the court recognized a right to medicine, food, clean water, sanitation, and access to medical care); *see also* Fidler, *supra* note 31, at 308 (drawing on the 1977 *Ache Tribe Case* where the Court found that Paraguay's denial of medication during infectious disease epidemics violated the right to health and the 1985 *Yanomani Tribe Case*, where the court determined that Brazil infringed upon the right to health of the tribe by exposing them to diseases while building a road in the Amazon).

107 *See generally* Forman, *supra* note 91 (stressing the importance of litigation to advance a public commitment to the right to health through the example of a South American dispute in which pharmaceutical companies brought a lawsuit to fight a bill to lower prices and inadvertently stirred public sentiment, resulting in international resolutions affirming the right to medicine accessibility).

108 *See e.g.*, Hans V. Hogerzeil, *Essential Medicine and Human Rights: What Can They Learn from Each Other?* 84(5) WHO Bull. 371, 371 (May 2006), *available at* http://www.who.int/bulletin/volumes/en/ (observing that many nations are now taking actions to effectively implement the rights guaranteed under the right to health doctrine).

109 *See e.g.*, Michael de Looper & Gaetan Lafortune, *OECD Health Working Papers No. 43 Measuring Disparities in Health Status and in Access and Use of Health Care in OECD Countries* 32 fig.13 (2009), *available at* http://www.oecd.org/searchResult/0,3400,en_2649_37407_1_1_1_1_37407,00.html (charting the percentage of the public covered by health insurance for thirty countries in 2006 and finding that the U.S. is only one of three nations, along with Mexico and Turkey, that has not achieved universal coverage and the percentage of the U.S. under public coverage was by far the smallest of all nations).

110 *See* Promotion and Protection of All Human Rights, *supra* note 30, ¶ 12 (discerning a trend over the last six decades that the international community recognizes health as an integral component of prosperity and development).

111 *See* Kinney & Clark, *supra* note 102, at 294 (ranking the commitment to health care in countries' constitutions on a scale of 0-3 and finding that, for example, Luxembourg spent the most to provide health care access, $2518 U.S. per capita, even though the constitution only achieved a score of 1).

112 *See supra* notes 99-113 and accompanying text.

113 *Cf.* Riedel, *supra* note 91, at 24 (commenting that states follow the instruments elaborating upon the right as if they are binding and the fact that they are not binding is therefore irrelevant).

[114] *See* Schachter, *supra* note 45, at 335 (explaining that a states' acceptance of resolutions signals both consent and practice); *see also* Restatement (Third) of Foreign Relations Law §102 cmt. c (1987) (remarking that courts need not find evidence of *opinio juris* because they can infer it from state action).

[115] *See* Riedel *supra* note 91, at 23 (raising U.N. declarations as evidence of the commitment to the right to health, including the Vienna Declaration and Program of Action of 1993 and the U.N. Millennium Declaration); *see also* Schachter, *supra* note 45, at 89 (pondering that the votes on declarations and resolutions in the United Nations manifest the expression of the governments involved and thus provide evidence of *opinio juris*); WHO Fact Sheet, *supra* note 29, at 1 ("...States have committed themselves to protecting this right through international declarations, domestic legislation and policies, and at international conferences.").

[116] *See* The Universal Declaration of Human Rights: A Common Standard of Achievement, *supra* note 6, at xxx (noticing that many scholars believe that the UDHR itself is customary international law and that it has weight beyond most General Assembly resolutions); *see also* Restatement (Third) of Foreign Relations Law §102(2) (1965) (contending that international conferences may provide an occasion for states to express a consensus on a norm which supports its status as customary international law).

[117] *See supra* notes 36-39 and accompanying text.

[118] *See* Meier, *supra* note 37, at n.72 (arguing that the right to health is now customary international law because of the proliferation of treaties containing the obligation); *see also* Barry E. Carter, Phillip R. Trimble & Allen S. Weiner, International Law 135-36 (5th ed., 2007) (believing that multilateral treaties can hasten the establishment of a custom and that the process of treaties creating customary international law will likely increase due to the clarity of treaties and their convenience); Kinney, *supra* note 32, at 1464 (asserting that the International Covenant on Economic, Social, and Cultural Rights may be customary international law due to this principle).

[119] *See e.g.*, Restatement (Third) of Foreign Relations Law §102 cmt. i (1987) (clarifying that even bilateral treaties can create customary law when states create many bilateral agreements containing comparable terms and these treaties are tantamount to state practice); Fidler, *supra* note 31, at 48 (explaining that the practice is thus followed consistently based on a legal obligation, and even nations who did not join the treaty may begin to feel bound); Malanczuk, *supra* note 92, at 72 (noting that the existence of two bilateral treaties containing the same obligations is not enough to demonstrate the creation of customary law and that bilateral treaties are less likely to support custom than multilateral agreements).

[120] *Cf.* Riedel, *supra* note 91, at 25 ("The network of international treaty law instruments with significant for the right to health is very elaborate.")

[121] *See* Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. Int'l L.J. 325, 336 (2003) (pointing out that the right is included in as many instruments as any classic civil right).

[122] *See* Forman, *supra* note 91, at n.22 (enumerating that an "effective universality" of states, 193, are a party to the Children's Rights Convention, 185 to the Convention on the Elimination of Discrimination against Women, 173 to International Convention on the Elimination of Racial Discrimination, and 157 to the International Covenant on Economic, Social, and Cultural Rights).

[123] *See supra* notes 104-122 and accompanying text (showing that the right to health meets the standards of customary international law and satisfies the methods the ICJ uses to determine customary law in relation to human rights).

[124] *See* Oppenheim's International Law (Robert Jennings & Arthur Watts eds., 9th ed. 1992), *reprinted in* Steiner, *supra* note 94, at 224 (entitling such law "universal international law" for this reason, and treaty law "particular international law" because it does not apply universally).

[125] *Cf.* Kinney, *supra* note 32, at 1463 (neglecting to reach a conclusion on whether or not the right to health is customary international law, but affirming that if it were the case, the doctrine would impose legal obligations on all nations, including the U.S.).

[126] *See Yamin*, *supra* note 121, at 330 (lauding the General Comment for combating previous ambiguity and promoting a clear picture of the right to health that can be implemented).

[127] *See infra* note 132 and accompanying text; *see also* Keener & Vasquez, *supra* note 106, at 603 (concluding that the General Comment has been integral in resolving the ambiguity of the definition of the right to health); Yamin, *supra* note 121, at 352 (explaining that the three-part requirement to respect, protect, and fulfill the obligations of the right to health, as asserted in General Comment No. 14, is "well-established" in international law and that a similar framework is now used in regional human rights bodies and domestic legal systems).

[128] *See* Keener & Vasquez, *supra* note 106, at 603 (referring to the document as the "most authoritative and comprehensive articulation of the right to health"); *see also* Kinney, *supra* note 8, at 364 (proposing that comparing national legislation to General Comment No. 14 is "an excellent approach to assessing [right to health] issues").

[129] *Cf.* Schachter, *supra* note 45, at 87 (positing that the response of a treaty's parties is the main concern to determine the power of a treaty analysis, and if the parties agree in a resolution that an interpretation of the treaty is valid, then it is authoritative); *see also* Yamin, *supra* note 121, at 337 (referring to Article 12 of ICESCR as the "core provision" on the right to health).

[130] *See* Continental Shelf (Tunis. v. Libya) 1985 I.C.J. 3, 29-30 (Apr. 14) (proclaiming that courts look at state practice and *opinio juris* to determine the boundaries of customary international law, even where treaties "may have an important role to play in recording and defining rules deriving from custom, or indeed in developing them.").

[131] *Cf.* Riedel, *supra* note 91, at 32 (speculating that the core obligations contained within the General Comment replicates the practice of "very many" states domestically and concluding it thus creates customary international law); *see also* Riedel, *supra* note 91, at 27 (acknowledging that U.N. Committees, such as CESCR, state their perceptions of international consensus on the law in General Comments, thus upholding their duty to interpret without legislating).

[132] *See e.g.*, Hans V. Hogerzeil, *The Concept of Essential Medicines: Lessons for Rich Countries* 329 Brit. Med. J. 1169, 1170-71 (Nov. 13, 2004) (opining that many developing countries implemented national programs to promote the availability, accessibility, and affordability of medications, the four core duties under General Comment No. 14).

[133] *See* Riedel, *supra* note 91, at 32 (remarking that these requirements are sufficient to prove General Comment No. 14 establishes the right to health in customary international law).

[134] *See supra* notes 129-33 and accompanying text.

[135] *See* Riedel, *supra* note 91, at 32 (believing the fundamental concepts within General Comment No. 14 may additionally be "general principles of law," another classification of international law).

[136] *Cf.* Carmalt & Zaide, *supra* note 5, at 13 (surmising that the U.S. health care system "falls far short" of the standards imposed through international human rights law despite the government's extensive spending).

[137] *See General Comment No. 14*, *supra* note 40, ¶ 12 (clarifying that these requirements are all vital to executing the right to health doctrine and may overlap).

[138] *See* discussion *supra* Part I.D (outlining the growing problem of U.S. citizens neglecting their prescription regimen because of an inability to afford medications).

[139] *See* Marks, *supra* note 100, at 82-97 (likening that right to essential medicines to the right to water and concluding that they are both urgently needed and linked to all other legal rights as a precondition that must be fulfilled to benefit from any other entitlement).

[140] *See General Comment No. 14*, *supra* note 40, ¶ 17 (emphasizing that the right to health includes the necessity to protect both mental and physical health through proper goods and services); *see also*, Marks, *supra* note 100, at 83 (explaining WHO defined essential medicines as "those that satisfy the priority health care needs of the population and are intended to be available within the context of functioning health systems at all times...at a price the individual and community can afford").

[141] Yamin, *supra* note 121, at 336 (arguing that access to medications is a vital component of the obligations inherent in the right to health and the right to access medicines may in itself be customary international law); *see also* Marks, *supra* note 100 at 94 (ascribing a new phenomenon of access to medications as a separate right stemming from the right to health doctrine, to the AIDS pandemic and the struggle to access antiretroviral treatments).

[142] *Cf.* Benjamin Mason Meier and Larisa M. Mori, *The Highest Attainable*

Standard: Advancing a Collective Human Right to Public Health 37 Colum. Hum. Rts. L. Rev. 101, 117 (Fall 2005) (warning that the focus on individual accessibility may be detrimental to promoting health care collectively and that this concern is particularly pertinent in the human rights field when individuals do not have standing to challenge violations of the right).

143 *See* Promotion and Protection of All Human Rights, *supra* note 30, ¶ 43 (imparting the fact that there is no set definition of equity, but offering "equal access to health care according to need" as a useful understanding).

144 *See General Comment No. 14*, *supra* note 40, ¶ 12(b) (proscribing discrimination based on the basis of any prohibited grounds); WHO Fact Sheet, *supra* note 29, at 7 (defining discrimination as "any distinction, exclusion or restriction made on the basis of impairing or nullifying the recognition, enjoyment or exercise of human rights and fundamental freedoms" and noting that it is particularly relevant to vulnerable groups that are disproportionately burdened with health impairments); *see also General Comment No. 14*, *supra* note 40, ¶ 18 (listing reprehensible grounds of discrimination to include, *inter alia*, the basis of race, sex, language, religion, national origin, sexual orientation, and social status).

145 *Cf. General Comment No. 14*, *supra* note 40, ¶ 12(b) (stipulating that poorer families should not be "disproportionately burdened" with expenses in comparison to others and mentioning in ¶ 19 a "special obligation" to supply for individuals who do not have the economic capability to access health care on their own); *see also* Riedel, *supra* note 91, at 29 (providing the example that if a health center charges fees that some cannot pay, it is not economically accessible and governments must assess strategies for change).

146 *See General Comment No. 14*, *supra* note 40, ¶ 12(b) (elucidating that accessibility includes non-discrimination, economic accessibility/affordability, and information accessibility); *see also* Riedel, *supra* note 91 at 29 (pinpointing affordability as the most important component of accessibility).

147 *Cf. General Comment No. 14*, *supra* note 40, ¶ 12(b) (including economic accessibility for goods and services as part of the minimum core standards of the right to health which all countries must provide).

148 *See General Comment No. 14*, *supra* note 40, ¶ 18 (underscoring that states must protect vulnerable populations even when a country experiences "severe resource constraints").

149 *See* Backman et al., *supra* note 99, at 2049 (presuming that policymakers must create national policies that target traditionally vulnerable communities, such as women, people living with HIV, senior citizens, and people living with disabilities); *see also* WHO Fact Sheet, *supra* note 29, at 7 (ascertaining that states may need to compensate for a particular population's health needs if that population disproportionately experiences a health problem, such as susceptibility to a particular ailment).

150 *See* WHO Fact Sheet, *supra* note 29, at 7 (presenting Article 5 of the Convention on the Elimination of All Forms of Racial Discrimination, which requires the eradication of racial discrimination in access to health care, as an example of the international documents reinforcing these requirements).

151 *See supra* notes 138-50 and accompanying text (drawing out the obligations created by the accessibility facet of the right to health and demonstrating that they lead to the conclusion that a state must ensure essential medicines are equitably and indiscriminately accessible, or the state must act to ameliorate problems in access).

152 *See* Part I.D (presenting studies that show almost a quarter of U.S. patients cannot comply with prescription regimens).

153 *See supra* Part I.D (outlining the problem that many Americans do not have health insurance, and even those who do may not have adequate coverage, and subsequently a considerable portion of the population cannot comply with their prescription regimen).

154 *See* Kinney, *supra* note 8, at 374 fig.2 (proffering the results of a study which contrasted health care performance in the U.S. to Canada, Australia, New Zealand, and the United Kingdom, finding that in addition to the lowest medication accessibility, the U.S. health care system ranked highest in medication errors, such as receiving the wrong prescription or dose, and had the highest prevalence of patients who were unable to pay medical bills.).

155 *See* Kennedy & Morgan, *supra* note 57, at 215 (displaying that this figure compares poorly to statistics from Canada); Cohen et al., *supra* note 64, at 1 (tracing trends in health care which show access is increasingly strained).

156 *See* Kennedy & Morgan, *supra* note 57, at 216 tbl.I (separating the individuals reporting CRNA by income level and finding that 13.8% receive a below-average income).

157 *See* Kennedy & Morgan, *supra* note 57, at 216 tbl.I (reporting that 21% of individuals experiencing CRNA receive an average income and 15% receive an above average income)

158 *Cf.* Davis, *supra* note 79, at 8 exhibit 2 (utilizing estimates from the Congressional Budget Office that find that even after the health care reform bill is in full effect, between twenty-one and twenty-six million nonelderly individuals will remain uninsured).

159 *See* Kennedy & Morgan, *supra* note 57, at 214 (referencing variables that attribute to CRNA which include age, race, substandard health, and lower income).

160 *Cf.* Kinney, *supra* note 8, at 368 (revealing that the United States ranked thirty-seventh for health care in a WHO Report principally because of race and income inequality); Yamin, *supra* note 33, at 1158 (invoking over one thousand studies that concluded that widespread disparities exist in the U.S. health care system).

161 *See* Carmalt & Zaide, *supra* note 5, at 15 (drawing the conclusion that health care costs amount to the highest percentage of income for families in the most economically vulnerable population and that this situation directly contradicts CESCR's requirements); Briesacher et al., *supra* note 55, at 866 (demonstrating that lack of health insurance or prescription coverage strongly prohibits an individual's ability to afford medications).

162 *See* Kennedy et al., *supra* note 54, at 609 (finding that African Americans were more likely than any other ethnic group, followed by Hispanic populations, to experience CRNA).

163 *Cf.* Carmalt & Zaide, *supra* note 5, at 7 (pointing out that discrimination of any type violates human rights law, regardless of whether the discrimination is on an individual level or systemic).

164 *See supra* Part II.B (determining that access to essential medications and the eradication of discrimination are both core obligations of the right to health).

165 *See General Comment No. 14*, *supra* note 40, at ¶ 33 (expanding upon these obligations by adding that the responsibility to fulfill contains additional mandates to facilitate, provide, and promote aspects of the right to health); *see also* discussion *supra* note 127 (demonstrating that this three-level framework is accepted throughout international human rights law).

166 *See*, Yamin, *supra* note 121, at 354 (furnishing the example that the Inter-American Court considers price increases on health care goods as a *prima facie* violation of the right to health).

167 *See General Comment No. 14*, *supra* note 40, ¶ 35 (instructing states to enact legislation if necessary to guarantee that any privatization in the health care system does not prevent the realization of the right to health).

168 *See General Comment No. 14*, *supra* note 40, ¶ 33 (encompassing legislative, administrative, budgetary, judicial, promotion, and "other measures" among the necessary actions to ensure the community enjoys the right to health).

169 *Cf. General Comment No. 14*, *supra* note 40, ¶ 33 (permitting states to use a public or private system, or a mixture of the two, as long as a the nation has an insurance plan that is affordable for all); Marks, *supra* note 100, at 97 (surmising that General Comment No. 14 "strongly suggests" states should intervene where the actions of pharmaceutical companies detrimentally affect to the right to health).

170 *See infra* notes 172-186 and accompanying text (comparing the requirements to respect, protect, and fulfill the right to health with the legal framework in place in the United States).

171 *See* discussion *infra* notes 172-186 and accompanying text.

172 *See General Comment No. 14*, *supra* note 40, ¶ 35 (mandating governments to ensure that allowing privatization or third parties marketing practices do not threaten accessibility).

173 *Cf.* Kaiser, *supra* note 52, at 5 (listing techniques insurance companies use to redistribute higher pharmaceutical costs to customers such as excluding a greater number of medications from coverage, use of quality dispensing limits, such as only covering generic forms of a prescription, and increasing out-of-pocket copayments).

174 *See* Carmalt & Zaide, *supra* note 5, at 9 (highlighting the fact that U.S. laws leave millions of Americans without the ability to afford health care); Kinney, *supra* note 8, at 357 (ascertaining that U.S. public insurance programs only provide for 27% of the population).

[175] *See General Comment No. 14*, *supra* note 40, ¶ 37 (affirming that nations must facilitate the population's attainment of the right to health, provide for those who cannot realize the benefits on their own, and promote the health of the population).

[176] *See*, *e.g.*, Wendy Mariner, *Toward an Architecture of Health Law* 35 Am. J.L. & Med. 67, 76 (2009) (imagining how different American laws might fit within the framework established by General Comment No. 14 and placing programs to provide disaster relief and state programs to fund clinics within the duty to fulfill as well).

[177] *See generally* Ava Stanley et al., *Holes in the Safety Net: A Case Study of Access to Prescription Drugs and Specialty Care* 85(4) J. Urb. Health 555 (July 2008) (finding that the health care "safety net" within the U.S., which consists of a network of organizations such as clinics and hospitals that are meant to fill gaps in health care access, is highly inadequate as access to care and prescription drugs are still out of reach for many).

[178] *See id*.; *see also* Kennedy & Morgan, *supra* note 57, at 218 (noting that universal prescription coverage, as provided by the government in Quebec, best resolves the problem of cost-related nonadherence).

[179] *Cf. General Comment No. 14*, *supra* note 40, ¶ 49 (warning that a state can violate the obligations of the right to health through inaction or a failure to take proper action).

[180] *See e.g.*, Duff Wilson, *Drug Makers Reform Prices in Face of Health Care Reform*, N.Y. Times, 15 Nov. 2009 (chronicling pharmaceutical companies' actions in raising prices at an accelerated rate when reforms appeared imminent despite decreasing expenses).

[181] *See* Congressional Budget Office, *HR 4872, Reconciliation Act of 2010*, 9 (final Health Care Legislation), http://www.cbo.gov/doc.cfm?index=11379 (deducing that 6% of nonelderly legal residents will remain uninsured in 2019).

[182] *See id.* (predicting an 11% decrease in legal nonelderly uninsured).

[183] *See* Hoffman, *supra* note 14, at 49 (commenting that introducing an individual mandate to acquire health insurance coverage without restructuring the current health insurance market may force individuals with less money or more health costs to pay more than others because those individuals are likely to be grouped into the same plans and therefore will not have more wealthy, healthier individuals in the mix to pool expenses); *see also* Hoffman, *supra* note 14, at 60 (observing that individuals with health problems that are not currently covered by employer coverage will benefit the least from actuarial ratings for health insurance coverage).

[184] *See generally* John Holahan and Linda Blumberg, Urb. Inst., *Can a Public Insurance Plan Increase Competition and Lower the Costs of Health Reform?* (2008), http://www.urban.org/UploadedPDF/411762_public_insurance.pdf (concluding that a public health insurance option is more likely to experience lower administrative costs and contain costs better than private health insurance plans and would be more likely to invest in researching and developing improved treatment for individuals with costly health conditions).

[185] *See General Comment No. 14*, *supra* note 40, ¶ 12 (outlining that the implementation of the right to health is colored by the specific conditions of a country and its developmental level). *But see General Comment No. 14*, *supra* note 40, ¶ 18 (asserting that adjusting policies and strategies can often be accomplished with minimal cost).

[186] *See General Comment No. 14*, *supra* note 40, ¶ 12 (outlining that the implementation of the right to health is colored by the specific conditions of a country and its developmental level).

[187] *Cf.* Yamin, *supra* note 121, at 327 (theorizing that in human rights, "cost-effectiveness concerns are balanced with other priorities and the state has a critical role to play both in ensuring basic health care goods and services" and the focus of the inquiry is whether the states "takes steps by all appropriate means to make medications accessible").

[188] *See General Comment No. 14*, *supra* note 40, ¶ 47 (laying out the standards to be considered to decide if a state violates the right to health and considering that the country must take all "necessary steps to the maximum of its available resources").

[189] *See* Carmalt & Zaide, *supra* note 5, at ii (condemning the current emphasis on profits in the U.S. health care system and attributing this driving force with creating the problems in accessibility).

[190] *See infra* notes 191-94 and accompanying text.

[191] *See* Kinney, *supra* note 8, at 375 (employing an analysis based on the World Bank indicators on governance which indicate that the government received a 91.9% ranking for government effectiveness, revealing that the United States government is powerful and able to implement change and, therefore, could likely create an effective health care system that embodies the standards from General Comment No. 14).

[192] *See* Central Intelligence Agency, *The World Factbook: County Comparison-GDP* (2009), *available at* https://www.cia.gov/library/publications/the-world-factbook/rankorder/2001rank.html (ranking the U.S's 2009 GDP above 226 other nations, with China coming in third at approximately $9 trillion).

[193] *See* Kinney, *supra* note 8, at 368 (observing that the country spends "by far the highest amount per capita on health care of all the countries of the world.").

[194] *Compare supra* note 193 (noting that the U.S. spends more than any other country on the health care sector) *with OECD Working Papers*, *supra* note 109, at 32 fig.13 (demonstrating that seventeen countries are able to establish 100% insurance coverage for core services).

[195] *Compare General Comment No. 14*, *supra* note 40, ¶ 40 (reminding countries that they must uphold the obligations of the right to health to the maximum of their resources) *with supra* notes 190-94 (utilizing World Bank indicators on governance, national GDP, and spending on health care to illustrate the fact that the United States is highly capable).

[196] *See supra* Part II.C.2 (harmonizing the provisions of General Comment No. 14 to show that nations must enact the right to health to their full ability and therefore more capable nations must do more than others to implement the right to health).

[197] *Cf.* Kinney, *supra* note 32, at 1471 (avowing that states will differ in their implementation of health rights because it is reasonable to require the United States to ensure universal health care access, but extending the requirement to the Sudan would be absurd).

[198] *See generally supra* Part II.C.3

[199] *See* Carmalt & Zaide, *supra* note 5, at 3 ("The relentless grow in health costs, combined with the severe downturn in the economy, has deepened the health insurance crisis facing families across the country...".).

[200] *See supra* Part II.C.

[201] *Cf.* Cohen et al., *supra* note 66, at 1 (implying that providing statistics on health insurance trends can lead to the creation of better policies).

[202] *See supra* Part I.D.

[203] *See* Carmalt & Zaide, *supra* note 5, at 3 ("The relentless grow in health costs, combined with the severe downturn in the economy, has deepened the health insurance crisis facing families across the country...".).

[204] *See* Collins, *supra* note 62, at 8 (projecting that the bill would cover covering 96% of uninsured legal working-age residents, whereas the Senate's version would only cover 94%).

[205] *See* Kinney, *supra* note 8, at 356 (affirming that "[h]ealth insurance coverage is the most important means" for enabling health care accessibility).

[206] *See supra* note 184.

[207] *See* Forman, *supra* note 91, at 41 (embracing the idea that rights expressed as law may "ensure systemic trends towards justice"); Meron, *supra* note 46, at 9 (agreeing that the invocation of a norm as customary international law adds "rhetorical strength" to the necessity to comply); Yamin, *supra* note 33, at 1159 ("[F]raming an otherwise acknowledged problem such as disparities in treatment as a "rights violation" suggests that the situation could be different and that the government bears responsibility.").

[208] The Declaration of Independence (July 4, 1776), *available at* http://www.archives.gov/exhibits/charters/declaration_transcript.html.

[209] Senator Edward Kennedy, Speech at the Democratic National Convention (Aug. 25, 2008) (transcript *available at* http://www.americanrhetoric.com/speeches/convention2008/tedkennedy2008dnc.htm).

Safety and Access: Is the UK Regulatory Model Right for America?

*Jocelyn Sweet**

I. Introduction

The development and advancement of assisted reproductive technologies (ARTs) has created both hope and controversy. Infertile couples and individuals now have many choices when it comes to reproduction. At the same time these new technologies have created a huge industry that is in need of regulation. Ethical and financial issues are at stake. On the one hand, couples should have autonomy in deciding how to address fertility issues and start a family. On the other, it is important to ensure that fertility doctors and clinics are acting in the best interest of both the mother and the fetus and are following guidelines to ensure that procedures are being done in a safe and ethical manner. The question becomes: what is the best regulatory model given the ethical and safety issues at stake?

As with many health care issues, regulation of ART is driven by various ethical principles. The United States and Great Britain have approached the regulation of ART in starkly different ways. While the US has allowed fertility clinics and doctors to operate largely unregulated by law, the UK has passed laws to regulate almost all aspects of reproductive technologies.[1] These different policy choices have led to criticism on both sides and sparked varying opinions on whether the US should consider a more heavily regulated system. This paper will focus specifically on the regulation of fertility doctors, clinics, and research in each country. The first section addresses the history of regulating ART in the US and the UK and the current status of the law. The second section examines some of the more controversial regulatory issues, the approaches to regulation taken in each country, and how guidelines protect the health and safety of patients and fetuses. The third section addresses whether different regulatory practices lead to different outcomes in terms of access and fairness. Lastly, this paper discusses whether the US would benefit from more federal and state regulation of ART.

* **Jocelyn Sweet** is a third year law student at American University, Washington College of Law and former Co-Editor-in-Chief for the Health Law and Policy Brief in 2009-2010. She received her Bachelor of Arts with honors in the College of Social Studies at Wesleyan University in 2004. While in law school she interned at the Departmental Appeals Board at HHS, the National Women's Law Center, and the National Council on Aging.

II. Regulation in the United States

A. Federal Law

Regulation of fertility clinics and doctors in the US comes largely from independent professional societies, supplemented with some federal and state law. The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires fertility clinics to report pregnancy success rates,[2] and also requires states to develop and administer certification programs for embryo laboratories.[3] As part of the certification program the law required, within two years of its enactment, that the Centers for Disease Control (CDC) "develop a model program for the certification of embryo laboratories to be carried out by the States."[4] Embryo laboratories are defined as facilities in which human oocytes (eggs) or embryos are "subject to assisted reproductive technology treatment or procedures based on manipulation."[5] Essentially, the laboratories, not the fertility doctors or clinics themselves, are certified under this program. The law also specifically states that in developing or adopting the certification program, neither the Secretary of the Department of Health and Human Services (HHS) nor the State could, "establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technologies."[6]

The CDC published its final notice of the "Model Program for the Certification of Embryo Laboratories" in the Federal Register in 1999.[7] In deciding on a model, the CDC consulted with several groups, including the American Society for Reproductive Medicine (ASRM), the Society for Assisted Reproductive Technology (SART), and the College of American Pathologists (CAP).[8] During the notice and comment period, there was some concern over whether to allow unannounced inspections due to the delicate nature of the work and concerns over patient confidentiality.[9] The CDC believed that states adopting the model program should have the option of unannounced inspections, "so that investigations of complaints of truly egregious behavior could be conducted immediately and unannounced."[10] There was also some disagreement over whether there should be mandatory minimums for training and performance of certain procedures. Some commentators argued that the laboratory director should decide "the adequacy of

each employee's training/experience."[11] The CDC disagreed, stating that its minimums were developed to be consistent with ASRM guidelines.[12]

The Model Certification Program provides requirements for State administration of the program, including minimum standards for agreements with laboratories and standards for the laboratories themselves.[13] These standards include provisions on personnel qualifications and responsibilities, facilities safety, and quality management.[14] Although the guidelines do provide a framework for States, the certification program is voluntary for both States and the laboratories themselves. The preamble states that, "[w]hile Congress anticipated that the cost of Federal and State monitoring and oversight of embryo laboratories would be covered by the fees paid by participating laboratories, participation . . . is voluntary and laboratories not willing to pay these fees would not be limited in their ability to operate."[15] According to the Institute on Biotechnology & the Human Future, some states have based accreditation requirements on the Model Program, but no state has officially adopted it.[16] The result is that there is no federal law mandating the licensing, accreditation, or inspection of fertility clinics or embryo laboratories in the US.[17]

B. State Law and Practice Guidelines

States have also attempted to regulate ARTs. Most state laws focus on insurance coverage of infertility treatment, a topic which will be discussed in detail in the third section of this paper. Some of these states have chosen to follow the federal approach of requiring disclosure of success rates. The focus is on consumer protection and ensuring that clinics are upfront about the chances that their services will result in a live birth. The main concern seems to be on cost-effectiveness for the consumer; i.e., what are the chances the investment will result in a baby? For example, in Virginia, physicians are required to disclose success rates for different age groups at the particular clinic or hospital for the ART procedure being performed.[18] Laws like these contribute little to the federal regulations already in place.

Louisiana has some of the strictest and most comprehensive laws governing ART procedures and embryo disposition. The laws specifically prohibit the sale of any embryo or ovum and the creation of a fertilized ovum solely for research purposes.[19] The law also gives an in vitro fertilized human ovum status as a juridical person prior to implantation.[20] Patients are given ownership over embryos, but physicians are responsible for safekeeping.[21] The law requires that facilities meet standards of both the American Fertility Society and the American College of Obstetricians and Gynecologists, and are directed by a licensed physician with specialized training in the field.[22] The law also allows for adoptive implantation when the donor parents renounce parental rights, but no compensation can be paid or received.[23]

Other state laws seem to be reactive rather than proactive, addressing specific situations as opposed to the broader picture. For example, in California, lawmakers sprang into action after a scandal at the University of California, Irvine's Center for Reproductive Health.[24] In that case, the clinic was accused of stealing eggs from nine women who believed they were undergoing routine procedures, while instead the clinic was implanting the eggs in other women.[25] The clinic was also accused of unauthorized use of an unapproved drug and research misconduct.[26] After the incident the California Legislature found that, "[t]he continued risk of these unethical transfers and implantations without informed consent warrants stronger legislative protections for California families undergoing in vitro and other assisted production procedures."[27] The resulting law made it unlawful for providers to "implant sperm, ova, or embryos . . . without the signed written consent of the . . . provider and recipient."[28] The law imposed penalties of imprisonment for three to five years, a fine of up to $50,000, or both the fine and imprisonment.[29] Although the California Legislature responded quickly to the UC-Irvine scandal, the law was narrowly tailored to address consent issues and did not veer into murkier issues such as embryo disposition or the implantation of multiple embryos. Moreover, the situation involving the Irvine clinic was fairly straightforward in terms of illegality. In contrast, many of the other regulatory issues surrounding ART are not so clear cut.

In the wake of the 'octomom' controversy, in early 2009, both Georgia and Missouri proposed laws that would limit the number of embryos allowed to be implanted during a single fertility treatment.[30] As first introduced in the State Senate, the proposed Georgia bill would have limited the number of embryos that could be transferred into a woman under forty to two and to a woman over forty to three.[31] That provision did not make it into the version that eventually passed in the Senate. The bill was not enacted in the 2009 session and is currently in the House. The version of the bill that passed the Georgia Senate made it unlawful to create an in vitro embryo by means other than fertilization or ICSI and prohibited the creation of an in vitro embryo for any purpose other than initiating a pregnancy for the treatment of infertility.[32] In other words, the bill bans stem cell research. In Missouri, the bill would have mandated the current ASRM guidelines limiting embryo transfer be followed.[33] Both of these bills were opposed by industry and consumer groups.[34]

Other states have taken a more proactive approach. In New York, for example, the Task Force on Life and the Law (the Task Force) released a report entitled "Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy"[35] Although the report addressed a wide variety of issues regarding ART and set forth some guidelines, the Task Force was reluctant to put the power of law behind its recommendations. The report found that:

> [P]hysicians offering assisted reproduction are under no legal or ethical obligation to treat every individual or couple who requests their services . . . physicians are entitled to consider the welfare of any child who might be born as a result of an assisted reproduction procedure. Physicians should also develop written policies setting forth their standards and procedures for the screening of patients and their partners. Regarding multiple gestations . . . ART practitioners have a professional obligation to minimize the likelihood of multiple gestations resulting from the use of ARTs. Specific limits . . . should not be adopted as a matter of state law.[36]

Fertility clinics and doctors are not required to be members of SART and ASRM, nor is there strict monitoring as to whether guidelines are actually being followed. It is estimated that about ten percent of US clinics are not members, that as many as eighty percent do not follow guidelines on the number of embryos that should be implanted during IVF, and that some clinics violate guidelines by advertising and providing nonmedical sex selection.

The Task Force essentially relied on professional societies and individual physicians to set practice guidelines when it comes to issues like reduction of multiple gestations and the number of times a woman can donate eggs.[37]. In a few circumstances the Task Force did recommend state regulation. For example, the report recommended that the state enact legislation to establish minimum standards for obtaining informed consent for ART procedures.[38] The Taskforce also concluded that, "[t]o provide maximum oversight of the laboratory procedures involved in assisted reproduction, New York should participate in the certification program for embryo laboratories currently under development by the CDC."[39] The Task Force noted that, although the program would not be required under Federal Law, the state should mandate participation for all of its assisted reproduction laboratories and that the Department of Health itself should provide oversight, as opposed to delegating to private accreditation organizations.[40] As of yet these recommendations have not been fully adopted.

The Task Force addressed access to ARTs and discrimination in two distinct ways. In terms of marital status, the report states that, "[t]he law should neither prohibit nor require the provision of assisted reproductive services to unmarried individuals, including lesbians."[41] When it comes to sexual orientation, the Task Force leaves access decisions in the hands of individual providers. In contrast, the report reinforces that with ART, "[a]s with other medical treatments, physicians may not refuse . . . services on the basis on race, color, creed, religion, or national origin."[42] It is troubling that the Task Force leaves gender and sexual orientation off of this list.

C. Professional Societies

Beyond the limited state and federal laws currently on the books, the fertility industry in the US is largely self-regulated. Two organizations, the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART), have taken the lead. The organizations work together to issue guidelines and best practices. ASRM is a non-profit organization, "dedicated to the advancement of the art, science, and practice of reproductive medicine . . . through the pursuit of excellence in education and research and through advocacy on behalf of patients, physicians, and affiliated health care providers."[43] ASRM is a multi-disciplinary organization that, among other things, issues practice guidelines, works on legislative issues, and publishes the well-known journal *Fertility and Sterility.* [44] SART is a professional society of member clinics. It represents ninety-five percent of ART clinics in the US with a mission of "set[ting] and help[ing] maintain the standards for ART in an effort to better serve our members and our patients."[45] SART is involved in data collection, setting practice guidelines and standards, government interaction, quality assurance, and ART research.[46] In order to be a SART member, a clinic is required to:

- Have an accredited laboratory. The lab accreditation program run by ASRM with the College of American Pathologists (CAP) has explicit standards on the identification and documentation of all tissues involved.
- Adhere to all standards and recommendations of the ASRM Practice Committee.
- Adhere to all standards and recommendations of the ASRM Ethics Committee.[47]

Both ASRM and SART publish a series of practice guidelines and standards on their websites.

Fertility clinics and doctors are not required to be members of SART and ASRM, nor is there strict monitoring as to whether guidelines are actually being followed. It is estimated that about ten percent of US clinics are not members, that as many as eighty percent do not follow guidelines on the number of embryos that should be implanted during IVF, and that some clinics violate guidelines by advertising and providing nonmedical sex selection.[48] Moreover SART can only punish its member clinics by revoking their membership status.[49]

The American Medical Association (AMA) has also issued a series of guidelines in order to, "ensure ethical practices in assisted reproductive technology."[50] These guidelines encourage disclosure of clinic specific success rates, self-regulation, clinic participation in credible professional accreditation programs, reporting unethical practices, full patient consent, and a payment scheme not based on outcomes.[51] The American Academy of Fertility Care Professionals (AAFCP) requires its members to pledge adherence to a code of ethics and report the unethical behavior of any member.[52]

III. Regulation in Great Britain

In contrast to a largely self-regulated American industry, fertility clinics in the UK are heavily regulated by the government. The Committee of Inquiry into Human Fertilisation and Embryology was created to address, among other issues, whether the National Health Service (NHS) should provide treatment for infertility and then to address who should be eligible for such treatment.[53] The committee, established in 1982, was created in response to the birth of Louise Brown[54] and

rapid technological developments in the fields of IVF and embryology.[55] In 1984 the committee released the "Report of the Committee of Inquiry into Human Fertilisation and Embryology" (known as the "Warnock Report").[56] The report lays the groundwork for a robust regulatory framework for ART, stating that:

> We believe that all the techniques require active regulation and monitoring, even though, as we realize, such restrictions may be regarded by some as infringing clinical or academic freedom . . . The interests of those directly concerned, as well as those of society in general, demand that certain legal and ethical safeguards should be applied.[57]

In order to achieve that goal, the report recommended the creation of a, "new statutory licensing authority to regulate both research and those infertility services which we have recommended should be subject to control"[58] The Warnock report envisioned that this new regulatory agency would have both advisory and executive functions.[59] In its advisory role, the agency would issue practice guidelines and advise the government on the changing landscape.[60] The executive role would include granting licenses to doctors and clinics, both in the public and private sector, and to grant licenses to researchers in the field.[61] The recommendations and framework set forth in the Warnock report are reflected in the current legislation and regulatory authority.

Then in 1990, the British government passed the Human Fertilisation and Embryology Act of 1990 (HFEA).[62] Notably, as recommended by the Warnock Report, HFEA created the Human Fertilisation and Embryology Authority (the Authority) to license and monitor fertility doctors and clinics to ensure compliance with HFEA.[63] A glance at the Authority website practice guidelines compared to those of SART or ASRM reveals little difference on the surface. Both have sections for patients and donors. Both will help you find a fertility clinic in your area and report success rates. Both provide operational and ethical guidance for fertility clinics and doctors. The difference is clearly in the force behind the guidelines. Whereas SART and ASRM encourage member clinics to report unethical practices, the Authority has strict compliance standards and penalties.[64] Failure to comply with HFEA can include both informal warnings and formal sanctions.[65] For example, the Authority can monitor compliance with unannounced visits or go so far as to recommend that a practices' license be revoked or suspended.[66] Formal action is permitted when the individual responsible for the facility is unable to properly manage[67], when a clinic has not taken remedial action within a specified timeframe, if there is a previous history of non-compliance or failure to take remedial actions, if there is risk to patients, gametes, or embryos, or when there is evidence of criminal behavior.[68] It is important to note that although there are both public and private fertility clinics in the UK, the Authority regulates and inspects all clinics that provide any type of fertility treatments or storage.[69]

The Authority has been able to address concerns from critics that regulation cannot keep pace with technological development. Although the most sweeping reforms came in 2008, several changes have been made over the years. Amendments in 1991 and 1996 allowed extended storage periods for eggs and embryos in certain situations.[70] In 2001, the regulations were amended to allow embryonic stem cell research.[71] The 2008 amendments to HFEA reflect both advances in ART and shifts in societal values. For example, the amendments extend parental rights to same-sex couples and unmarried heterosexual couples.[72] Other highlights include clarifications on what is allowed in terms of embryo research, specifically in relation to 'human admixed embryos'[73] and a ban on sex-selection for social reasons.[74] The Authority is implementing the amendments in three stages. As of April 9, 2009, the new definitions of parenthood went into effect.[75] Then in October 2009 the amendments to the 1990 legislation took effect.[76] Lastly, as of April 2010, same sex and unmarried couples were able to apply to be the parents of children born using a surrogate.[77]

The 2008 version of HFEA also makes several key changes to the compliance cycle. The new compliance structure includes a "Risk Tool" designed to allow facilities to assess their compliance level before being inspected.[78] The new tool uses generic performance indicators (GPIs) and a self assessment questionnaire (SAQ).[79] The SAQs are meant to replace the current pre-inspection questionnaires, a change which the Authority suggests will allow for more focused inspections.[80]

IV. Important Regulatory Issues

A. Number of Embryos Implanted During IVF

One of the most controversial regulatory issues is the number of embryos allowed to be implanted during a procedure. Over forty years after the birth of Louise Brown, Nadya Suleman, more commonly known as 'octomom', stirred up the debate when she gave birth to octuplets after a fertility doctor implanted her with six embryos.[81] The case garnered national attention, but the number of multifetal pregnancies has been on the rise for years. In fact, between 1980 and 2000, the rate of infants born in triplet or higher order went from thirty-seven to 181 for every 100,000 births.[82] Although the entirety of the increase is not attributable to ART, one estimate finds it responsible for forty percent.[83] Another estimate suggests that ART accounted for sixteen percent of twin births, forty-five percent of triplet births and thirty percent of quadruplet births in 2003.[84]

There are many dangers associated with high order pregnancies. Generally speaking, the more fetuses carried to term, the greater likelihood of premature births and the lower the birth weight of each fetus.[85] Multiples are also more likely to suffer from a variety of complications, congenital malformations, and long-term handicaps.[86] Even twins have a sixty percent greater chance of being born prematurely.[87] In addition to the danger to the fetuses and infants, there are also more instances of maternal health problems in women carrying multiples.[88] Despite the dangers associated with multiple gestation, "there is an attitude among infertility physicians that the wishes of the infertile couple must be respected. This reflects a certain prioritization of values, according to which the desire of the couple to have a baby is more important than avoiding risks to the offspring."[89] The focus is on patient autonomy rather than best practices.

Another motivation to implant more embryos is linked to doctor success rate. In the 'octomom' case, the octuplets were not Nadya's first foray into IVF. In fact, between 2000 and 2006, Nadya gave birth to six children, including a set of twins, as a result of fertility treatments.[90] Those five live births represented just over twenty percent of the total live births to women under thirty-five at the clinic in question during the six-year span.[91] This led many to believe that Nadya's doctor was using her to, "boost his stats and improve his standing in the highly competitive and lucrative fertility field."[92] More disturbing is the revelation that Nadya was implanted with

six embryos for each of the pregnancies.[93] The implantations were a clear violation of professional guidelines that state patients under the age of thirty-five should consider implantation of only one embryo, and should not be implanted with more than two embryos.[94] Under no circumstances do the guidelines recommend implanting more than five embryos at any stage.[95]

Even though Nadya's doctor violated the guidelines he received no penalization other than the media and professional backlash. Although Nadya's doctor was expelled from membership in ASRM and SART, there is nothing stopping him from continuing to practice.[96] The high danger to both Nadya and her unborn children was at odds with the low repercussions for Nadya's doctor. That tension is present in the guidelines themselves, which state first that, "[h]igh-order multiple pregnancy (three or more implanted embryos) is an undesirable consequence (outcome) of assisted reproductive technologies (ART). Multiple gestations lead to an increased risk of complications in both the fetuses and the mothers." [97] Only two paragraphs later the guidelines state that, "[s]trict limitations on the number of embryos transferred, as required by law in some countries, do not allow treatment plans to be individualized after careful consideration of each patient's own unique circumstances."[98] Cleary ASRM and SART have traditionally supported a deregulated industry that allows the greatest flexibility for doctors, clinics, and patients. Yet at the same time these professional societies encourage safe and ethical practices. Cases like Nadya's, where a doctor manipulates the process in order to report greater success rates, demonstrate the need for a more consistent and compliance oriented regulatory environment in which there are true penalties for dangerous procedures.

In the UK, the Authority has similar guidelines for fertility clinics in terms of actual numbers. The law mandates that in a single cycle no more than two embryos can be implanted for women under forty, and no more than three for women over forty.[99] Also, at a minimum, clinics must keep individual records explaining the reasons for implanting three embryos and have a "multiple births minimisation strategy."[100] In cases where multiple embryos are implanted into a woman who meets the criteria for single embryo transfer, the clinic must also include an explanation for the action and a note "confirming that the risks associated with multiple pregnancy have been fully discussed with the patient."[101] Failure to comply can result in any of the informal and formal penalties discussed in the previous section.

B. Sex-Selection & Preimplantation Genetic Diagnosis

Another controversial issue is sex-selection and preimplantation genetic diagnosis (PGD). PGD is defined as the process of testing to see whether a specific mutation from one or both parents has been transmitted to an embryo.[102] First, it is important to distinguish between sex-selection for medical reasons and sex-selection for non-medical reasons. Sex-selection for medical purposes allows parents to prevent the transmission of sex-linked genetic diseases.[103] ASRM explicitly approves of preimplantation sex-selection when used for medical reasons because of its ability to limit disease and suffering and the inherent lack of gender bias.[104]

In the UK, HFEA not only specifically bans sex-selection for non-medical reasons, but it also states that an embryo may only be tested to determine if the embryo has a "gene, chromosome, or mitochondrial abnormality" that would impact whether it would result in a live birth or when there is a particular risk of the embryos having such an abnormality.[105] PGD can only be carried out in two specific instances. The first is when there is a "particular risk" that the embryo will have a "genetic, mitochondrial or chromosomal abnormality" that will result in a "serious disability, illness or medical condition."[106] In that situation PGD is used to determine whether the embryo has the specific genetic abnormality. The second situation in which PGD is allowed in the UK is for medical sex-selection. In that case PGD is allowed "where there is a particular risk that any resulting child will have or develop a gender related serious disability, illness or medical condition."[107] In that situation the Authority must first determine that the condition in question affects only one sex or disproportionately affects one sex more than the other.[108] These are mandatory requirements that all fertility clinics in the UK are required to follow.

The arguments in favor of sex-selection for non-medical reasons center on reproductive choice. The logic is that individuals should be allowed to make their own choices when it comes to bearing children and that choosing the sex of a child is a natural extension of that right.[109] Other arguments in favor of sex-selection include, "social goods such as gender balance or distribution in a family with more than one child, parental companionship with a child of one's own gender, and a preferred gender order among one's children."[110] In a 2001 report published in *Fertility and Sterility*, ASRM concluded that preconception, "sex selection aimed at increasing gender variety in families may not so greatly increase the risk of harm to children, women, or society that its use should be prohibited or condemned as unethical in all cases."[111] Preconception sex-selection is distinct from PGD because it takes place before the egg is fertilized, often in the form of sperm separation.

There are several arguments against engaging in sex-selection for non-medical reasons. One concern is that there is a 'slippery slope' once parents are given control over "nonessential characteristics of children."[112] If parents can decide the gender of their child, why not eye or hair color? Another argument is that engaging in sex-selection encourages gender discrimination and could in fact lead to sex ratio imbalances. In terms of sex-selection for "social reasons" HFEA specifically bans all "practices designed to ensure that a resulting child will be of a particular sex."[113] This includes both PGD and preconception sex-selection.

ASRM's guidelines regarding sex-selection have not stopped fertility clinics and doctors in the US from exploring the notion of using PGD to select the gender and even other physical traits of a child. In fact, the Fertility Institutes clinic in Los Angeles advertises that it can guarantee the gender of a child, stating that, "If you want to be *certain* your next child will be the gender you're hoping for, be aware that *no other method comes close* to the reliability of PGD. While traditional sperm-screening techniques have a success rates of 60-70%, only PGD offers *virtually 100% accuracy*."[114] Sex-selection, which is offered for both fertile and infertile couples, is quoted as costing $18,490.[115]

Although there is not yet any mention of it on the website, the Fertility Institutes also recently said that it would begin offering services to help couples select other physical traits in their unborn children.[116] The clinic claims that the service has been requested by several couples.[117] A survey conducted by the New York University School of Medicine revealed that of 999 people seeking genetic counseling most supported PGD to screen for certain genetic diseases.[118] This reflects the stance taken by ASRM and

other professional organizations. Notably, however, ten percent of patients surveyed said they would use genetic testing to determine athletic ability and another thirteen percent supported genetic testing to ensure superior intelligence.[119] The director of the Fertility Institutes is quoted as saying that "[t]his is cosmetic medicine. Others are frightened by the criticism, but we have no problems with it."[120]

C. Controversial Techniques and Research

Another interesting issue that arises with regulation is the use of experimental or investigational techniques. In the UK, the Authority works with professional and scientific organizations to develop policy regarding fertility treatment and human embryo research.[121] HFEA and the Authority specifically regulate what is allowed in terms of research techniques. Currently much of the new research revolves around preventing the transmission of genetic defects and diseases.[122] In the US, the use of experimental ART techniques is not regulated. Instead professional societies offer guidance. ASRM defines experimental procedures as such until there is sufficient published medical evidence as to their, "risks, benefits, and overall safety and efficacy."[123] ASRM warns that experimental or investigational procedures should not be marketed as established or routine.[124]

Despite guidelines, doctors in the U.S. do turn to experimental procedures in extreme cases. In 1993, Susan and Bill McNamara began to see a fertility specialist after they were unable to conceive on their own.[125] They faced a myriad of fertility issues. Bill's sperm count was extremely low, Susan had a misshapen uterus that would require major surgery to hold a fetus, and Susan was literally allergic to Bill's sperm.[126] The McNamaras turned to a technique known as co-culture, when human embryos are grown in the uteruses of other species or on fallopian tube cells.[127] The practice began in the late 1980s, but went unnoticed by the Parental Drug Association (PDA) until 2002 when it began sending letters telling clinics to stop the unapproved use of co-culture.[128] Even co-culture using human cells poses the risk of transmission of infectious disease from the cell line to the embryo.[129] Despite the risks of disease transfer from animal to human, the PDA did not ban co-culture, but instead requires clinics to fill out an Investigational New Drug (IND) application.[130] The PDA also recommended life-long monitoring, including reporting unusual symptoms and abstaining from blood and tissue donation, for co-culture children and families.[131] On the upside, Susan and Bill were able to have three children as a result of co-culture. On the other hand, at least one of their children has a birth defect that may have been caused by the use of ART to conceive.[132] In contrast to the more permissive stance taken by the PDA, in 1990 the HFEA specifically banned placing an embryo in any animal.[133]

Another procedure that has raised concern is intracytoplamic sperm injection (ICSI). ICSI involves injecting a single sperm directly into a human egg.[134] In contrast, typical IVF involves placing an egg in a petri-dish with thousands of sperm and letting fertilization occur on its own.[135] ICSI is generally used to help couples with male fertility issues, such as low numbers of or poor quality sperm.[136] One risk of ICSI is that the egg will be irreparably damaged by the needle.[137] Additionally some doctors believe that ICSI children have slightly higher chances of having sex chromosome abnormalities passed on through defective sperm.[138] In contrast to co-culture, ICSI is a widely used procedure that is no longer considered an experimental procedure by ASRM.[139] In the UK, HFEA requires that clinics provide couples using ICSI with information regarding the risks, including, "a reduced number of eggs being available for treatment (compared to IVF), due to eggs being immature or damaged by the process of ICSI"[140] and that, "children conceived [will have] . . . inherited genetic, epigenetic or chromosomal abnormalities (including cystic fibrosis gene mutations, imprinting disorders, sex chromosome defects and heritable sub-fertility)."[141] ASRM recommends that couples dealing with male infertility be counseled before using the ICSI technique to conceive.[142]

Despite the risks of experimental procedures like co-culture, and less experimental procedures like ICSI, proponents of a de-regulated infertility industry argue that each individual patient has different needs and responds differently to treatment. The question becomes whether it is fair to outlaw or regulate certain practices that might allow a couple to have a baby when they otherwise could not. In September 2009, ASRM published a report addressing the issue of fertility treatment for couples with little or no chance of success.[143] The article recognized that, "[m]isunderstandings may arise when couples and/or individuals seek to initiate or continue treatment regarded by practitioners as having either a very low or virtually nonexistent chance of success."[144] Although ASRM concluded that in cases of futility, it is unethical to continue treatment, it stressed that clinics should remain flexible based on the individual patient and potential differences of opinion among doctors.[145]

D. Embryo Mix-ups

Recently several cases of embryos being accidently implanted into the wrong woman have raised concerns

> "The number of multifetal pregnancies has been on the rise for years. In fact, between 1980 and 2000, the rate of infants born in triplet or higher order went from thirty-seven to 181 for every 100,000 births."

> Without help from insurance, IVF can cost between $10,000 and $15,000 per cycle… The high prohibitive cost of fertility treatments in the U.S. means, in most cases, that only the wealthy have access.

over laboratory policies in both the US and the UK. In the US, the most recent incident involved an Ohio woman who received the embryo of another couple.[146] The Ohio couple hoped to use their remaining frozen embryos to have a fourth child, but was informed early in the pregnancy that there had been a mix-up.[147] The American Fertility Association (AFA), a non-profit professional organization, issued several statements in response to the incident. In their legal statement, the AFA addressed only the custody issues at stake and did not discuss possible repercussions for the clinic.[148] It is unclear exactly what those repercussions, if any, would be.

Another case involved a New Orleans hospital where it was discovered that as many as 100 couples were affected by a labeling error.[149] Although a spokesperson said there was no reason to believe that any embryo was actually implanted in the wrong woman, the program described the problem as a "significant labeling issue."[150] In addition to the possibility that embryos were wrongly implanted, several frozen embryos were lost or accidently destroyed.[151]. At least two couples whose embryos were lost have since filed suit. One of the couples was told that even if their embryos were found, it was determined that required screenings for sexually transmitted diseases had not been done prior to freezing.[152] In a San Francisco case, all of a couple's embryos were destroyed without their consent when it was discovered that the embryos were implanted with the wrong sperm.[153] A lawyer for the couple said that, "There is no regulation of these fertility clinic laboratories where the particular jobs like fertilizing eggs or preparing embryos for transfer are done. If there was better regulation, I think we would not have these kinds of problems."[154]

These problems are not unique to the US. From 2007 to 2008, the Authority reports that two embryo or gamete mix-ups occurred.[155] In 2004, a clinical embryologist in London became concerned when she discovered errors in patient notes, including missing signatures and security checks.[156] She was ignored by her superiors and eventually contacted the HFEA, which determined that although she had breached patient confidentiality by bringing the evidence to light, she nevertheless acted in the best interests of her patients.[157] The hospitals in question responded by introducing new procedures to ensure proper labeling.[158]

Current HFEA guidelines classify an embryo misidentification or mix-up as a "serious adverse event" for which responsible parties must provide the Authority with a report analyzing the cause and effects of the event.[159] The Authority can then take corrective measures. Recently, the Authority has begun to publish incident reports on its website.[160] Previously, the Authority made the determination not to publish these reports because, "[w]e wanted to build trust, to assure centres that our aim was to learn and promote higher standards, not to punish human error."[161] In these reports, embryo mix-up ups are classified as grade "A" incidents, which are the most serious offenses. Despite new reporting guidelines, the issue of embryo mix-ups in the UK has created tension between affected couples and the Authority, which is hesitant that stricter guidelines "will drive our patients abroad for treatment because our clinics are more severe."[162] Despite such tension, the fact that there is a central body to investigate and report these incidents provides better consumer information and gives clinics added incentive to follow regulations.

V. Access/Fairness

An additional issue that comes up in the regulation debate is deciding who should have access to ART. When Nadya Suleman gave birth to octuplets, much of the uproar surrounded the fact that she was an unemployed single mother on disability assistance with six children in addition to the eight infants.[163] Beyond the medical issues discussed in the previous section, Suleman's case upset people in terms of her ability to mother and provide for all fourteen children.[164] The public sentiment was that Suleman never should have been allowed to conceive using ART procedures. These issues go to the heart of the access dilemma. Should there be limitations on who has access to ART? If so, who should decide?

There are definite access issues on both sides of the regulatory model. In the US, access to IVF depends on whether an individual or couple can either afford the procedures on their own or whether their private insurance plan happens to cover certain ART procedures, most commonly IVF.[165] A few states have passed laws regarding insurance coverage for certain ART procedures. For example, in Arkansas, all insurers that cover maternity benefits are also required to cover IVF.[166] The law exempts HMOs and also has strict eligibility requirements.[167] Arkansas also requires that the patient's eggs be fertilized with her spouse's sperm.[168] Clearly, this eligibility requirement makes it considerably more difficult for same-sex couples to access IVF and other ART procedures. It also discriminates against single women seeking to have children. On a more positive note, the law promotes safety and best practices by requiring that the IVF procedure be performed in facilities certified by the Arkansas Department of Health.[169]

In Illinois, insurance policies that provide coverage to more than twenty-five individuals and that already provide pregnancy benefits are required to cover the diagnosis and treatment of infertility.[170] The coverage includes a wide variety of ART, including IVF, artificial insemination, and gamete intrafallopian transfer. The Illinois law also requires that facilities meet the standards set forth by either ASRM or the American College of Obstetricians and Gynecologists.[171] Although the law does not require that patients be married, it does require that patients have "used all reasonable, less expensive and medically appropriate treatments and [are] still unable to get pregnant or carry a pregnancy."[172] The implication is that a same-sex couple seeking fertility treatments will not receive coverage unless infertility is medically established. Both New York and California require some insurers to cover treatment for infertility, but specifically exclude IVF from the mandate.[173]

The wide variety of state laws makes ART procedures more accessible in some states than others. It also means that, in some states, fertility clinics are required to follow best practice guidelines in order to accept payment from insurance companies, but there is no consistent mandate. The concern over mandating insurance coverage for ART procedures goes beyond cost concerns. In fact, one estimate suggests that even if usage of IVF rose 300 times when added to an employer health plan, the average premium would only increase by nine dollars a year.[174] The thought is that despite the high costs of IVF, the fraction of the population that needs the treatment is still relatively low.[175]

The debate about covering IVF also focuses on cost effectiveness. Despite the popularity of the procedure, success rates are still relatively low and vary greatly across clinics. A 2007 survey of all SART member clinics revealed that for women under thirty-five, about forty percent of cycles using fresh embryos from non-donor oocytes resulted in live births. Thirty-four percent of cycles using thawed embryos resulted in live births for the same population.[176] The numbers are significantly lower for women over thirty-five, with a live birth percentage rate of just over thirty percent for both fresh and thawed embryos.[177] Given these success rates, the question becomes whether it is cost effective for insurance companies to cover IVF. Moreover, should companies be allowed to limit access for older women who are less likely to get pregnant? Some state insurance mandates do address the age issue. For example, Connecticut law requires that the covered individual be under the age of forty.[178] In New York, patients have to be between the ages of twenty-one and forty-four.[179]

Without help from insurance, IVF can cost between $10,000 and $15,000 per cycle.[180] For women under thirty-five, this means that the average cost to get pregnant is more like $34,000 because it generally takes more than one cycle. For women over forty, that price tag can exceed $100,000. The high prohibitive cost of fertility treatments in the US means, in most cases, that only the wealthy have access. In her article discussing access and regulation, June Carbone argues that access to fertility treatments allows wealthier women to wait longer to have children and accumulate greater wealth and education.[181] In contrast, "[f]or the poor, and particularly poor African Americans, waiting may instead mean permanent childlessness . . . The cost of the new reproductive technologies places them out of the reach of poorer women."[182]

In the UK, the NHS will cover ART procedures, but has strict regulations as to who is eligible and how many times a person can receive treatment.[183] The NHS website explains that, "[f]ertility treatment, funded by the NHS, currently varies across the UK. In some areas, waiting lists for treatment can be long. The criteria you must meet in order to receive treatment can also vary."[184] These variations are regional, based on what is known as the 'postcode lottery'. The term 'postcode lottery' describes "seemingly random countrywide variations in the provision and quality of public services."[185] Despite the existence of the NHS, there is not a standard of care and instead access to infertility services depends on where you live.

The website includes a section on seeking out private treatment, which for a cycle of IVF is estimated to cost between £4000 and £8000.[186] The NHS will typically cover one IVF cycle per eligible couple.[187] Although eligibility determinations are made locally by primary care trusts (PCTs)[188], the basic eligibility criteria is that the women is between the ages of twenty-three and thirty-nine and that either the reasons for infertility have been identified or the couple has been experiencing fertility problems for at least three years.[189] The guidelines also note that priority is typically given to couples without other children.[190] Despite the fact that the NHS covers fertility treatments, many couples in the UK end up using private services and are left in a similar position to their American counterparts.[191] That is, access to fertility treatments often times ends up relying on wealth despite the existence of nationalized health care.

One problem is the lack of standards across PCTs. PCTs have the freedom to set their own eligibility requirements. Different PCTs have different criteria for eligibility. For most, the maximum age of eligibility is thirty-nine, but some PCTs have a maximum age of thirty-seven.[192] Another variation in criteria is the minimum length of relationship or period of infertility. The minimum ranges from one to three years, while some simply require that the relationship be "stable."[193] At least forty-six PCTs require infertile women to give up smoking in order to be eligible for treatment.[194] Some even require that the woman's partner also be a non-smoker. More troubling are some of the other "social criteria" that PCTs set to exclude certain women, including weight, sexual preference, and whether the individual or their partner have other children.[195] According to one report, fifty-four percent of PCTs bar access to IVF for couples that have other children, including when the partner not seeking to get pregnant has children from a previous relationship.[196] In one case, a woman trying to conceive was told that if she found a partner other than her husband of three years, who had children from a previous relationship, she would be immediately eligible for NHS funded IVF.[197] At least six PCTs explicitly deny IVF access to same-sex couples, while most others have an unspecified policy.[198]

In 2004, The National Institute for Health and Clinical Excellence (NICE) recommended that infertile women be given three free cycles of IVF.[199] According to a 2008 article, only nine of 151 PCTs followed that recommendation. Four were not offering IVF at all (that number is now down to one).[200] According to the article, "[e]ven where IVF treatment is funded, there is wide variation in the eligibility criteria set by different PCTs . . . across the whole of South Central . . . only women aged between 36 and 39 are eligible and only if neither partner has any children from a previous relationship. . . In many areas women under the age of 25 cannot have free IVF, while [some] women will not be treated until they reach the age of 35."[201] As discussed, success rates are significantly lower for women over the age of thirty-five. In one case, a couple was denied access to IVF because the woman was only twenty-six years old and the eligibility

requirements stated that the woman had to be between thirty-five and thirty-eight years old.[202] In that case the couple had been trying for six years and was told that IVF was their only possibility for conception.[203] If that particular couple lived in a different part of the country, they would have had no problem getting approved for treatment.

One concern is that the failure to fund the recommended treatments will increase instances of multiple births because of the pressure to succeed in the first cycle.[204] The lack of funding for multiple cycles of IVF frustrates the Authority's goal of minimizing multiple births. While clinics are required to have minimization strategies, PCTs that refuse to fund the recommended cycles are de-incentivizing the policy choice. This will either result in clinics ignoring guidelines on the number of embryos they implant or in much lower success rates for patients trying to get pregnant. According to the National Infertility Awareness Campaign, "'with the move to single embryo transfer, it is even more important to end this totally unacceptable and allow patients access to the treatment promised to them by the government.'"[205]

There is also controversy in the UK surrounding the use of surrogates. Not all PCTs will fund IVF for women using a surrogate.[206] The regulations are unclear. For example, "guidance from the National Institute for Health and Clinical Excellence states that where reason for the infertility is known patients should be fast-tracked for NHS funded treatment but it goes on to say surrogacy lies outside the remit of guidance."[207] The most recent version of HFEA only addresses the illegality of commercial surrogacy arrangements.[208] In the UK, commercial facilitation of surrogacy is a crime and persons seeking a surrogate either has to seek out a friend or relative or turn to one of a few non-profits that help match parents with surrogates.[209] The US has taken a similarly confusing approach to surrogacy. The laws differ greatly state to state. For example, of the six states that allow surrogacy contracts, three only allow gestational surrogacy[210] and three only allow for uncompensated surrogacy agreements.[211] In eleven states and the District of Columbia surrogacy is illegal in some or all circumstances.[212] In cases where a surrogate is necessary, access in both countries, once again, depends on where you live.

VI. Should the US Regulate ART?

Currently policies and regulation of ART in the US are comprised of a combination of minimal federal law, varied state laws, and guidance from professional societies. There are pros and cons to adopting a federal regulatory scheme for ARTs in the US. One of the pros of the UK model is that there is better protection against, "unscrupulous practices of unethical providers who have made headlines and eroded confidence in the US system."[213] There is also, "access to better information about individual clinics and providers."[214] The regulatory model in the UK has led to better consumer protection, which coincidently was one of the goals that drove the US to enact the FCSRCA. The stated purpose of the bill was to, "provide the public with comparable information concerning the effectiveness of infertility services and to assure the quality of such services by providing for the certification of embryo laboratories."[215] A more comprehensive regulatory system in the US would likely provide better protection for consumers.

One theory as to why a federal regulatory scheme would be difficult in the US is the idea that there is a "lack of national moral consensus," when it comes to setting ART policies.[216] Without federal regulation there is more room for divergent ethical and political viewpoints.[217] Moreover, "[r]ules imposed in the US by an HFEA-type regulatory body appointed by an executive elected by a bare majority of the population would face fierce court challenges and political opposition."[218] It would be difficult to have a consistent policy with power shifts from one party to another. The US experience with stem cell research is demonstrative; with policy shifting from funding the creation of stem cells for research during the Clinton Administration to a much more limited policy under Bush.[219] Now, under the Obama Administration, the pendulum is swinging back towards full support for federal funding of stem cell research.

In the US there is a heavy focus on choice and autonomy when it comes to making health care decisions.[220] There is also general suspicion of government regulation.[221] As was evident in the current debate over health care reform, many Americans feel that the government should stay out of personal health care decisions. The US has avoided federal regulation of ART over and over again. In the early 1990s IVF was one of only a few medical procedures to be "explicitly excluded from the standard health benefit package in the Clinton administration's Health Security Act."[222] Also telling is the fact that the one federal law currently in place, by requiring doctors to disclose success rates, has actually ended up putting pressure on doctors to ignore guidelines limiting the number of embryos implanted in order to maximize success at a minimal cost.[223]

The argument against centralized regulation of ARTs focuses on the autonomy of the individual to make his or her own reproductive choices. The bioethicist John Robertson has been instrumental in leading this side of the debate. He believes in "procreative liberty" or what he describes as protecting, "the freedom to contract for the provision, receipt, transfer, and storage of embryos and gametes, when necessary to achieve protected reproductive goals."[224] For him these rights come from the Constitution and are fundamental.[225] As fundamental rights, Robertson believes they should be free from governmental constraint.[226] Most recently Robertson has been involved in the argument over reprogenetics, or the use of assisted reproduction and genetics to engineer embryos.[227] He argues against a centralized regulatory scheme, claiming that to date the system of "muddling through" has worked for other applications of assisted reproduction.[228]

At the same time, without regulation of fertility clinics, doctors are able to ignore or pick and choose which guidelines to follow when it comes to ART procedures. The existence of a Constitutional right does not mean that regulation is impossible or unnecessary. Without a national regulatory agency akin to the Authority in the UK, there is no way to ensure that clinics are following guidelines when it comes to health and safety. Professional societies in the US argue that regulation would limit the type of treatments available to women desperately seeking fertility treatments.[229] They make a personalized medicine argument against strict regulations.[230] They also argue that there is no way for the law to keep pace with technology.[231] At the same time, a closer look at regulation in the UK demonstrates that the HFEA does allow treatment options to vary depending on the patient, while requiring documentation and informed consent.[232] Moreover the most recent amendments to HFEA have been able to keep up with technological and social advances.[233]

When it comes to mandating guidelines and licensing for clinics and doctors, the US has much to learn from the UK's centralized regulatory

scheme. But, that does not mean that a completely centralized regulatory body is the only option. States, as opposed to the federal government, typically regulate medical practice.[234] Given the recent debates over federal government intervention into health care, one option in the US is to mandate laws like the recommendations set forth by the CDC. That is, create minimum requirements for the regulation of ART that states can use to create their own laws, so long as those laws do not violate the constitution. A recent study of the Constitutional implications of regulating ART concluded that pursuant to their police powers, States can regulate ART "in order to protect the health, safety, and welfare of their citizens" but that any regulation distinguishing "socially disfavored groups" will be strictly scrutinized.[235] The author makes a compelling argument that states, "are the most natural regulators of procreation," because with their policing powers states hold, "the kinds of governmental interests that the Supreme Court has held may justify interfering with individual's reproductive liberty – public welfare, health, and safety."[236]

Another option is to integrate the current self-regulating scheme with federal enforcement. In the US, critics of regulation ask whether a federally regulated regime would be effective without a national health care system akin to that in the UK. The reality is that the Authority in the UK is able to regulate both public and private facilities. Although there are lingering access issues as a result of the NHS, these are not a direct result of the guidelines that regulate safety and best practices. Just as other agencies within the Department of Health and Human Services regulate private industry; it would be possible to create a new agency to regulate the fertility industry. Considering the current role that professional societies play in regulating ART in the US, it makes sense to allow them to continue setting practice guidelines and leading the industry forward. The US should consider creating a regulatory enforcement agency that creates real consequences for clinics and physicians that violate these professional guidelines.

No matter what type of regulatory scheme emerges, the tide in the professional community does seem to be shifting towards support for greater regulation. The controversy over octomom re-ignited the regulation debate in the US. In the wake of the media storm, ASRM issued a press release stating that, "[t]he time has come for policymakers to sit down with the leading experts in the field to explore ways we can codify our standards to give them additional regulatory teeth."[237] ASRM also revoked the membership of Nadya's doctor.[238] The statement prompted responses on both sides of the issue. On the one hand, some providers were outraged. The former president of ASRM was quoted as calling the willingness to regulate "ridiculous," stating that "[e]veryone has the goal of not having multiples, but the more you have a regulatory agency interfere with your ability to practice medicine, the more unintended consequences will occur."[239] Another doctor expressed that the "invitation" to regulate would have serious consequences for the doctor-patient relationship: "[c]odification of these standards would be a tragic error that would severely restrict the ability of physicians to provide appropriate, individualized medical care to their patients."[240] On the other hand, proponents of regulation praised the statement as long overdue. A representative of the Center for Genetics and Society, a group that advocates for regulation, blamed the problem partly on competition between fertility clinics, and stated that, "[t]here are a lot of fertility doctors who have lots of integrity and are completely responsible, but it's a situation where, because of the lack of public policy, it creates – and encourages – bad apples."[241] Despite some opposition, the fact that SART and ASRM are moving in a direction that supports greater regulation is a promising step towards addressing the current patchwork of regulations and guidelines in the US. If the federal government does decide to regulate ART, either through a centralized agency like the Authority in the UK or by requiring that States create their own guidelines, it will be important to have the support of these professional organizations that have traditionally set forth practice guidelines.

1 Human Fertilisation and Embryology Act, 1990 (amended 2008) ch. 37 (Eng.).
2 The Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C.A. §263a(1).
3 *Id*. §263a(2).
4 *Id*.
5 *Id*.
6 *Id*. §263i(1- 2).
7 A Model Certification Program for Embryo Laboratories, 64 Fed. Reg. 39374 (July 21, 1999).
8 *Id*. at 39375.
9 *Id*. at 39376.
10 *Id*.
11 *Id*. at 39379.
12 *Id*.
13 *Id*. at 39382-86.
14 *Id*. at 39386.
15 *Id.* at 39382.
16 http://www.thehumanfuture.org/topics/reproductive_technology/policy.html (last visited Nov. 21, 2009).
17 Alicia Ouellette et al., *Lessons From Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 Am. J.L. & Med. 419, 429 (2005).
18 Va. Code Ann. Tit. 54.1, § 2971.1 (2009).
19 La. Rev. Stat. Ann. § 122 (2009).
20 *Id.* § 123.
21 *Id.* §§ 126-27.
22 *Id.* § 128.
23 *Id.* § 130.
24 Lee Kuo, Comment, *Lessons Learned from Great Britain's Human Fertilization and Embryology Act: Should the United States Regulate the Fact of Unused Frozen Embryos*, 19 Loy. L.A. Int'l & Comp. L.J. 1027, 1028 (1997).
25 Noel Cohen, *Allegations Against Fertility Clinics Draw Calls for Regulation*, 13 NO. 1 Med. Malpractice L. & Strategy 5 (1995).
26 *Id.*
27 S.B. 1555 (c) (Ca. 1996).
28 Cal. Penal Code § 367g (b) (1996).
29 *Id*. § 367g(c).
30 MacKenna Roberts, Progress Educational Trust, '*Octomom' Backlash Causes US States to Propose New Law on Fertility Clinics* (Mar. 9, 2009), *available* at http://www.ivf.net/ivf/octomom_backlash_causes_us_states_to_propose_new_laws_on_fertility_clinics-o4042.html.
31 Ethical Treatment of Embryos Act, S.B. 169, 153rd Gen. Assem. Reg. Sess. §19-7-67, (Ga. 2009).
32 Ethical Treatment of Embryos Act, S.B. 169, 153rd Gen. Assem. Reg. Sess. §19-7-61, (Ga. 2009).
33 Kimberly D. Krawiec, *Why We Should Ignore the "Octomom"*, 104 Nw. U. L. Rev. Colloguy 120, 127 (2009).
34 *Id.*
35 http://www.health.state.ny.us/nysdoh/taskfce/taskbio.htm (last visited Nov. 2, 2009).
36 *Id*.
37 *Executive Summary of the Task Force on Life and the Law,*1, 3-7 (Oct. 2001), *available at* http://www.health.state.ny.us/nysdoh/taskfce/execsum.htm.
38 *Id*. at 6.
39 *Id*. at 16.
40 *Id*.

[41] *Id*. at 5.
[42] *Id*.
[43] American Society for Reproductive Medicine, *available at* http://www.asrm.org/detail.aspx?id=60.
[44] *Id.*
[45] Society for Reproductive Technology, www.sart.org/WhatIsSART.html (last visited Oct. 31, 2009).
[46] *Id*.
[47] Robert A. Rebar, MD, ASRM Responds to Incidents at IVF Clinics (Sept. 25, 2009), *available at* http://www.asrm.org/news/article.aspx?id=2223 (last visited Nov. 19, 2009).
[48] Jesse Reynolds, *A new line from the fertility industry?,* (Oct. 21, 2009), *available at* http://www.biopoliticaltimes.org/article.php?id=4954 (last visited Nov. 19, 2009).
[49] Ouellette, *supra* note 17 at 434.
[50] American Medical Association, Opinion 2.055- Ethical Conduct in Assisted Reproductive Technology (adopted June 1996), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2055.shtml.
[51] *Id*.
[52] American Academy of FertilityCare Professionals, Code of Ethics Pledge, http://www.aafcp.org/files/AAFCP_Code_of_Ethics.pdf www.aafcp.org/code_of_ethics.html (last visited Nov. 2, 2009).
[53] Joan Mahoney, Great Britain's National Health Service and Assisted Reproduction, 35 Wm. Mitchell L. Rev. 403, 405 (2009).
[54] *See id*. at 404 (describing that in 1978 Louise Brown became the first baby born as a result of IVF).
[55] Human Fertilisation Embryology Authority, Warnock Report, http://www.hfea.gov.uk/2068.html.
[56] The report was named after its committee chair, Mary Warnock.
[57] Mary Warnock, *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, 75 (1985).
[58] *Id*. at 80.
[59] *Id*. at 76.
[60] *Id*.
[61] *Id*.
[62] Human Fertilisation and Embryology Act 1990, §5(1).
[63] *Id*.
[64] Human Fertilisation & Embryology Authority Compliance and Enforcement Policy, *available at* http://www.hfea.gov.uk/docs/Compliance_and_Enforcement_Policy.pdf (last visited Dec. 18, 2009).
[65] *Id*. §§3.2 and 3.3
[66] *Id*.
[67] Id.§3.4.
[68] *Id*.
[69] Human Fertilisation & Embryology Authority, *available at* http://www.hfea.gov.uk/159.html (last visited Dec. 18, 2009).
[70] Human Fertilisation & Embryology Authority, Changes to legislation 1991-2004, http://www.hfea.gov.ok/2221.html (last visited Nov. 11, 2009).
[71] *See id*. The regulations "extended the purposes for which embryo research could be licensed to include 'increasing knowledge about the development of embryos', 'increasing knowledge about serious disease', and 'enabling any such knowledge to be applied in developing treatments for serious disease.'"
[72] Human Fertilisation and Embryology Act 1990, § 54(1-2).
[73] Human admixed embryos combine human and animal materials.
[74] Human Fertilisation and Embryology Act 2008, ch 22, 57. (Eng.).
[75] Human Fertilisation & Embryology Authority, The HFE Act (and other legislation), www.hfea.gov.uk/134.html (last visited Dec. 18, 2009)
[76] *Id*.
[77] *Id*.
[78] Compliance Cycle, Human Fertilisation & Embryology Authority, http://www.hfea.gov.uk/5257.html (last updated Aug. 21, 2009).
[79] *Id*.
[80] *Id*.
[81] Naomi R. Cahn & Jennifer M. Collins, *Eight is Enough*, 103 Nw. U. L. Rev. Colloguy 501 (2009).
[82] Carson Strong, *Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities*, 31 J.L. Med & Ethics 272 (2003).
[83] *Id*. at 272-73.
[84] Krawiec, *supra* note 33, at 123-24.
[85] Carson, *supra* note 82, at 273.
[86] *Id*.
[87] Stephanie Saul, *The Gift of Life, and Its Price*, N.Y. Times, Oct. 10, 2009 *available at* http://www.geneticsandsociety.org/article.php?id=4945 (last visited Sept. 27, 2010).
[88] Carson, *supra* note 82, at 274.
[89] *Id.* at 277.
[90] *Octuplet's mom, doctor benefitted from alliance: Nadya Suleman's birth record boosted fertility clinic's success rate*, Associated Press, Feb. 22, 2009, *available at* www.msnbc.msn.com/id/29331080 (last visited Sept. 27, 2010).
[91] *Id*.
[92] *Id*.
[93] *Id*.
[94] Guidelines on Number of Embryos Transferred, American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, [92] Fertility and Sterility 5 1518 (Nov. 2009) *available at* http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/Guidelines_on_number_of_embryos%281%29.pdf.
[95] *See id*. at 1518-19. (recommending that for patients 41-42, no more than three blastocyts or five cleavage-stage embryos should be transferred).
[96] Reynolds, *supra* note 48.
[97] American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, *supra* note 94.
[98] *Id*.
[99] Krawiec, *supra* note 33, at 125.
[100] Multiple Birth Guidelines, Human Fertilisation & Embryology Authority, http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/Guidelines_on_number_of_embryos%281%29.pdf(last visited Sept. 27, 2010).
[101] *Id*.
[102] American Society of Reproductive Medicine, *Preimplantation Genetic Testing: a Practice Committee Opinion*, 90 Fertility and Sterility 3 S136 (Nov. 2008) *available at* http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/Preimplantation_genetic_testing%281%29.pdf.
[103] Ethics Committee of the American Society of Reproductive Medicine, *Sex Selection and Preimplantation Genetic Diagnosis*, 72 Fertility and Sterility 4 595, 596 (Oct. 1999) *available at* http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/Sex_Selection.pdf.
[104] *Id*. at 595-97.
[105] Embryo Testing and Sex Selection, Human Fertilisation & Embryology Authority, http://www.hfea.gov.uk/496.html (last visited Sep. 27, 2010).
[106] *Id*.
[107] *Id*.
[108] *Id*.
[109] Ethics Committee of the American Society of Reproductive Medicine, *supra* note 103.
[110] *Id*.
[111] Ethics Committee of the American Society of Reproductive Medicine, *Preconception Gender Selection for Nonmedical Reasons*, 75 Fertility and Sterility 5 861 (May 2001) *available at* http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/preconceptiongender.pdf (last visited Sept. 27, 2010).
[112] *See id*. at 862 (describing general ethical concerns including characteristics of offspring).
[113] Human Fertilisation & Embryology Authority, *supra* note 105.
[114] Sex Selection and Family Balancing, The Fertility Institutes, http://www.fertility-docs.com/fertility_gender.phtml.
[115] Fertility Evaluation and Procedures, The Fertility Institutes, http://www.fertility-docs.com/fertility_fees.phtml.
[116] *See* Gautam Naik, *A Baby, Please. Blond, Freckles – Hold the Colic*, Wall St. J., Feb. 12, 2009, at A10.
[117] *Id*.

[118] *Id*.
[119] *Id.*
[120] *Id*.
[121] *See* Human Fertilisation and Embryology Authority, How we Develop Policies, http://www.hfea.gov.uk/1413.html (outlining the general process of policy development).
[122] *See generally* Human Fertilisation and Embryology Authority, New Techniques, http://www.hfea.gov.uk/107.html (last visited Nov. 30, 2009).) (listing various new experimental ART techniques).
[123] American Society of Reproductive Medicine, Definition of "experimental procedures", 92 Fertility and Sterility 5, 1517 (Nov. 2009), *available at* http://asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/Definition_of_experimental%281%29.pdf .
[124] *Id*.
[125] Rebecca Skloot, *Sally Has 2 Mommies + 1 Daddy and Other Side Effects of Experimentation on Unborn Children in the Underregulated World of High-Tech Fertility Treatments*, 262 Popular Science, Mar. 2003 at 72.
[126] *Id*.
[127] *See id*.
[128] *Id*
[129] *See* Advanced Fertility Center of Chicago, In vitro fertilization with coculture, http://www.advancedfertility.com/coculture.htm (last visited Dec. 18, 2009).
[130] Skloot, *supra* note 124.
[131] *Id.*
[132] *See id*.
[133] Human Fertilization and Embryology Act 1990, §3(3)(b).
[134] *See* UCSF Medical Center, Intracytoplasmic Sperm Injection Information and Questions, http://www.ucsfivf.org/ucsf-icsi.htm.
[135] *See* Advanced Fertility Center of Chicago, Possible risks to the child from intracytoplasmic sperm injection – ICSI, http://www.advancedfertility.com/icsirisks.htm (last visited Dec. 18, 2009).
[136] *See* Lynn R. Fraser, *ART: Boon or Bane?*, Nature Cell Biology & Nature Medicine, Oct. 1, 2002, at S10, *available at* http://www.nature.com/fertility/content/full/ncb-nm-fertilitys10.html (last visited Dec. 18, 2009).
[137] *See* UCSF Medical Center, *supra* note 133.
[138] *See* Fraser, *supra* note 134 at s11.
[139] *See* American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, Genetic Considerations related to intracytoplasmic sperm injection, 90 Fertility and Sterility 3 S182 (Nov. 2008) *available at* http://asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/Definition_of_experimental%281%29.pdf .
[140] Human Fertilisation & Embryology Authority, Information for people seeking treatment with ICSI §21.1(a), http://www.hfea.gov.uk/3466.html (last visited Dec. 18, 2009).
[141] *Id*. §21.1(b).
[142] American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, *supra* note 13.
[143] *See* Ethics Committee of the American Society for Reproductive Medicine, Fertility treatment when the prognosis is very poor or futile, 92 Fertility and Sterility 4 1194 (Oct. 2009) *available at* http://www.asrm.org/Media/Ethics/futility.pdf.
[144] *Id*.
[145] *See id*. at 1196.
[146] *See* Patrick Sawer and Leonard Doyle, *'Wrong Embryo' mother to give up baby boy to his biological parents after mix-up*, The Telegraph, Sept. 26, 2009, available at http://www.geneticsandsociety.org/article.php?id=4934 (last visited Nov. 19, 2009).
[147] *See id.*
[148] *See* The American Fertility Association Responds to Alleged Embryo Mix-up Case in Ohio, http://www.fertilityauthority.com/news/2009/sept/24/afa-responds-alleged-embryo-mix-case-ohio (last visited Dec. 11, 2009).
[149] *See* Michael Kunzelman, *Fertility center suspects errors labeling embryos*, Associated Press, Sept. 25, 2009, available at http://www.geneticsandsociety.org/article.php?id=4935 (last visited Nov. 19, 2009).
[150] *See id*.
[151] Katy Reckdahl, *Ochsner fertility clinic lost embryos, attorney for couple says*, The Times-Picayune, Sept. 26, 2009, available at http://www.nola.com/news/index.ssf/2009/09/oschner_lost_embryos_couple_s.html (last visited Dec. 11, 2009).
[152] *See id*.
[153] *See* Michael Cook, *US IVF Scandals Come to Light,* http://www.bioedge.org/index.php/bioethics/bioethics_article/us_ivf_clinic_scandels_come_to_light (last visited Dec. 11, 2009).
[154] *Id*.
[155] *HFEA to publish incident reports*, Human Fertilisation & Embryology Authority (Oct. 2, 2009), http://www.hfea.gov.uk/5571.html.
[156] *My fight to stop IVF mix-ups*, BBC News (Aug. 27, 2009), http://news.bbc.co.uk/2/hi/health/8220965.stm.
[157] *Id*.
[158] *Id*.
[159] Guidance Notes, 2009, HFEA Code of Practice. 8th § 27.2(b) (U.K.), *available at* http://www.hfea.gov.uk/3476.html
[160] *HFEA to publish incident reports*, *supra* note 152.
[161] *Id*. (Quote from Prof. Lisa Jardine., Chair of the Authority).
[162] *My fight to stop IVF mix-ups*, *supra* note 153.
[163] Cahn, *supra* note 81 at 501-02.
[164] *Id*. at 502.
[165] Mahoney, *supra* note 53 at 403.
[166] State Infertility Insurance Laws, American Society for Reproductive Medicine, http://www.asrm.org/insurance.aspx (last visited Nov. 9, 2009).
[167] *Id*.
[168] *Id*.
[169] *Id*.
[170] *Id*.
[171] *Id*.
[172] *Id*.
[173] *Id*.
[174] Peter J. Neumann, *Should Health Insurance Cover IVF? Issues and Options*, 22 J. Health Pol. Pol'y & L. 1215, 1221 (1997).
[175] *Id*. at 1220-21.
[176] Society for Assisted Reproductive Technology, Clinic Summary Report https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0 (last visited Dec. 11, 2009).
[177] *Id*. For women between the ages of 35-37.
[178] *Supra* note 163.
[179] *Id*. at N.Y.
[180] *A Comparison of the IVF Cost Worldwide*, IVF Cost (Aug. 27, 2008), http://www.ivfcost.net/ivf-cost/a-comparison-of-the-ivf-cost-worldwide.
[181] June Carbone, If I Say "Yes" to Regulation Today, Will You Still Respect Me in the Morning?, 76 Geo. Wash. L. Rev. 1747, 1765 (2008).
[182] *Id*.
[183] Mahoney, *supra* note 53 at 403.
[184] *Id*.
[185] Patrick Butler, *Q&A: Postcode Lottery*, Society Guardian (Nov. 9, 2000) http://www.guardian.co.uk/society/2000/nov/09/NHS/print
[186] Mahoney, *supra* note 53 at 403.
[187] *Id*.
[188] Primary Care Trusts (PCTs) in the UK are local organizations that contract with health care providers. They currently control eighty percent of the NHS budget. *See* About the NHS, NHS.UK, http://www.nhs.uk/NHSEngland/aboutnhs/Pages/NHSstructure.aspx (last visited Dec. 18, 2009).
[189] IVF, NHS.UK, http://www.nhs.uk/conditions/IVF/Pages/Introduction.aspx?url=Pages/What-is-it.aspx (last visited Dec 19, 2009).
[190] *Id*.
[191] Mahoney, *supra* note 53 at 410.
[192] Can You Get IVF Where You Live? Find Out Here, GUARDIAN.CO.UK, http://www.guardian.co.uk/news/datablog/2009/aug/06/fertility-problems-nhs (last visited Nov. 16, 2009).
[193] *Id*.
[194] Kirsty Horsey, *Access to IVF in UK barred to Smokers*, BioNews (June 23, 2008, http://www.bionews.org.uk/page_13419.asp.
[195] *Id*.
[196] Denis Campbell, *Women denied IVF on NHS 'by postcode lottery'*, GUARDIAN.CO.UK, (Aug. 5, 2009) http://www.guardian.co.uk/lifeandstyle/2009/aug/05/ivf-restrictions-nhs-postcode-lottery.

[197] *Id*.
[198] *Supra* note 189.
[199] Jess Buxton, *'Postcode lottery' Continues for infertile English Couples*, BioNews (June, 30, 2008), http://www.bionews.org.uk/page_13424.asp.
[200] *Id*.
[201] *Id*.
[202] Sarah Guy, *Petitions call for end to IVF discrimination and 'Postcode Lottery' in the UK*, BioNews (May 26, 2009), http://www.bionews.org.uk/page_13820.asp.
[203] *Id*.
[204] Buxton, *supra* note 196.
[205] Sarah Guy, *Postcode lottery rages on as IVF funding lacks continuity*, BioNews (Jan. 19, 2009), http://www.bionews.org.uk/page_13628.asp.
[206] Rebecca Smith, *Women Denied NHS Fertility Treatment because 'they cannot carry the child themselves',* The Telegraph (Oct. 30, 2009), http://www.telegraph.co.uk/health/healthnews/6396366/Women-denied-NHS-fertility-treatment-because-they-cannot-carry-child-themselves.html.
[207] *Id*.
[208] Human Fertilisation and Embryology Act 2008, § 59.
[209] Natalie Gamble, *Modern Surrogacy in the UK*, 124 The Review Sept. 2009 at 58-9.
[210] Gestational Surrogacy is when that the surrogate mother does not contribute the biological egg.
[211] Human Rights Campaign, Surrogacy Laws: State by State, http://www.hrc.org/issues/2486.htm (last visited Nov. 9, 2009).
[212] *Id*.
[213] Ouellette, *supra* note 17, at 435.
[214] *Id.*
[215] S.R. No. 102-452 (Oct 1, 1992).
[216] Ouellette, *supra* note 17, at 435.
[217] *Id*.
[218] *Id*.
[219] *Id*. at 436.
[220] Ellen Waldman, Cultural Priorities Revealed: the Development and Regulation of Assisted Reproduction in the United States and Israel, 16 Health Matrix, 65, 75 (2006).
[221] *Id*.
[222] Neumann, *supra* note 171, at 1216.
[223] Saul, *supra* note 87.
[224] John A. Robertson, Embryos, Families, and Procreative Liberty: the Legal Structure of the New Reproduction, 59 S. Cal. L. Rev 939, 1040 (1986).
[225] *Id*.
[226] *Id*.
[227] John A. Robertson, The Virtues of Muddling Through, 37 The Hasting Center Report 4 (2007).
[228] *Id*.
[229] Ouellette, supra note 17 at 433.
[230] *Id*.
[231] *Id*.
[232] *See generally*, About the Human Fertilisation and Embryology Authority, available at http://www.hfea.gov.uk/docs/About_the_HFEA.pdf (last visited Dec 19. 2009).
[233] Mahoney, *supra* note 53, at 409-10 (explaining that the 2008 amendments to HFEA allow sperm and embryo usage after the death of the donor and allow gay and lesbian couples to seek out fertility treatments).
[234] R. Alta Charo, *Children by choice: reproductive technologies and the boundaries of personal autonomy*, Nature Cell Biology and Natural Medicine, Oct. 1, 2002 at s23, s24, available at http://www.nature.com/fertility/content/full/ncb-nm-fertilitys23.html (last visited Dec 19, 2009).
[235] Michelle N. Meyer, *States' Regulation of Assisted Reproductive Technologies*, The Rockefeller Institute at 1, *available at* www.rockinst.org (last visited Dec. 18, 2009).
[236] *Id*. at 5.
[237] Kevin B. O'Reilly, *Fertility doctors tighten guidelines in wake of "octomom" controversy*, American Medical News, Nov. 9, 2009, *available at* http://www.geneticsandsociety.org/article.php?id=4980 (last visited Nov. 19, 2009).
[238] *Id*.
[239] Jesse Reynolds, *Strong Reactions From Fertility Docs to Potential Regulation*, Center for Genetics and Society, Nov. 10, 2009, *available at* http://www.biopoliticaltimes.org/article.php?id4981 (last visited Nov. 19, 2009).
[240] *Id*.
[241] O'Reilly, *supra* note 234.

Problems and Developments in the Tax-Exemption of Health Care Providers

*Patrick Manders**

The charitable status of tax-exempt providers is being challenged and is increasingly subject to financial pressures, exacerbated by the recent financial crisis. Although the crisis affected all areas of the economy, the traditional difficulty of non-profit entities, including charitable health care institutions, at raising capital, presents unique problems.[1] Since the decision in *Utah County v. Intermountain Health Care, Inc.*, state governments have increasingly limited the extent of or the requirements to obtain tax-exempt status by charitable institutions.[2] Recently, the federal requirements for a charitable tax-exemption under the "community benefits" standard explicated by Revenue Ruling 69-545 was modified in the Patient Protection and Affordable Care Act to provide more stringent accounting of community benefits.[3] A balanced approach to assessing community benefit is necessary to ensure the public receives the actual value of tax-exemption, but must allow for current and structural difficulties facing non-profit charitable institutions, as well as flexibility to account for the inherent differences between health care providers.

This article evaluates prospective requirements for non-profit health care providers to qualify for tax-exemption, in consideration of the risks and difficulties facing these providers. To do so, the article will first address the overall federal basis for tax-exemption under I.R.C. Section 501(c)(3) and the prevailing community benefits standard. The reasons and theories justifying a tax-exemption will be considered to understand the basis for exemption.[4] Then, recent state and federal initiatives to require minimum charity to qualify for tax-exempt status are considered in order to evaluate their effect on non-profit charitable health care providers. Finally, disparities in charitable activity and financial difficulties among non-profit hospitals will be considered as they underlie the need for effective requirements concerning community benefits.

Historically, tax-exemption derived from early English law allowing exemption to encourage "socially desirable behavior."[5] The English Statute of Charitable Uses first comprehensively defined charity by including the "relief of aged, impotent and poor" and the "maintenance of sick and maimed soldiers" as proper use of charitable trusts.[6] After the Revolutionary War, the former colonies encouraged charitable entities to act in corporate form, allowing a tax-exemption at the state and eventually the federal level after implementation of the federal income tax.[7] From the colonial period through the late-19th century, charitable hospitals mainly served the impoverished indigent and were primarily financed through voluntary charitable donations with little government funding or patient fees.[8] Physicians and aides at these early hospitals worked without remuneration.[9] Tax-exemption was justified because these hospitals relieved the government of its burden of caring for the indigent.[10] Accordingly, these hospitals not only served medical issues among the poor, but also were social institutions for the indigent.[11] The wealthier parts of society depended upon private physicians and largely avoided hospital care.[12]

Starting in the early-20th century, hospitals began to operate along commercial principles financed by patient fees.[13] Advances in medical science increased the costs of providing care, making the modern hospital system more lucrative and more practical for the provision of modern medical treatment.[14] By the late-20th century, non-profit hospitals were increasingly commercial in nature, often with large revenues, actively competing with other non- and for-profit hospitals.[15] The rise in for-profit hospitals and the similar commercial nature of both for-profit and non-profit hospitals created vulnerabilities in justifying an exemption that gave non-profits a competitive advantage over for-profit hospitals.[16] Accordingly, most modern hospitals no longer depend upon charitable contributions or the primary use of volunteers for the provision of services.[17] In short, as non-profit hospitals took on more aspects of for-profit enterprises, they faced increasing difficulties justifying tax-exemption.

The modern composition of hospitals indicates the decreasing distinction between non-profit and for-profit hospitals. Today, non-profit hospitals make up slightly more than half of all registered hospitals, with for-profits making up roughly seventeen percent of total hospitals, and the rest split among government and non-government institutions.[18] Reports indicate

* **Patrick Manders** is from St. Louis, Missouri and graduated from the University of Richmond in December 2007 with B.A. in political science. He is a J.D. candidate (2011) at American University Washington College of Law.

> Today, non-profit hospitals make up slightly more than half of all registered hospitals, with for-profits making up roughly seventeen percent of total hospitals, and the rest split among government and non-government institutions.

relatively little difference in the provision of charity care between non-profit and for-profit hospitals, demonstrated by a 0.5 percent operating expense difference between uncompensated care provided by non-profit and for-profit hospitals.[19] Several studies conclude that non-profit hospitals acquired by for-profit hospitals do not reduce their provision of community benefits, despite becoming non-charitable institutions.[20] To define charitable purposes, federal law and many states refer to the "community benefits" standard.

Federal tax-exemption of non-profit health care providers derives from I.R.C. Section 501(c)(3), which exempts organizations operated exclusively for charitable purposes if no earnings inure to the benefit of a private individual.[21] Revenue Ruling 69-545 explicates the community benefits standard to determine whether a non-profit health care provider qualifies for exemption as a charitable organization.[22] The standard's general factors are whether a tax-exempt provider (1) is governed by a board of trustees or directors drawn from the community; (2) has an open medical staff policy; (3) operates a full time emergency room open to all regardless of pay; and (4) admits as patients those able to pay whether by private payment, third parties, or government programs.[23] Revenue Ruling 83-157 allows hospitals without an emergency room to show the needs for that service are otherwise met in their community.[24] The community benefits standard does not require a minimum level of charity care or that charity care be provided to all members of the community, so long as the class of beneficiaries is not so small as to provide no benefit to the community.[25] At issue are state and federal initiatives further defining a minimum requirement of charity and the continuing societal value of tax-exemption.

A tax-exempt corporation must operate exclusively for "charitable purposes" under Section 501(c)(3), which is met through the organizational and operational tests.[26] The organizational test requires the exempt organization, in its articles of organization, to: (1) limit the purpose of the organization to one or more exempt purposes; and (2) not expressly empower the organization, except as insubstantial part of activities, in activities not in furtherance of exempt purposes.[27] The operational test requires the exempt organization to engage primarily in activities accomplishing an exempt purpose of Section 501(c)(3), and will not be exempt if more than an insubstantial part of activities is not in furtherance of the exempt purpose.[28] Exempt purposes include charity, which is understood in the "generally accepted legal sense," including the provision of public health.[29] An organization may satisfy Section 501(c)(3) even though it operates a trade or business as a substantial part of its activities, so long as the business is in furtherance of an exempt purpose and the organization is not organized primarily to carry on the business.[30] Section 511 allows the imposition of a tax on unrelated business income of Section 501(c)(3) exempt organizations.[31]

The original rationale justifying tax-exemption for providers is that the exemption subsidizes the provision of public goods represented by charitable care.[32] The subsidy rationale posits that tax-exempt hospitals relieve the government of a burden it would otherwise have to bear, shifting the costs by forgoing revenue it would garner from exempt entities to compensate the entity for the costs of providing a public good, providing charitable care to those unable to pay. [33] The Supreme Court recognized this principle in *Bob Jones University* by stating that, "charitable exemptions are justified on the basis that the exempt entity confers a public benefit."[34] But this rationale only explains a subsidy so far as it relieves the public of the costs of indigent care.[35]

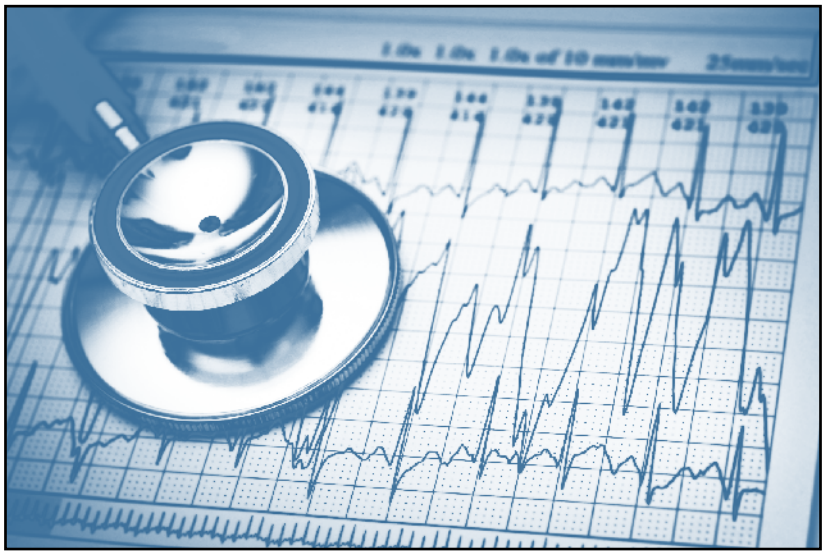
Another theory justifying tax-exemption is income measurement, which argues that the income for non-profit and charitable organizations is difficult to define and tax under current tax law.[36] The significant number of for-profit hospitals and the commercial nature of many non-profit hospitals argue against the income measurement theory as applied to modern hospitals.[37] The Capital Formation Theory states that tax-exemption compensates non-profit entities for lack of access to traditional investment through equity.[38] Other theories postulate that the exemption is based on altruism or philanthropy.[39] The Risk Compensation Theory justifies a continuing tax-exemption for charitable organizations based on the inherent risk of providing public goods without any expectation of financial return.[40] Risk Compensation posits that tax-exemption allows the non-profit sector to provide goods that neither the private for-profit or government sector is able to provide in sufficient quantity. Basic to any of these theories is the assumption that the benefits to society of charitable activity are worth the financial costs of exempting part of the tax base.[41]

A continuing tax-exemption for non-profit hospitals should comport with actual social benefits to balance the costs implicit in exempting a significant sector of the economy from taxation. Tax-exemption results in at least three identifiable costs on society: (1) the risk of undeserving organizations benefiting from an exemption; (2) subsidizing some organizations but not others; and (3) the diminishment of the tax base,

with a corresponding increase in the burden on others.[42] Because non-profit hospitals share many characteristics with their for-profit competitors, the conferral of a tax-exemption should balance a measurable benefit to society.[43] Many states have limited the risk of undeserving organizations from obtaining an exemption by imposing stricter requirements regarding charitable status, including stripping health care providers from long-standing exemptions.[44]

I. Recent Treatment of Tax-Exempt Providers by State Governments

The majority of states follow the federal treatment of public health as a charitable purpose deserving of tax-exemption.[45] The actual state tax-exemption qualifications vary widely. Roughly fifteen states have a community benefits requirement similar to the federal standard, while many others make reference to community benefits in hospital reporting or licensure, but do not explicitly require it for exemption.[46] Five states, including Texas, require specific minimum amounts of community benefits.[47] Community benefits states typically require that that the hospital identify community needs and then develop and implement a plan to meet those needs, with reporting and disclosure of community benefits provided.[48] The recently enacted Patient Protection and Affordable Care Act of 2010 (PPACA) includes similar requirements.[49] States often exempt charitable organizations from local property or sales taxes as well as income taxes. Since 1985, states have increasingly challenged local tax-exemption, often through local tax-collecting authorities claiming lack of sufficient charity.[50]



State governments primarily limit non-profit hospital tax-exemption through the exclusivity requirement or by requiring a minimum level of care to qualify for tax-exempt treatment.[51] Recently some states have considered, but not implemented, certain taxation or even complete revocation of the tax-exemption for non-profit hospitals.[52] The Supreme Court of Illinois recently upheld the denial of a charitable tax-exemption on the grounds the hospital devoted only 0.7 percent of its revenue to charitable care.[53] Texas has instituted specific requirements for minimum charity care in order to obtain tax-exemption.[54]

Although a number of states have since reviewed the qualifications for charitable tax-exemption, the decision in *Utah County v. Intermountain Health Care, Inc*. is the first major decision by a state high court revoking the long-held tax-exempt status of a health care provider.[55] In 1985, the Supreme Court of Utah ruled on the validity of a statute based upon the state constitutional provision allowing property tax-exemption of land used for charitable purposes.[56] The Court held that the health care provider did not demonstrate the property was used exclusively for charitable purposes and prospectively stripped the provider from future property tax-exemption, reaffirming that a statute cannot expand, limit, or defeat the exemption provided by the Utah Constitution.[57] Utah County contended that the statute unconstitutionally expanded the charitable exemption granted in the Utah Constitution, but did not dispute that the hospital complied with the statute.[58]

In order to interpret the Utah constitutional exemption provision, the Court defined the meaning of "charitable" purposes as the contribution or dedication of something valuable to the common good.[59] Distinguishing from historical bases of charitable tax-exemption, the Court concluded that the modern medical-industrial complex transformed a traditional charitable basis to a business model.[60] A particular example of the change is that Intermountain owned at least one for-profit subsidiary and competed with for-profits.[61] Although some of Intermountain's stated purposes satisfied the requirement of charitable use, the Court identified similar rates of charge for services and free services constituting less than one percent of revenue as demonstrating a lack of charitable purpose.[62] Drawing on the operating similarity between Intermountain and its for-profit competitors, the Court rejected the dissent's claim that revoking tax-exemption would increase costs to consumers or lower quality of care.[63] Distinguishing state tax-exemption requirements from federal, the Court concluded that Intermountain confused state constitutional requirements of charity as a gift to the community, with the separate concept of community benefit or usefulness to the community.[64]

In response to a challenge by the Texas Attorney General against the tax-exempt status of a large non-profit hospital, the Texas legislature passed a statute requiring non-profit hospitals to provide a specific percent of revenue to charitable care or community benefits to qualify for tax-exemption.[65] The statute requires tax-exempt charitable hospitals to develop a community benefits plan to serve the community's health care needs determined through a community needs assessment.[66] The level of benefit must meet one of the following standards: (1) a level reasonable in relation to community needs as determined through the assessment; (2) charity care provided at least equal to 100 percent of the hospital's state tax-exemption; or (3) charity care and community benefits in an amount equal to at least five percent of the hospital's net patient revenue.[67]

Reports are unclear regarding the effect of the Texas statute on charity care, but do not support a substantive increase in charitable care.[68] Furthermore, hospital organizations disapprove of similar statutes that enforce a "hard" minimum of charity without regards to the wide disparities in hospital and community types.[69] A recent Internal Revenue Service (IRS) Exempt

Organizations study noted significant variations in the level of charity care and community benefits provided among different types and hospital sizes.[70] Although the precise effects of the Texas statute on charitable care is unclear, provisions requiring hospitals to report charity and community benefits should provide a clearer picture of the value of the tax-exemption through community benefits provided.[71]

In 2002 the Director of the Illinois Department of Revenue denied Provena Covenant Medical Center (PCMC) tax-exempt status solely on the grounds that PCMC devoted only 0.7 percent of revenue to charity care.[72] After Provena appealed revocation in circuit court, the court held Provena was entitled to both a charitable and a religious exemption.[73] On appeal the Supreme Court of Illinois upheld the revocation of Provena's tax-exempt status and assessed a $1.1 million property tax.[74] Because Illinois state law allows a property tax-exemption for property used exclusively for charitable purposes, the main issue was exclusive charitable use relative to the amount of charity care and the commercial nature of the business.[75]

The taxpayer was Provena Hospitals, a corporation created by a consolidation of Roman Catholic health care operations running six hospitals, including PCMC.[76] Although the taxpayer qualified under other tax-exemptions, the case concerned the revocation of the property tax-exemption for PCMC.[77] The Supreme Court of Illinois noted that charitable donations to PCMC were virtually non-existent, only $6,938 in 2002, that PCMC was profitable, and that it spent substantial amounts of money on advertisement, but did not advertise any discounted or free care despite a stated policy to do so.[78] Only 0.27 percent of PCMC's total patients in 2002 received any charity care.[79] The Supreme Court of Illinois first emphasized that exemption was by far the exception to taxation, as shown through a strictly construed statutory exception where any doubt must be resolved in favor of taxation.[80]

The Supreme Court of Illinois identified the characteristics of charitable institutions as: (1) has no capital, capital stock or shareholders; (2) earns no profits or dividends, but derives funds mainly from charity holding them in trust; (3) dispenses charity to all who need it and apply; (4) does not provide private gain or profit; and (5) does not place obstacles to those who would avail themselves of charity.[81] Although health care providers are charitable institutions, the provision of health care alone is not sufficient to justify a property tax-exemption as a charitable use.[82] The first and fourth factors clearly weighed in favor of exemption for PCMC, but the Court found the remaining factors weighed against exemption as a charitable institution.[83] The second factor of charitable donation was completely negligible and the Court found the level of charity care was insufficient to qualify under the third and fifth factors.[84] Although the Court mainly relied upon exclusive charitable use of the property and lack of charity care as grounds for revoking PCMC's tax-exemption, the inclusion of charitable donations as a factor is problematic for modern hospitals that depend almost entirely upon patient fees.[85]

The subsidization rationale for tax-exemption, where certain activities are exempted on the basis they relieve the government of burdens it would otherwise bear, is explicitly recognized as a *sine qua non* of charitable status for Illinois state property tax-exemption.[86] A specific dollar-for-dollar amount comparing lost taxes and charity provided by the hospital is not necessary, but it must show that it relieves some government financial burden.[87] Distinguishing from *People ex rel. Cannon v. Southern Illinois Hospital Corp.*, where the hospital in question demonstrated it provided discounted care to the county government that paid for indigent care, the Court found that Provena's offset of government costs through charity care was *de minimus*.[88]

The minimal amount of charity care is significant to the issue of whether the property was used solely for charitable purposes. Because Provena did not advertise its financial assistance policy and typically forwarded all unpaid bills to collection agencies, there was practically no difference between Provena's behavior and the behavior of a for-profit institution.[89] Provena argued that PCMC served an area that did not require additional charitable services, but the Court rejected the claim on grounds that 13.4 percent of the county's population was below the federal poverty level.[90] Provena's discounted care was rejected because PCMC still ran a surplus and expected to make up revenue by charging higher amounts to other users.[91] Such "cross-subsidizing" is an established practice among business enterprises and makes Provena even more similar to its for-profit competitors.[92] The Court rejected counting Medicare and Medicaid underpayments as charity, noting that the programs were voluntary and consistent with the hospital's financial interests.[93]

The *Provena Covenant* case illustrates the difference between federal and state exemptions, which can vary widely. In Illinois, the property tax-exemption at issue required the use of the property to be charitable and alleviate a government burden, so the state does not take into account activities the local government is not responsible for.[94] For example, the Court rejected the use of medical training as a charitable expense by Provena because the training was not within the local government's jurisdiction, nor was it a cost the local government would bear.[95]

II. Recent Treatment of Tax-Exempt Providers by the Federal Government

Federal initiatives have focused on collecting information on the value of tax-exemption to non-profit hospitals. The PPACA borrows from some state requirements by mandating a community needs assessment. The IRS began the Hospital Compliance Project in May 2006 to gather information regarding community benefit by non-profit hospitals and issued the final report in February 2009.[96]

The second major federal effort to evaluate community benefit by tax-exempt non-profit hospitals started in 2008 when hospitals were required to report community benefit and other information on Form 990, Schedule H.[97] Schedule H is intended to promote uniform reporting through clear standards and filing, but does not completely address issues related to some questionable community benefits, such as bad debt and Medicare shortfalls.[98] The required reporting includes six parts: (1) charity care and other community benefits at cost; (2) community building activities; (3) bad debt, Medicare, and collection practices; (4) management companies and joint ventures; (5) facility information; and (6) supplemental information (e.g. community needs assessments).[99] Schedule H also allows for hospitals to account for non-quantifiable community benefit by explaining the activity, even if it does not fit into the other quantifiable activities.[100]

Hospital organizations must file a single Schedule H that aggregates the relevant information for the tax year.[101] Hospital organizations must separately list and account for each individual health care facility.[102] The

American Hospital Association (AHA) is seeking modification on Schedule H reporting because of studies indicating many hospital organizations will file "multiple and seemingly unconnected Schedule H's."[103] Prospective duplicative filing may interfere with the uniformity Schedule H is intended to promote.

PPACA stipulates specific requirements non-profit hospitals must satisfy to qualify for tax-exempt status.[104] PPACA does not establish a "hard" minimum of charity care, but instead requires a community needs assessment and the implementation of a policy to meet these needs.[105] For a hospital to qualify as a Section 501(c)(3) tax-exempt entity PPACA requires that the hospital implement: (1) a community health needs assessment; (2) financial assistance policy requirements; (3) requirements on charges; and (4) billing and collection requirements.[106]

The community health needs assessment is similar to those required by many states.[107] PPACA states that the assessment "takes into account input from persons who represent the broad interests of the community served by the hospital facility" and that it be widely available to the public.[108] The assessment must be completed in the taxable year or in either of the two prior years.[109] The hospital must then adopt and implement a plan to meet the health needs identified in the assessment.[110] Since many states already require community needs assessments, this provision would not further burden those hospitals and allows for a flexible approach to meeting the needs of widely differing communities.[111] By requiring a community needs assessment the hospital must investigate and account for the specific needs of different communities, which may mitigate the wide variations in the provision of community benefits within community and hospital types.

The financial assistance policy requirement mandates a written policy setting forth the eligibility for financial assistance.[112] The basis for calculating charge amounts and applying financial assistance must be widely publicized within the community.[113] *Provena Covenant* illustrates the necessity of wide publication because PCMC had a written financial assistance policy that was not widely publicized, resulting in only 0.27 percent of patients availing themselves of the policy.[114] PPACA further requires a written statement regarding provision of emergency medical care.[115] PPACA also limits charges for emergency or medically necessary care to individuals eligible under the financial assistance policy to no more than the lowest charges to individuals with insurance coverage.[116] Simply put, PPACA requires charges under the financial assistance policy to be no higher than the lowest charge for insured care. PPACA's billing requirement mandates a hospital make reasonable efforts to determine if the individual is eligible for assistance under the policy before beginning "extraordinary" collection actions.[117]

PPACA requires hospital organizations consisting of multiple hospitals to account for each specific hospital individually with penalties to each individual hospital if they do not satisfy the new requirements.[118] The AHA recently urged the IRS against individual reporting on Schedule H by alleging it adds complexity and skews the reporting of community benefits.[119] Although the AHA's complaint is concerned with Schedule H reporting and not the PPACA's Section 501 requirements, both treat hospitals on an individual basis without taking into account the entire organization. The AHA reports that because nearly sixty percent of non-profit hospitals are part of multi-hospital organizations, requiring individual reporting may not accurately assess their community benefit.[120] By making each individual hospital meet the requirements, PPACA may more efficiently address the problems of disparities in community benefit because measuring benefits through the entire hospital organization would not address some hospitals providing substantially more or less of the overall benefit of the hospital organization.

Unlike the Texas statute, which depends solely on revocation of tax-exempt status to punish offenders, the Act allows a fifty thousand dollar excise tax on charitable hospitals that fail to comply.[121] The excise tax allows greater flexibility in enforcing the new Section 501 requirements and avoids the extremity of full revocation. An excise tax would be a more efficient and effective enforcement mechanism than full revocation of tax-exemption because the non-profits would be less willing to bear the litigation costs and would simply pay the tax.

In 2003, the Tenth Circuit affirmed the Tax Court's denial of tax-exempt status to IHC Health Plans, which was a health maintenance organization (HMO) set up by non-profit IHC to integrate its health care services.[122] To determine whether IHC Health Plans qualified for tax-exemption the Court asked two questions: (1) whether the services provided by IHC were charitable in nature and (2) whether IHC operated primarily for charitable purposes.[123] Charitable services are understood in the "generally accepted legal sense" and must therefore serve a public, not a private, interest.[124] Although the promotion of public health is clearly charity in the form of community benefit, the Court stressed that not every activity promoting health qualified for tax-exemption.[125]

> "Disparities in charity, as measured through community benefit, can reflect both legitimate differences in the hospitals and their communities, as well as a disproportionate provision of community benefits within the non-profit sector."

Applying a totality of the circumstances standard, the qualifications for charitable tax-exemption generally require the provider to make services available to the entire community and to provide an additional community benefit by furthering the function of a publicly funded institution or providing a service otherwise not provided in the community.[126] The benefit provided must show that providing a public benefit is the primary purpose of the institution.[127]

Although noting that charity in the form of reduced fees, as opposed to entirely free services, can qualify alone as a community benefit, the Tenth Circuit affirmed the revocation of tax-exempt status on the grounds that IHC Health Plans did not operate primarily for charitable purposes.[128] In so holding, the Court distinguished IHC Health Plans, which operated as an HMO, from IHC, a tax-exempt charitable corporation that controlled IHC Health Plans.[129] Even though IHC Health Plans operated to integrate the delivery of health care by IHC, and charged reduced premiums in some cases, it was not held to operate exclusively for charitable purposes.[130]

III. Disparities in the Provision of Charity

The pressures faced by non-profit, tax-exempt hospitals to account for minimum charity reflect the underlying problem of disparities in their provision of charity. Disparities in charity, as measured through community benefit, can reflect both legitimate differences in the hospitals and their communities, as well as a disproportionate provision of community benefits within the non-profit sector.[131] The challenge is to ensure each tax-exempt hospital bears a share of community benefits sufficient to justify the costs of exemption while accounting for both legitimate differences in community needs and the different activities that may count as community benefits. In the process, a uniform concept of what qualifies as community benefits must be defined to provide predictable standards for non-profit hospitals to apply.

The significant disparities in the amount of charitable activity vary depending on: (1) the size of the hospital and (2) the community being served. The IRS initiated the Hospital Compliance Project in 2006 to study non-profit hospitals and community benefits and released the final report in February 2009.[132] The report found overall average community benefits expenditures of nine percent of total revenue and a median expenditure of six percent of total revenue.[133] The report divided between two extremes of hospital size, as measured by revenue, because the largest and smallest sized hospitals displayed the most acute differences in community benefits: (1) hospitals with revenue less than $25 million and (2) hospitals with revenue more than $500 million.[134] The former reported an average community benefits expenditure of 9.9 percent of total revenue and a median expenditure of 3.3 percent of total revenue.[135] The latter high revenue hospitals reported average community benefits expenditures of 12.4 percent of total revenue and a median expenditure of 10.5 percent of total revenue.[136] Not only is there significant variation in the overall community benefits expenditures between the size of hospitals, as shown by the twenty five percent more spent on community benefits by high revenue hospitals as a percentage of total revenue, but the wide difference in medians indicates significant variation within the group of low revenue hospitals.[137]

Given that the average expenditures for both large and small revenue hospitals is above the average for all hospitals, the intermediate size hospitals must provide lower amounts of benefits than the two extremes. Because the median represents the middle point in the sample, the 6.6 percent difference between the median and average spending in low revenue hospitals means that the portion of the sample above the median must spend significantly more on community benefits than the portion below the median to raise the overall average to three times the median.[138]

Although the average 2.5 percent of additional revenue spent by high revenue hospitals shows significant variation depending on the size of the hospital, the difference may be explained by high revenue hospitals' greater ability to provide for charity and other factors.[139] There is a much smaller difference (1.9 percent) between the median and average percent of community benefits as a percentage of total revenue for high revenue hospitals.[140] This smaller difference indicates a more uniform spread of community benefits across the sample of large hospitals. Measured by the size of the hospital (indicated by total revenue) the greatest variations therefore are shown within the category of the low revenue hospitals.[141] These disparities may indicate other factors that determine overall community benefits, most particularly the character of the community being served.

The report accounted for community differences in four community types: (1) high population; (2) other urban and suburban hospitals; (3) critical access hospitals, which the report defined as hospitals treating rural areas with no other hospital within thirty-five miles; and (4) rural, non-critical access hospitals.[142] High population hospitals reported an average community benefits expenditure of 12.7 percent of total revenue with a median of 9.8 percent; other urban and suburban hospitals reported an average 8.9 percent

"Although the average 2.5 percent of additional revenue spent by high revenue hospitals shows significant variation depending on the size of the hospital, the difference may be explained by high revenue hospitals' greater ability to provide for charity and other factors."

with a median 5.8 percent.[143] The 3.8 percent difference between averages indicates hospitals serving the highest populations produce the most reported community benefits, a trend that continues with the rural hospitals.[144] The relatively small difference (2.9 percent) between the median and average for high population hospitals indicates a relatively small disparity within the category, as compared to other community categories.[145] The difference between the average and median of other urban and suburban community hospitals was 3.1 percent, indicating slightly more variation within that category.[146]

The most significant differences are in rural hospitals. Critical access hospitals have an average community benefits expenditure of 6.3 percent with a median expenditure of 2.8 percent; meanwhile, non-critical access rural hospitals have an average community benefits expenditure of 8.4 percent and a median of 3.2 percent of total revenue.[147] Critical access hospitals are below the average (nine percent of revenue) expenditures for hospitals generally by a wide margin, with significant variation within the category shown by a 3.5 percent difference between the average and median, where the average is almost twice the median.[148] The variation within rural hospitals is the most significant, with the average expenditure more than two and one half times higher than the median.[149] This variation indicates significant disparity in community benefits expenditures between urban/suburban and rural hospitals. However, the significant disparities within the rural community hospitals that cannot be explained by differences in communities that result in different needs and therefore produce different benefits are more troubling.

Moreover, both within and among the hospital categories across the board, significant variations in the provision of community benefits exist. The IRS found that community benefits "were not evenly distributed by the hospitals in the study, but were concentrated in a relatively small number of hospitals."[150] The spending concentration is most clearly displayed by the fact that twenty-one percent of hospitals reported spending less than two percent of revenue on community benefits expenditures and forty-seven percent reported spending less than five percent of revenue on community benefits, despite an average expenditure of nine percent of revenue.[151] Such disparity in the provision of community benefits is problematic, both because it indicates a large share of the societal burden is unevenly distributed and because the variation is so significant within types of hospitals. The uneven societal distribution argues for stronger measures to ensure each individual hospital is providing sufficient community benefits to justify tax-exemption. Likewise, given the competitive nature of many non-profit hospitals, a more even distribution of community benefits is necessary to prevent the providers that are acting most charitably from being disadvantaged. Nonetheless, evaluations of community benefits are limited by the ambiguous definition of what community benefits actually constitute.

IV. Uncertain Definition of Community Benefits

There is significant uncertainty regarding what qualifies as community benefits and how to measure the activities that do qualify. A Government Accountability Office (GAO) report on non-profit hospitals found significant uncertainty on the qualifications and measurement of community benefits, partially due to the great variety of state standards.[152] The differences in hospital definitions of community benefits led to significant variations in the measurement of reported community benefits.[153] The GAO identified four main categories of community benefit: (1) charity care; (2) bad debt; (3) Medicare shortfalls; and (4) other activities.[154] Although charity care is clearly a community benefit, it is unclear whether the other three categories are included.[155]

A Congressional Budget Office (CBO) report came to substantially the same conclusion, finding little consensus on what qualifies as a community benefit.[156] Recognizing the difficulties in categorizing community benefits the report measured benefits as: (1) uncompensated care (charity care and bad debt); (2) provision of Medicaid-covered services; and (3) provision of specialized facilities (burn intensive care, emergency room care, high-level trauma care, and labor and delivery services).[157] The CBO includes Medicaid payment shortfalls because they are unprofitable for hospitals and serve a needy community so are analogous to a community benefit. The GAO, CBO, and IRS reports all include various shortfalls resulting from underpayment of services by government sponsored insurance as community benefits.[158] The IRS report found that forty-four percent of responding hospitals included bad debt as a community benefit and fifty-one percent included private and public insurance shortfalls.[159] The inconsistency in reporting bad debt and shortfalls as community benefits argues for a more definite inclusion of these categories. Because it is unlikely that hospitals not reporting bad debt or shortfalls did not experience them, an accurate assessment of whether the hospitals provide adequate community benefits requires a more uniform definition.[160]

Payment shortfalls from means-tested government programs, like Medicaid, are generally included as community benefits, but there is no consensus regarding shortfalls from non-means-tested programs, like Medicare.[161] Of the major industry groups the GAO examined, only two believed Medicare shortfalls should not count as community benefits, while the remaining groups believed Medicare shortfalls could count.[162] The Centers for Medicare and Medicaid Services (CMS) and the IRS have not taken a position on the issue, but do gather data concerning the amount of Medicare payment shortfalls and the IRS allows hospitals to explain why these costs should be included as community benefits.[163] PPACA specifically requires the Treasury Department to submit reports including the costs of both means-tested and non-means-tested programs as part of its reporting requirements on "levels of charity care."[164] The title implies that non-means-tested payment shortfalls could count as charity care, and therefore community benefits, but PPACA does not conclusively state one way or the other.[165] The GAO report found that Medicare payment shortfalls made up a substantial part of operating costs, ranging from 5.4 percent to 13.3 percent across the four states the report examined.[166]

Similarly, the inclusion of bad debt into community benefits lacks consensus. The Catholic Health Association (CHA) and the Veterans Health Administration (VHA) state that bad debt should not count as community benefits because the hospitals should instead identify patients eligible for charity care.[167] The Healthcare Financial Management Association (HFMA) does not precisely define bad debt as community benefits, but states hospitals should use more outside information to determine eligibility for charity care policies, as opposed to simply including bad debt as charity.[168] The AHA and several state hospital associations affirmatively include bad debt as community benefit because bad debt generally applies to patients that would otherwise qualify for charity care if the hospital had

the necessary information to make that determination.[169] As with non-means-tested payment shortfalls, the IRS includes bad debt in reporting, but does not include it as community benefits unless the hospital explains why parts of the costs should count as community benefits.[170]

The release of Schedule H ameliorated some of these problems by accounting for bad debt and Medicare shortfalls.[171] The IRS Exempt Organizations report split community benefits into four categories: (1) uncompensated care; (2) medical training; (3) medical research; and (4) community programs.[172] The report included bad debt and other shortfalls into uncompensated care. The significant variations between hospitals resulted in fourteen percent of hospitals providing sixty-three percent of uncompensated care.[173] Medical training and research expenditures increased vastly with the size of the hospital and generally corresponded to higher population areas.[174] Most medical research was concentrated in a group of fifteen hospitals.[175] Community health programs are the most open-ended category of community benefits.

Virtually all types and sizes of hospitals provide some form of community program as a community benefit, usually including immunization and health promotion.[176] These programs vary widely, but focus on education, prevention, and the encouragement of health.177 While these benefits were consistent across each type of hospital, overall community programs were the smallest expenditure of community benefits, though they most closely tie into prevention and health education in the community.178 With the expected increase in insurance coverage due to PPACA, hospitals should be encouraged to set up community programs to offset less need for charity care.[179] Community programs are by nature more apt to focus on preventative care and promote overall health.

The lesson is that, even with Schedule H, there remain disparities in the provision of community benefits and difficulties in defining what activities should count as a community benefit. Although the vast differences in types of hospitals and their serving communities argues against a one-size-fits all approach to requiring certain community benefits, it is necessary to come up with a concrete inclusion of community benefits to properly assess hospital compliance.[180] Bad debt and shortfalls should be included as community benefits because they represent expenses incurred by the hospital for the community's well-being and offset corresponding government expenses. Since Medicare is a government program, any shortfalls suffered by the hospitals necessarily offset some burden on the government, while bad debt typically represents a less formal method of charity care by forgoing payment.[181]

By allowing non-profit hospitals tax-exemption they presumably must differentiate themselves from for-profit hospitals through the provision of community benefits to show charitable purpose. Beneficial costs that are substantially shared with for-profit hospitals as operating costs necessary to do business do not differentiate non-profits from for-profits. Even operating costs can provide community benefits that should be encouraged and the non-profit structure forgoes certain financing that is available for their for-profit competitors.[182] The decline in charitable contributions exacerbates the problem with non-profit financing, as compared with for-profit.[183] When assessing bad debt and Medicare shortfalls one must take into account the degree they represent operating costs that are shared with for-profit hospitals and so by themselves do not justify tax-exemption as provision of community benefits.[184]

Costs shared with for-profit hospitals should not be dispositive in determining whether the expenditure amounts to a community benefit. As the CBO report indicates, expenditures on uncompensated care are only slightly less in for-profit hospitals than in non-profit, demonstrating that for-profit hospitals can and do provide community benefits that overlap with those provided by non-profit hospitals.[185] Some states require all hospitals to provide community benefits through licensure, resulting in similar behavioral incentives shared by for- and non-profit hospitals.[186] Costs shared between both sectors are hardly a reason to exclude such costs from a realistic recognition as community benefits. Doing so discredits admirable behavior by for-profit entities and does not accurately assess the real community benefits provided by any hospital.[187] Taken to extreme, this argument could include benefits such as employment, increased property value, and the like. But the standard of community benefits is in reference to the charitable purpose of providing public health and so relevant benefits should be limited to those directly providing, or otherwise bearing the costs of, public health.

Although a non-profit should be distinguished from a for-profit to justify its exemption, denying a genuine area of community benefit only distorts the measurement of benefit provided. Tax-exempt hospitals should provide greater or more effective community benefits, but benefit cannot be accurately measured by denying certain types.[188] The lack of a "hard" monetary minimum requirement of community benefits means that benefits provided can be assessed on a case-by-case basis, allowing the flexibility to adjust requirements upwards where the hospital appears to rely too much on questionable types of benefits, like bad debt and Medicare shortfalls.

The review of studies on the level of community benefits by tax-exempt hospitals demonstrates that, despite legitimate differences between types of hospitals and their communities, some hospitals bear a disproportionate amount of community benefit costs. Although there are legitimate causes for different levels of community benefits, including differences in the provider's financial situation and the opportunity for certain kinds of benefit, each hospital must justify its charitable tax-exemption through its individual activities. Since the exemption is from taxes the non-profit would otherwise have to pay, a financial inability to provide community benefits is insufficient to explain low amounts of community benefits.189 Differences in community needs are not sufficient to explain low levels of community benefits because reports demonstrate a wide variety of qualifying activities.190 Even if there is little need for charity care, other benefits like community outreach to increase preventative care would be beneficial to the community.[191] Particularly considering the PPACA, reducing the number of uninsured, and thus reducing the need for charity care, any definition of community benefit should be widely construed to include a variety of activities that can improve and maintain the community's health and well-being. [192]

The concern behind excluding these costs from community benefits is that it provides competitive advantage to non-profit entities and does not sufficiently distinguish non-profit behavior from for-profit behavior.[193] The simple fact of shared behavior between non-profit and for-profit hospitals ignores activity by for-profit hospitals that is clearly charitable, like charity

care.[194] Instead, bad debt and Medicare shortfalls can be approached as included, but not alone sufficient for determining community benefits. This approach recognizes the true significance of promoting community health and offsetting government costs, while acknowledging the concern of including operating costs shared with for-profit hospitals as community benefits. A non-profit hospital would still need to provide significant other benefits that a for-profit entity would not. The IRS approach, where these costs are reported but not included as community benefits without a specific explanation, effectively enacts this approach while placing the burden on the hospital to justify the costs as community benefits.[195] Having hospitals justify the inclusion as community benefits seems more effective since they are in the best position to report on their own operations.

It is unjustified for some hospitals to allow others to carry the financial burden and moral justification for a continuing tax-exemption. The remaining problem is to account for legitimate differences between hospitals and their communities, while preventing too large a disparity within types that is indicative of a few hospitals bearing the largest share of the burden.

V. A Flexible Approach to the Provision of Community Benefits

The wide variety in types of hospitals and communities served argues against the use of a one-size-fits-all approach to requiring a minimum level of community benefit. The most obvious example of this approach is in Texas, where the statute requires specific expenditures on charity in order to qualify for tax-exemption.196 By doing so, the State effectively requires a certain level of community benefit, regardless of the actual necessity within the community, potentially resulting in an inefficient use of resources to meet a non-existent need.[197] By requiring minimum levels of charity it may create incentives towards benefits that are more easily measurable, even if those benefits are not optimal to meet the community's needs.[198] By requiring a set amount, the statute potentially encourages over-reporting of community benefit, which is exacerbated in Texas by the lack of sufficient oversight and audit of hospital reporting.[199] This approach is criticized by the hospital industry because it does not sufficiently differentiate between types and organizations of hospitals and their communities.[200] The AHA states that, by approaching each individual hospital instead of the overall hospital organization, the IRS creates needless complexity and lessens the overall impact of the hospital organization's community benefits.[201] Simply requiring a set amount of community benefit risks distorts the most efficient and beneficial spread of resources by requiring a set amount that may not be most beneficial to the community.

A flexible description and requirement of community benefit is necessary to account for the disparities in hospitals and their communities; it also allows the providers, who are in the best position, the freedom to determine optimal types of community benefits. The disparities in community benefits indicates a strong need for minimum requirements of care, but a flexible approach to account for legitimate differences resulting in varying amounts of community benefit, while ensuring the hospital is not riding off the benefits provided by others.[202] This approach includes three main points: (1) a flexible description of community benefits, (2) reporting requirements, and (3) more versatile punishments for providers that fail to qualify.[203] This approach is reflected in a number of jurisdictions and to some degree is present in PPACA.

A flexible description of community benefits is most exemplified through the requirements in many states and the PPACA, instituting a "community needs assessment" that identifies the specific needs of the community.[204] A broad qualification for community benefits takes into account the great disparity in communities and hospitals and does not risk putting too much focus on a particular benefit that is disproportionate to its effect. Given the predicted increase in health insurance coverage, the traditional community need for free or discount care should decrease.[205] As the formerly uninsured are covered, the community need would change, arguing for a broader application of community benefits. A flexible description would allow for changing conditions. By weighing a broad description of community benefits on a case-by-case basis, the disparities in situations can be accounted for, while preventing insufficient benefit. For example, the largest research hospitals generally provide very little community benefit besides significant research, but clearly fall within tax-exempt standards.[206] Other hospitals may depend upon benefits like bad debt or payment shortfalls that are insufficient by themselves to qualify because they are part of the cost of doing business.[207] Although bad debt and shortfalls should count as community benefits because they aid the community and offset government costs, too great a dependence on "operating costs" and a corresponding minimal amount of other benefits should detract from charitable status.[208]

Reporting requirements are essential to ensuring sufficient community benefits to justify tax-exemption, but must be scrutinized to prevent discrepancies. The reporting requirements in Texas resulted in inconsistencies that lack sufficient oversight

> "Community programs are by nature more apt to focus on preventative care and promote overall health."

infrastructure to regulate, instead depending upon self-reporting.[209] Schedule H and the IRS can provide some oversight, while the lack of a specific minimum required community benefit should lessen the incentive to over-report.210

Enforcement of minimum community benefits requires a wider range of punishment beyond the extreme of invalidating tax-exemption. PPACA allows for an excise tax of up to fifty thousand dollars, providing greater flexibility to the enforcement of minimum community benefits standards.[211] Providing sanctions that are less extreme than revoking tax-exemption, allows an enforcement mechanism that can flexibly address possible insufficiencies, such as cases where the amount of benefits is not clearly insufficient. For example, a hospital may provide only a very small amount of expenditures on community benefits, but either faces significant financial difficulty or a community that does not need significant benefits beyond what the hospital already provides.[212] By allowing fines less extreme than total revocation of tax-exemption, it is possible to sanction insufficient community benefits in a manner more commensurate to the offense.[213] An excise taxes coincides with the subsidization rationale of exemption because fines can be tailored to subsidize the hospital relative to the benefit it did provide. Even if the benefit is not enough to justify an exemption, the excise tax effectively takes back that part of the exemption that was not justified.

VI. Conclusion

The evolution of the hospital system towards a commercial model has resulted in a changing justification of continuing tax-exemption. The prevailing community benefits standard raises issues both state and federal governments have addressed by requiring more stringent reporting requirements and ensuring a minimum level of community benefit. Recent reports show significant disparities in the provision of community benefits among hospitals and their communities that may indicate an unfair and inefficient distribution of benefits.[214] Any approach should account for the reality that each hospital must justify its exemption individually and should not ride on the efforts of others.[215] Any effort to require more stringent enforcement of the community benefits standard should account for the legitimate differences in communities and their hospitals through a flexible approach. A flexible approach to measuring and requiring certain levels of community benefit is necessary because it can account for the costs of providing a tax-exemption, while allowing for legitimate differences in the community needs these benefits address.

[1] Alice A. Noble, Andrew L. Hyams, Nancy M. Kane, *Charitable Hospitable Accountability: A Review and Analysis of Legal and Policy Initiatives*, 26 J.L. Med. & Ethics 116, 117 (1998).
[2] *See* 725 P.2d 1357 (Utah 1986) (rejecting automatic exemptions or minimal efforts at charity, ruling only that the specific taxpayer did not prove gift to the community sufficient for exemption).
[3] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 9007, 124 Stat. 119, 737-41 (2010).
[4] *See* Tex. Health & Safety Code Ann. § 311.045 (2009); *see also Provena Covenant Med. Ctr. v. Dep't of Revenue*, 894 N.E.2d 452 (Ill. App. Ct. 2008), *aff'd* No. 107328, 2010 Ill. LEXIS 289 (Ill. 2010).
[5] *See* Kevin M. Wood, Note, *Legislatively-Mandated Charity Care for Nonprofit Hospitals: Does Government Intervention Make any Difference?*, 20 Rev. Litig. 709, 713 (2001); *see also* Margaret A. Potter & Beaufort B. Longest, Jr., *The Divergence of Federal and State Policies on the Charitable Tax Exemption of Nonprofit Hospitals*, 19 J. Health Pol'y & L. 393, 396 (1994).
[6] The Statute of Charitable Uses, 43 Eliz. Ch. 4 (1601) (Eng.); *see also* Nina J. Crimm, *An Explanation of the Federal Income Tax Exemption for Charitable Organizations: A Theory of Risk Compensation*, 50 Fla. L. Rev. 419, 425 (1998).
[7] Crimm, *supra* note 6, at 425.
[8] William P. Gunnar, *The Fundamental Law that Shapes the United States Health Care System: Is Universal Health Care Realistic Within the Established Paradigm?*, 15 Annals. Health L. 151, 174-76 (2006).
[9] Gabriel O. Aitsebaomo, *The Nonprofit Hospital: A Call for New National Guidance Requiring Minimum Annual Charity Care to Qualify for Federal Tax Exemption*, 26 Campbell L. Rev. 75, 76 (2004).
[10] *Id.*
[11] *See id.*; *see also* Wood, *supra* note 5, at 713.
[12] *See* Gunnar, *supra* note 8, at 174-76.
[13] *Id.*
[14] *Id.*
[15] David A. Hyman, *The Conundrum of Charitability: Reassessing Tax Exemption for Hospitals*, 16 Am. J. L. and Med. 327, 336 (1990).
[16] *See id.*; *but see* Lawrence E. Singer, *The Conversion Conundrum: The State and Federal Response to Hospitals' Changes in Charitable Status*, 23 Am. J. L. and Med. 221, 221-222 (1997) (concerning a trend in hospitals to convert from non-profit to for-profit status to take advantages of increased capital).
[17] *See* Eugene Steuerle, *A Method for Measuring and Partially Testing 'Charitability,'* TAX NOTES, July 30, 2007, at 393-94, *available at* http://www.urban.org/publications/1001097.html.
[18] American Hospital Association, Fast Facts on US Hospitals (2009), http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html; *see also* Cong. Budget Office, Nonprofit Hospitals and the Provision of Community Benefits, , 12 (Dec. 2006).
[19] CBO, *supra* note 18, at i, 8 (finding an average expenditure on uncompensated care by nonprofit hospitals of 4.7% of operating costs and an average of 4.2% of operating costs by for-profit hospitals).
[20] *See id.*
[21] I.R.C. § 501(c)(3) (2010).
[22] Rev. Rul. 69-545, 1969-2 C.B. 117.
[23] *See* Aitsebaomo, *supra* note 9, at 82-83 (discussing that the factors depend upon the circumstances and are not necessarily determinative).
[24] Rev. Rul. 83-157, 1983-2 C.B. 94.
[25] Rev. Rul. 69-545, 1969-2 C.B. 94.
[26] Treas. Reg. § 1.501(c)(3)-1(a) (2010); *see also* Noble, *supra* note 1, at 118.
[27] Treas. Reg. § 1.501(c)(3)-1(a); *see also St. David's Health Care Sys. v. United States*, 349 F.3d 232, 234 (5th Cir. 2003).
[28] *See* 349 F.3d at 234; *see also* Treas. Reg. § 1.501(c)(3)-1(a).
[29] Treas. Reg. § 1.501(c)(3)-(d)(2) (2010).
[30] *Id.* at (e)(1).
[31] *Id.* at (e)(2).
[32] *See Utah County v. Intermountain Health Care, Inc.*, 709 P.2d 265, 267 (Utah 1985); *see also* Aitsebaomo, *supra* note 9, at 84-85.
[33] *See* Aitsebaomo, *supra* note 9, at 84-85.
[34] *Bob Jones University v. United States*, 461 U.S. 574, 591 (1983); *see also IHC Health Plans, Inc. v. Comm'r*, 325 F.3d 1188, 1195 (10th Cir. 2003).
[35] 709 P.2d at 276-77.
[36] *See* Crimm, *supra* note 6, at 425.
[37] Declines in charitable donation and the rise of third-party payment makes modern non-profit hospitals operate much like a commercial enterprise and like their for-profit competitors. *See Utah County*, 709 P.2d at 270-72.
[38] *See* Crimm, *supra* note 6, at 429-30.
[39] *See id.*
[40] *See id.* at 462.
[41] *See Bob Jones University*, 461 U.S. at 591; *see also IHC Health Plans* 325 F.3d 1194.
[42] *See* Hyman, *supra* note 15, at 330-336.
[43] *See id.* at 336.
[44] *See Utah County*, 709 P.2d 265; *see also* Provena Covenant Med. Ctr. V. Dep't of Revenue, 925 N.E.2d 1131 (Ill. 2010); Stephanie Strom, *States Move to Revoke Charities' Tax Exemptions*, N.Y. Times, February 28, 2010, at A21.

[45] *See* Noble, *supra* note 1, at 119.
[46] U.S. Gov't Accountability Office, GAO-08-880, Nonprofit Hospitals Variation in Standards and Guidance Limits Comparison of How Hospitals Meet Community Benefit Requirements 16 (2008).
[47] *See id.*
[48] *See id.*
[49] Pub. L. No. 111-148, 124 Stat. 119-1025.
[50] *See Provena Covenant Med. Ctr.*, 925 N.E.2d 1131; *see also* Noble, *supra* note 1.
[51] *See* Tex. Health & Safety Code Ann. § 311.045 (West 2009); 210 Ill. Comp. Stat. 89/1 (2010); *see also Utah County*, 709 P.2d 265.
[52] *See* Strom, *supra* note 44; *see also* James Drew, *Call for Hospital Reform Widens*, Baltimore Sun, February 23, 2009, at 1A.
[53] *See Provena Covenant Med. Ctr.*, 925 N.E.2d 1131.
[54] Tex. Health & Safety Code Ann. § 311.045.
[55] 709 P.2d 265.
[56] Utah Const. Art. XIII, § 2; *see also Utah County*, 709 P.2d at 267.
[57] *See Utah County*, 709 P.2d at 277.
[58] *See id.*
[59] *See id.* at 267.
[60] *See id.* at 268.
[61] *See id.* at 270-71.
[62] *See id.* at 271-73 (rejecting the argument that third-party payment makes philanthropic hospitals an anachronism because the development of third-party payment is a major cause of the erosion of the difference between non-profit and for-profit hospitals).
[63] *See Utah County*, 709 P.2d at 275.
[64] *See id.*
[65] Tex. Health & Safety Code Ann. § 311.045; *see also* Wood, *supra* note 5, at 722-24.
[66] Tex. Health & Safety Code Ann. § 311.045.
[67] *Id.*
[68] *See* Wood, *supra* note 5, at 733-735 (noting the reported increase in care after the statute was enacted is in contrast to the actual substantive effect).
[69] *Id.*
[70] Internal Revenue Service, IRS Exempt Organizations (TE/GE) Hospital Compliance Project Final Report (2009).
[71] *See* Wood, *supra* note 5, at 730-34.
[72] *Provena Covenant Med. Ctr. v. Dep't of Revenue*, 925 N.E.2d 1131, 1131, 1140 (Ill. 2010).
[73] *Id.* at 1135-36.
[74] *Provena Covenant Med. Ctr. v. Dep't of Revenue,* 894 N.E.2d 452, 456 (Ill. App. Ct. 2008), *aff'd* 925 N.E.2d 1131 (Ill. 2010).
[75] 35 Ill. Comp. Stat. 200/15-65 (2010); *see also* 925 N.E.2d at 1145.
[76] 925 N.E.2d at 1135.
[77] *Id.*
[78] *Id.* at 1138.
[79] *Id.* at 1140.
[80] *Id.* at 1143-45.
[81] *Methodist Old Peoples Home v. Korzen*, 233 N.E.2d 537, 541-42 (Ill. 1968); 925 N.E.2d at 1145.
[82] *See* 925 N.E.2d at 1145.
[83] *Id.*
[84] *Id.*
[85] 894 N.E.2d at 469, *aff'd* 925 N.E.2d at 1131.
[86] 925 N.E.2d at 1147-48.
[87] *Id.* n.10.
[88] *Id.* at 1148-49; *People ex rel. Cannon v. Southern Illinois Hospital Corp.*, 88 N.E.2d 20 (Ill. 1949).
[89] 925 N.E.2d at 1148-49.
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] *See id.* (explaining that the state requirements for a charitable purpose must be distinguished from the federal community benefits standard that is used to show a charitable purpose and that in consideration of Illinois' recognition of the subsidization rationale, the local government does not entirely, or at all, bears the costs of Medicaid and Medicare).
[94] *Id.* at 1153-54.
[95] *Id.*
[96] IRS, *supra* note 70, at 1-2.
[97] *Id.* at 147.
[98] *Id.* at 149.
[99] *Id.*
[100] *See id*. (clarifying that Schedule H allows for hospitals to explain why bad debt and Medicare shortfalls should be treated as community benefits).
[101] *Id*. at 147.
[102] *Id.* at 147-48.
[103] *See* American Hospital Association, AHA Seeks Modification from IRS on Community Benefit Reporting (Mar. 5, 2010), *available at* http://www.aha.org/aha/press-release/2010/100305-pr-schedH.html. (urging the IRS to improve the Schedule H to reflect the benefits that nonprofit hospitals provide to their communities).
[104] Pub. L. No. 111-148, § 9007, 2010 Stat. 1, 737-38.
[105] *Id.*
[106] *Id.*
[107] GAO, *supra* note 46, at 52-56 (Appendix III).
[108] Pub. L. No. 111-148, § 9007, 2010 Stat. 1, 737-38.
[109] *Id.*
[110] *Id.*
[111] *See* IRS, *supra* note 70, at 6-8 (explaining the different ways non-profit hospitals could meet the community benefits requirements).
[112] Pub. L. No. 111-148, § 9007, 2010 Stat. 1, , 856.
[113] *Id.* at 857.
[114] *See* 925 N.E.2d at 1140.
[115] Pub. L. No. 111-148, § 9007, 2010 Stat. 1, 857.
[116] *Id.*
[117] *See id.*
[118] *See id* at 856-57.
[119] *See* AHA, *supra* note 103.
[120] *See id.*
[121] Pub. L. No. 111-148, § 9007, 2010 Stat. 1, 857.
[122] *See* IHC Health Plans, Inc. v. Commissioner, 325 F.3d 1188, 1194-95 (10th Cir. 2003).
[123] *Id.* at 1194.
[124] Treas. Reg. § 1.501(c)(3)-1(d)(2).
[125] *See* IHC Health Plans, 325 F.3d at 1195-97; *see also* Rev. Rul. 98-15, 1998-1 C.B. 718 (stating that "not every activity that promotes health supports tax exemption under § 501(c)(3)").
[126] IHC Health Plans, 325 F.3d at 1197-98.
[127] *See id.* at 1197-98.
[128] *See id.* at 1201-02.
[129] *See id.* (recognizing the 'integral-part doctrine' but declining to rule on its application, because the Health Service and the petitioner lack a nexus of activities).
[130] *See id.* at 1203.
[131] *See* IRS, *supra* note 70, at 4 (finding that aggregate community benefits expenditures were unevenly distributed and "concentrated in a relatively small group)."
[132] *Id*. at 1.
[133] *Id.* at 3.
[134] *Id.*
[135] *Id.* at 6.
[136] *Id.*
[137] *See id.*
[138] *See id.*
[139] *See id.*
[140] *See id.*
[141] *See id.*
[142] *Id.* at 12-14 (explaining that critical access was defined through certification with the Centers for Medicine and Medicaid Services (CMS), and which typically referred to rural hospitals without other hospitals nearby, or otherwise designated as critical access by the relevant state).
[143] *Id.* at 6.
[144] *See id.*
[145] *See id.*
[146] *See id.*
[147] *Id.*

[148] *See id.*
149 *See id.*
[150] *Id.*
[151] *Id.* at 4, 3
[152] GAO, *supra* note 46, at 7.
[153] *See id.* at 19.
[154] *Id*. Bad debt refers to amounts owed to the hospital that has no probability of collection. Medicare shortfalls refer to unreimbursed costs associated with payment in the Medicare program. Other activities include a variety of donations and operations within the community to encourage health.
[155] *Id.*
[156] CBO, *supra* note 18, at 1.
[157] *Id.* at 9-10.
[158] *See id.*; *see also* GAO, *supra* note 46; IRS, *supra* note 70. Government sponsored insurance mostly consists of Medicaid, Medicare, and other smaller programs.
[159] IRS, *supra* note 70, at 153.
[160] *See* Ernst & Young LLP, American Hospital Association, Community Benefit Information from Non-Profit Hospitals, ii-iii (2006) (supporting uniformity in reporting, but acknowledging hospitals should be allowed to "tell their community benefit story").
[161] *See* GAO, *supra* note 46, at 24-25.
[162] *Id.*
[163] *Id.*
[164] Pub. L. No. 111-148, § 9007, 2010 Stat. 1, 739-41.
[165] *See id.*
[166] GAO, *supra* note 46, at 28.
[167] *Id.* at 20-22.
[168] *Id.*
[169] *Id.*
[170] *See id.; see also* IRS, *supra* note 70, at 149.
[171] *See* IRS, *supra* note 70, at 149.
[172] *Id.* at 6-8.
[173] *Id.*
[174] *Id.*
[175] *Id.* The fifteen research hospitals are relative to the 544 non-profit hospitals the IRS selected for the Hospital Compliance Project and not to all non-profit hospitals.
[176] *Id.* at 45. The IRS included the following as discrete types of community programs: lectures, seminars and education; medical screening; publications; improved access to care; immunization programs; other health promotion; and community needs studies. *See also* AHA, *supra* note 155, at 5-6. The AHA includes substantially the same initiatives as community programs.
[177] IRS, *supra* note 70, at 45; *see also* GAO Report, *supra* note 46, at 49-51 (Appendix II).
[178] IRS, *supra* note 70, at 7.
[179] *See* CBO, letter to the Honorable Nancy Pelosi, providing estimated budgetary and coverage effects of the reconciliation and PPACA, 9 (March 20, 2010), *available at* http://www.cbo.gov/doc.cfm?index=11379. The CBO estimates the number of uninsured will be reduced by 32 million by 2019, leaving 23 million still uninsured.
[180] *See* AHA, *supra* note 160, at ii-iii.
[181] *See* GAO, *supra* note 46, at 21; *see also* American Hospital Association, Uncompensated Care Cost Fact Sheet 2 (2009), *available at* http://www.aha.org/aha/content/2009/pdf/09uncompensatedcare.pdf (including bad debt as uncompensated care).
[182] *See* Singer, *supra* note 16, at 221-222.
[183] *See id.*
[184] *See id*.
[185] *See* CBO, *supra* note 18, at i.
[186] *See* GAO, *supra* note 46, at 66. Specifically, Rhode Island requires all licensed hospitals to comply with community benefits, charity care, and uncompensated care standards. Non-compliance can result in suspension or revocation of the license. Knowing violation or willingly giving the state false information regarding compliance carries potential fines of up to $1 million and a prison term of no more than five years.
[187] *See* CBO, *supra* note 18, at i. (finding an average expenditure on uncompensated care by nonprofit hospitals of 4.7% of operating costs and an average of 4.2% of operating costs by for-profit hospitals).
[188] Treas. Reg. § 1.501(c)(3)-1(c)(2). Regardless of their provision of community benefits for-profit hospitals are disqualified from tax-exemption on the grounds that their profits inure to private individuals, so the level of benefits for-profits provide is relevant here only for comparative purposes.
[189] But even if the entity was taxed, if it was financially unable to provide community benefits it would not likely have substantial corporate income tax liability. State taxes levied on non-income would still be liable even if the entity was financially unable, so the money saved would presumably go towards the charitable basis of the exemption.
[190] IRS, *supra* note 70, at 7.
[191] *See id.* at 45; *see also* GAO, *supra* note 46, at 49-51.
[192] *See* CBO, *supra* note 179. The CBO estimates the number of uninsured will be reduced by 32 million by 2019, leaving 23 million still uninsured.
[193] *See* Noble, *supra* note 1, at 130.
[194] *See* CBO, *supra* note 18, at i.
[195] *See* IRS, *supra* note 70, at 149; *see also* GAO, *supra* note 46, at 20-23.
[196] Tex. Health & Safety Code Ann. § 311.045 (West 2010).
[197] *See* Wood, *supra* note 5, at 734.
[198] *See id.* (noting that the Texas statute provides economic incentives towards certain types of reporting resulting in distortions in how hospitals report benefits).
[199] See *id.* at 735.
[200] *See id.* at 736-737.
[201] *See* AHA, *supra* note 103.
[202] *See* IRS, *supra* note 70, at 6-7.
[203] *See* Wood, *supra* note 5, at 734. (noting the enforcement problems with the Texas statute, which only allows full revocation of tax-exemption as punishment for failure to comply).
[204] *See* Pub. L. No. 111-148, § 9007, 2010 Stat. 1, 119, 855-859.
[205] *See* CBO, *supra* note 179 at 9. The CBO estimates the number of non-elderly uninsured will be reduced by 32 million by 2019, leaving 23 million still uninsured.
[206] *See* IRS, *supra* note 70, at 6-7.
[207] *See id.* at 7-8, 93-94; *see also* Wood, *supra* note 5, at 739.
[208] *See* GAO, *supra* note 46, at 5, 11-13. Noting the lack of consensus among government and industry groups whether Medicare and bad debt costs should count as community benefit, but acknowledging they reflect in some part benefits to the community. Nonetheless, such costs may also be part of underlying structural costs necessary to the operation of a modern hospital.
[209] *See* Wood, *supra* note 5, at 735.
[210] IRS, *supra* note 70, at 147.
[211] *See* Pub. L. No. 111-148, § 9007, 2010 Stat. 1, 119, 855-859.
[212] As stated earlier, financial inability does not excuse a non-profit hospital from providing sufficient community benefits to justify an exemption from taxes it would otherwise have to pay, but should be viewed in the context of the hospital's historical behavior. Furthermore, it does not behoove the community benefit to add additional stressors to what may simply be temporary financial difficulties.
[213] *See* Wood, *supra* note 5, at 734; *see also* Noble, *supra* note 1, at 131. (suggesting the implementation of sanctions against non-compliance).
[214] *See* IRS, *supra* note 70, at 6.
[215] IRS, *supra* note 70, at 8. The significant variations within community and hospital types indicate at least some hospitals are providing less community benefits than others without justification.

Health Law and Policy In the News

The Looming Crisis of Health Care

Jake Harper, First Year JD Candidate

Medicare represents the most critical revenue stream for doctors and hospitals throughout the United States. Medicare funding in 2008 was 20% of all federal spending, or $599 billion. Because the program is so heavily funded, it has attracted its fair share of abusers of the system.

The federal government has taken many reactive steps to address the surge of fraud and abuse in the Medicare system, reinforced by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA, while enacted to help protect private health information, also was designed to combat health care fraud. HIPAA allocated substantial funds to the Department of Health and Human Services (HHS) through the Health Care Fraud and Abuse Program to implement more effective anti-fraud measures. Currently, hundreds of millions of dollars are used to fight Medicare fraud. HHS has created special entities designed solely to address fraud over the past few years, including Recovery Audit Contractors, Program Safeguard Contractors and Zone Program Integrity Contractors and, as well, strengthened FBI and HHS fraud investigative units.

Why, then, is there still a crisis looming for our health care system? Simply put, these anti-fraud programs have also swept up many well-meaning providers during their reviews, driving legitimate doctors, clinics and hospitals out of business. Medicare contractors utilize data mining, where they review claims data to identify outliers. With a myriad of ways to review the data, nearly every provider can become an outlier in some respect. Once selected for review, a health care provider then undergoes the extremely difficult audit process, which may result in massive penalties and overpayments, or even complete exclusion from the Medicare program by the HHS Office of Inspector General. Many doctors fear these audits, and others are simply choosing to opt out of Medicare, thereby rejecting Medicare patients altogether. This trend is not only rising, but accelerating. With the federal government taking an even greater role in health care in the coming years, substantial reform in identifying and prosecuting fraudulent activities is warranted.

Electronic Medical Records: Too Much Too Soon?

Jake Harper, First Year JD Candidate

Electronic medical records (EMR) are the future of health care and undoubtedly will someday help improve the quality of care for patients. But before backing the full implementation of EMR, it is important to consider some of its shortcomings and inadequacies.

The most startling concern for both patients and providers is the potential breach of security and privacy to which EMR is susceptible. Americans have long feared the unapproved use of their personal health information, a sentiment embodied in the HIPAA. Additionally, the widespread use of the Internet in recent years has led to a sharp increase in identity theft, particularly of medical information. With EMR emerging as the preferred choice for medical documentation, those involved must first be sure that the system is adequately secure. This becomes especially problematic when attempting to integrate the security and compatibility of numerous independently-developed software platforms. While the HHS Office of the National Coordinator for Health Information Technology is expected to remedy this problem, EMR is currently easy for unauthorized individuals to access. Moreover, EMR multiplies the number of people with access to a patient's records (providers, clinics, hospitals, billers, insurers and auditors) from about 120 interventions with paper records to over 600,000 through EMR. Until these privacy problems are addressed, patients and doctors alike should remain cautious about the use of EMR.

Aside from the privacy issue, the cost-benefit of EMR has not been affirmatively established, especially for individual doctors and clinics. While billions of dollars in savings have been projected through the implementation of EMR, the costs of purchasing, training and beginning "meaningful use" of EMR are generally too high for individual providers. Though the government has incentivized the program to some extent through the HITECH Act, part of the ARRA (the stimulus law), the current rewards and penalties are insufficient for doctors to justify the cost, even from a purely economic standpoint. Until standard

programs and procedures for EMR are established, with little to no upfront cost to those mandated to use it, it is unlikely that the implementation of EMR will be as successful as proponents have forecasted.

The Children's Health Insurance Battle

Krista Maier, Third Year JD Candidate

The battle over children's health insurance coverage is in full swing. It began in September, when major health insurers, including WellPoint, CIGNA and CoventryOne, announced that they will no longer offer child-only plans. This announcement came days before the start of the Patient Protection and Affordable Care Act's (PPACA) prohibition against denying health coverage for people with pre-existing medical conditions. The insurance companies stated that uncertainty in the market and fear that parents will wait until their children get sick before buying health insurance led to the decision to drop these plans. Advocacy groups and the HHS believed, however, that the move was a way to avoid providing new policies for sick children.

In October, HHS Secretary Kathleen Sebelius struck back. In a letter to the National Association of Insurance Commissioners (NAIC), Sebelius criticized the arguments that the insurance companies are relying on to deny coverage to children, stating that they are "legally infirm" and inconsistent with the language of PPACA. Sebelius outlined other ways to counter potential adverse selection: the premise that, if only sick people buy health insurance, an insurance company's costs will increase greatly. Most of Sebelius' suggestions are temporary fixes until the state health insurance exchanges are up and running in 2014—including the suggestion that insurers may adjust rates for children's plans based on health status, a policy which will be prohibited by PPACA for new plans starting in 2014. Sebelius also urged states to continue to regulate "discrimination against children" with pre-existing conditions.

So now, the proverbial ball is back in the insurance industry's court. Time will tell whether they accept Sebelius's suggestions, or develop their own solution to the children's health insurance issue.

Controlled Substance Prescriptions Now Allowed in Take-Back Programs

Krista Maier, Third Year JD Candidate

According to a 2009 Department of Justice report, crimes associated with controlled prescription drugs have increased nationwide over the past five years. In addition, the Office of National Drug Control Policy reported that, in 2008, one-third of all new prescription drug abusers were between ages 12 and 17. In an effort to limit access to prescription drugs, many states have implemented their own drug disposal programs, also called "take-back" programs. Through these programs, the state collects and destroys unused or expired medications, limiting teens' access to these medications in their homes.

Even with such programs in place, abuse of controlled prescription drugs continues to increase in the U.S. This is due in part because these programs generally do not accept controlled substances, such as amphetamine, morphine and codeine, as federal law requires special permission from the Drug Enforcement Administration and full-time police officers to receive the medication. To address this, President Obama signed into law the Secure and Responsible Drug Disposal Act of 2010 (S.3397). This law modifies existing controlled substances law, allowing people who have legally obtained a controlled prescription drug to bring that drug to a disposal program without advance permission. The law requires the Attorney General to provide regulations for controlled substance take-back programs, considering both public health and safety, and also the costs of implementing such programs.

In addition, the law allows long-term care facilities to dispose of their residents' controlled substances on their behalf, subject to guidelines from the Attorney General. Finally, the law also allows people who are authorized to dispose of a decedent's property to bring the decedent's controlled prescription drugs to a take-back program.

The "Stem Cell Age"

Kirsten Tullia, Second Year JD Candidate

With the first FDA license to use cell-based treatment in hand, Geron, a pharmaceutical and biologics manufacturer, began treatment on the first patient to receive human embryonic stem cells on October 11, 2010. Although Geron has not released many details concerning the procedure, the basic premise is that patients with spinal cord injuries will be injected with oligodendrocyte precursor cells, grown from human embryonic stem cells, in the hope that these new cells will regenerate damaged tissue. In this early phase of stem cell treatment, the aim is to determine the safety of the procedure rather than its efficacy.

This procedure is not without its risks, however. Embryonic stem cells are undifferentiated "master cells," leaving them capable of becoming any of the hundred of cell types in the human body –including cancer cells. Early tests using embryonic stem cells to treat Parkinson's disease met a grisly end when the cells reproduced at an uncontrolled rate and actually worsened the patients' muscle control problems. In order to lower the risk of unmitigated growth, Geron's researchers first ensured that the cells were differentiated into normal tissue before giving them to patients.

There are also important policy implications in embryonic stem cell implantation. Critics of embryonic stem cell research believe it is wrong to use an embryo to obtain the cells. President George W. Bush placed strict limitations on their use during his presidency. President Barack Obama loosened these limitations just weeks after he took office, allowing researchers to use embryonic stem cells from human embryos left over from fertility treatments.

Despite the controversial nature of the treatment, embryonic stem cell treatment is a huge step forward for those who suffer from degenerative diseases such as Parkinson's and muscular dystrophy. As Professor Pete Coffey of University College London said, "There are still many years of rigorous testing ahead and there will be setbacks and failures before we have safe and effective cell-based therapies. But this first in man study marks the dawn of the 'Stem Cell Age'."

Privacy in Hospital Rooms

Kirsten Tullia, Second Year JD Candidate

In response to a growing patient demand for private rooms, a number of local Washington, DC, area hospitals have already converted or are in the process of converting their facilities to all private rooms. One notable entity pushing for private patient rooms is Inova Fairfax Hospital, the largest hospital in Northern Virginia and the only Level 1 trauma unit in the Northern Virginia area. Inova Fairfax's expansion calls for a new general hospital tower comprised of private rooms and a new women's hospital. These renovations will cost approximately $161 million dollars, which Inova Fairfax plans to fund through debt and some use of cash reserves. Interestingly, however, this building expansion will not drastically increase the capacity of these already large hospitals. Inova Fairfax's construction plan, for example, will cost approximately $161 million dollars but only will produce about 174 new private rooms.

Hospital officials presented many different reasons for these changes, including fewer cases of infection and more space for medical equipment. Roger Urlich from Texas A&M University has a different opinion: "The attitude of viewing patients as objects has shifted. Hospitals are now in the consumer service business." With the passage of the Patient Protection and Affordable Care Act last winter and its first provisions coming to life just a few months ago, the American public is quickly becoming more versed in health issues, and is demanding more from its providers as a direct result of this knowledge. While the push for private rooms predates the Affordable Care Act, we can expect to see more action on the part of health care providers as they rise to the challenge of the new American health care consumer.

A Provision of Health Care Reform: Positive or Negative For People with Disabilities?

Gary C. Norman, Esq., LLM Candidate

The Patient Protection and Affordable Care Act of 2010 (PPACA) spurs the federal government into action by requiring a rulemaking on health care service delivery for people with disabilities by The Architectural and Transportation Barriers Compliance Board (commonly known as The U.S. Access Board). Section 4203 of the PPACA requires the promulgation of a new subsection of the Rehabilitation Act of 1973 to address the barrier of inaccessible diagnostic medical equipment.

The Board must promulgate standards on medical diagnostic equipment within twenty-four months after enactment, in consultation with the Food and Drug Administration and in accordance with the Administrative Procedures Act. Under the new standards, to the maximum extent possible, people with disabilities should be able to independently utilize—transfer to and from, enter and exit from—an array of examination chairs and tables in medical settings such as hospital emergency rooms. Mammography equipment is an example of the type of equipment specifically mentioned in the provision. Women with disabilities, especially mobility impairments, have also historically been victims of inaccessible gynecological exam equipment.

The requirements under section 4203 of the PPACA help to reveal a gap in current health care service delivery to more than fifty-four million citizens. Once these standards are enacted it will not a priori mean that providers will comply. Currently, the PPACA contains insufficient enforcement authority. Lacking is a clear indication of who has enforcement authority; as well, the PPACA does not provide sufficient appropriations for training on the standards. Since the PPACA designates the U.S. Access Board to formulate accessibility standards, many presume that the Board will also have enforcement authority on such standards. However, the Board is not an agency, and is best described as an advisory body or an information clearinghouse on accessibility issues. If the Board does not become the enforcement authority the next logical choice is the Office of Civil Rights at the United States Department of Health and Human Services.

Only time will tell if these standards constitute a valuable mechanism for improving the quality of health care for people with disabilities.

WASHINGTON COLLEGE OF LAW
AMERICAN UNIVERSITY

FOUNDERS' CELEBRATION 2011

Personalized Medicine: Ethics, Privacy, DNA & The Future of Medicine

February 15, 2011, 10:00am-3:00pm

Sponsored by: Health Law and Policy, Program on Law and Government; Health Law and Justice Initiative; and Health Law and Policy Brief

Personalized medicine is poised to be one of the next key fronts in helping to improve the quality and efficiency of our health care system and over the next few years the topic will continue to receive unprecedented exposure as new studies reveal the strengths - and weaknesses - of such an approach. This event will discuss the difficult questions that must be asked and answered by the law and policy community as this new form of medicine gains traction throughout the country.

Panels:

Personalized Medicine: Possibilities, Hurdles, Practical Solutions: The panel will provide an introduction to personalized medicine and provide a backdrop for the remainder of the conference re: legal challenges of implementation, possible solutions, and questions that must be answered to move forward.

Ethical and Privacy Considerations of Personalized Medicine: The panel will discuss the many complex ethical and privacy questions that personalized medicine brings to the forefront, both from a legal and practitioner perspective.

Moving Forward: The Goals of Personalized Medicine and Consumer Participation: The panel will wrap up the key issues for personalized medicine in the years to come, as well as provide a platform for issues relating to consumer participation and the remaining legal hurdles that consumers face before personalized medicine can truly become part of the everyday health care experience.

Speakers/organizations to be represented on the panel(s):
Moderator: Professor Corrine Parver, Practitioner-in-Residence and Executive Director, Health Law and Policy, Program on Law and Government.
Benjamin E. Berkman, JD, MPH, Deputy Director, Bioethics Core, National Human Genome Research Institute; Sharon F. Terry, President & CEO, Genetic Alliance.

Also Invited: Select DC Law Firms; Think Tanks and Policy Organizations with expertise in implementation challenges; Government Officials (HHS General Counsel, Office of the National Coordinator for HIT, OMB Health Reform).

RSVP: secle@wcl.american.edu

Health Law & Policy Institute Summer Session

June 20—June 30, 2011

Courses:

- *Medicine for Lawyers*
- *International Health and Human Rights*
- *Legal Issues in Health Care Fraud and Abuse*
- *Fundamentals of Health Law*
- *Genetics*
- *Bioethics*
- *Intellectual Property and Health Care*
- *Pharmaceuticals and the Law*
- *Health Care Compliance and Governance*

American University Washington College of Law announces the fourth annual summer ***Health Law and Policy Institute***. The ***Institute*** will provide J.D. and LL.M. students with training in a broad spectrum of health law and policy topics. Custom-developed courses taught by lawyers from private practice, health care organizations, government, and non-governmental organizations will provide an intensive learning experience. The ***Health Law and Policy Institute*** is designed for students who want to practice health care law, and offers training in theoretical and practical aspects of health law and policy. WCL'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. Guest lectures, panel discussions, and other activities involving leading health care attorneys from governmental and non-governmental Washington, D.C., will provide ***Health Law and Policy Institute*** students with dynamic learning and networking opportunities. ***Institute*** staff will act as a liaison to select participants interested in learning about internships/externships. For further information, visit our web site at:

www.wcl.american.edu/go/healthlaw

Phone: 202-274-4136
Fax: 202-730-4709
E-mails: health@wcl.american.edu;
cparver@wcl.american.edu

WASHINGTON COLLEGE OF LAW
AMERICAN UNIVERSITY

Health Law and Policy

Program on Law and Government

Bringing together lawyers from across the country and other nations, the Health Law and Policy Program utilizes lectures, group exercises, and practical simulations in the education of its students. WCL distinguishes itself with a pragmatic approach to health law, offering a distinctive, well-designed curriculum focused on providing students the skills needed for future practice, taught by expert faculty.

JURIS DOCTOR

Students may select their courses from several educational tracks during their studies at WCL. The tracks follow growing health law specializations with focus on potential career paths. Students also have the option to create their own program based upon their interests.

LL.M. Health Law Specialization

The law school's LL.M. Program on Law and Government offers a Master of Law with a specialization in health and policy. For more information, visit

http://wcl.american.edu/llmlawandgov

Legislative/Regulatory Health Law and Policy

Current Trends in American Health Policy

Health Care Legislative and Regulatory Process

Food and Drug Law

Administrative Law

Advanced Problems in Administrative Law and Regulatory Policy

AIDS and the Law

Bioethics

Disability Law and Disability Rights Clinic

Elder Law: Policies and Practice

Federal Regulatory Process

Genetics

Health Law

Lobbying and the Legislative Process

Public Health

Psychiatry and the Law

Regulatory Law and Policy

Reproductive Rights

Health Care and Business Law

Health Law

Legal Issues in Health Care Fraud and Abuse

Advanced Corporate Law

Antitrust

Biotechnology

Business Associations and Corporate Law

Corporate Bankruptcy

ERISA/Pensions, Employment and Labor law

Federal Corporate Income Tax Law

Health Care Compliance and Governance

Insurance Law

Intellectual Property, Patent Law and Access to Medicines

Medical Malpractice/Liability

Medicine for Lawyers

Mergers and Acquisitions

U.S. Patent Law

International Health and Human Rights

Economic, Social and Cultural Human Rights

Global Health and Comparative Health Systems

jkkkHealth Law

Human Rights

Intellectual Property, Human Rights and Development

International Business Transactions

International Health and Human Rights

International Health Care Organizations

International Humanitarian Law

International Trade Law

Public Health

AMERICAN UNIVERSITY
WASHINGTON, DC

American University Washington College of Law
4801 Massachusetts Avenue, NW
Washington, DC 20016

To submit an original article for possible publication in future issues of *HLP*, please email your article to hlp@wcl.american.edu, or mail a hard copy of your submission to *Health Law & Policy*, American University Washington College of Law, 4801 Massachusetts Avenue, NW Washington, DC 20016. Please submit your article in doubled-spaced paragraph format using Times New Roman, 12 pt. font. Additionally, please submit a short cover letter containing all authors' contact information, including home addresses, telephone numbers, and email addresses.

AMERICAN UNIVERSITY
WASHINGTON
COLLEGE OF LAW