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Letter from the Editors

Dear *Health Law & Policy* Reader:

On behalf of the Editorial Board and staff, it is with great enthusiasm that we present the third issue of Health Law & Policy. This issue is particularly special to us as it marks the end of our role as Co-Editors-In-Chief, a position we have proudly and enthusiastically held since the inception of this publication in the Spring of 2007. When we first introduced Health Law & Policy to the American University Washington College of Law (WCL) and the Washington, DC community last year, we could only hope that Health Law & Policy would become the substantive publication that we now present to you.

Given the rich political discussions that have been occurring the past few months, we wanted this issue of Health Law & Policy to truly capture the pulse of the vast array of legal developments, policy issues, and avant garde bioethical questions currently being discussed in the health care arena. Thus, in our effort to further enrich the breadth of Health Law & Policy's offerings, we sought to compliment the traditional array of practitioner- and student-written articles offered in this issue by including three pieces written from diverse perspectives of a political science scholar, a practicing physician, and a Lieutenant in the U.S. Marine Corps. Specifically, our third issue opens with the transcript of a keynote speech on physician-assisted suicide given by renowned Professor Raphael Cohen-Almagor at the Washington College of Law in January 2008, and is followed by an article presenting an innovative legal analysis of what is known as the ERISA "regulatory vacuum." This issue also presents two distinct analyses of physicians' obligations through articles addressing the potential implications of concierge medicine and the bioethical ramifications of patient-physician relationships in the military. Three authors writing for this issue tackle relevant issues in women's health through articles concentrating on access to reproductive health care in the context of hospital mergers, recent state approaches to HPV vaccine regulation, and the ethics of stem cell research and the potential for coercion when monetary compensation is involved. Finally, this issue includes an article that explores the varied perspectives held by members of the deaf community and analyzes the merits of different disability protections advocated for by the deaf.

As the old adage goes and this issue exemplifies, "the third time is a charm." Our dedicated readers may note this installment of Health Law & Policy is more than twice the length of the inaugural issue that hit the stands last spring. The length of this issue and the wide range of topics covered within serve as testaments to the ever-expanding interest in health care law held by WCL students and the legal world at large. Health Law & Policy is now distributed throughout the nation and our loyal reader base continues to grow with each passing issue.

We extend our genuine gratitude and thanks to our advisor, Professor Corrine Parver, for more than two years of dedication and guidance from the inception of this publication to its current success. We also graciously thank our past staff members for bringing this publication to its current success and our current staff members for their tireless efforts during the production of this issue. We sincerely hope that you enjoy this issue as much as we enjoyed putting it together, and we offer our very best wishes to the new executive board and staff in anticipation of many amazing issues to come!

Sincerely,

Georgiana Avramidis
Editor-in-Chief

Gabrielle A. Mulnick
Editor-in-Chief

The Right to Die with Dignity: An Argument in Ethics and Law

*Raphael Cohen-Almagor**

Raphael Cohen-Almagor

> This begs the question of whether we should die with the help of medical professionals or whether we should die with the help of our loved ones. It is a question of whether we can maintain our autonomy and self-respect at the end of life, without humiliation and without losing our honor and dignity.

My journey in the field of medical ethics has started in 1991. The major result of this journey is a book entitled: *The Right to Die with Dignity: An Argument in Ethics, Medicine, and Law*, which was published in 2001 (Rutgers University Press). The journey began when I participated in a seminar conducted by Ronald Dworkin on "Abortion, Dementia, and Euthanasia" at Oxford University, England. At the time, he was writing *Life's Dominion*, a book that was published in 1993 (Knopf). This was the most fascinating seminar I had ever attended. My research there took an unexpected twist and influenced my life and career in many ways, as I still commit some 30 percent of my research time to death, dying, and end of life issues.

I decided to title my book *The Right to Die with Dignity*. Dignity has many meanings. To have dignity means to look at oneself with self-respect, with some degree of satisfaction. Some of us, not all of us, would like to be able to determine the time of our death. We are born with no idea that we are about to come into this world and, in turn, some of us would like to decide the time in which we depart from this world. This is the argument that some people offer – that individuals should be allowed, whenever it is possible, to choose the time of their death.

Another issue I would like to discuss is the way that people die. Nowadays, many people die in hospitals, but that is not true in all countries throughout the world. In the Netherlands, many people die at home. This begs the question of whether we should die with the help of medical professionals or whether we should die with the help of our loved ones. It is a question of whether we can maintain our autonomy and self-respect at the end of life, without humiliation and without losing our honor and dignity. These are all questions we face at the end of life, especially when one considers the individuals who live with lingering diseases for months and even years, and are afflicted by certain kinds of cancers and other illnesses we are currently unable to cure.

Life *qua* life is not that important; instead, what one does with one's life is significant. Life in earnest is important, not just the mechanical forces that define life in the provincial meaning of the term. This is the argument offered by individuals who want to control the time of their death. The fact that one's heart is beating or that one is able to breathe are not sufficient reasons to maintain life. You must try to reconcile the duty of keeping a person alive – a duty bestowed upon medical professionals through the Hippocratic Oath – with the individual's right to keep her dignity, which may also be considered to have intrinsic value.

We face a dilemma. Suppose there is a person who suffers great pain and wants to die. Those who believe life is intrinsically valuable object to taking life and to taking any action on the person's desire because the end of life is something granted only to nature, and is not a decision that is incumbent on human beings. However, this objection ignores the autonomy of the agent's concerns, because she might say: "I would like to die. I would rather die in these circumstances because I don't feel that I am adding anything just by surviving." Can life be intrinsically valuable independent of the interests of the individual? Does the state have the right to impose its will over the will of the individual? This is the dilemma we face.

I would like to introduce another notion that accompanies the notion of dignity— the notion of respect. The objections to the sanctity of life moral that speaks about a higher being or nature as the only agent entitled to take life is accompanied by a respect-for-others' argument, derived from Immanuel Kant and the Kantian theological school which accords all people equal respect. Respect for a person means conceiving of the other as an end rather than as a means to something. As Kant explains, persons are not merely subjective ends whose existence has an effect on our actions, but such beings are objective ends; they exist as ends in themselves. An objective end, Kant maintains, is one for which there can be substituted no other end, for otherwise nothing of absolute value would be found anywhere.

We should give equal consideration to the interest of others and grant equal respect to a person's life

* Keynote presentation given by Raphael Cohen-Almagor, D.Phil., during "The Right to Die with Dignity: An Argument in Ethics and Law" lecture held during a symposium presented by the *Health Law Project, Program on Law and Government,* at American University Washington College of Law on January 30, 2008. Professor Cohen-Almagor is the Chair in Politics at the University of Hull in England and is currently a Fellow at the Woodrow Wilson International Center for Scholars in Washington, DC. He would like to thank Professor Corrine Parver for inviting him to speak on this important societal topic.

objects so long as they do not deliberately undermine the interests of others by interfering in a disrespectful manner. The popular culture of a democratic society is committed to seeking the influence of social cooperation that can be discerned on the basis of mutual respect between free and equal individuals. This line of reasoning should be supplemented by our emphasis on the notion of concern, which is seen as the value of well-being. We ought to show equal concern for each individual's good, to acknowledge that human beings are not only rational creations but irrational, emotional creatures. Treating people with concern means treating them with empathy – viewing people as human beings who may be furious and frustrated while, at the same time, are capable of smiling and crying, of careful decision-making, and of impulsive reactions. Concern means giving equal weight to a person's life and autonomy. This is a combination of mind, body, and communication between the agent and those around her bed.

In opposition to those who speak about the sanctity of life, there is another school of thought that emphasizes quality of life. Quality of life in many respects has positive connotations, for example in rehabilitation, in cosmetic treatments, in psychiatry, and in psychology. However, when discussing end-of-life issues, ethicists who support euthanasia and physician-assisted suicide (PAS), often refer to quality of life in a negative sense rather than in a positive sense; they do not seek to improve the patient's life, but rather to end it because the individual's quality of life is so poor. Quality of life considerations feature in end-of-life discussions, both in scholarly settings and in hospitals corridors.

I am a political scientist. I do not believe in pure philosophizing and being aloof from reality. Thus, after learning and studying what has been done in end-of-life care in the democratic world, I carried out fieldwork in hospitals and research centers. I should say that my conclusions are confined to the democratic world. I am not concerned with all countries around the world, not because I don't think that what I am saying is inappropriate or irrelevant to the entire world, but simply because I am realistic. If a country is not founded on the notions of equality, liberty, pursuit of happiness, individuality, and autonomy, then it would be futile for me to speak about these values. I can speak endlessly, but it would not strike any chord.

An Examination of Various Countries' End of Life Laws

In 1996, the Australian Northern Territory, comprised of mainly native Australian-indigenous people, enacted a law that allowed PAS in that province. For six months, this law was in operation, evoking a lot of criticism and debate in Australia at large. After six months, the national Senate of Australia decided to strike down and annul the law. During that period of time, a few people were put to death with PAS. For a short period of time, however, Australia's law created an important precedent.

As background, euthanasia, according to the Dutch definition, is the deliberate ending of life by taking action, usually by injection, to the veins of the patient, in order to kill him or her. PAS gives the control to the patient rather than the doctor. The doctor prescribes a certain lethal medication that can be put into yogurt or pudding, and the patient can ingest the yogurt with the lethal medication and kill herself. The major difference between the two is that, with euthanasia the doctor is in control, but with PAS, the patient is in control.

In England, there is no law allowing either PAS or euthanasia. There had been a few precedents with people in persistent unawareness, people with conditions similar to that experienced by Terry Schiavo. Most recently in the United Kingdom, there was the case of Diane Pretty, a woman in her fifties who suffered from ALS (Lou Gehrig's Disease), a degenerative disease which spreads from the limbs up, and eventually suffocates the patient. Unfortunately, this terrible illness is deadly and untreatable. Diane Pretty attempted to change the country's laws so that she could end her own life with the help of a doctor, and her case went all the way to the House of Lords (*Queen on the application of Dianne Pretty v. Director of Public Prosecutions and Secretary of State for the Home Department* UKHL 61 (29 November 2001)) and later to the European Court of Human Rights, where it was ultimately unsuccessful. The European Court of Human Rights ruled that England could decide on these matters. At present, the position in England is that neither PAS nor euthanasia is permissible.

Most if not all 50 states in the United States had, at some point or another, initiatives to legislate end-of-life laws, either PAS or some sort of end-of-life mechanisms. All such laws, with the exception of one, have failed. There may be some further attempts in Maine, Vermont, and California, but only Oregon to date has enacted PAS legislation. Every year, Oregon publishes a very detailed report about the previous year. Since the legislation was enacted in 1997, the situation has been more than satisfactory. Oregon can serve as a model for other nations.

Canada does not have any laws on PAS or euthanasia. The most important precedent in the country took place in 1993, when Sue Rodriguez, another ALS patient

"Treating people with concern means treating them with empathy – viewing people as human beings who may be furious and frustrated while, at the same time, are capable of smiling and crying, of careful decision-making, and of impulsive reactions. Concern means giving equal weight to a person's life and autonomy."

seeking to end her life with the country's approval, appealed her case to the Supreme Court of Canada (*Rodriguez v. British Columbia (Attorney General)* [1993] S.C.J. No. 94). In a 5-4 decision, the Court decided not to grant her permission to receive PAS. In spite of the unfavorable decision, Ms. Rodriguez received PAS from an anonymous physician, and the case was closed because of lack of public interest. I spoke with three Canadian Supreme Court justices about her case. One of them, who sat on this judgment, a very respectable judge in the five-person majority, told me that this was the most difficult decision he had faced in his life.

Switzerland has taken the most interesting position on these end-of-life issues. Since the 1960s, several end-of-life organizations can be contacted to cater for assisted suicide. The end-of-life services do not need to be performed by a doctor; anyone can perform the service. Although most people might opt for a doctor, a relative (wife, husband, sister, brother, father, or mother) is permitted to assist the person seeking end-of-life services. In addition, the assistance is not provided in hospitals; rather, it is done wherever it is feasible to be performed. One of the leading supporting organizations, DIGNITAS, is actually renting places to provide end-of-life services. At one point, the organization was renting an apartment, but neighbors grew upset because they saw people coming in and bodies going out. They felt such occurrences were bad for the reputation of the building. Then the organization opted for hotels, but hotel managers also did not like the idea of guests coming in and corpses coming out, since it was damaging the hotels' reputation. I understand that, consequently, DIGNITAS provided its services in remote parking lots, which was fine according to the organization.

The Netherlands and Belgium have legislation permitting euthanasia. Euthanasia has been popular in the Netherlands since the early 1970s, so it has almost 40 years of experience with euthanasia. Similar developments took place in Belgium, and relevant laws were passed in both countries in the span of six months during 2002.

I would like to highlight some of the concerns I have with regard to these two countries. When I wrote *The Right to Die with Dignity*, it was clear to me that I could not write this book without paying attention to the Netherlands. When I started my journey, I was very much in favor of euthanasia. Ethically speaking, I was convinced of the importance of euthanasia. As a political scientist, however, I had to examine the actual practice of euthanasia on the ground.

In 1994, I was invited to The Hastings Center in upstate New York, which is a great place for people interested in medical ethics. The Hastings Center is a relatively small institute with vast resources on medical ethics. For six weeks I read many journals and books about Dutch euthanasia. I was puzzled before I started; I was even more puzzled when I ended this seven-week-long research excursion.

The data about the Netherlands is quite clear. Since euthanasia is such an important issue, the country's government decided to appoint a committee of top researchers in the fields of medicine, sociology, statistics, and research methodology to study all aspects of euthanasia. The committee gathered qualified physicians who interviewed practitioners of euthanasia. The lengthy questionnaire was comprised of 250 questions. In 1990, the Netherlands published the first extensive report. I commend the country's government for taking this initiative. The data was clear, but the interpretations contradictory. As an academic, you learn that life is not black and white, but full of shades of gray and pink. In contrast, the interpretations of this report were disparately varied; some said the report and its findings show that the Netherlands was on the right track, presenting a model that more nations should follow, whereas others said the Netherlands served as a model to explain why euthanasia should never be permitted, advising other countries not to follow suit because the Dutch system was risky. As a researcher, I was baffled. Thus, in order to resolve this issue, I had to visit the Netherlands. At this point, my book was nearly finished, and its thrust was in favor of euthanasia.

I went to the Netherlands in 1999. Before arriving, I got in touch with the major figures in the Dutch euthanasia policy and practice. I contacted the person who wrote the law, the people who were part of that prestigious committee, the person in charge of medical ethics in the Dutch Ministry of Justice, the people who were heading the medical ethics departments in the Netherlands, scholars who wrote about euthanasia, and practitioners who practiced euthanasia. In total, I contacted 30 highly distinguished people who were very familiar with the topic, far more familiar than I was, as at that time I had been working on these issues for a mere eight years. Only one person, Dr. Chabot, explicitly declined my request for interview. He did, however, answer some questions in writing.

I went to the Netherlands as a supporter of euthanasia. After extensive research about death and euthanasia, however, I could no longer endorse euthanasia. Morally speaking, I can think of individual cases in which a person may ask and should receive euthanasia.

However, there is a fine line between ethics and policy, and when you are thinking as a policymaker, you must be very careful because peoples' lives are affected by the practice of your policy decisions. In the Netherlands, I heard of abuse — lots of abuse — and, as a result, I had to change my view about the practice of euthanasia. At the same time, I do support PAS.

I have visited the Netherlands five times for follow-ups. My findings are included in many articles and in a book, *Euthanasia in the Netherlands*, published in 2004 (Springer-Kluwer), in which I gave a voice to the issues, and detailing all that I found in the Netherlands. Here, I will present the data that troubled me the most.

Both the Netherlands and Belgium have accepted the Dutch definition, namely: euthanasia is the taking of someone's life by another upon her request. It follows, then, that euthanasia does not apply to incompetent people. If you are incompetent, if you cannot voice an opinion, if you are a minor, or if you are in a state of unawareness, euthanasia is inapplicable. It should not be practiced according to the Dutch medical guidelines, which were later translated into law. With regard to incompetent people, there is a different definition for termination of life. Stopping treatment conceived as "futile" is not euthanasia, and the term should not be used in these cases. What is sometimes termed indirect euthanasia, or the use of analgesics with the possible effect of shortening life, is also clearly distinguished from euthanasia. Euthanasia refers to using an injection in order to provide mercy killing; this principle must be very clear.

The Dutch attracted international criticism because of this practice. The Dutch government took it upon itself to issue comprehensive reports. As said earlier, the first euthanasia report was published in 1990; the following reports were published in 1995, 2001, with the last one in 2005.

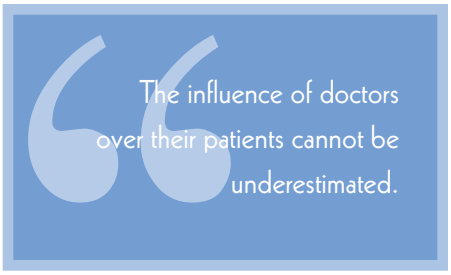
The most worrying data in all the Dutch euthanasia reports from 1990 until the present is that, consistent within the Dutch culture for twenty years or so, 0.4 percent of deaths were the result of the use of lethal drugs, not at the explicit request of the patient. This means that lethal drugs were injected to patient although the patient did not clearly state: "I want to die." This statement is now a prerequisite of the Dutch law and guidelines. The patient must sustain her wish to die, and express her desire to die over a period of time to provide evidence of her wishes. However in 0.4 percent of the cases, this did not happen. All published reports indicate that, every year, between 900 and 1,000 patients were put to death without clear volition to die.

According to the survey published in 2007, when life was ended without the explicit request of the patients, there had been previous discussions of the act or previous permission of the patient to perform the act in 60 percent of the patients, as compared with 26.5 percent in 2001. In 2005, the ending of life was not discussed with patients because they were unconscious (10.4 percent), or incompetent owing to young age (14.4 percent), or because of other factors (15.3 percent). Of all cases of the ending of life in 2005 without an explicit request by the patient, 80.9 percent had been discussed with relatives. That means that there was no evidence in writing, discussions with family substituted the need to discuss this important issue with the patient whose life was at stake, and unconscious patients were put to death although the law stipulates euthanasia is only for competent patients. In this context, one should further note that not all families are harmonious, especially when the patient is very ill and the possibility exists that there may be some ulterior motives.

One way to address this abuse is to advocate for PAS for all patients who are able to swallow the medication. In the Netherlands, however, there is a tradition in which the doctors administer the lethal drugs, and these doctors like to have control over the process. In both the Netherlands and Belgium, you find very few cases of PAS. What I suggest to both countries is to put this issue on public agenda, and speak to the public and the physicians about the findings and fear of abuse, and suggest PAS as a substitute for euthanasia. One thing that became clear to me when I spoke with doctors and physicians in both countries was that General Practitioners (GPs) have significant influence over their patients. In every case where the physician preferred euthanasia, his patients requested euthanasia. I met one doctor who did not like euthanasia, preferring PAS. Suddenly all his patients preferred PAS. The influence of doctors over their patients cannot be underestimated. We need to speak with doctors, to persuade them that the main consideration is not control: the issue is abuse, and this issue is far more important than having control over the process.

The last examination of euthanasia in the Netherlands shows that the number of cases has dropped. In 2005, 1.7 percent of all deaths in the Netherlands were the result of euthanasia, more than one-third less than the 3,500 cases in 2001. Only 113 cases were through PAS. Requests for euthanasia are most frequently from cancer patients, because cancer apparently is the most painful disease on earth. Furthermore, consistently since the 1990's, most acts of euthanasia have been carried out by GPs. A worrying development is the rise in number of terminal sedation (or terminal palliation) cases. Further research should be conducted in this sphere to verify that end-of-life decisions are carefully reached, serving the best interests of the patients.

In September 2004, the first major study into the effects of Belgium's new legislation permitting euthanasia found that approximately twenty terminally ill people per month asked doctors to help them die. This is not a large number. The study found that 259 acts of legal euthanasia were carried out in Belgium up until the end of 2003, about 17 registered cases each month. About 60 percent of euthanasia cases occurred in hospitals; this is in contrast to the Netherlands, where the act is performed by GP's in patients' homes. In both countries, the vast majority of people asking to be euthanized were suffering from terminal cancers.



My research in the Netherlands in 1999 revealed that the agenda of euthanasia had been pushed, while the issue of palliative medication had been largely ignored. Palliative medication had been underdeveloped in the Netherlands for many years. Palliative care is very expensive. If you want to opt for palliative care, you must invest a lot of resources, and up until that time, the Dutch government decided it did not want to invest those resources. The quickest way to die is through euthanasia, where there is no need for palliation. Indeed, until 2000, palliative care was underdeveloped in both Belgium and the Netherlands. In 2000, the Dutch government decided to develop palliative care, and at present, it is far more developed than it used to be when I started my research there. Research on palliative care

should continue, and comparisons should be drawn to see the extent to which palliation is being developed in these two countries as compared with other European countries.

In both countries, physicians are not obliged to carry out euthanasia. However, the culture in both countries is such that, if a physician is not willing to perform euthanasia, then her position might be undermined. A physician will find it difficult to advance to any higher rank in which she would be overseeing decisions if she opposes euthanasia. Euthanasia is part and parcel of the state, and a physician must be able to give full advice on all end-of-life-issues. Doctors are required to inform their patients that they do not provide euthanasia before starting to treat them so that the patients can decide if they want to work with the physician. Unsurprisingly, the majority of GPs in the Netherlands support euthanasia – it is part of the culture.

As a result of the euthanasia law, a Dutch physician is required to devote energies to explain everything to the patient and her loved ones, consult with specialists, and communicate with people with relevant concerns. There is scope to consider an improved physician-patient communication model. In the United States, Jack Kevorkian presents an example of a bad model for end-of-life issues. Jack Kevorkian helped 130 patients to die between 1990 and 1999. Some of those patients were healthy. They thought they were sick, but a coroner's examination found nothing medically wrong with them. Dr. Kevorkian was a retired pathologist who was accustomed to dealing with corpses, not with living people. For him, the issue of their illness was secondary — the main consideration was autonomy, that they wanted to die. The individuals sent Dr. Kevorkian their medical files and he agreed to provide the service without ever getting to know them professionally. In his book, *Prescription Medicide* (Prometheus Books, 1991), Dr. Kevorkian wrote that he knew his very first patient, Janet Atkins, for a short while before he assisted in her suicide. In my view, Dr. Kevorkian presented a rogue model of an overenthusiastic, self-promoter, media-crazed physician. There were no control mechanisms over his practice; he simply believed he recognized the need and entered into the legal lacuna with shocking insensitivity. As I noted earlier when I spoke about the issue of dignity, concern, and respect, some people want to determine the time of their death; 130 such people simply hired Dr. Kevorkian to help them do just that. I think Dr. Kevorkian's overzealousness is the wrong model to pursue.

One troubling issue is that, for many years, the Dutch believed that the issue of administering death was a personal and private issue, an issue between patients and their GP. Therefore, even though the Dutch Medical Association demanded and prescribed that the doctors must report euthanasia when it was performed, most of these physicians failed to report because they argued it was a breach of privacy and a breach of trust between them and their patients. In 1990, only 18 percent of doctors reported having performed euthanasia. After the law was passed legitimizing euthanasia, approximately 80 percent of doctors filed reports. While there has been a significant improvement in reporting, the goal is to reach 100 percent, where all doctors report participating in euthanasia cases.

Another issue that is highly troubling is the issue of consultation. The Dutch law prescribes that a physician must consult with an independent colleague who is an expert on the patient's disease before performing euthanasia. My fieldwork revealed that most of the time the doctors consulted a colleague in the same office, and thus, the consulting physicians were not independent nor were they necessarily experts of the disease under consideration. Moreover, my research revealed that sometimes consultations were devised over the phone. This is in breach of the Dutch guidelines because the role of consulting is said to be twofold. One aspect of consultation involves verifying the patient's medical situation, and the Dutch stipulate you cannot do this by looking at the files alone. Indeed, many of the doctors whom I met in the Netherlands, the United States, the United Kingdom, Canada, and Israel say it is necessary to do a physical examination to reach an accurate decision. The second important role of the consultant is to verify that euthanasia is the independent, autonomous wish of the patient. If it is only the physician who discusses the patient's condition with the consultant, then could the consultant know what the patient wants? I hope that such a bad practice of phone consultation is no longer in existence. I am told that Dutch physicians no longer conduct consultations over the phone.

The Dutch believed that the practice of doctors agreeing to serve as euthanasia consultants for each others' patients was not the best way. Consequently, they created a special committee of experts called Support and Consultation of Euthanasia in the Netherlands (SCEN) that began in Amsterdam and later spread throughout the country. At present, I am told most consultations about euthanasia are done with SCEN doctors. An expert who the GP is said not to know comes and examines the patient. Belgium has adopted a similar consultation mechanism. I applaud

this development, as it is far better than independent deals between not-so-independent doctors.

I previously mentioned the Oregon model and indicated it was a good model to follow for end-of-life issues. When the state first authorized the practice in 1994, the worry was that once the system was in place, the practice would spread and there would be many, many cases of PAS. However, there was not a huge increase in the number of people asking for PAS; more or less, there are the same number of people requesting PAS -- about 30 each year (341 in ten years, 1997-2007). The highest number of PAS cases was in 2007, when 49 Oregonians ended their lives by taking a lethal drug dose. Secondly, the other concern was that PAS would be disproportionately applied to kill the poor, the uneducated, the neglected, the deserted, those who could not take care of themselves, and the underprivileged. This has not happened. Most of the people asking for and accepting this service are well-educated middle class people, and it seems there is no abuse of the system. Therefore, I think this model is a good path for others to follow. That being said, Oregon should continue to have close annual scrutiny of the practice and keep an alert eye against potential abuse.

Guidelines for End-of-Life Issues

I have devised a set of guidelines to improve the current system. I would like to advance the issue of PAS, because I recognize that individuals should have the power to decide end-of-life issues, and because I oppose euthanasia. I developed these guidelines by studying what has been done in Oregon, the Netherlands, Belgium, Switzerland, and the Northern Territory of Australia. Let me conclude with the following recommendations and suggestions:

- The physician should not suggest PAS to the patient. Instead, it is the patient who should have the option to ask for such assistance. What I discovered in my independent field research in the Netherlands is that, many times, the patients did not ask for euthanasia. It was the doctor, a trusted GP whom the patient had known for many years, sometimes 30 or 40 years, who offered death to the patient with cancer. This practice may compromise the issue of voluntariness; it is difficult for many patients to contest the advice of a loyal GP. The GP may present the patient the range of available options without manipulation, and with due respect for patient's life and wishes.
- The request for PAS should be voluntary and come from a competent adult, 18 years-of-age or older, who suffers from an intractable, incurable, irreversible disease. The decision should be made by the patient, and not by the family or as a result of family pressures. Some families can make the decision to end life because they feel overwhelmed by the individual's illness – it is troublesome and very demanding to have a cancer patient in the home. It is also very sad, and many people cannot cope with the fact that their loved one is suddenly dying. For these reasons, the PAS decision has to be reached without any pressures. The patient should state this wish repeatedly over a period of time. This recommendation is similar to the one invoked in laws and guidelines in Oregon, the Netherlands, Belgium, and Australia.
- It is the task of social workers to examine to what extent the patient is affected by external pressures. The decision-making process shall include a second opinion in order to verify the medical diagnosis and minimize the chances of misdiagnosis, as well as to allow the discovery of other medical options. A specialist who is not dependent on the first doctor should provide the second opinion. A committee like the Netherlands' SCEN can be a good system. It is advisable for the identity of the consultant to be determined by a committee of specialists who will review the request for PAS.
- At times the patient's decision might be influenced by severe pain, and therefore, the role of palliative care can be, and is, crucial. Palliative care is required in both Belgium and Oregon.
- The patient must be informed of her situation, the prognosis for recovery or escalation of her disease, and the degree of suffering that may be involved. There must be an exchange of information between doctors and patients. The laws in Belgium and Oregon contain these guidelines.

"The physician should not suggest PAS to the patient. Instead, it is the patient who should have the option to ask for such assistance.

- Sometime prior to the performance of PAS, a doctor and a psychiatrist shall be required to visit and examine the patient to verify that this is the genuine wish of a person of sound mind, and that the individual is not depressed or being coerced or influenced by a third party. The conversation between all doctors and the patient should be held without the presence of family members in order to avoid familial pressures.
- The patient must be able to rescind her decision to pursue PAS at any time and in any manner, as it is the case in Australia and Oregon. In Belgium, the patient can withdraw her declaration at anytime.
- PAS may be performed only by a doctor in the presence of another doctor. I am very much opposed to family members administering assisted suicide (or euthanasia), as I think it can lead to abuse. The decision-making team should include at least two doctors and a lawyer who will examine the legal aspects involved and ensure there is protocol in place which will prevent against possible abuse. Perhaps a public representative should also be present during the entire procedure, including the decision-making process and the performance of PAS.
- PAS may be conducted in one of three ways, all of which should be discussed openly and decided upon by the physician and the patient: (1) Oral medication; (2) Self-administered, lethal intravenous infusion; or (3) Self-administered lethal injection. In this context, I should note that some medication may be difficult or impossible for patients to ingest because of nausea or other side-effects of the illness. The only exception in which the physician would be allowed to administer the lethal injection would occur in the event that medications have been provided and the patient's dying process has been lingering on for long hours. I would only allow euthanasia after the failing of PAS, or if the patient cannot physically administer the medications to herself.
- Doctors may not demand a special fee for the performance of PAS. There must be no financial incentive to perform or assist with the procedure since the motive for PAS is humane. There should be no special payment that might cause commercialization or promotion of such procedures.
- There must be extensive documentation in the patient's medical file, including: (1) the disease diagnosis and prognosis by the attending and the consulting physicians; (2) attempted treatments; (3) the patient's reasons for seeking PAS; (4) the patient's request in writing or documented on a video recording; (5) documentation of conversations with the patient; (6) the physician's offer to the patient to rescind her request; (7) documentation of discussions with her beloved people; and (8) a psychological report confirming the patient's condition.
- The drugs required to end one's life are known. Since there are 900 to 1,000 patients in the Netherlands who are killed every year without clear volition, pharmacists should be required to file a report every time lethal medications are sold to act as a control mechanism. Then it would be possible to track down the medication to the doctor, and keep track of how many times PAS was performed.
- Doctors should not be coerced into taking actions that conflict with their conscience, particularly since some religious individuals think only nature should be left to take its course. No coercion should be involved in the process.
- The local medical association should establish a committee whose role should be to investigate underlying facts of cases which are reported, as well as to investigate whether there were mercy cases which were not reported or cases which did not comply with the guidelines. There were some cases in both Belgium and the Netherlands that reached the courts because there was a perception that the law was compromised. The common penalty for those physicians was reprimand. This cannot be said to be a severe deterrence. Further sanctions should be taken to punish health care professionals who violate the guidelines, fail to consult with other physicians or file reports, engage in involuntary termination of life without the patient's consent, or engage in involuntary termination of life with incompetent patients. Physicians who fail to comply with the guidelines should be charged and procedures to sanction them should be enforced by the disciplinary tribunal of the relevant medical association. Sanctions should be significant and include revocation of the physician's medical license.

The ERISA "Regulatory Vacuum": The Liability of HMOs for Negligent Utilization Review *After Aetna Health Inc. v. Davila*

*Ernesto Gonzales**

I. Introduction

On June 21, 2004, the Supreme Court held in *Aetna Health Inc. v. Davila*[1] that the Employee Retirement Income Security Act of 1974 (ERISA)[2] preempted two Texas patients' state tort law claims against their respective Health Maintenance Organizations (HMOs) for injuries allegedly caused by the HMOs' failure to exercise reasonable care in making utilization review decisions.[3] This decision effectively shields HMOs from most (or all) claims by patients seeking damages for injuries suffered as a result of negligent utilization review.[4] The same day the Supreme Court decided *Davila*, U.S. Representative John Dingell (D-MI), then ranking Democrat on the House Committee on Energy and Commerce, announced that he would introduce a patients' bill of rights in the House, stating that "HMOs, foreign diplomats and the mentally insane are the only people in this country who are exempt from the consequences of their decisions."[5] His bill, which would have given ERISA-regulated plan beneficiaries the right to sue their HMO without limitations on damages, never became law.[6] However, Rep. Dingell's words represented, and still represent, the feelings of many legislators, judges, and commentators that the Court's current ERISA jurisprudence unjustly denies average Americans who suffer injuries as a result of a wrongful denial of coverage by their HMO the right to recover damages for their injuries.[7] More than ten years before the *Davila* decision, one U.S. Senator described the effects of ERISA during a committee debate in the following terms:

> Under current law, states can do nothing to ensure that insurance companies act fairly. When an insurance company denies a claim, an individual has little hope of finding an attorney to take his or her case. For the few who do succeed in retaining an attorney, all they can hope for is that after two or three years of court action their claim will be paid, but with no damages.[8]

The Court's unanimous decision in *Davila* to close the door to aggrieved ERISA- regulated plan beneficiaries seeking "make-whole" relief from their HMO makes this assessment of ERISA even more accurate today than when first made.

"Under the Court's current interpretation of ERISA, an employee participating in an ERISA-regulated plan can sue the plan to recover only wrongfully denied benefits, and not a penny more."

Under the Court's current interpretation of ERISA, an employee participating in an ERISA-regulated plan can sue the plan to recover only wrongfully denied benefits, and not a penny more.[9] Under ERISA, the employee cannot recover damages for injuries resulting from her HMO's negligent denial of coverage.[10] Moreover, after *Davila*, it is clear that ERISA preempts any state law claim that the employee could raise against the HMO to recover for her injuries.[11] This leaves the employee with no option but to raise a claim under ERISA's civil enforcement provisions and to hope to at least receive denied benefits.[12] As Justice Ginsburg expressed in her concurrent opinion in *Davila*, the Court's current ERISA jurisprudence leaves a "regulatory vacuum" where "virtually all state law remedies are preempted but very few federal substitutes are provided."[13]

Some commentators see the *Davila* decision as the Court's final statement to Congress that addressing the "regulatory vacuum" left by ERISA is the responsibility of the legislature, not the courts.[14] Others, however, express hope that the Court, as Justice Ginsburg anticipates in her concurring opinion, will eventually revise the current interpretation of ERISA's remedial scheme to allow aggrieved patients to obtain make-whole relief from their HMO.[15]

This article seeks to assess the effects of the *Davila* decision on the ability of ERISA-plan participants and beneficiaries to obtain relief for a wrongful denial of benefits by their HMO. Part II provides an introduction to the relevant ERISA provisions and how the Court has interpreted them. Part III analyzes the Court's holding in *Davila* and discusses the legal and socioeconomic effects of the decision. This article concludes that the *Davila* decision closed the door on plan participants and beneficiaries seeking to recover damages from their HMO for injuries caused by the HMO's negligent denial of benefits. Based on this conclusion, Part IV calls on Congress to amend ERISA so as to allow the states to narrow the regulatory gap left by the Court's current ERISA jurisprudence through patients' rights legislation.

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II. ERISA Background

Congress enacted ERISA to "protect . . . the interests of participants in employee benefit plans and their beneficiaries . . . by establishing standards of conduct, responsibility, and obligation for fiduciaries of employee benefit plans, and by providing for appropriate remedies, sanctions, and ready access to the Federal courts."[16] Congress was responding to long-ignored claims by American workers that their employers were recklessly underfunding their pension plans and creating unnecessary obstacles to full benefits eligibility.[17] Although Congress enacted ERISA primarily to protect private employee pension plans,[18] ERISA also covers employee welfare plans.[19] A "welfare plan" under ERISA is "any plan, fund, or program . . . established or maintained by an employer or by an employee organization . . . for the purpose of providing for its participants or their beneficiaries . . . medical, surgical, or hospital care or benefits," among other benefits.[20] Section 502(a) of ERISA allows welfare plan participants and beneficiaries to bring a civil action in federal court to protect their interests in the plan.[21]

In order to "promote uniformity and avoid inconsistent state regulation of pension benefits,"[22] Congress included an express preemption clause in Section 514 of ERISA.[23] Section 514(a) provides that ERISA shall supersede any state law that "relate[s] to any employee benefit plan."[24] Section 514(b)(2)(A), however, carves out an exception to ERISA preemption, stating that "nothing in [ERISA] shall be construed to exempt or relieve any person from any law of any State which regulates insurance . . . ."[25] Section 514(b)(2)(A), which is commonly known as the "savings clause," has, in turn, its own exception.[26] Section 514(b)(2)(B), called the "deemer clause," provides that no "employee benefit plan . . . shall be deemed to be an insurance company or other insurer . . . or to be engaged in the business of insurance . . . for purposes of any law of any State purporting to regulate insurance companies [or] insurance contracts . . ."[27] Thus, ERISA preempts state laws that "relate to any employee benefit plan," except those state laws that regulate insurance, but no employee benefit plan can itself be considered an insurer.

Among the civil actions that ERISA-regulated plan participants and beneficiaries can bring under Section 502(a) is an action to hold ERISA-regulated plan fiduciaries liable for a breach of their fiduciary duties to the plan.[28] The Court, however, has held that HMOs do not act as fiduciaries for purposes of ERISA when they make mixed eligibility and treatment decisions, thus limiting the scope of this cause of action.[29]

A. ERISA Civil Enforcement Provisions and Complete Preemption

Section 502(a) allows an ERISA-plan participant or beneficiary to bring a civil action in federal court "to recover benefits due to him under the terms of his plan, or to enforce . . . or . . . clarify his rights to future benefits under the terms of the plan."[30] A participant or beneficiary can also bring a civil action "to enjoin any act or practice which violates any provision of [ERISA] or the terms of the plan, or to obtain other appropriate equitable relief."[31] The Court has viewed section 502(a) as providing for ERISA-regulated plan participants and beneficiaries a total of "six carefully integrated civil enforcement provisions,"[32] which "represent a careful balancing of the need for prompt and fair claims settlement procedures against the public interest in encouraging the formation of employee benefit plans."[33]

Section 502(a) preempts any state law that "duplicates, supplements, or supplants" its civil enforcement provisions.[34] This section derives its preemptive power from the Supremacy Clause of the Constitution, which resolves conflicts between state and federal laws in favor of the later.[35] When federal legislation is substantially broad in one particular area, it is said that such legislation "occupies the field" in question to the exclusion of state law, even when this exclusive "occupation" leaves a "regulatory vacuum."[36] When this happens, the federal statute invalidates even state laws that are consistent with its provisions.[37] The Court explained in *Davila* that Section 502(a) of ERISA falls within this category of federal legislation, and therefore, completely preempts even state laws attempting to provide only additional remedies not available under ERISA.[38] The Court noted that this complete preemption arises from Congress's clear intent to make ERISA's "comprehensive civil enforcement scheme" exclusive.[39] The Court reasoned that "[t]he policy choices reflected in the inclusion of certain remedies and the exclusion of others . . . would be completely undermined if ERISA-regulated plan participants and beneficiaries were free to obtain remedies under state law that Congress rejected in ERISA."[40]

Section 502(a) preemption automatically removes to federal court any cause of action that could have been brought under any of its provisions.[41] The Court has explained that section 502(a)'s preemptive force "converts [even] an ordinary common law complaint into one stating a federal claim."[42] Justice Thomas, writing for the Court in *Davila*, summarized Section 502(a)'s preemptive effect in the following: "if an individual, at some point in time, could have brought his claim under ERISA Section 502(a)(1)(B), and where

"When federal legislation is substantially broad in one particular area it is said that such legislation "occupies the field" in question to the exclusion of state law, even when this exclusive "occupation" leaves a "regulatory vacuum."

there is no other independent legal duty that is implicated by a defendant's actions, then the individual's cause of action is completely preempted."[43]

B. Section 514 Preemption and the "Savings" and "Deemer" Clauses

In addition to Section 502(a), ERISA preemption finds support in Section 514(a), which provides that "the provisions of [ERISA] shall supersede any and all State laws insofar as they . . . relate to any employee benefit plan."[44] Before *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*,[45] the Court interpreted the "relate to" language of section 514 very broadly, so that a state law was found to "relate to" an employee benefit plan "if it ha[d] a connection with or reference to such a plan."[46] Following this approach, the Court found ERISA preemption even of state laws that "merely exert[ed] some effect, however indirect, on employee benefit plans."[47] In *Travelers*, however, the Court realized that a textualist interpretation of Section 514(a)'s "relate to" did not reflect legislative intent because "if 'relate to' were taken to extend to the furthest stretch of indeterminacy, then for all practical purposes pre-emption would never run its course."[48] The Court thus decided to look beyond the language of Section 514(a) to interpret this section in light of the congressional objective of preventing a "multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans."[49] Although the *Travelers* Court did not elaborate a clear rule to determine what state laws "relate to" employee benefit plans for ERISA purposes, it observed that in prior cases "ERISA pre-empted state laws that mandated employee benefit structures or their administration" and "laws providing alternative enforcement mechanisms."[50]

In the "savings clause," Congress provided an exception to Section 514(a) preemption for state laws that regulate insurance.[51] Congress did so in part because insurance had historically been, and still remains, an area subject to state regulation, and in part to preserve the complex systems of insurance regulation the states had in place.[52] In *Kentucky Ass'n of Health Plans, Inc. v. Miller*,[53] the Court developed a two-prong test to determine whether a state law regulates insurance for purposes of ERISA Section 514.[54] First, the Court asks whether the state law in question is "specifically directed toward entities engaged in insurance."[55] Second, the Court determines whether such law "substantially affects the risk pooling arrangement between the insurer and the insured."[56]

Although Congress was willing to "save" a state law that regulates insurance from ERISA preemption, it felt that the scope of state insurance regulation had to be curtailed in some way in order to prevent states from supplanting ERISA regulation of employee welfare plans with state regulation.[57] Congress thus added the "deemer clause" in Section 514, which provides that no "employee benefit plan . . . shall be deemed to be an insurance company or other insurer . . . or to be engaged in the business of insurance . . . for purposes of any law of any State purporting to regulate insurance companies [or] insurance contracts . . . ."[58] In *Metro. Life Ins. Co. v. Massachusetts*[59] the Court interpreted the "deemer clause" as effectively removing employer self-funded welfare plans from the scope of the "savings clause" and placing them beyond state regulation and within ERISA.[60]

C. *Pemgram v. Herdrick*[61] and Fiduciary Acts Under ERISA

ERISA Section 409 provides in part that "any person who is a fiduciary with respect to an [employee benefits] plan who breaches any of the responsibilities, obligations, or duties imposed upon fiduciaries by [ERISA] shall be personally liable to make good to such plan any losses . . . resulting from each such breach."[62] In *Pegram,* the Court faced the issue of whether a treatment decision made by an HMO physician constituted a fiduciary act under ERISA, thus subjecting the HMO to potential liability under ERISA Section 409.[63] Cynthia Herdrich, an ERISA plan beneficiary, suffered injuries when her treating physician, Dr. Lori Pegram, an HMO employee, required her to wait eight days to have an abdominal ultrasound performed at a facility staffed by the HMO located 50 miles away.[64] While waiting, Herdrich's appendix burst, causing peritonitis.[65] She brought suit against Dr. Pegram and the HMO, claiming medical malpractice and fraud.[66] Defendants removed the case to federal court under ERISA.[67] Herdrich then amended her complaint to include a claim for breach of fiduciary duty under ERISA Section 409.[68]

The Court declared that the "threshold question" in analyzing claims for breach of fiduciary duty under ERISA is "not whether the actions of some person employed to provide services under a plan adversely affected a plan beneficiary's interest, but whether that person was acting as a fiduciary, in that it was performing a fiduciary function to complaint."[69] The Court held that while pure eligibility decisions (decisions regarding coverage of medical treatment under an employee welfare plan) are strictly administrative and thus fiduciary in nature, mixed treatment and eligibility decisions do not qualify as fiduciary decisions for purposes of ERISA.[70] The Court argued that as a practical matter, it is almost impossible to separate the eligibility and treatment aspects of a mixed eligibility-treatment decision.[71] The Court also feared that ERISA-regulated

> The [*Pegram*] Court also feared that ERISA-regulated plan participants and beneficiaries may disguise medical malpractice claims as claims for breach of fiduciary duty under ERISA to reach the HMO in addition to the physician.

plan participants and beneficiaries may disguise medical malpractice claims as claims for breach of fiduciary duty under ERISA to reach the HMO in addition to the physician.[72] Allowing mixed eligibility-treatment decisions would therefore mix state malpractice claims and federal ERISA actions, creating uncertainty and confusion in the law.[73] The Court found that Dr. Pegram's decision to make Herdrich wait eight days for her ultrasound was a mixed decision, not made in a fiduciary capacity.[74] Therefore, the Court held that Herdrich could not bring a breach of fiduciary duty claim against the HMO under ERISA.[75]

III. The *Davila* Decision

In *Davila* the Supreme Court consolidated two cases brought by ERISA-regulated plan participants/beneficiaries against their respective HMO under the Texas Health Care Liability Act (THCLA).[76] THCLA, which was part of the first state patients' bill of rights in American history, was intended to protect beneficiaries of managed care organizations (MCOs), including HMOs, from wrongful denials of benefits.[77] THCLA required HMOs and health insurance carriers "to exercise ordinary care when making health care treatment decisions," and subjected them to liability "for damages for harm to an insured or enrollee proximately caused by [the HMO's or insurance carrier's] failure to exercise such ordinary care."[78] In both cases the plaintiffs sought to recover damages for injuries allegedly resulting from their HMO's negligent denial of coverage.[79]

A. Factual Background

Juan Davila, an ERISA-regulated plan participant, suffered from arthritis. His physician prescribed Vioxx to treat his arthritis pain, but Aetna Health Inc. (Aetna), which administered Davila's health benefits plan, refused to pay for the drug.[80] Aetna based its decision on the grounds that Davila's plan provided that Aetna would pay for Vioxx only if no other equivalent drug in Aetna's formulary was suited for treating a participant's condition.[81] Davila then began taking the genetic drug Naprosyn, which Aetna covered. However, this drug caused him to experience internal bleeding and he was rushed to the hospital, where he spent days in critical care.[82] As a result of his reaction to Naprosyn, Davila became incapable of receiving any medication via his digestive track.[83]

A related case involved Rudy Calad, a beneficiary of an ERISA-regulated plan administered by CIGNA.[84] After Calad underwent a complicated hysterectomy, a CIGNA discharge nurse certified her stay in the hospital for only one day following surgery.[85] The CIGNA discharge nurse decided that only a one-day stay was "medically necessary" despite Calad's treating physician's recommendations that she remain in the hospital for an extended period.[86] Following her discharge, Calad experienced post surgery complications and returned to the hospital.[87]

B. Procedural Background

Davila and Calad brought separate suits against their respective HMOs in Texas State Court, claiming that the HMOs had violated their "duty to exercise ordinary care when making health care treatment decisions" under THCLA for the denied coverage for Davila's drug and Calad's extended hospital stay.[88] Defendants removed both cases to federal district courts on the theory that petitioners' causes of actions were preempted under ERISA Section 502(a).[89] The district courts agreed with the defendant's argument, and refused to remand the cases to state court.[90] Both Davila and Calad failed to amend their respective complaints to state claims under ERISA and the district courts dismissed their complaints with prejudice.[91]

Davila and Calad appealed the decisions of the district court, and the U.S. Court of Appeals for the Fifth Circuit consolidated the cases along with others raising similar issues.[92] The Fifth Circuit reasoned that ERISA completely preempts state law causes of action that "duplicat[e] or fal[l] within the scope of an ERISA § 502(a) remedy."[93] The panel further observed that only two provisions of ERISA Section 502(a) might preempt the claims brought by Davila and Calad: "§ 502(a)(1)(B), which provides a cause of action for the recovery of wrongfully denied benefits, and § 502(a)(2), which allows suit against a plan fiduciary for breaches of fiduciary duty to the plan."[94] Relying on the Supreme Court analysis in *Pegram* stating that mixed eligibility-treatment decisions are not fiduciary decisions under ERISA, the panel found that the HMOs' decisions were of the mixed type, and therefore neither Davila nor Calad could have brought their claims under Section 502(a)(2).[95] The panel also determined that neither plaintiff could have brought claims under Section 502(a)(1)(B) because their THCLA claims were basically tort claims while the remedies that Section 502(a)(1)(B) provides are contractual in nature.[96] The panel reasoned that Davila and Calad were not trying to obtain reimbursement for benefits denied them, but instead were seeking tort damages based on "an external, statutorily imposed duty of 'ordinary care.'"[97]

The Supreme Court granted *certiorari* on November 3, 2003.[98] At the time, a circuit split had become apparent. On one hand, the Eleventh Circuit and the Second Circuit held in *Land v. CIGNA Healthcare of Florida*[99] and *Cicio v. Does*[100] respectively that an HMO's decision to deny coverage for a particular type of medical treatment based on a finding by the HMO that such treatment was not medically necessary constituted a mixed eligibility-treatment decision, and therefore, was not subject to Section 502(a) preemption.[101] On the other hand, the Third Circuit in *DiFelice v. Aetna U.S. Healthcare*[102] found complete preemption in the same kind of scenario.[103]

C. The Supreme Court Decision

The Court found that ERISA preempted Davila and Calad's THCLA claims and therefore reversed the decision of the Fifth Circuit.[104] The Court discussed ERISA's role as a comprehensive federal statute intended to "provide a uniform regulatory regime over employee benefit plans."[105] The Court emphasized that Congress designed ERISA so as to ensure that the regulation of employee benefit plans would be a matter "exclusively of federal concern."[106] The Court considered the Fifth Circuit's reliance on *Rush Prudential HMO, Inc. v. Moran*[107] and its conclusion that ERISA preempted only those causes of action that "duplicat[e] or fal[l] within the scope of an ERISA § 502(a) remedy."[108] It rejected the Fifth Circuit's formulation of the holding in *Rush Prudential*, observing that "nowhere in *Rush Prudential* did we suggest that the pre-emptive force of ERISA 502(a) is limited to the situation in which a state cause of action precisely duplicates a cause of action under ERISA 502(a)."[109] The Court instead set forth the rule that "any state-law cause of action that duplicates, supplements, or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore pre-empted."[110] In order for Davila and Calad's causes of action to escape

ERISA preemption, they must allege a violation of a legal duty arising independently of ERISA.[111]

The Court rejected the Court of Appeals' reasoning that Davila and Calad's claims did not fall within the scope of ERISA Section 502(a)(1)(B) because they sought tort damages, so their claims did not duplicate the contractual remedies available under that section.[112] The Court viewed as immaterial the distinction between tort damages under THCLA and contractual remedies under ERISA on which the Fifth Circuit relied.[113] The Court reasoned that determining which claims ERISA preempts on the basis of this distinction would "elevate form over substance and allow parties to evade' the pre-emptive scope of ERISA simply 'by relabeling their contract claims as claims for tortuous breach of contract.'"[114]

The Court found that the duty that THCLA imposed upon the HMOs was not independent of ERISA because the HMOs would have been liable under THCLA only due to the fact that the HMOs administered ERISA-regulated plans.[115] Because "interpret[ing] the terms of respondents' benefit plans form[ed] an essential part of [Davila and Calad's] THCLA claim," their claims depended on the status of the HMOs as administrators of ERISA plans and therefore did not arise independently of ERISA.[116] The Court concluded that Davila and Calad's THCLA claims sought "to rectify a wrongful denial of benefits promised under ERISA-regulated plans, and [did] not attempt to remedy any violation of a legal duty independent of ERISA."[117] The Court held that Davila and Calad's claims fell "within the scope of ERISA § 502(a)(1)(B) . . . and are therefore completely pre-empted by ERISA § 502 and removable to federal district court."[118]

The Court also found that the HMOs' decisions in these cases were pure-eligibility decisions, and therefore the HMOs were acting as fiduciaries when they made these decisions.[119] The Court reiterated its holding in *Pegram* that mixed eligibility-treatment decisions do not constitute fiduciary decisions for purposes of ERISA.[120] The Court, however, narrowed its *Pegram* decision by suggesting that *Pegram* applied only to situations in which "the underlying negligence also plausibly constitutes medical maltreatment by a party who can be deemed to be a treating physician or such a physician's employer."[121] The Court distinguished the decisions made by the HMO in *Pegram*, where through its physician-employee the HMO decided both what treatment to provide for the patient and whether such treatment was covered, from the decisions made by the *Davila* HMOs, which involved a determination of medical necessity for the purpose of deciding whether the treatment or procedure at issue was covered under the plan.[122] Therefore, the Court concluded, Davila and Calad could have brought claims under ERISA Sections 502(a) and 409(a) against the HMO for breach of fiduciary duty, thus ERISA preempted their THCLA claims.[123]

D. Ginsburg's Concurrence

Justice Ginsburg's concurrence, which Justice Breyer joined, was concerned primarily with adding yet another voice to "the rising judicial chorus urging that Congress and [this] Court revisit what is an unjust and increasingly tangled ERISA regime."[124] Although she explained that she joined the majority opinion because it was consistent with the Court's prior ERISA cases, Justice Ginsburg expressed concerned about the "regulatory vacuum" left by ERISA.[125] She discussed very briefly three cases where the Court limited the amount of damages available to aggrieved ERISA-regulated plan beneficiaries.[126] She mentioned *Massachusetts Mutual Life Insurance Co. v. Russell*,[127] where the Court held that an ERISA-regulated plan beneficiary could not recover extra-contractual or punitive damages in an action for breach of fiduciary duty under ERISA Section 409(a), and expressed reluctance about allowing extra-contractual or punitive damages under other sections of ERISA.[128] The second case she discussed was *Mertens v. Hewitt Associates*,[129] in which the Court held that "appropriate equitable relief" in ERISA Section 502(a)(3) does not include money damages.[130] The third case was *Great-West Life & Annuity Insurance Co. v. Knudson*,[131] where the Court reiterated that Section 502(a)(3) does not allow money damages as "appropriate equitable relief."[132] After reviewing the above cases, Justice Ginsburg extended an invitation to the Court to reconsider allowing extra-contractual damages under ERISA, stating that "[a]s the array of lower court cases and opinions documents . . . fresh consideration of the availability of consequential damages under § 502(a)(3) is plainly in order."[133] She even provided a specific example of a situation where consequential damages may be allowed under ERISA.[134] She suggested that although the Court's current interpretation of ERISA Section 502(a)(3) does not allow consequential damages against a *non-fiduciary*, this section may be interpreted as allowing "at least some forms of 'make-whole' relief against a breaching *fiduciary* in light of the general availability of such relief in equity at the time" ERISA was enacted.[135]

E. The Effects of the *Davila* Decision

The effects of *Davila* go far beyond the holding in the case. At the very least there is a consensus among commentators that *Davila* closed all the doors to ERISA-regulated plan beneficiaries seeking money damages under state law for injuries resulting from a wrongful denial of benefits by their HMO.[136] This consensus is well-founded. Courts interpreting ERISA preemption after *Davila* have consistently found in favor of preemption.[137] Only

months after the Supreme Court issued its decision in *Davila*, the Fourth Circuit found ERISA preemption of a claim brought by a plan beneficiary against her HMO alleging medical malpractice and wrongful death.[138] In *Kuthy v. Mansheim*, a husband accused his wife's HMO of committing medical malpractice when it failed to approve an experimental bone marrow transplant that his wife's treating physician had recommended.[139] The wife died of non-Hodgkin's lymphoma.[140] Relying on *Davila*, the Court of Appeals held that the claim did not arise independently of the ERISA-regulated plan and was therefore preempted.[141]

The Third Circuit also relied on *Davila* to hold in favor of ERISA preemption of a claim based on Pennsylvania's "bad faith" statute.[142] In *Barber v. Unum Life Insurance Co.*, an ERISA-regulated plan participant sought to recover punitive damages from his HMO, alleging that the HMO terminated his disability benefits in violation of Pennsylvania's "bad faith" statute.[143] The Court of Appeals, invoking the Supreme Court reasoning in *Davila*, dismissed the State's "bad faith" claim on the basis that it allowed damages beyond those available under ERISA Section 502(a)'s exclusive remedial scheme.[144]

After *Davila*, the Eleventh Circuit revisited *Land v. CIGNA Healthcare of Florida* on remand.[145] In *Land*, the plaintiff, an ERISA-regulated plan participant, sued the HMO alleging negligence in the treatment of a hand infection which resulted in the amputation of a finger.[146] Before *Davila*, the Eleventh Circuit decided the case against ERISA preemption, holding that the claim arose out of a mixed eligibility-treatment decision by the HMO.[147] On remand from the Supreme Court after *Davila*, however, the Eleventh Circuit found that the claim sought only "to remedy the denial of benefits under an ERISA-regulated benefit plan," and held in favor of preemption.[148]

The Fifth Circuit also had the opportunity to address ERISA preemption after *Davila*. In *Mayeaux v. Louisiana Health Service & Indemnity Co.*, a patient and her treating physician sued the patient's insurer under state tort law to recover for the denial of coverage for an experimental treatment.[149] The court rejected the plaintiffs' argument that the HMO's decision was a mixed eligibility-treatment decision.[150] Relying on *Davila*, the court explained that the narrow exception that the Supreme Court carved out for mixed decisions in *Pegram* applied only in situations where the treating physician performed a dual role as health provider and plan administrator.[151] The court held in favor of preemption.[152]

The Tenth Circuit has also relied on *Davila* to find ERISA preemption of state law claims seeking damages for injuries resulting from a wrongful denial of benefits.[153] In *Lind v. Aetna Health, Inc.*, an HMO utilization review doctor decided to discontinue coverage of a drug for multiple sclerosis before the patient first tried a "step drug," despite the vociferous protest from the treating physician.[154] The patient brought, among others, a claim of medical negligence based on a theory of *respondeat superior* against the HMO, and sought punitive damages.[155] The plaintiff argued that the claim of *respondeat superior* medical malpractice fell outside the scope of *Davila*, because a doctor employed by Aetna "made the determination that Ritalin rather than Provigil was the appropriate drug to treat [plaintiff's multiple sclerosis]" and that "Aetna then imposed this determination upon [plaintiff's] treating physician."[156] The court rejected this argument, explaining that the Aetna doctor was not providing treatment for the plaintiff and there was "no agency relationship between [the treating physician]—an outside provider—and Aetna for the purposes of prescribing medication."[157] The court found that plaintiff's "medical negligence claim is unavoidably linked to, and is therefore preempted by, ERISA."[158]

The Seventh Circuit has also joined those jurisdictions relying on *Davila* to find ERISA preemption of state law causes of action for damages against HMOs. In *McDonald v. Household Int'l, Inc.*, an HMO administering an ERISA plan failed to properly activate an employee's health insurance.[159] Unable to afford his blood pressure medication, he did not take the drugs he needed and, as a result, suffered a stroke.[160] The employee brought a number of state law claims against the HMO, alleging that it "committed acts of gross negligence, willful or wanton misconduct, or intentional wrongs that led to [the employee's] lack of health coverage and ultimately to the stroke."[161] The court found that the facts of this case were significantly similar to those of *Davila* and held that ERISA preempted the employee's claims.[162]

As the above cases indicate, commentators are right to conclude that *Davila* put a definite stop to all attempts by ERISA-regulated plan beneficiaries to obtain "make-whole" relief under state law for injuries caused by their HMO's negligence, and in some cases, one may argue, intentional denial of benefits.[163] *Davila* erected, or rather, finished or solidified a wall of protection around HMOs with dire consequences to the average middle-class American employee receiving health care benefits through an ERISA-regulated plan. On one hand, the wide regulatory gap left by the Supreme Court's interpretation of ERISA preemption creates an economic incentive for HMOs to wrongfully deny benefits to ERISA-regulated plan beneficiaries. On the other hand, Justice Thomas' subtle recommendation in *Davila* that an employee in a situation in which her

"As the above cases indicate, commentators are right to conclude that Davila put a definite stop to all attempts by ERISA-regulated plan beneficiaries to obtain "make-whole" relief under state law for injuries caused by their HMO's negligence, and in some cases, one may argue, intentional denial of benefits."

> The Court's unanimous decision in *Davila* should send a strong message to Congress that the courts are not up to the job of fixing the regulatory gap left by ERISA preemption any time in the near future.

HMO wrongfully denies benefits can pay out of pocket and then sue the HMO under ERISA to recover for the denied benefits does not constitute a viable alternative for the average American.[164] The average American employee most likely does not have enough out-of-pocket money to pay for medical expenses when faced with a wrongful denial of benefits. Although Justice Ginsburg's concurrent opinion leaves open the possibility of a turnaround in the Court's approach to ERISA's remedial scheme, and suggests allowing some form of make-whole relief under ERISA Section 502(a), the fact that only Justice Breyer joined Justice Ginsburg's opinion makes this possibility look distant at best.[165]

The Supreme Court's current ERISA jurisprudence not only leaves a wide gap in the regulation of HMOs, but actually creates incentives for HMOs to defraud ERISA-regulated plan beneficiaries by intentionally denying due benefits, or at least to act with less than ordinary care in making utilization review decisions.[166] ERISA preemption provides HMOs with broad immunity to state law causes of action brought by ERISA-regulated plan participants attempting to obtain damages for injuries resulting from a wrongful denial of benefits.[167] All that these aggrieved ERISA-regulated plan participants can do is sue the HMO under ERISA and obtain an injunction against the HMO or recover the cost of wrongfully denied benefits.[168] Thus, because the only risk of refusing to pay for some medical treatment or procedure for an ERISA-regulated plan participant is to have to eventually pay for such treatment or procedure, it makes good business sense for HMOs to at the very least, err on the side of denying benefits covered under the plan when making utilization review decisions.[169] Considering the hassles and high costs of litigation, chances are that the sick or recovering patient will not even sue.[170]

Another potential effect of the *Davila* decision is to move medical treatment decision-making from the treating physician to the HMO.[171] While affirming its decision in *Pegram* that mixed treatment-eligibility decisions made by the treating physician are not fiduciary in nature and, therefore, fall outside the scope of ERISA, the *Davila* Court held that when ERISA-regulated plan administrators make "medical necessity" decisions in order to determine eligibility, they act as fiduciaries for purposes of ERISA.[172] Thus, "a wrongful decision to deny care is now significantly less costly when made by a plan administrator rather than a treating physician."[173] This "liability imbalance," coupled with the HMOs' sticks and carrots directed at physicians to discourage over-utilization,[174] may encourage physicians to leave certain medical decisions, particularly treatment decisions, in the hands of the HMO by recommending every possible "adequate" treatment and letting the HMO decide which one is "covered" under the plan.[175]

These incentives for the HMO to disregard patients' rights, and for the treating physician to "delegate" treatment decisions to the HMO, operate, of course, to the detriment of patients. In the best scenario, patients receive lesser-quality health care in the form of less-than-optimal treatment.[176] In the worst scenario, patients find themselves in a situation like that of the patients in *Davila*, in which most needed treatment is wrongfully denied and no alternative is provided, or the alternative treatment results in severe injuries to the patient.[177] Patients who find themselves in the second type of situation often do not have the money to pay for the needed treatment or procedure out of pocket. In this type of situation, therefore, a wrongful denial of coverage by the HMO constitutes in practice a denial of treatment.

IV. Recommendations

The Court's unanimous decision in *Davila* should send a strong message to Congress that the courts are not up to the job of fixing the regulatory gap left by ERISA preemption any time in the near future.[178] It is now time for Congress to hear "the rising judicial chorus urging that Congress and [the] Court revisit what is an unjust and increasingly tangled ERISA regime."[179] Congress should undertake the job of amending ERISA to eliminate ERISA preemption of state law actions brought patients against their HMOs to recover consequential damages for injuries caused by negligent denials of benefits.

On various occasions, Congress has unsuccessfully attempted to pass a patients' bill of rights.[180] In 2001, both the Senate and the House passed different versions of a patients' bill of rights.[181] The Senate's version of the bill called for "extensive new opportunities to challenge decisions by health maintenance organizations and insurers—including a two-tiered review process—and, if a patient remains unsatisfied, a right to sue insurers and HMOs over decisions that lead to injury or death."[182] The Congressional effort, however, came to an end in the midst of confrontations between Congress and the White House over "whether federal rules or stronger state rules would govern patients' appeals."[183] The bill was reintroduced in 2004 by Senator Barbara A. Boxer (D-CA), but died after the Senate Committee on Health, Education, Labor, and Pensions failed to take action on it.[184] Since the Court issued its decision in *Davila*, Representative John Dingell has twice introduced legislation giving patients the right to sue their insurers and HMOs, but both bills failed to attract much legislative attention.[185] Some commentators have expressed hope that after the Democratic takeover of both the House and the Senate in 2006, Congress will

attempt to pass patients' rights legislation.[186]

Whether having a federal comprehensive patients' bill of rights is a good idea is beyond the scope of this article. Patients' rights legislation, such as THCLA, has pros and cons.[187] While it allows patients to recover consequential damages from their HMOs for breach of a duty to exercise ordinary care in making treatment decisions might encourage responsible utilization review and promote equity in plan coverage by protecting vulnerable patients, such legislation may also result in increased risks for HMOs and higher health care prices.[188] The ultimate effects of patients' rights laws are largely unknown.[189] Fortunately, "the federalist structure of the American government is well-suited to handle such issues."[190] As Justice Brandeis put it in his famous dissent in *New State Ice Co. v. Liebmann*,[191] "It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[192] But the unhappy incident of ERISA preemption is that states cannot serve as laboratories for patients' rights laws.[193] The Court in *Davila* closed the door to such experimentation.[194] As one commentator eloquently put it:

The *Davila/Calad* holding precludes a federalist experiment on remedies against HMOs. States may not test and compare the benefits and disadvantages of tort liability statutes or other types of remedies. States must accept the ERISA Section 502 remedies as exclusive. *Davila/Calad* undercuts one of the significant strengths of the American form of government—a strength that is well- designed to address the very problems that motivated ERISA's passage.[195]

Congress should take action to amend ERISA to allow the laboratory of the states to test the efficacy of patients' rights laws.

V. Conclusion

The Supreme Court's decision in *Davila* closed the door on patients seeking state tort law damages from their HMO for injuries suffered as a result of a wrongful denial of benefits by the HMO.[196] After *Davila,* it is clear that ERISA preempts state laws designed to protect patients from intentional or negligent denials of benefits by their HMOs and leaves patients without the possibility of obtaining "make-whole" relief for injuries suffered as a result of such denials.[197] The unanimity of the decision suggests that the Court is unlikely to change the course of its ERISA jurisprudence anytime soon.[198] For these reasons, Congress should take action to amend ERISA to correct the regulatory gap left by the Court's interpretation of ERISA preemption.

1 542 U.S. 200, 124 S. Ct. 2488 (2004).
2 29 U.S.C. 1001-1461 (2000 & Supp. II 2002).
3 *See Davila*, 124 S. Ct. at 2502 (holding that the Texas patients' causes of action sought "to remedy only the denial of benefits under ERISA-regulated benefit plans," and therefore "fall within the scope of, and are completely preempted by, ERISA § 502(a)(1)(B)).").
4 *See id.* at 2491 ("Any state-law cause of action that duplicates, supplements, or supplants ERISA's civil enforcement remedy conflicts with the clear congressional intent to make that remedy exclusive, and is therefore preempted."); *see also* Theodore W. Ruger, *The United States Supreme Court and Health Law: The Year in Review*, 32 J. L. Med. & Ethics 528, 529 (2004) (noting that a patient "who suffers grievous harm as a direct result of an improper denial of treatment may recover ex post only the value of that treatment, and nothing for the injuries that were a foreseeable consequence of such denial").
5 Emily Heil, *Dingell Introduces Patients' Rights Bill, but Frist Has Doubts*, Congress Daily, June 22, 2004, 2004 WLNR 17661710 (Representative Dingell urged Congress to pass patients' rights legislation to counter the effects of the Court's decision in Davila, stating "[n]ow we need to do our job and legislate to clear the air, otherwise the Supreme Court will have to act over and over again.").
6 *See* Laura B. Benko, *New Call for Patients' Bill of Rights: Docs Worry Ruling Limiting HMO Suits Will Boost Medical Malpractice Filings*, Mod. Healthcare, June 28, 2004, at 12; Heil, *supra* note 5 (noting that the bill would have ensured patients access to care that their doctor considered medically necessary, and would have granted patients the right to a "fair, independent review process" in cases where the HMO denies a particular treatment); *see also* Elizabeth Barnidge, *What Lies Ahead for ERISA's Preemption Doctrine After a Judicial Call to Action is Issued in Aetna Health Inc.*, 43 Hous. L. Rev. 125, 153 (2006) ("Dingell's 2004 bill failed to take shape in the House, so he once again reintroduced the bill as the Patients' Bill of Rights Act of 2005 in May 2005. To date, this bill has also failed to gain any steam in the House.").
7 *See Davila*, 124 S. Ct. at 2503 (Ginsburg, J., concurring) (observing that the Court's broad interpretation of ERISA preemption and narrow construction of the "equitable relief" available under ERISA § 502(a)(3) has created a "regulatory vacuum" where "virtually all state law remedies are preempted but very few federal substitutes are provided," and joining "the rising judicial chorus urging that Congress and [the Supreme Court] revisit what is an unjust and increasingly tangled ERISA regime."); *DiFelice v. Aetna U.S. Healthcare*, 346 F. 3d 442, 453-54 (3d Cir. 2003) ("Existing ERISA jurisprudence creates a monetary incentive for HMOs to mistreat those beneficiaries, who are often in the throes of medical crises and entirely unable to assert what meager rights they possess."); Heil, *supra* note 5; Barnidge, *supra* note 6, at 150-53 (outlining the history of congressional attempts to pass a comprehensive patients' bill of rights, partly as an effort to fix the "regulatory vacuum" left by the Court's current ERISA jurisprudence); *see generally Leading Cases: C. ERISA*, 118 Harv. L. Rev. 456, 462-63 (Nov. 2004) ("Davila, coupled with ERISA's limited remedial scheme, leads to a troubling incentive structure in managed care utilization review [that] encourages HMOs to take decisions about 'medical necessity' our of the hands of physicians and place them into the hands of administrators. . . . Taken to an extreme, this incentive structure may even lead HMOs to 'instruct their doctors to recommend every possible treatment and leave the real decision to HMO administrators.' Such an outcome, minimizing the policing of managed care and increasing the risk to patients, is unacceptable."); Leonard A. Nelson, *Recent Developments in Health Care Law: Aetna v. Davila/Cigna v. Calad: A Missed Opportunity,* 31 Wm. Mitchell L. Rev. 843, 845 (2005) ("This case [Davila] had huge national importance, and the issue deserved better and more careful analysis than it was given by the Court"); Michael E. Nitardy, Moran, *Kentucky Ass'n of Health Plans, and* Davila*: The (R)evolution of ERISA Preemption*, 18 St. Thomas L. Rev. 139, 140 (Fall, 2005) (asserting that the Supreme Court's ERISA preemption as "the bane of patients and the savior of insurers").
8 The ERISA Preemption Amendments of 1991: Hearing on S. 794 Before the Subcomm. on Labor of the Comm. on Labor and Human Resources, 102nd Cong. 2 (1991) (opening statement of Senator Howard M. Metzenbaum (D-OH), Chairman of the Subcommittee).
9 *See Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 221 (2002) (holding that ERISA does not authorize "the imposition of personal liability. . . for a contractual obligation to pay money"); *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255, 257-58 (1993) (finding that ERISA's "appropriate equitable relief" does not include compensatory damages); *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 148 (1985) (observing in dicta that "there is a stark absence—in the [ERISA] statute itself and in its legislative history—of any reference to an intention to authorize the recovery of extra contractual damages").
10 *See Knudson*, 534 U.S. at 221; *Mertens*, 508 U.S. at 255; *Russell*, 473 U.S. at 148.
11 *See Davila*, 124 S. Ct. at 2491 ("Any state-law cause of action that duplicates, supplements, or supplants ERISA's civil enforcement remedy conflicts with the clear congressional intent to make that remedy exclusive,

and is therefore preempted."); *Leading Case: C. ERISA, supra* note 7, at 456-57 (*Davila* "closed the door on state legislation granting patients a right to sue their HMOs for negligent utilization review."); Edward F. McArdle, *2003-2004 Survey of New York Law: Health Law*, 55 Syracuse L. Rev. 1107, 1127 (2005) (noting that *Davila* made it clear that ERISA does not allow private lawsuits by patients based on state law malpractice or negligence causes of action).

12 *See* Nitardy, *supra* note 7, at 145-46 (explaining that ERISA preemption forces the claimant to bring suit only under ERISA whether or not preemption is complete or conflict-based). *See also* discussion *infra* Part II (B) (1) and (2) (discussing and comparing ERISA "complete" and "conflict" preemption).

13 *See Davila*, 124 S. Ct. at 2503 (Ginsburg, J., concurring).

14 *See* Ruger, *supra* note 4, at 530 ("By shifting the equilibrium point of managed care regulation from a shared federal-state enterprise to one that is (in this area, at least) exclusively federal, the Court has put more immediate pressure on federal government actors to come forward with concrete solutions to public concerns about managed care decision-making"); Barnidge, *supra* note 6, at 149-50 ("The *Davila* decision has now made the issue of "fixing" the ERISA preemption doctrine a congressional one, instead of a judicial one."). Barnidge argues that the Justices found themselves with their hands tied behind their backs in *Davila*: "[I]t is apparent that the Court finally felt bound by the constraining language of the ERISA statute. There was no longer a set of facts present that would allow 'wiggle room' or a loophole for the Court to maneuver through in order to provide some form of relief. At oral argument, Justice Breyer stated that the denial in treatment by the HMOs 'seems to be the thing that ERISA forbids. I don't see how to get around it.'"; *id.* at 148.

15 *See Davila*, 124 S. Ct. at 2503 (Ginsburg, J., concurring) (proposing that "fresh consideration of the availability of consequential damages under § 502(a)(3) [of ERISA] is plainly in order", and suggesting that ERISA § 502(a)(3) may "allow at least some forms of 'make-whole' relief against a breaching *fiduciary* in light of the general availability of such a relief in equity at the time of the divided bench.") (emphasis in the original). *See generally* Charlotte Johnson, *Justice Ginsburg's Fiduciary Loophole: A Viable Achilles' Heel to HMOs' Impenetrable*, 2006 B.Y.U.L Rev. 1589 (2006) (arguing that § 502(a)(3) of ERISA allows ERISA-regulated plan beneficiaries to sue their HMO for consequential damages on a theory of breach of fiduciary duty to the ERISA plan).

16 29 U.S.C. 1001(b) (2000).

17 *See DiFelice*, 346 F.3d at 454; Jeffrey W. Stempel & Nadia von Magdenko, Doctors, HMOs, ERISA, and the Public Interest After Pegram v. Herdrick, 36 Tort & Ins. L.J. 687, 694-95 (2001).

18 *See* Stempel & Magdenko, *supra* note 17, at 697 (noting that the preemption clause, which extended regulation to all employee benefits plans, "was adopted without the thorough investigation, spirited debate, and careful study that otherwise characterizes Congress' work in drafting the statute because the final preemption language was added only ten days before Congress approved the final bill"). *See also* Kathy L. Cerminara, *Protecting Participants in and Beneficiaries of ERISA-Governed Managed Health Care Plans*, 29 U. Mem. L. Rev. 317, 326 (1999); Robert L. Aldisert, *Blind Faith Conquers Bad Faith: Only Congress Can Save Us After Pilot Life Ins. Co. v. Dedeaux,* 21 Loy. L.A. L. Rev. 1343, 1350 (1988).

19 *See* Cerminara, *supra* note 18, at 326; Aldisert, *supra* note 18, at 1350.

20 29 U.S.C. 1002(1).

21 29 U.S.C. 502(a). *See* discussion *infra*, Part II (A) ERISA Civil Enforcement Provisions.

22 *See* Stempel & Magdenko, *supra* note 18, at 698; Aldisert, *supra* note 18, at 1355 (discussing background of section 514).

23 *See* 29 U.S.C. 1144(a); Nitardy, *supra* note 7, at 142 ("One stated purpose of ERISA was to create a single uniform body of law to cover the area of pension and welfare benefits. This was so that fifty different regulatory schemes will not challenge ERISA for its regulatory power, and also so that employers would not be excessively burdened by the added cost of keeping up with 50 different regulatory schemes. To make that exclusive control more apparent, Congress enacted an express preemption provision.").

24 *See* ERISA § 29 U.S.C. 1144(a).

25 *See* 29 U.S.C. 1144(b)(2)(A).

26 *See* 29 U.S.C. 1144(b)(2)(B).

27 *Id.*; *Metro. Life Ins. Co. v. Massacusetts*, 471 U.S. 724, 733 (1985) (referring to ERISA Section 514(a)(2)(B) as the "deemer clause").

28 *See* discussion *supra* Part II(C).

29 *See id.*

30 ERISA § 29 U.S.C. 1132(a)(1).

31 ERISA § 29 U.S.C. 1132(a)(2).

32 *See Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 54 (1987); *see also* Nelson, *supra* note 7, at 871 (noting that Section 502(a) actually contains nine enforcement provisions, and explaining that the Court probably referred only to those provisions that allow for enforcement by private party when it spoke of six enforcement provisions).

33 *See Pilot Life Ins. Co.*, 481 U.S. at 54.

34 *See Davila*, 124 S. Ct. at 2491.

35 *See* U.S. Const. Art. VI; Nitardy, *supra* note 7, at 147-48 ("ERISA receives its power to preempt state laws and other contrary causes of action from the powers imbued to it by Congress and the Supremacy Clause of the Constitution. When Congress acts within an area assigned to it, Article VI provides Congress with the necessary power to trump other state laws attempting to work in or along side the area in which Congress explicitly controls.").

36 Nitardy, *supra* note 7, at 148.

37 *Id.*

38 *See Davila*, 124 S. Ct. at 2494-96.

39 *See id.* at 2495 (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 54 (1987)); Stempel & Magdenko, *supra* note 16, at 699 (explaining that complete preemption was first found in ERISA Section 502(a)).

40 *See Davila*, 124 S. Ct. at 2495 (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 54 (1987)).

41 *See id.* at 2496. *See also* Karen A. Jordan, *The Complete Preemption Dilemma: A Legal Process Perspective*, 31 Wake Forest L. Rev. 927, 956 (1996) ("[R]emoval pursuant to the doctrine of complete preemption in ERISA cases hinges on whether the claim is within the scope of 502(a)."); Barnidge, *supra* note 6, at 133-34 ("only section 502(a) serves to automatically remove a case brought under its parameters").

42 *See Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 65-66 (1987).

43 *See Davila*, 124 S. Ct. at 2496 (explaining further that "if an individual brings suit complaining of a denial of coverage for medical care, where the individual is entitled to such coverage only because of the terms

of an ERISA-regulated plan, and where no legal duty (state or federal) independent of ERISA or the plan terms is violated, then the suit falls 'within the scope of' ERISA").
44 *See* 29 U.S.C. 1144(a).
45 *See* 514 U.S. 645 (1995).
46 *See Pilot Life Ins. Co.*, 481 U.S. at 48.
47 *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983); Aldisert, *supra* note 18, at 1360; Barnidge, *supra* note 6, at 134 ("Originally, the Court applied a textualist interpretation to section 514, which resulted in 'a staggeringly broad preemptive scope.'").
48 *See Travelers Ins. Co.*, 514 U.S. at 655-56.
49 *See id.* at 657 (noting that the objective of Section 514(a) "was described in the House of Representatives by a sponsor of the Act, Representative Charles Dent (R-PA), as being to 'eliminate the threat of conflicting and inconsistent State and local regulation'"); Jordan, *supra* note 41, at 63-64 ("[I]n more recent years, the Court has also more clearly refined limitations on the broad scope of ERISA preemption. The Court has determined that the analysis should be guided by the objectives of ERISA and should involve consideration of the nature and purpose, as well as the effect, of the state law at issue.").
50 *See Travelers Ins. Co.*, 514 U.S. at 658.
51 *See* 29 U.S.C. 1144(b)(2)(A).
52 *See* Nitardy, *supra* note 7, at 147 ("The Savings Clause was inserted into the express provision language in order to leave for the states areas that have historically remained under their purview."); Russell Korobkin, *The Failed Jurisprudence of Managed Care, and How to Fix It: Reinterpreting ERISA Preemption*, 51 UCLA L. Rev. 457, 467 (2003) ("The clear intent of [the "savings clause"] is to prevent the relates-to clause from being read so broadly as to supersede the myriad, complicated, and historically rooted regulation of the business of insurance by state legislators and regulators.").
53 538 U.S. 329 (2003).
54 *Id.* at 341-342.
55 *Id.*
56 *Id.*
57 *See* 29 U.S.C. 1144(b)(2)(B); Nitardy, *supra* note 7, at 147.
58 *See* 29 U.S.C. 1144(b)(2)(B).
59 471 U.S. 724 (1985).
60 *See* 29 U.S.C. 1144(b)(2)(B); *Metro. Life Ins. Co.*, 471 U.S. at 746-47 ("We are aware that our decision results in a distinction between insured and uninsured plans, leaving the former open to indirect regulation while the latter are not. By so doing we merely give life to a distinction created by Congress in the "deemer clause," a distinction Congress is aware of and one it has chosen not to alter.").
61 530 U.S. 211 (2000).
62 29 U.S.C. 1109(a).
63 *Pegram*, 530 U.S. at 214.
64 *Id.* at 215.
65 *Id.*
66 *Id.*
67 *Id.* at 215-16.
68 *Id.* at 216.
69 *Id.* at 226.
70 *Id.* at 228-29 ("What we will call pure 'eligibility decisions' turn on the plan's coverage of a particular condition or medical procedure for its treatment. 'Treatment decisions,' by contrast, are choices about how to go about diagnosing and treating a patient's condition: given a patient's constellation of symptoms, what is the appropriate medical response?").
71 *Id.* ("In practical terms, these eligibility decisions cannot be untangled from physicians' judgments about reasonable medical treatment.").
72 *Id.* at 235-36.
73 *Id.* at 235-37 ("Thus, for all practical purposes, every claim of fiduciary breach by an HMO physician making a mixed decision would boil down to a malpractice claim, and the fiduciary standard would be nothing but the malpractice standard traditionally applied in actions against physicians.").
74 *Id.* at 237.
75 *Id.*
76 124 S. Ct. 2488, 2492 (2004); Tex. Civ. Prac. & Rem. Code Ann. §§ 88.001-88.003 (2004 Supp. Pamphlet).
77 *See* Nelson, *supra* note 7, at 852 (explaining that THCLA was a legislative response to long-ignored claims by consumer advocate groups that managed care organizations were relying on the fact that the intricate and detailed language of the plans they covered made it difficult for lay persons to understand their benefits under the plans to wrongfully deny such benefits). Nelson provides an excellent analysis of the benefits and risks of having a piece of legislation like THCLA. *Id*. at 878-80.
78 THCLA, Tex. Civ. Prac. & Rem. Code Ann. § 88.002(a).
79 *Davila*, 124 S. Ct. at 2492; Tex. Civ. Prac. & Rem. Code Ann. § 88.002(a).
80 *Davila*, 124 S. Ct. at 2493-94.
81 *See generally, Davila,* 124 S. Ct 2488.
82 Brief for Respondents at 6-7, *Aetna Health Inc. v. Davila*, 124 S. Ct. 2488 (2004) (Nos. 02-1845, 03-83).
83 *Id.* at 7.
84 *Davila*, 124 S. Ct. at 2493-94 (describing the employee benefit plan arrangements as follows: "Under Davila's plan . . . Aetna reviews requests for coverage and pays providers, such as doctors, hospitals, and nursing homes, which performed covered services for members; under Calad's plan sponsor's agreement, CIGNA is responsible for plan benefits and coverage decisions").
85 *Id.* at 2493-94; Brief for Respondents at 5, *Aetna Health Inc. v. Davila*, 124 S. Ct. 2488 (2004) (Nos. 02-1845, 03-83).
86 *Davila*, 124 S. Ct. at 2493-94.
87 *Id.*
88 *Id.* at 2493.
89 *Id.*
90 *Id.*
91 *Id.*
92 *Id.* at 2493-94.
93 *Id.* at 2494.
94 *Id.*
95 *Id.*
96 *Id.*
97 *Id.*
98 *Id.*; *CIGNA Health Care of Tex., Inc. v. Calad*, 124 S. Ct. 463 (2003).
99 *Land v. CIGNA Healthcare of Fla.*, 339 F.3d 1286 (11th Cir. 2003).
100 *Cicio v. Does*, 321 F.3d. 83 (2d Cir. 2003).
101 *See* Nelson, *supra* note 7, at 860.
102 *DiFelice*, 346 F.3d 442.
103 *See id.* at 449; Nelson, *supra* note 7, at 860.
104 *See Davila*, 124 S. Ct. at 2502.
105 *Id.* at 2495; *see* Nelson, *supra* note 7, at 883 (attacking the proposition that ERISA is a comprehensive statute). Nelson argues that ERISA may be referred to as a comprehensive statute with respect to its regulation of pension plans, but the same cannot be said regarding

its welfare plan provisions. He explains that while ERISA "regulate[s] the procedural standards and content of pension plans," it does not regulate the content of welfare plans.
106 *Id.*
107 *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002).
108 *See Davila*, 124 S. Ct. at 2494.
109 *Id.* at 2499.
110 *Id.* at 2495
111 *Id.* at 2498-99.
112 *Id.*
113 *See Davila*, 124 S. Ct. at 2499.
114 *Id.*
115 *Id.* at 2497-98.
116 *Id.*
117 *Id.* at 2498.
118 *Id.*
119 *See Davila*, 124 S. Ct. at 2501-02.
120 *Id.* at 2501 ("Congress did not intend [the defendant HMO] or any other HMO to be treated as a beneficiary to the extent that it makes mixed eligibility decisions acting through its physicians.").
121 *Id.* at 2502 (citing *Cicio* 321 F.3d at 109 (Calabresi, J., dissenting in part)).
122 *Id*. at 2501-02.
123 *Id.*
124 *See Davila*, 124 S. Ct. at 2503 (Ginsburg, J., concurring) (quoting *DiFelice v. Aetna U.S. Healthcare*, 346 F. 3d 442, 453-54 (3d Cir. 2003) (Becker, Circuit Judge, concurring)).
125 *Id.*
126 *Id.*
127 473 U.S. 134 (1985).
128 *See Davila*, 124 S. Ct. at 2503; *Russell*, 473 U.S. at 148.
129 508 U.S. 248 (1993).
130 *See Davila*, 124 S. Ct. at 2503 (quoting *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 256 (1993)) (noting that the *Mertens* Court "held that § 502(a)(3)'s term 'equitable relief' . . . refer[s] to those categories of relief that were *typically* available in equity (such as injunction, mandamus, and restitution, but not compensatory damages)" (emphasis in original)).
131 534 U.S. 204 (2002).
132 *See Davila*, 124 S. Ct. at 2503; *Knudson*, 534 U.S. at 221. *See also* Johnson, *supra* note 15, at 1624 ("All that remains of 'typically equitable' remedies after Great-West is '(1) injunction, for which Congress did not need to provide 'other equitable relief' in section 502(a)(3), having already expressly authorized injunction earlier in the same sentence; and (2) restitution for cases that might have been brought as constructive trust actions before fusion.'").
133 *See Davila*, 124 S. Ct. at 2503-04.
134 *Id.*
135 *Id.* emphasis in original.
136 *See, e.g.* Cameron Krier, *One Step Forward, Two Steps Back: The Impact of Aetna Health Inc. v. Davila on ERISA and Patient's Rights*, 38 Tex. Tech L. Rev. 127, 129, 148 (2005) (declaring that "*Davila* left millions of Americans without the ability to obtain fair compensation and access to state courts" because "[t]he Supreme Court essentially slammed state courthouse doors to millions of Americans seeking relief against their HMOs."); Nelson, *supra* note 7, at 870 ("*Davila/Calad*'s primary effect is the determination that ERISA preempts and thus invalidates state laws that purport to impose tort liability against HMOs."); Donald T. Bogan, *ERISA: State Regulation of Insured Plans After Davila*, 38 J. Marshall L. Rev. 693, 693 (2005) ("*Aetna Health, Inc. v. Davila* . . . establishes that ERISA prohibits plan participants from pursuing extra-contractual damages under state law in actions arising from abusive claims settlement practices committed by ERISA plan insurers."); Elizabeth Khoury, *HMO Liability After* Aetna Health Inc. v. Davila*: Are Patients' Rights at Risk?*, 91 Iowa L. Rev. 1621, 1642 (2006) (noting that after *Davila*, "in the event a patient wanted to dispute a denial of medical coverage, section 502 would be the only source of relief. State tort claims against HMOs [are] preempted"); McArdle, *supra* note 11, at 1121 ("In *Aetna Health Inc. v. Davila*, the Supreme Court dealt a severe blow to the ability of patients to bring damages lawsuits against [HMOs] and other managed care health insurers based on state law causes of action."); Barnidge, *supra* note 6, at 126 ("In short, the Court's decision effectively shuts the door on the majority of patients' compensation claims for injuries sustained as a result of a denial of coverage or benefits by their Health Maintenance Organization (HMO).").
137 *See, e.g. Kuthy v. Mansheim*, 124 Fed. Appx. 756, 757 (4th Cir. 2004); *Barber v. Unum Life Ins. Co.*, 383 F.3d 134, 136 (3d Cir. 2004); *Land v. CIGNA Healthcare of Fla.*, 381 F.3d 1274 (11th Cir. 2004); *Mayeaux v. L.A. Health Serv. & Indem. Co.*, 376 F. 3d 420 (5th Cir. 2004); *Lind v. Aetna Health, Inc.*, 466 F.3d 1195, 1201 (10th Cir. 2006); *McDonald v. Household Int'l, Inc.*, 425 F.3d 424 (7th Cir. 2005).
138 *See Kuthy* 124 Fed. Appx. at 757.
139 *Id.* at 757.
140 *Id.*
141 *Id.* at 757-58.
142 *See Barber*, 383 F.3d at 136.
143 *Id.*
144 *Id.*
145 *Id.*
146 *See Land*, 381 F.3d at 1276.
147 *Id.*
148 *Id.*
149 376 F. 3d at 431-32.
150 *Id.*
151 *Id.*
152 *Id.* at 432.
153 *Lind,* 466 F.3d at 1201.
154 *Id.* at 1197-98.
155 *Id.*
156 *Id.* at 1199.
157 *Id.*
158 *Lind*, 466 F.3d 1199.
159 425 F.3d 424.
160 *Id.*
161 *Id.* at 426.
162 *Id.* at 429.
163 *See* text accompanying note 137; discussion *supra* Part III (E) (discussing a number of federal circuit court cases decided after *Davila*).
164 *See Davila*, 124 S. Ct. at 2497 ("Upon the denial of benefits, respondents [*Davila* and *Calad*] could have paid for the treatment themselves and then sought a preliminary injunction.").
165 *See* Barnidge, *supra* note 6, at 149 (referring to Justice Ginsburg's prediction that one day the Court may confirm that "Congress . . . intended ERISA to replicate the core principles of trust remedy law, including the make-whole standard of relief" as a "bold statement" given that only one member of the Court joined her concurrence, but observing that Justice Ginsburg's prediction may become a reality if Congress refuses to act to correct the problems of ERISA); *McDonald*, 425 F.3d at 430 (recommending to the plaintiffs in the case that on remand "they may wish to take note of Justice Ginsburg's comment in her concurring opinion in *Davila*, in which she drew attention to the Government's suggestion that ERISA "as currently written and interpreted, may allow at least some forms of 'make-whole' relief against a breaching *fiduciary* in light of the general availability of such relief in equity at the time of the divided bench."").
166 *See* Johnson, *supra* note 15, at 1623 ("Including a cause of action in ERISA for breach of fiduciary duty that preempts state law claims yet denies individual compensatory relief creates a vehicle for HMOs to defraud."); Khoury *supra* note 136, at 1643-44 (proposing that under the Court's interpretation of ERISA, "the benefits are shifted to the HMOs and the burdens to patients. In fact, because HMOs need not fear tort damages for wrongful denials of care, HMOs might have more of an incentive to provide less coverage for care").
167 *See* Krier, *supra* note 136, at 129; Nelson, *supra* note 7, at 870; Donald T. Bogan, *ERISA: State Regulation of Insured Plans After Davila*, 38 J. Marshall L. Rev. 693, 693 (2005); Khoury *supra* note 136, at 1642; McArdle, *supra* note 11, at 1121; Barnidge, *supra* note 6, at 126.
168 The ERISA Preemption Amendments of 1991: Hearing on S. 794 Before the Subcomm. on Labor of the Comm. on Labor and Human Resources, 102nd Cong. 2 (1991) (opening statement of Senator Howard M. Metzenbaum, Chairman of the Subcommittee) (stating that "all [ERISA plaintiffs] can hope for is that after two or three years of court action their claim will be paid, but with no damages."); Johnson, *supra* note 15, at 1623

("[W]ith only 'equitable' remedies under ERISA, as interpreted by the courts, the most that could happen is the HMO would be forced to cover only the medical treatment in question and not any resulting harm from the HMO's decision to deny the physician's prescribed medical treatment.").
169 *See* Johnson, *supra* note 15, at 1623; *but see* Ruger *supra* note 4, at 530 (noting that "even if a plan faced full after-the-fact liability for every denial of care, a rational plan administrator might still deny care and pay later to capture the time value of the money otherwise spent on benefits"). However, Ruger expresses some preoccupation that the incentives for the HMO to defraud patients are overstated. He points out that "market pressures and the threat of consumer revulsion place some practical limits on a plan's ability to deny care."
170 *See id.* ("Participants in the midst of medical crises are generally in no position to appeal their beneficiary rights.").
171 *See* Krier *supra* note 136, at 148-49.
172 *See Davila*, 124 S. Ct. at 2500-01.
173 *See* Krier *supra* note 136, at 148-49; Ruger *supra* note 4, at 530.
174 *See* Nelson *supra* note 7, at 848-49.
175 *See* Krier *supra* note 136, at 148-49 ("*Davila* may force physicians to make a difficult choice between maximizing traditional clinical autonomy and slightly reducing malpractice risk by relinquishing control over certain decisions to plan administrators."); Ruger *supra* note 4, at 530; David L. Trueman, *Will the Supreme Court Finally Eliminate ERISA Preemption?,* 13 Ann. Health L. 427, 445 (2004) (arguing that, as things stand today, "if the physician recommends treatment and the HMO denies coverage, the patient has no recovery. [t]herefore, the Corcoran decision allows the HMO to escape liability if the HMO tells the physicians to recommend every possible, but leaves the real decision to the HMO administrator").
176 *See* Khoury *supra* note 136, at 1643-44; L. Darnell Weeden, *ERISA's Preemption Ruling Prevents a Patient from Suing an HMO Under State Malpractice Law: After* Aetna Health, Inc. v. Davila *Who Will Grant the Working Middle Class a Meaningful Right to be Heard?,* 7 U. Pa. J. Lab. & Emp. L. 715, 741 (2005) (encouraging recognition that through the utilization review process HMOs "use an incidental or ministerial coverage question to undermine the quality of medical treatment decisions made by [the] treating physician").
177 *See* Brief for Respondents at 6-7, *Aetna Health Inc. v. Davila*, 124 S. Ct. 2488 (2004) (Nos. 02-1845, 03-83); *Davila*, 124 S. Ct. at 2493-94.
178 *See* Barnidge, *supra* note 6, 150.
179 *See Davila*, 124 S. Ct. at 2503 (Ginsburg, J., concurring) (quoting *DiFelice v. Aetna U.S. Healthcare*, 346 F. 3d 442, 453-54 (3d Cir. 2003) (Becker, Circuit Judge, concurring)).
180 *See* Barnidge, *supra* note 6, at 150-53 (providing a brief chronology of Congress' efforts to pass a patients' bill of rights).
181 *See* Bipartisan Patient Protection Act, S. 1052, 107th Cong. (2001) (as passed by Senate, June 29, 2001); Bipartisan Patient Protection Act, H.R. 2563, 107th Cong. (2001) (as passed by House, Aug. 2, 2001).
182 Bipartisan Patient Protection Act, S. 1052, 107th Cong. (2001) (as passed by Senate, June 29, 2001); Helen Dewar & Amy Goldstein, *Senate Passes Patients' Rights Bill*, Wash. Post, June 30, 2001, at A1.
183 *See* Barnidge, *supra* note 6, at 152 ("Senator Edward M. Kennedy of Massachusetts placed the blame solely on the White House stating that 'if they had been willing to hold the HMOs and the insurance industry accountable, we could have gotten legislation.' The White House fired back with its own criticism, quipping that 'it appears some are still not able to break loose from the grip of powerful personal injury trial lawyers.'").
184 *See Sen. Boxer Introduces Patients' Bill of Rights*, States News Service, Feb. 17, 2004; Barnidge, *supra* note 6, at 152.
185 *See* Stephen Taub, *Senate Revives Patient-Rights Bill: Federal Laws Must Be Enacted for Patients to Be Able to Sue Their HMOs in State Courts*, CFO.Com, June 24, 2004; Barnidge, *supra* note 6, at 152-53.
186 *See* Lydell C. Bridgeford, *Democrats to re-evaluate health care*, Employee Benefit News**,** February 1, 2007.
187 *See* Nelson, *supra* note 7, at 878-80 (providing an excellent analysis of the pros and cons of patients' rights legislation).
188 *See id.* (concluding that "THCLA could have the undesired effect of actually shrinking the social safety net").
189 *See id.* at 881 ("In the abstract then, the reasons for allowing tort liability against HMOs are countered by equally weighty reasons for disallowing such liability. Whether, in practice, the policy considerations would remain in balance, or whether one set of principles would be seen to predominate over the other cannot be known except through experience.").
190 *See id.*
191 285 U.S. 262 at 311 (1932).
192 *Id.* at 262, 311 (Brandeis, J., dissenting).
193 *See* Nelson, *supra* note 7, at 882.
194 *See id.*
195 *See id.*
196 *See Davila*, 124 S. Ct. at 2502.
197 *See* Krier, *supra* note 136, at 129; Nelson, *supra* note 7, at 870; Bogan, *supra* note 173, at 693; Khoury *supra* note 136, at 1642; McArdle, *supra* note 11, at 1121; Barnidge, *supra* note 6, at 126.
198 *See* Barnidge, *supra* note 6, 150.

Concierge Medical Practices within the Regulated Medicine Environment: Are They Ethical, Workable, Legal?

*J. Kevin Markwell, M.D.**

> . . . [T]he concierge physician is able to guarantee such services as: priority, same day, extended appointments; 24-hour pager, e-mail, or cell phone access to the physician; house calls or other care outside the office, including accompanying patients on visits to specialists; elegant waiting rooms and spa-like amenities; free and more thorough physical exams; and preventive care, wellness, weight loss, and nutrition counseling.

I. Introduction

According to Webster's Dictionary, the French word *concierge*, derived from the Latin *conserves*, or fellow slave, is defined as: doorkeeper, custodian, head porter. The implied image to prospective patients when used in the context of the nascent national phenomenon of exclusive priority medical care for a prepaid premium would appear to be that of a ready and willing caretaker who is always available to the patient fortunate enough to be in the program. The reciprocal connotation regarding the provider, then, is evidently that of a highly skilled "Johnny on the spot" or handmaiden. The unavoidable question then becomes why a well-qualified physician would willingly choose to put him or herself in such a role. What would transform the honorable call to serve many pressing needs of one's fellow man into a sycophantic subservience to the few who can afford instant and, perhaps often times, superfluous attention?

Answering this question will help explain the genesis of this emerging trend, commonly known as Boutique Medicine, Cadillac Care, Platinum Practice, and other specific elitist sounding names, such as that of one of the largest current concierge franchises, MDVIP. After a brief background, this article will explore this interesting psychosocial question of how economic forces have influenced individual physician choices, and address the more important overarching issues of whether society should sanction, pay to support, or even tolerate such private contracts. Finally, the article defines and predicts the application of the law and controlling regulations relevant to these controversial enterprises.

A. What is a Concierge Medical Practice?

Concierge care is a relatively new concept in health care delivery that is generally offered by Family Medicine practitioners or Internists providing out-patient primary care who also sell special services for an additional annual fee. By significantly decreasing his or her panel of patients from typically 3,000 per provider to 300 or 600 patients, the concierge physician is able to guarantee such services as: priority, same day, extended appointments; 24-hour pager, e-mail, or cell phone access to the physician; house calls or other care outside the office, including accompanying patients on visits to specialists; elegant waiting rooms and spa-like amenities; free and more thorough physical exams; and preventive care, wellness, weight loss, and nutrition counseling. The fees charged vary from $1,500 to $13,500 per person per year.[1] The more expensive plans accept no insurance and are, therefore, the province of the truly wealthy members of society. These rare plans raise legal issues regarding insurance regulations, but involve no governmental health care regulatory questions, per se, and will not be discussed in this article.

The more common concierge practice does accept reimbursement from private health insurance and Medicare. In fact, the annual concierge fee is not intended to pay for specific medical service such as labs, x-rays, medicines or other services covered by the patient's primary payer. This article discusses in the next sections how the concierge concept under these circumstances correlates with the Medicare rules and what the goals should be of the federally subsidized health care system regarding concierge care as it exists.

B. What Motivates Physicians to Chauffer the Cadillac?

Unfortunately, the morale of many physicians today is low. Ask almost any practitioner and he or she will recount a litany of hassles encountered on a daily basis, including Medicare or other insurance paperwork, diminished reimbursements, restrictions imposed by managed care, lack of time for patients, and encroachment on their personal time. Gone are the days when a physician was the master of his or her own practice, an independent, self-employed entrepreneur. Physicians feel increasingly squeezed by administrative burdens and rising overhead costs, such as increasing malpractice insurance premiums, at the very time physician reimbursements are being reduced and are often delayed. To compensate and support their incomes, physicians have typically resorted to treating an ever increasing number of patients, leading to an upward spiral of burgeoning frustrations.

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Concierge care has come along just at the time many physicians are crying uncle, and, rather than throwing in the towel, are electing to change the rules of the game and shift to a kinder, gentler arena. The profound allure of a concierge practice is that it offers the marvelously counterintuitive double incentive of a less hectic pace, although perhaps less predictable and, for nearly all primary care providers, a pronounced increase in their incomes. What could be better: less patients, more money? As a concrete example, consider that the average primary care provider makes $153,000 per year and sees 112 patients per week.[2] If that same provider develops an MDVIP[3] franchise practice, he receives $1,000 of the patient's $1,500 enrollment fee – the remainder going to the parent company – in addition to the normal reimbursements earned performing medical procedures or treating patients. The math is quite astounding when one considers that an MDVIP provider with a panel of 600 patients typically sees 30 patients per week.[4] The major downside, evidently, is that any one of those patients may request to be seen when the provider is teeing up on the fourth hole or brushing his teeth at bedtime, yet the physician remains obligated under the concierge arrangement to respond to that unwelcome call.

C. In a Free Market Society, Why is Concierge Care Controversial?

Since the inception of Boutique Medicine, newspaper editorial pages, medical journals, letters to editors, and the blogosphere have included numerous arguments both for and against concierge practices. Addressing the debate on what it prefers to refer to in non-elitist terms as "retainer practices," the American Medical Association (AMA) perhaps best encapsulates the issues in a one page report of its Council on Ethical and Judicial Affairs (CEJA). This official AMA policy statement serves well as an outline to follow to address the relevant principles and list of concerns enumerated by the CEJA.[5]

The AMA generally supports physicians' entrepreneurial right to freely contract for the medical care they provide with some significant caveats. The CEJA maintains that providing special services and amenities to patients who pay additional fees is "consistent with pluralism in the delivery and financing of health care."[6] The abstract concept of pluralism in our capitalist economic environment is apparently the CEJA's sole ethical justification for permitting such exclusivity because, after making this contention in the first two sentences of the report, the rest of the document lays out the ethical and practical conundrums and potential medical-legal landmines encountered by living with such a free market principle in a country with limited medical resources.

Looking to the broader ethical and philosophical considerations is necessary because, as a strict matter of statutory interpretation, what at first glance seems to be rigidly controlling law has been rendered malleable in the hands of the current federal government. The Medicare statute requires physicians to submit claims for all procedures performed on Medicare patients, even if the physicians do not accept assignment.[7] Medicare also prohibits physicians who accept assignment of a patient's claim from charging more than the Medicare fee schedule amount. Those physicians who do not accept assignment are prohibited from charging more than 115 percent of the fee schedule amount.[8] In 2002, five Democratic members of the House of Representatives challenged the legality of the Florida-based MDVIP's practices under the statute.[9] They also introduced legislation to prohibit doctors from charging Medicare beneficiaries membership fees or any incidental fees, or to require them to purchase non-covered items or services as a condition of receiving covered services. This legislation has gone nowhere in the Republican-controlled Congress. In a letter responding to their complaints, then Secretary of Health and Human Services (HHS), Tommy Thompson, determined that, as long as the concierge fees charged by MDVIP were for non-covered services, such fees would not violate the Medicare rules and added that HHS would continue to carefully monitor such practices.[10] What that monitoring process is exactly looking for has not been elucidated. Besides the statute, which is evidently open to interpretation, and beyond this predictable general philosophical disagreement across the Congressional aisle lie the five following dilemmas addressed by the CEJA that frame the arguments on both sides.

First, in laying out the policy of how physicians could "opt out" of traditional Medicare or insurance reimbursable health care delivery, the CEJA document stresses honesty and fair dealing in contracting by stating that patients must also be able to opt out of a retainer contract without undue inconveniences or financial penalties. This is a mutually libertarian principle on its face: physicians are able to decide who they see based on who can afford the services they choose to offer, and patients can decide to get on board or leave as they please. However, it is not without irony when one considers that once a physician has pared his practice down to a small number of patients, should a significant number of them decide to get off the boat midstream, the physician could be left up the proverbial creek with too few paddles supporting his practice. This situation is not dissimilar to the reverse consequences of a significant number of physicians opting out of Medicare,

. . . [O]nce a physician has pared his practice down to a small number of patients, should a significant number of them decide to get off the boat midstream, the physician could be left up the proverbial creek with too few paddles supporting his practice.

effectively leaving patients high and dry without a boat to navigate the turbulent health care waters.

This first provision goes to the heart of the gamble physicians take when they restrict the pool of patients they can recruit. The CEJA document specifically cautions that a patient's health insurance should not be jeopardized by the arrangement. The potential compromise of a patient's health insurance coverage is a real concern because some plans prohibit charges beyond what is covered. It is a violation of some state licensing boards and insurance laws to hold managed care enrollees responsible for any additional charges for covered services. [11] The net effect of this need to rely on and preserve each patient's underlying health insurance may be that the requirements for entry into boutique plans are further elevated beyond the reach of the average citizen. Effectively, only those with the most robust, and presumably most expensive insurance policies, or those whose jobs already provide excellent health insurance, would qualify; otherwise, both physician and patient are put at risk. Analogously, not only would one have to be able to afford the dues to the country club, but the security of one's source of income would have to meet muster, as well.

> . . . [N]ot only would one have to be able to afford the dues to the country club, but the security of one's source of income would have to meet muster, as well.

Second, the CEJA emphasizes that "it is important that a retainer contract not be promoted as a promise for more or better diagnostic and therapeutic services . . . . Physicians who engage in mixed practices . . . must be particularly diligent to offer the same standard [of care] to both categories of patients."[12] Concierge physicians are cognizant of this admonition and attempt to walk the line between promising to provide equivalent levels of care to all their patients while reassuring their wealthier clients that they are getting their money's worth. A representative testimonial of a concierge provider proclaims: "We don't claim to be practicing better medicine, but the fact that we can spend more time with our patients means they're going to get better care."[13] Below, the inherent inequities that are likely to occur in a two-tiered practice despite the rhetoric otherwise are discussed.

Third, the CEJA firmly states it is imperative that physicians do not abandon their patients.[14] Avoiding a claim of patient abandonment is one issue that warrants more than the soft ethical guidelines proposed in the document because well-defined caselaw creates a significant legal risk for a physician who takes no steps to find subsequent care for patients who leave his or her practice. Such charges can be expected when, for example, 2,500 patients are forced to find a new doctor; however, in practice, reducing a practitioner's patient load is done by well-known procedures any time a physician leaves town or moves to a smaller practice. Most physicians transitioning to a concierge practice obtain the necessary legal help to comply with these requirements. Nevertheless, care must be taken to avoid the perception or reality that the sickest patients are not offered the same opportunities to stay on, or that only those with the best insurance policies are kept in the new practice. From a policy perspective, the practice of "creaming off the top" only the healthiest and wealthiest patients should not be tolerated by concierge franchises or the community, whether or not there are specific laws against such a practice. If for no other reason than creating harmony among colleagues, the remaining non-concierge physicians in the community should not be expected to absorb only the least fortunate patients who are dumped in their laps.

Fourth, after reiterating the maxim that physicians must be honest in their billing practices, the CEJA states: "[i]t is desirable that retainer contracts separate clearly special services and amenities from reimbursable medical services."[15] Separating covered services from the extras is more than merely desirable; it is the legal *sine qua non* on which a concierge medical practice depends if it hopes to include Medicare patients in its clientele. In 2002, then HHS Secretary Tommy Thompson declared that, as long as the concierge fees charged by MDVIP were for non-covered services, such fees would not violate the Medicare limiting charge rules prohibiting fees above and beyond the physician fee schedule amount.[16] But the boundary between "special services and amenities" and "reimbursable medical services" remains unclear, apparently enough so that the CEJA statement continues: "[i]n the absence of such clarification, identification of reimbursable services should be determined on a case-by-case basis."[17] This invites the questions – determined by whom, when, and by what criteria? In most cases, crossing the boundary between an amenity and a covered service is clear enough that it does not require fine line analysis.

Like so many legal questions, the issue comes down to one of defining and categorizing terms; this has not occurred in any formal statute or regulation regarding concierge care. The central question involves the actual verses and semantic differences between a retainer fee, an access fee, and a charge for a non-covered service. The $1,500 to $13,500 paid annually to a physician in a concierge practice logically has to be considered one of the three. A retainer is a concept more familiar to the legal profession than the practice of medicine, its use in the latter context being more of a nebulous descriptor, rather than a legal term with attendant references or history. An additional access fee is clearly prohibited under Medicare rules that limit charges and prohibit balance billing, accounting for the complete shunning of

the term by any proponents of boutique medicine.[18] Therefore, classifying their surplus fees as charges for non-covered services provides the current categorical haven which allows concierge practices to exist.

However, as used, the term "non-covered service" is also an ill-defined concept that serves as a shape-shifting accounting black box. A physician's cell phone number, a plush monogrammed waiting gown, and an escort to an appointment with a specialist are clearly not covered services, but if a patient never utilizes any of them over the course of the year, can the patient be required to pay for them up front simply because they must in order to have any access at all to their doctor? This payment for an open-ended contingency would then not fit the definition of a charge for an actual non-covered service, but rather, could be considered nothing other than a payment for the privilege of access. Hence the AMA's preferred term, "retainer fee," is entirely appropriate if interpreted as an access fee, and cannot masquerade as a charge for an uncovered service. The legal catch-all case-by-case analysis proposed by the CEJA could only be applied after the fact to determine if indeed the extra amenities actually provided throughout the year amounted to sufficient services to reasonably justify the charge. Any excess beyond the fair market value of services rendered would have to be accounted for. Strict adherence to the HHS Secretary's guidance would then require the concierge practice to refund the balance of the retainer not used for the unneeded non-covered services. This is neither happening nor envisioned.

To counter this conclusion, concierge franchises must argue that the services they provide to all their clients, such as a more thorough annual physical exam and nutrition and lifestyle counseling, justify the entire retainer charge. If that is the case, the concierge practices should say so. But they do not itemize only these specific services as such in a bill and completely discount the value of the remainder of the variably utilized services they market. The fee is for a package of potential services and, as it stands, a healthy client's single visit for an annual exam effectively costs significantly more on a pro-rated basis than that of the needier client who makes use of the myriad of other benefits available under the flat fee. If the uniformly provided services truly justify the entire retainer fee, the practice then would be providing every other non-covered service as a free courtesy. It would be disingenuous at best to maintain such a contention.

Importantly, a $1,000 physical exam and $500 worth of "eat right and exercise more" would not stand up to the laugh test. But if the boutiques agree that the fee is for the whole package as advertised, the only other interpretation of the untapped, upfront cost paid by the healthy client is that it serves as insurance – and that involves a whole other kettle of regulatory fish that concierge practices do not operate under today nor likely contemplate abiding. Therefore, under this analysis, the AMA's stated desire for separation of charges is not being fulfilled and may well be unworkable. The current hybrid boutique practices that accept both Medicare and private paying patients such as MDVIP would be hard-pressed to pass a closely scrutinized investigation because not fulfilling the CEJA's desire to separate charges is in reality not complying with a legal requirement. Interestingly, Tommy Thompson, the former Secretary of HHS who did not see it this way when he gave his blessing to the concierge concept in 2002, is now employed by MDVIP.

The fifth and final "ethical concern that warrants careful attention" raised by the concierge concept addressed by the CEJA is the long-accepted notion that "physicians have a professional obligation to provide care to those in need, regardless of ability to pay, particularly to those in need of urgent care."[19] The first evidence that this may be an endangered, if not forsaken, ideal in the modern era, where the terms "provider" and "consumer" have replaced "physician" and "patient," is that at the drafting of the CEJA statement, the AMA proponents of boutique medicine argued that the word "urgent" in this document should be limited to "emergency."[20] Their concerns must be rooted in the practical reality of operating as a concierge practice where it would seem to be difficult for the doctor to take time or go out of the way to provide any type of charity care when he or she is obligated to remain immediately available around the clock to a personal panel of patients. A concierge provider presumably could set aside a block of vacation time to do charity work, but holding up his or her end of each of the 300 to 600 contracts with patients would significantly inhibit integrating any "pro bono" work into the day-to-day routine, as is the custom of most traditional practitioners.

. . . [W]hen a patient with a concierge contract requests attention at the same time as a Medicare-only patient, whose problem should take precedence?

The unstated parallel consideration is that it would be similarly problematic to operate a mixed practice that includes non-enrolled patients in addition to patients entitled to the concierge treatment. This mixing remains a common practice and often occurs at least temporarily as a physician transitions from an old practice to the new model. In such a practice, how is it determined which of these patients gets the provider's "urgent" attention? Traditionally, such triage decisions are based on the severity of the problem coupled with the time sensitivity of the indicated intervention. In a homogenous patient population where everyone begins with equal rights, i.e. they have all either paid a retainer fee, or they all have not, when simultaneous calls go into the doctor for an acute problem no one has a legitimate gripe when the doctor employs such a medical decision analysis. However, when a patient with a concierge contract requests attention at the same time as a Medicare-only patient, whose problem should take precedence? Arguably, the medical triage principle should still apply. But if that is the case, what is the concierge patient paying for? We are back to that $1,000 physical exam and $500 worth of counseling. On the other hand, if the concierge patient with a lesser problem takes precedence, is it ethically justifiable to make the otherwise entitled but worse off patient wait? The obvious but difficult to implement answer is that the choice should only swing the premium paying patient's way when his problem is clearly more urgent, or so similar as to be a toss-up. In the final analysis with respect to prioritizing urgent care, the fee entitles the payer to jump a rung in the triage ladder only in the instance of a coincidental tie in the level of urgency. In actuality, these head-to-head conflicts would seldom occur so bluntly, but are illustrative of the more subtle inequities that must be dealt with by patients and managed by providers in a two-tiered practice.

For instance, consider the Medicare-only patient, Mrs. Jones, with out of control diabetes and all its sequelae, who dutifully waits until her regularly scheduled brief appointment on Monday morning with Dr. Hilton, who was delayed that morning making a house call with Mr. Rich, who had a cold. Dr. Hilton is running behind schedule and knows that the MDVIP franchise audits his practice to ensure he maintains the strict timeliness standards they require, and he knows that the next patient after Mrs. Jones, Mr. Trump with the itchy scalp, is a demanding concierge customer who threatens to lodge a formal complaints when his contractual promises are not fully met, including the sixty-minute visit to discuss Rogaine. Could these monetarily driven superimposed conditions on Dr. Hilton apply undue extraneous pressures to cause him to invert the priorities that the traditional egalitarian medical ethic would demand in such circumstances? The unavoidable conclusion makes the fair management of a mixed practice a questionable proposition.

"It is not hard to imagine a small community where some providers cull their practices by 80 percent to establish concierge practices and effectively dump thousands of less well-off patients on the remaining already strapped providers."

It is not too far a reach to extend this same concern about the functioning of a single medical practice to the community. Thus far, concierge practices are cropping up primarily in the affluent areas of big cities. Should they spread to the small towns or less well served areas of cities, the consequences could exacerbate the pervasive problems of medical access. It is not hard to imagine a small community where some providers cull their practices by 80 percent to establish concierge practices and effectively dump thousands of less well -off patients on the remaining already strapped providers. The AMA recognizes this potential harm to society if concierge practices were to become widespread, but the CEJA stopped short of proscribing the spread, stating only that "if no other physicians are available to care for non-retainer patients in the local community, the physician *may* be ethically obligated to continue caring for such patients."[21] Again, this begs some questions, such as: Who monitors the fair distribution of health care resources? Who does the epidemiologic assessment when providers want to make the switch? Who enforces these vague ethical obligations? Thus far, no answers have been forthcoming from Congress or HHS. It appears that market forces, political lobbying, and the philosophical leanings of the administration interpreting the rules will determine the answers to these questions in addition to the numerous others raised by this new medical phenomenon.

II. Conclusion

Boutique medicine remains a very small portion of the health care industry, but despite these far reaching ethical and public policy concerns, the number of concierge practices is growing. The personal attractions for those who can afford it are undeniable. In that dichotomous small town scenario where overbooked harried providers toil alongside relaxed physicians standing by ready to roll out the red carpet for the select few, who would not want to have his or her elderly parents enrolled in the concierge practice? The retainer fee could readily be considered worth the peace of mind gained by knowing they would not get lost in the overburdened medical bureaucracy. Is that peace of mind the uncovered medical service that justifies the fee? If so, does that mean the vast majority of the population who cannot afford the fee are not entitled to the security of knowing the health care system is up to the task of taking care of them? If there is to be a two-tiered system, who is responsible for assuring the viability of the system sans surcharges?

Many liken using medical boutiques to the guilt-free convenience of flying first class. This analogy makes intuitive sense if the shared destination of all passengers is good health care, since everyone on board the plane gets to the same destination. However, in the big picture view that acknowledges limited medical resources, the analogy must be extended to encompass the reality that if enough jumbo seats are put in enough airliners, some people will be left standing on the ground. Certainly, there is no right to fly, and taking the bus or walking are always alternatives. But unlike the mere inconvenience of a delayed travel arrival, a delayed medical diagnosis and compromised treatment are potentially so much more consequential as to make the analogy break down.

When the air traffic controllers went on strike in the 1980s, President Ronald Reagan stepped in to ensure all citizens had continued access to air travel. At this stage in the development of the boutique medicine trend it is a stretch to compare the impact of the small number of doctors leaving traditional practices to a complete industry strike. But if enough doctors elect to opt out of Medicare, at what point should the federal government consider stepping in to ensure adequate access to medical care for its citizens? Or if enough Medicare patients are required to pay thousands of dollars simply to have access to a provider, who decides when that bill is too steep? I would argue that given the 48 million uninsured patients who are effectively denied the opportunity to become customers, the point for additional government support for the underserved is already at hand. Even the AMA, through the CEJA, has acknowledged that there is a potential volume of physician converts that would not be ethically sustainable.[22]

If a new administration should decide that line has been crossed in the dwindling physician supply, physicians are not federal employees, and any intervention to address

the problem would have to take a form different than the President's Executive Order in the airline instance. To curb the trend, it is currently within the realm of the regulatory function of HHS to interpret the existing statutes in such a way as to limit the propagation of concierge practices. Simply requiring itemized billing, much like most cosmetic plastic surgery practices, would effectively change the enterprise into a fee for service arrangement. Any fee charged not accounted for as reasonably going toward an uncovered service would properly be interpreted as balance billing and be disallowed. Simply put, calling a lump sum payment a retainer would not obviate the fact that some Medicare patients' identical physical exams are costing more than other's. If a concierge practice persisted in collecting unredeemed charges, appropriate sanctions or exclusion would be called for. Concierge practices containing Medicare patients paying the retainer would then properly be tightly audited.

Alternatively, they could elect to be totally segregated from any federally subsidized plans. Such a practice could contain Medicare patients only if none of them were paying any access fees. Such a mixed practice would be rife with all the conflicting ethical and contractual obligations raised above and make life hard for the conscientious physician trying to do the right thing for all his patients. To continue to operate under the current paradigm where the access fee is up front, not subject to scrutiny, and the provider can comfortably promise similar access and treatment to all his patients would effectively limit the existence of medical boutiques to the truly exclusive neighborhoods where enough patients not dependent on any federal assistance could fully populate a practice. Concierge physicians would undoubtedly love to have such a practice, but the number of such pure, Medicare-free panels of patients would be quite limited as, I believe, it should.

When debating how government should act in shaping a proposed outcome, it is important to realize that the economic reasoning regarding the correct public policy relevant to the distribution of health care resources does not fit neatly into traditional philosophical camps. To further exploit my airline analogy, it is true that in the widening economic divide between the "haves" and the "have-nots," the coach passengers may envy the first class passengers, but those at the back of the plane generally do not and should not begrudge those up front their privilege. The American way is to work toward the day when flying supplants the bus to when flying first class makes cramped seats a thing of the past. Every hard working capitalist wants that legroom and a martini to be waiting for them when they finally arrive. However, the hardships imposed by inadequate health care on an individual's road to prosperity are fundamentally more difficult to overcome than any economic or social hurdle encountered on one's path. In other economic respects it can be legitimately argued that it is not the government's job to clear all the obstacles or lift every burden. But the government should recognize that the vaunted entrepreneurial spirit cannot take flight without a healthy body to sustain it. If the downtrodden are indeed expected to pick themselves up by their bootstraps, they must first have a modicum of health and strength with which to attempt it. Unlike economic success, people cannot will themselves to good health. It is different. Ill people without resources need help and all people without resources will one day become ill. A poor person with an idea, ambition and willingness to work hard and take risks may or may not need a government loan or other such boost to succeed. But when that person needs health care, all of his efforts will be for naught if what is available is inadequate to allow him to remain a productive member of society.

Toward that end, the proverbial leg up medical assistance provides cannot be granted to as many people as need it if a broad based health care infrastructure is not available. Therefore, the four-star treatment concierge plans offer should not be subsidized by the government in the form of continued Medicare or Medicaid payments to retainer practices if those practices charge more than 115 percent of the fee schedule amount allowed by law. In most cases the retainer fee amounts to a surcharge above and beyond the allowable charges and is tantamount to smoke and mirrors to circumvent the Medicare rules. Enforcing the Medicare restrictions would be consistent with a government policy that protects Medicare recipients from coercive billing practices, and ultimately helps ensure the larger society has greater access to medical care.

1 *See* R.M. Portman, *Concierge Care: Back to the Future of Medicine?*, 15:5 ABA Health Lawyer (August 2003).

2 *See* Wayne Guglielmo, *How To Set Up a Concierge Practice,* Medical Economics, Aug. 22, 2003, *available at* http://www.medicaleconomics.com/memag/article/articleDetail.jsp?id=112475 (last visited Feb. 24, 2008) (citing the American Academy of Family Physicians 2003 Physician Survey).

3 *See* MDVIP Concierge Medial Care Group, http://www.mdvip.com/NewCorpWebSite/index.aspx (last visited Feb. 24, 2008).

4 *See id.*

5 *See* Report of the Council on Ethical and Judicial Affairs: Retainer Practices, CEJA Report 3-A-03 *available at* www.ama-assn.org.goceja (last visited Feb. 24, 2007).

6 *See* Monique Johnson, *A Different Approach to Health Care: "Boutique" Medical Practices Attempt to Strengthen the Doctor-Patient Relationship- and Local Residents are Opening Up their Wallets*, The Almanac, June 8, 2005, *available at* http://www.almanacnews.com/

morgue/2005/2005_06_08.health1.shtml (last visited Feb. 24, 2007).
7 42 U.S.C. § 1395w-4(g)(4).
8 42 U.S.C. § 1395w-4(g)(2).
9 *See* Letter from Representatives Henry Waxman (D-CA), Sherrod Brown (D-OH), Pete Stark (D-CA), Benjamin Cardin (D-MD), and Senator Richard Durbin (D-IL) to Tommy Thompson and Janet Rehnquist (Mar. 4, 2002); *see also* M. Hawryluk, *Boutique Medicine May Run Afoul of Medicare Rules*, American Medical News, April 8, 2002.
10 *See* Letter from Secretary Tommy Thompson to Rep. Henry Waxman (D-CA) (May 1, 2002).
11 *See, e.g.* MAHHLMI MA-CLE 5-1, Massachusetts Continuing Legal Education, Inc. PHYSICIANS, 2004.
12 *See* CEJA *supra* note 5.
13 *See* Guglielmo, *supra* note 2.
14 *See* CEJA, *supra* note 5.
15 *See id.*
16 *See* Letter, *supra* note 10.
17 *See* CEJA, *supra* note 5.
18 42 U.S.C. § 1395w-4(g)(2).
19 *See* CEJA, *supra* note 5.
20 *AMA Delegates Adopt Ethical Guidelines for Retainer Practices*, AMA News Release, June 17, 2003 *available at* http://www.ama-assn.org/ama/pub/article/1616- 7783.html (last visited Feb. 24, 2007).
21 *See* CEJA, *supra* note 5 (emphasis added).
22 *See* CEJA, *supra* note 5.

When Views Collide: How Hospital Mergers Restrict Access to Reproductive Health Care

*Sabrina Dunlap**

> Hospital mergers are becoming increasingly common as the health care system in the United States changes, and as health care providers attempt to control costs in an overburdened system.

I. Introduction

As access to reproductive health services decreases, the need for such services continues. About half of all pregnancies in the United States are unintended, and roughly half of these unintended pregnancies end in abortion.[1] Nearly half of American women will experience an unintended pregnancy at least once in their lives, and nearly 25 percent of all pregnancies in this country end in an abortion.[2] Approximately 89 percent of women of child-bearing age who do not wish to become pregnant use some form of contraception.[3] While there is clearly a need for women to have access to reproductive health services, since 1973 when *Roe v. Wade* established the right to choose to terminate a pregnancy, there has been an incessant backlash against reproductive rights, resulting in increasingly limited access to reproductive health services.[4]

Supreme Court rulings that uphold restrictive laws, and laws that prohibit public funding of abortions for indigent women hit low-income women and women living in rural areas the hardest.[5] In addition to ever-more restrictive laws, practical barriers limit women's abilities to choose abortion. It is estimated that 87 percent of all U.S. counties lack an abortion provider, in either a clinic or hospital setting.[6] Though abortion is the most common obstetrics surgical procedure, few medical students learn how to perform abortions, and approximately half of all graduating OB/GYNs have never conducted the procedure.[7] Not only is the overall number of abortion providers decreasing in this country, but as of 1999, 91 counties had a Catholic institution as their only hospital provider. For low-income women in rural areas, this often means they have no real choice in a health care provider, and no viable options in terms of accessing abortion services.[8]

There is a real need in the United States for abortion services to be part of a broader health care system that includes a wide range of reproductive health services. Hospital mergers are becoming increasingly common as the health care system in the United States changes, and as health care providers attempt to control costs in an overburdened system.[9] Between 1993 and 2003, there were roughly 170 mergers between non-religious hospitals and Catholic health care providers.[10] In these scenarios where a non-religious hospital merges with a Catholic hospital, frequently the Catholic entity insists that the newly formed entity abide by and be bound by the "Ethical and Religious Directives" (Directives) of the Catholic Church.[11] This not only means that non-religious private hospitals are "swallowed" by a religious health care entity, but reproductive health services often are extremely restricted, or entirely removed from decisions regarding the services that the hospital offers.[12]

These restrictions are usually significant—the Directives dictate basically all reproductive health issues, many of which are essential for women to receive adequate health care services.[13] The Directives prohibit abortion entirely (sometimes allowing the procedure only to save the woman's life), prohibit administering or discussing contraceptive devices (including condoms), and prohibit sterilization procedures and infertility treatment (such as in-vitro fertilization).[14] Perhaps most disturbing, the Directives do not even allow the dissemination of information regarding the morning-after-pill (also known as emergency contraception, or Plan B) for victims of rape or sexual assault, nor do they allow for the referral of such victims for morning-after-pill services.[15]

Women's access to reproductive health services seems to be becoming increasingly restrictive, paradoxically at a time in which science and technology support safe and effective birth control methods, abortion procedures, and sterilization procedures. Hospital mergers between secular and Catholic institutions contribute to the diminishing availability of reproductive health care services offered in this country. Some communities have fought off mergers and succeeded, while in others, doctors become bound by the rules of a religious institution, often the Catholic Church, and are forced to deny women reproductive health care services.[16]

The threat posed by religiously affiliated hospitals to reproductive health services is unnecessary. As "quasi-public" institutions, and often as the only health care provider available to women in rural areas, religiously affiliated hospitals should not be allowed to harm women's health by denying them vital reproductive health care services.[17] Basic reproductive health care is a necessary part of basic primary health care.[18] A merger between a secular hospital and a religious institution may be problematic under legal theories of antitrust

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laws, the First Amendment, and charitable trust laws, because the religious institution may be unsympathetic to reproductive rights, and may prevent the secular hospital from offering reproductive health services to women.

II. Background

A. Mergers

Hospital consolidation is happening all over the United States at a fairly rapid rate.[19] The Catholic influence in hospitals is widespread, and can be found in five of the ten biggest health care systems in this country.[20] Catholic institutions comprise the largest group of non-profit hospitals in the United States. Ascension Health System, the nation's largest Catholic and largest nonprofit health system has net revenues of roughly $7.2 billion. Eighteen percent of all hospitals in the United States are Catholic. Furthermore, in 2000, one study found that there were 48 Catholic managed care plans and, of these, 15 Catholic HMOs contracted to serve Medicaid recipients.[21]

Many of these mergers occur when public and private hospitals claim that they need to merge with religious health care systems in order to stay open.[22] Another reason often given for mergers is the hospital industry's belief that hospitals must grow larger, thus enabling them to lower their costs and increase their "market power."[23] As the entire managed care system changes in this country, many hospital owners view mergers as a way to reduce costs, function more efficiently, and increase the amount of control the hospital has over how much to charge for its services.[24] Notably, mergers involving Catholic institutions tripled between 1997 and 1998, resulting in what some commentators call "merger mania."[25]

Catholic hospitals have tremendous clout in the industry despite, or perhaps because of, their non-profit status. Rather than being victims of hospital consolidation, Catholic hospitals are increasingly part of large health care systems including secular and religious hospitals. These large networks are able to compete in the health care market much more effectively than small, private hospitals.[26] Additionally, Catholic hospitals are generally non-profits, which means they benefit from property, sales, and excise tax exemptions.[27]

When Catholic and secular institutions merge, the Directives will often supersede the rules of the secular institution, and the newly merged hospital is bound by the Directives, which basically prohibit all reproductive health services.[28] If, for example, Catholic health care systems sell "low-performing" hospitals, they can require that, as a condition of the sale, the new institution will continue to be bound by and follow the Directives.[29] Even if two institutions do not fully merge, the Directives can still control when secular health plans, including Medicaid and private insurance plans, contract with Catholic hospitals.[30]

Despite the surge in mergers in the past decade, the Federal Trade Commission (FTC) has taken an increased role in attempting to prevent hospital mergers or dissolving them once they have occurred. The FTC published a report in 2004 that found that many studies have linked rising hospital costs with increased consolidation.[31] The report shows that hospital mergers often increase costs to the consumer and, in particular, they increase costs if the merging hospitals are in the same vicinity.[32] If mergers do not necessarily lower costs for patients, and if they are not necessary for the survival of hospitals, then it is unacceptable that mergers that result in reduced access to reproductive health services are allowed to take place.

B. Impact of Mergers on Reproductive Health Care Services

Mergers between secular and religiously affiliated hospitals have a generally limiting affect on reproductive health services. Choices that women would otherwise normally have in a hospital setting no longer exist, especially in a situation involving the Catholic Church where the Directives control

"If, for example, Catholic health care systems sell "low-performing" hospitals, they can require that, as a condition of the sale, the new institution will continue to be bound by and follow the Catholic Directives."

what doctors can and cannot do regardless of whether providing a particular service would be in a woman's best interest. Many of these prohibitions on doctors' and patients' choices result in dangerous situations, as doctors cannot freely decide what is medically best for their patients.[33] Many procedures that are widely accepted in the medical field, such as sterilization or abortions for ectopic pregnancies,[34] are not allowed in Catholic hospitals. Thus, women must go elsewhere to seek such procedures.[35]

One example of this dividing-up of procedures, involves sterilization. According to the American College of Obstetricians and Gynecologists (ACOG), the proper time for doctors to perform voluntary sterilizations is generally at the time of delivery.[36] The Directives, however, prohibit sterilization, thus forcing women to seek the operation "at another time, at another facility with an increased risk of infection, experiencing adverse side effects of anesthesia, additional costs, and the risk of another pregnancy."[37] As such, women must either find a hospital in which to give birth that does allow sterilization. This could be difficult or impossible for some low-income women. If a woman is unable to find another hospital in this instance, she will need to endure a second medical procedure at another time and place with a different doctor, thus subjecting herself to a greater risk of harm.[38]

"It is unconscionable for an institution that holds itself out as a provider of health care services to fail to offer something as fundamental to women's reproductive health as contraceptives."

Access to birth control is also severely limited or eliminated altogether at religiously affiliated hospitals.[39] This is an astonishing fact, given the incredibly widespread use of, and need for, contraceptives in this country. There is clearly a need to continue to promote contraceptive use and educate people about the proper use of contraceptives, given that the United States has the highest teen pregnancy rate in the industrialized world and one of the highest abortion rates, at approximately one million every year.[40] Additionally, 31 percent of women become pregnant by the time they reach twenty years old, resulting in roughly 750,000 births, 80 percent of which are unintended pregnancies.[41] In a 2005 study, the Guttmacher Institute reported that there are 43 million women of childbearing age who do not wish to become pregnant and 89 percent of them use some form of contraceptive method.[42]

Despite this obvious need for hospitals to provide comprehensive reproductive health care, Catholic hospitals are bound by the following Directive regarding contraception: "Catholic health institutions may not promote or condone contraceptive practices but should provide, for married couples and the medical staff who counsel them, instruction both about the Church's teaching on responsible parenthood and in methods of natural family planning."[43] Not only are these hospitals excluding non-married couples by only providing information on "natural family planning" to married couples, but they are also promoting methods, such as the "rhythm method," which has an incredibly high failure rate compared to other methods of birth control, such as the Pill.[44] Perhaps more troubling is the fact that Catholic hospitals will not provide the morning-after-pill to women, even if they have been sexually assaulted.[45] It is unconscionable for an institution that holds itself out as a provider of health care services to fail to offer something as fundamental to women's reproductive health as contraceptives.

Another reproductive service eliminated at Catholic hospitals is abortion. Necessary late-term abortions (*i.e.*, abortions performed after the first trimester which are necessary for the woman's health or because of severe fetal abnormalities) often must be performed at hospitals because of the complications involved.[46] Especially if a woman has a medical condition, such as high blood pressure, a hospital setting is necessary for performing an abortion.[47] As with sterilization, when Catholic hospitals refuse to provide women with this service, it puts them at a greater risk by forcing them to travel elsewhere to obtain services, causing dangerous delays.[48]

While obtaining an abortion is still a legal "right" in the United States, in some areas of the country it is a right in name only—in practical terms, it is becoming difficult or near impossible for some women to access these services. According to a Guttmacher Institute study, in 2005 about 87 percent of counties in America did not have an abortion provider.[49] The geographic location in which women live has a tremendous impact on the availability of abortion. For example, in the Midwestern and Southern United States, more than 90 percent of counties were without any abortion providers.[50] A 2000 Guttmacher study found that 94 percent of all abortion providers are located in metropolitan areas, and 34 percent of women live in a county without an abortion provider.[51] The number of abortion providers has dropped for a number of reasons, one of which is the threat of violence directed at abortion clinics since the mid-1970s.[52] By the mid-1990s, at least half of all abortion clinics reported in a survey that they had been hit with intense anti-choice violence, including bomb threats, death threats, and blockades at the entrance of clinics.[53]

Access to reproductive health services is becoming more restricted in general, but it is especially restricted for low-income women. The government reduced access for low-income women first with the Hyde Amendment in 1976, cutting off virtually all public

funding of abortions for indigent women, even if the abortion is deemed medically necessary, and again in 1988 when the government enacted a gag rule on Title X clinics.[54] The government began funding Title X clinics in 1970 to provide vital family planning services to low-income people. However, in 1988, the government changed the law so that Title X clinics were no longer able to offer any sort of information, counseling, or referrals involving abortion – essentially gagging the employees of Title X clinics.[55] The Supreme Court upheld this seeming violation of the First Amendment in *Rust v. Sullivan* in 1991; this is yet another example of how women's access to reproductive health care is unjustly limited for political reasons.[56]

With so few abortion providers in this country, compared to the high number of women who seek abortions,[57] some women depend on hospitals to provide these services.[58] The number of hospitals that performed abortions declined in the late 1990s, and now hospitals that once may have performed abortions might stop such services after merging with a religiously affiliated hospital.[59] This becomes a real problem when women, particularly low-income women, have no other choice of health care provider and are effectively denied most reproductive health care services, like abortion.

These sorts of blanket prohibitions by religiously-affiliated hospitals not only put women's health in danger, but also assume that women will be able to seek care elsewhere. However, as the managed care system changes, these choices are increasingly rare.[60] Often a religiously affiliated hospital will be the *only* choice, especially if a woman is indigent or lives in a rural area.[61] As an issue of practicality, the fewer hospitals that provide reproductive health care, especially in rural areas, the more difficult it will be for women to receive adequate health care.

III. Analysis

A. Legal Theories to Challenge Mergers of Secular and Religiously Affiliated Hospitals

There are a number of legal theories under which doctors or patients can challenge the mergers of secular and religiously affiliated hospitals – some with a higher chance of success than others. Antitrust laws can be effective tools to challenge mergers. Certain antitrust acts prohibit mergers that might adversely impact competition between entities, and thus adversely impact services to customers.[62] In the context of reproductive rights, antitrust issues arise when mergers unfavorably affect reproductive health services.

Strong arguments for First Amendment violations can also be made regarding hospital mergers. Some religiously affiliated hospitals can be considered quasi-public institutions by receiving federal dollars and, as such, should not limit services based on religious beliefs.[63] Finally, a theory of charitable trust laws could be an effective way to challenge mergers between secular and religiously affiliated hospitals. In states where charitable trust laws apply to hospitals, if a merger "significantly alters the mission" of both or one of the hospitals, it could violate charitable trust laws.[64]

i. Challenges Using Antitrust Laws

Lawmakers designed antitrust laws to ensure competition between adversary providers of certain services and to encourage providers to offer customers the highest level of care possible.[65] When two hospitals merge, and the religious directives dictate the service provided by the newly formed entity, the diminished competition between institutions leads to less access to reproductive health care services.[66] Though not a shoo-in for reproductive rights advocates in terms of proving a violation under antitrust laws, this is still a viable option for challenging mergers.[67]

a. Why Hospitals Merge

There is no agreement in the health care industry concerning why hospitals decide to merge.[68] Hospital executives often argue that mergers are increasingly necessary as costs increase for health care providers and are sometimes necessary for hospitals to remain open in certain areas.[69] Additionally, hospital executives also point out that mergers help hospitals contain operating costs, which then translate into savings for health care consumers.[70]

Despite these claims by hospital executives, recent studies provide strong evidence against these arguments, and instead show that generally mergers lead to considerably higher prices for consumers.[71] Some commentators in the health care field argue that mergers are not a reasonable response to supposed financial pressures on hospitals, and that mergers are driven by a desire to increase profits rather than a necessity to continue functioning.[72] Hospital executives also might be more concerned with gaining leverage in a field with more competitors as they might feel compelled to increase their bargaining power to negotiate with the increasing power of managed care organizations and large pharmaceutical companies.[73] These concerns might have some validity, but they are not strong enough to justify reducing reproductive health care services or access to services especially for low-income women.[74]

b. Merger Regulations

The U.S. Department of Justice (DOJ) and the FTC are the two agencies in charge of investigating possible mergers between hospitals.[75] Two federal acts also apply to mergers: Section 7 of the Clayton Act and the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR). The Clayton Act regulates institutional mergers, both interstate and intrastate, by prohibiting any activity that might lead to the creation of a monopoly and to any entities engaged in activities that might affect interstate commerce.[76] The HSR requires a pre-merger report which the DOJ or FTC reviews. These are all generally preventative measures designed to stop a merger before any anti-competitive harm can be done.[77]

One of the issues the agencies look at is market power—that is the degree to which a hospital might control a geographic region, thus leaving patients with fewer options for health care.

The DOJ and FTC use a set of guidelines to analyze pre-merger deals or mergers that seem to be anti-competitive.[78] One of the issues the agencies look at is market power—that is the degree to which a hospital might

control a geographic region, thus leaving patients with fewer options for health care.[79] If a merger results in a market with less competition and fewer services and options for patients, there could be a potential problem under the Clayton Act.[80] If a merger results in reduced competition, and institutions are able to join together to raise prices, whether through implicit or express collusion, a valid challenge under the Clayton Act could arise.[81] Similarly, if one institution is essentially a monopoly such that consumers have no viable options besides one provider and are forced to pay higher prices, this could be problematic as well.[82]

c. Possibility of Success of Antitrust Challenge

Though a private party or the government that brings a challenge under Section 7 of the Clayton Act does not have to show with certainty that a merger will result in an impermissible level of market power that might lead to anti-competitive results, courts have traditionally been deferential to the hospital industry.[83] Despite this deference, in more recent years the government has challenged large hospital mergers with more frequency due, in part, to a desire of the FTC to prevent hospital mergers that are detrimental to consumers.[84] In the context of larger hospital mergers, or in situations where one hospital becomes the only provider of health care for a geographic region, private actions against hospital mergers might have a better chance of success. If a plaintiff can show that a hospital merger will entirely eliminate certain reproductive health care services and that patients reasonably cannot otherwise find these services in their region, the suit has a viable chance of success.[85]

Despite the applicability of antitrust laws to hospital mergers, it is unclear how successful parties will be in bringing these challenges. Success in these cases might turn on whether a plaintiff can prove that the elimination of reproductive health care services can be construed as anti-competitive.[86] If a plaintiff can do so, then the antitrust laws, which are designed to protect consumers from anti-competitive mergers, not to protect the merging institutions, might help in protecting access to reproductive health care at hospitals.[87]

ii. Challenges Under the First Amendment

Mergers between secular and religiously affiliated institutions might also present a number of problems under the First Amendment. Generally, an argument can be made that religiously affiliated hospitals violate the Establishment Clause of the First Amendment by using public funds strictly for religious purposes.[88] As quasi-public institutions, hospitals that receive public funding and tax-exempt status should be required to provide full reproductive services and follow "generally accepted" medical guidelines, not the dictates of a particular religion.[89] Especially in situations where a hospital is the only health care provider in a certain region, hospitals should not be permitted to refuse providing certain reproductive health care services to patients.[90]

> "... [A] hospital that receives public funds should not refuse reproductive services based on the religious tenants of a hospital because the health needs of a patient should outweigh the desire of a hospital to follow religious directives."

a. Public Funding and the Establishment Clause

If a hospital has non-profit status, which many do, it enjoys large benefits through tax exemptions, including property and sales tax.[91] It also generally enjoys a large amount of public funding from federal and state governments.[92] Non-profit hospitals exist, by design, to serve the public and provide for health care services. As such, the public has an acute interest in these hospitals serving the public good.[93] First Amendment issues arise when religiously affiliated hospitals receive public funding,[94] yet restrict access to reproductive health care services.[95]

Catholic hospitals have particularly restrictive mandates regarding reproductive health care. When the government assists or funds these hospitals, it might be in violation of the Establishment Clause of the First Amendment. The Supreme Court has developed extensive First Amendment jurisprudence and, in the context of the Establishment Clause, the Court developed the *Lemon* test in *Lemon v. Kurtzman*.[96] The *Lemon* test has three main prongs: under the first prong, there must be a clear secular purpose for the law; under the second prong, the programs must not advance nor inhibit religion; and under the third prong, there must not be excessive entanglement of the government with religion.[97] A government action must satisfy each prong of the *Lemon* test to pass judicial scrutiny. Failure to satisfy one pong is enough to show an Establishment Clause violation.[98]

In the context of government funding in health care, strong arguments can be made that such funding advances religion (second prong of *Lemon*). The government might have a secular purpose when funding Catholic hospitals, but the effect of such actions is to advance the Directives of such a hospital. When a Catholic hospital that receives government funds refuses reproductive health care services to a patient, then the government has played a part in helping an institution that refuses to provide a certain type of care based on religion.[99] Especially where Catholic hospitals hold themselves out as, or function as, public or quasi-public institutions, they should be prohibited from endorsing a singular religious viewpoint restricting reproductive health care.[100]

As a policy matter, hospitals that serve the public's needs should not discriminate in the types of services they provide, regardless of religious affiliation. Religiously affiliated hospitals do not exclusively serve patients who happen to have beliefs in line with the institution; they serve the general public and people with a wide range of beliefs.[101] As such, a hospital that receives public funds should not refuse reproductive services based on the religious tenants of a hospital because the health needs of a patient should outweigh the desire of a hospital to follow religious directives.

> Many religious hospitals function in conflict with a widely accepted medical standard, and patients should be informed of this fact before they choose a hospital at which to receive care.

b. Unjustly Limiting Doctors' and Patients' Choices

The severe restrictions that some hospitals place on reproductive health services force doctors to go "underground" with their medical choices.[102] Physicians for Reproductive Choice and Health (PRCH) reported that many doctors feel compelled to disregard the restrictions at religious hospitals in order to serve their patients' needs as they see fit.[103] Some hospitals force doctors to sign agreements binding them to the religious directives of the hospital, even if it is silently understood that the hospital will not actively interfere with doctors' medical choices. These "don't ask, don't tell" policies can be dangerous for doctors. PRCH warned that doctors take a serious legal risk by choosing to breach such a contract, even if done in good faith.[104]

The phenomenon of "undercover medicine" can be dangerous for patients. If doctors are compelled to practice medicine as they see fit despite strict religious directives, it might force them to alter medical records to hide that a certain procedure had been performed.[105] Such actions might prevent accurate records, making it difficult to find an accurate medical history of the patient in the future.[106]

Patients can be harmed as well when hospitals refuse to provide full information regarding their medical choices or access to certain procedures. Often, patients do not know that religious restrictions at a hospital can prevent them from receiving the type of care they need or desire, creating a barrier to informed consent and successful decision-making regarding reproductive health.[107] Some HMOs have what is known as a "gag rule" which effectively prohibits doctors from letting their patients know what negative effects a merger might have on access to reproductive services; this is especially damaging given that many women are not even aware that a religiously-affiliated institution can deny them certain care.[108]

Many religious hospitals function in conflict with a widely accepted medical standard, and patients should be informed of this fact before they choose a hospital at which to receive care.[109] One example of this involves sterilization. ACOG advises that the best time to perform a desired

sterilization on a woman is right after delivery.[110] When religious hospitals refuse to perform sterilization because of religious directives (very common in Catholic hospitals), women are forced to have the sterilization done at another time and at another facility, thereby increasing the risk of health problems such as side effects and infection.[111] Religious hospitals should at least be forced to disclose this sort of information to patients, so that potential patients are aware of the possible restrictions on the services they can receive.

c. Religious Hospitals Should Not be Saved by Conscience Clauses

In the aftermath of *Roe v. Wade* in 1973, the Catholic Church was at the forefront of the anti-choice movement, working to overturn *Roe*, and doing everything possible to limit women's access to abortion. Congress passed the "Church Amendment," named after its sponsor, Senator Frank Church (D-ID), in an effort to allow health care providers to "opt out" of performing certain reproductive services like abortion and sterilization.[112] At first, the Church Amendment allowed only opting out of abortion and sterilization, but one year later Congress enlarged the opt-out to include *any* service that might conflict with religious or moral beliefs.[113] This "conscience clause," allowed entire hospitals to refuse to provide reproductive health care, which resulted in fewer hospitals, religious or not, performing abortions.[114] Some states have gone even farther, enacting legislation that allows providers to not only refuse certain care based on religious grounds, but also to refuse to provide information or counseling about such procedures.[115] These sorts of provisions undoubtedly limit women's access to reproductive health services and unjustly put the religious interests of hospitals before the interests, rights, and needs of patients.

One disturbing example of a conscience clause at the federal level that prohibits low-income women from receiving vital information regarding their health care is the Balanced Budget Act of 1997 (BBA). The BBA includes an extensive conscience clause that allows MCOs serving Medicaid recipients to refuse to cover counseling, referrals, or costs of procedures that the MCO might object to on "moral or religious grounds."[116] The result of this conscience clause is that many women enrolled in Medicaid might be refused essential information regarding their reproductive health.

This is especially problematic when a religious hospital might be the only health care provider in a given area and women, therefore, have no where else to seek information regarding their reproductive health.[117] Given the consolidation of providers and hospitals in the health care industry, many people no longer have a choice about where they receive their care.[118] Since women's health is at stake, women's access to basic reproductive health care services should be protected over the religious interests of hospitals.[119]

iii. Charitable Trust Theory

The charitable trust theory is an additional theory under which one could challenge a merger or proposed merger. Charitable trust laws can potentially prevent mergers or result in the "divorce" of two hospitals if upon merging the mission of one or both institutions is altered.[120] If providing full reproductive health services was part of an institution, the loss of such services as a result of a merger could be illegal under the theory that the public is the "beneficiary" of the hospital's charitable contributions, and thus has a right to its hospital preserving its stated mission.[121] Likewise, if part of a hospital's mission is to follow the tenants of a religious institution, like the Catholic Church, the merger with a secular institution could alter the religious mission in such a way that charitable trust law does not allow.

Some argue that every merger between a secular and religious hospital results in some loss of reproductive services. If this is the case for a hospital whose original mission includes providing access to reproductive health services, a challenge under charitable trust law could be successful.[122] The use of charitable trust law is limited by the fact that not all states have such laws apply to hospitals and often if a state does have charitable trust law, it applies only to non-profit entities.[123] Still, if a state has applicable charitable trust law, it can be an effective tool in challenging a merger.

A good example of charitable trust law forcing the dissolution of a merger is in the Optima Health case in New Hampshire, discussed in more detail below. The charitable trust theory is one of the main arguments the Attorney General used to prove that the merger between the Elliot Hospital, a secular institution, and Catholic Medical Center (CMC), a Catholic institution, to form Optima Health was not legitimate. According to the Attorney General, each hospital was "bound by a social contract with the community" under New Hampshire law,[124] as charitable non-profit institutions, these hospitals had a fiduciary duty to ensure that the "fundamental charitable mission" of each hospital remain the same.[125] In the case of Optima Health, the Attorney General found that Optima Health failed to reconcile the opposing commitments of each hospital —CMC's commitment to being a Catholic institution, and the Elliot's commitment to providing women with reproductive health services.[126] If mergers elsewhere also alter the mission of a hospital, challenging such mergers under charitable trust laws is a viable option.[127]

B. Case Study: Optima Health

i. The Elliot Hospital and Catholic Medical Center

In 1994 the two largest hospitals in New Hampshire struck a merger deal. The result of the merger between the Elliot Hospital and CMC into Optima Health resulted in years of costly litigation, and an eventual dissolution of the newly merged hospitals in 1997. Large amounts of time, money, and energy were wasted on a deal that seemed flawed from the beginning. This case exemplifies what can happen when finances get in the way of sound policy and decision-making, and when secular hospitals merge with religious institutions.

The Elliot Hospital and CMC both functioned as two of the most important health care institutions in Southern New Hampshire, serving the city of Manchester and its surrounding areas. The Elliot, founded in 1881 by an act of the New Hampshire legislature, has been exempt from property taxes as a public charity for as long as it has existed—something the New Hampshire legislature has continued to reaffirm.[128] In 1974, two Catholic hospitals formed CMC, established as a nonprofit corporation with the intention of carrying on the Catholic mission of the two predecessor Catholic hospitals. One of the main goals under CMC's Articles of Agreement is to "maintain its identity as a Catholic Hospital," and to follow the "Ethical and Religious Directives of the Catholic Health Facilities as promulgated by the National Conference of Catholic Bishops."[129]

ii. The Merger

After a time of antagonistic competition between the Elliot and CMC, the management of the respective institutions began talks of a merger between the two. The management claimed that the initial express reason for the merger was to enable the two hospitals to continue to function as charitable institutions. They also reported projected savings of $150 million if the merger were to go through—savings, management claimed, would help the two hospitals continue in their role of providing quality health care to the Manchester area.[130] Throughout all of the negotiations, the management of both the Elliot and CMC claimed repeatedly that the two institutions would continue to function as self-regulating and independent institutions.[131]

In 1994, Optima Health took over management of the Elliot and CMC, and after the merger gave itself complete control over the two hospitals; Optima Health modified the by-laws of the Elliot and CMC and made the two hospitals subsidiaries of Optima Health.[132] Optima Health also unilaterally decided to discontinue acute care at CMC and to consolidate all acute care at the Elliot campus—an unanticipated move.[133] Also, and perhaps most troubling, Optima's Articles of Agreement included a requirement to preserve CMC's Catholic identity.[134] This is the decision that ultimately would contribute to the dissolution of the merger between the Elliot and CMC.

iii. The Attorney General's Report

In New Hampshire, the Attorney General is statutorily charged with overseeing the state's charitable trusts. As such, the AG produced a report on the Elliot and CMC merger—both nonprofit charitable institutions, bound by a social contract with their respective communities.[135] The report began by stating that the hospitals, as public charities, owed to their communities a certain level of honesty and openness in their dealings and could not, in good faith, exclude the AG or the community from important decisions that may affect the functioning of the hospital.[136]

Among other failures, Optima Health did not fulfill its "duty of candor," as it neglected to include the community in the decisions regarding the merger, did not inform the community of the impact of the merger's affect on the functioning of the hospitals (i.e., did not inform the community that Elliot and CMC were stripped of their independence and became controlled by Optima Health) and did not disclose the inconsistent and opposing ways that each hospital viewed certain reproductive health services (e.g., practices regarding terminating pregnancies).[137] The failure to address the role Catholic doctrine would play in regards to the merged hospitals. This omission seems the most glaring; rather than devising a policy making the secular and religious parts of each institution compatible, Optima Health essentially ignored the problem. Optima Health went ahead with an "unfocused, incomplete and confusing" policy vis-à-vis Catholic moral doctrine and how it would affect the day-to-day operations of the merged institution rather than devising a clear policy on whether or not the Directives would indeed dictate the practices of the newly merged entity.[138]

Prior to the merger, the CEO of the Elliot, Phillip Ryan, had alluded to the fact that the Elliot's policy regarding abortion was the same as CMC's (i.e., that the Elliot did not generally perform abortions). This, in fact, was not true.[139] The Elliot had clinical records documenting abortions that the Elliot doctors had performed.[140] These were clearly procedures that could not have occurred under the Directives of CMC. Despite Ryan's representation to Catholic representatives that the Elliot's policy on abortion mirrored that of CMC's, it did not, and Elliot doctors were unaware that a major change regarding abortion policy would take place after the merger.[141] The Chairman of the Obstetrics Department at the Elliot, Dr. Robert Cervenka, asked Ryan specifically if the merger would affect the ability of Elliot OB/GYNs to perform abortions.[142] Ryan told Dr. Cervenka that the Directives "would apply only within the four walls of CMC" and would not have an affect on the actual practices of Elliot doctors.[143] This, too, was untrue.

Optima Health neglected to address significant and crucial issues for reproductive health, such as policies affecting family planning, sterilization, and abortion—issues that are treated entirely differently by CMC and the Elliot. One doctor who continued to work at the newly merged Optima Health hospital reported that Optima Health assured doctors that they would be allowed to continue to perform medically necessary abortions and tubal ligations. An anti-choice group, known as "Save CMC," found out that the Elliot had scheduled a medically necessary abortion, and began to "rally" around the issue of abortion, demanding that abortions not take place in the hospital.[144] Clearly, the policies regarding abortion at the Elliot did not mirror the policies of CMC: subsequently the Catholic Church demanded that such procedures cease, or it would threaten dissolution of the merger.[145] In response, and in order to ensure the merger went forward, the Trustees of the Elliot adopted a policy that effectively banned abortions at the Elliot for any reason other than saving the life of a woman.[146]

iv. The Dissolution of the Merger

At that point, both of the original identities of each hospital had been significantly altered. Doctors at the Elliot were concerned that the Directives forbiddance of any abortions, including medically necessary abortions, was inconsistent with generally accepted medical treatment.[147] The merger compromised the Elliot's "traditionally secular approach to medicine" by forcing its doctors to follow the Directives of the Catholic Church and by essentially ending all abortion services.[148] Additionally, CMC's mission as

a Catholic hospital, following the Directives of the Catholic Church, had not been maintained either.[149]

Eventually, the newly merged Optima Health divorced and the hospital became two separate entities as they had been prior to the merger. By June 2000, Optima Health officially dissolved, a process which reportedly cost about $10 million, with expected losses in revenue equaling nearly $20 million over five years.[150] This is a fine example of the harm that can arise from hospital mergers, especially mergers that are not done properly. Optima Health failed to adequately assess whether CMC and the Elliot could retain their independent charitable missions upon merging, and in regards to reproductive health, it was clear neither of them could. The merger forced the Elliot's doctors to abide by Catholic Doctrine, denying their patients acceptable levels of reproductive health care. Similarly, the merger forced CMC to compromise part of its mission as a Catholic institution as some Elliot doctors continued to provide some level of reproductive health services.

The pitfalls of this troubled merger could have been avoided had Optima Health executives adequately addressed the issue of maintaining each hospital's identity and mission. Paradoxically, both hospitals lost their identities in a unique way. CMC lost much of its mission as a provider of health care, as most acute care services were moved to the Elliot's campus in Manchester, and though the Elliot maintained its acute care services, its mission changed as Optima Health forced the Directives on it.[151] This failed merger demonstrates the importance of addressing which hospital's identity will prevail in a merger—the secular or the religious. Additionally, in a state with applicable charitable trust laws, the issue of the individual hospital missions must be addressed. Under New Hampshire law, since each hospital had a fiduciary relationship with the community as a result of charitable trust law (both the Elliot and CMC were non-profit institutions), each had to maintain its contract with the community. The Elliot as a secular provider of health care by including a wide-range of reproductive services, and CMC as a Catholic hospital, was bound by the Directives of the Catholic Church.[152]

When a merger involves two completely different health care entities, each with a duty to the community it serves, the public must be included in the decision-making process. Optima Health failed to do this, as it inaccurately represented the situation to the community. Ultimately, huge cost-savings from the merger never actually came to fruition. The public should have reviewed the merger. Ultimately, the effected community held Optima Health accountable for the problematic merger.[153]

IV. Recommendations

The Optima Health merger and its subsequent dissolution exemplifies the way in which a community can have a real impact in fighting mergers that adversely affect them. Under New Hampshire law, as charitable trusts, both hospitals had a fiduciary duty to their communities to "protect their charitable assets and to ensure that those assets are used for purposes consistent with the fundamental charitable missions of the respective institutions."[154] Additionally, as charitable trusts, each hospital owed its community the duty of "candor and inclusion," but this they did not do.[155]

This aspect of the charitable trust law deserves emphasis because it shows that the community being served must be included in the decision-making process regarding mergers, and the mission of a newly merged hospital must reflect the principles and standards of the community in which it functions.[156] When Optima Health failed to fulfill its duty to the community in Southern New Hampshire served by the Elliot and CMC, the respective communities of each hospital stood up for the values the hospitals had previously fostered. The charitable trust laws of New Hampshire gave the communities of the respective hospitals the legal right to keep their hospital's stated mission intact.

Challenging a merger that has already taken place under the charitable trust laws of a state can clearly be an effective way to fight a merger that results in the elimination of women's reproductive health care. In many states, if a hospital is a non-profit, charitable trust laws will apply.[157] If the merging of a religiously-affiliated hospital and a secular hospital would fundamentally alter the mission of a hospital, or prevent the hospital from fulfilling its fiduciary duty to the community, then the merger might be forced to dissolve, as in the case of the Elliot and Optima Health.

Trying to stop mergers before they actually occur is also an effective way to prevent the loss of reproductive health services. Since federal agencies, such as the FTC and DOJ, have the ability to block a proposed merger before it is carried through, they are a good place to begin.[158] This potential "merger-stopper" would require the use of antitrust laws. One would have to have a strong case for the fact that a merger, once completed, would significantly lower the competition in a certain area. If one can also prove that a merger would not only result in the loss of women's reproductive health care, but other health care as well (perhaps, for example, end-of-life care), then the case for anticompetitive results would be even stronger.[159]

Many hospitals merge, not because they have to but for financial gain and greater market power.[160] If the public is aware of a possible merger that could adversely affect reproductive health care, it must work within its community to prevent the merger. In the case of the Optima Health merger, that so fundamentally altered the mission of the Eliot, eventually it was the public and the doctors at the Elliot who came together to fight the merger. The public can work at the grassroots level to prevent mergers, in addition to working on a larger scale, by pressuring their representatives in Congress to be aware of the possible threats of mergers.

Communities can also come together to lobby local government officials to remove tax-exempt status from non-profit hospitals that deny women adequate health care.[161] Religiously affiliated hospitals reap the rewards of tax-exempt status, which results in huge savings on property and sales tax.[162] As the Optima Health merger exemplifies, often mergers end up costing their communities millions of dollars in higher medical costs. It seems unjust that these institutions should enjoy tax-exempt status. A Catholics for a Free Choice poll showed that 78 percent of people think that hospitals should lose their tax-exempt status if they refuse to provide adequate medical care.[163] If hospitals had to either comply with certain standards and provide full reproductive health services or risk losing their tax-exempt status, perhaps they would do more to accommodate the health needs of women.

At the federal level, there have been attempts to pass legislation that would require hospitals that receive federal money to provide adequate reproductive health services. Senator Barbara Boxer (D-CA) and House

Speaker Nancy Pelosi (D-CA) proposed legislation that would have conditioned the receipt of public funds on providing a wide range of reproductive health services, including abortion.[164] Though this legislation did not pass in Congress, it represents a type of law that the public should be pressuring members of Congress to enact. The more awareness people have of the threat of mergers to women's reproductive health care, the more likely they will be able to effectively prevent such mergers.

V. Conclusion

In a time in which the political climate is hostile to women's reproductive health, now more than ever it is vital to ensure that women have access to full reproductive services at hospitals. Non-profit hospitals that receive federal money should not be allowed to evade provision of these services merely because they follow religious teachings, such as the Directives. If the hospital functions as a public institution, the medical needs of women should trump a religiously affiliated hospital's desire to follow religious directives. Especially in the scenario of low-income women, or women who live in rural areas who already have limited access to care, hospitals must provide adequate reproductive health services, for they are often the only choice of health care provider.

Mergers of secular and religious hospitals particularly threaten access to abortion. As a practical matter, it has become increasingly difficult for women to obtain abortion services in certain parts of the country due to a diminishing number of clinics.[165]

This lack of availability forces many women throughout the country to rely on hospitals for abortion procedures. Additionally, women with certain health conditions, such as diabetes, might only be able to obtain an abortion in a hospital if overnight stays are necessary due to possible health complications.[166]

Given the recent Supreme Court decision in *Gonzales v. Carhart*, where the so-called "Partial Birth Abortion" ban was held constitutional, it is clear the assault on women's reproductive rights continues. The need for reproductive services, such as birth control and abortion, is abundantly clear. In terms of public policy, it seems obvious that health care providers should be offering comprehensive reproductive health services to women, no matter where they live or their socio-economic status. Since so many issues involved with women's reproduction have become so politicized, and limiting reproductive rights has become such an integral part of the religious right's political agenda, women's health tends to get lost in the shuffle.

If religiously affiliated hospitals are going to hold themselves out to the public as providers of health care and receive public funds, they must not be permitted to deny women basic reproductive health care. When hospitals receive public money, they should be required to follow generally accepted medical standards, which include providing adequate reproductive health services.[167] Policy makers and government officials must not allow hospitals that use public funds, and function as many people's only provider of health care, to continue to deny women reproductive health services.[168]

The interests of doctors and patients should outweigh a hospital's desire to better its bottom line; rather, access to health care must be a top priority. Access to contraception, abortion, and sterilization are services that should be considered an essential part of basic health care. It is disingenuous to imagine that women's health care can be complete without access to such services. Yet, under the protection of whichever church a hospital may be affiliated with, hospitals deny such necessary care every day. When hospital mergers result in the loss of critical reproductive health services, it is another disconcerting example of how willingly people in power deny reproductive rights, and trivialize the health needs of women. If hospitals have the capacity and technology to provide women with reproductive health services, it is an intolerable injustice that they can so easily deny women such basic care.

1 *See Facts on Induced Abortion in the United States*, Guttmacher Institute (2006), http://www.guttmacher.org/pubs/fb_induced_abortion.pdf [hereinafter *Facts on Induced Abortion*].
2 *See id.*
3 The Guttmacher Institute, Facts in Brief: Contraceptive Use (2005) *available at* http://www.guttmacher.org/pubs/fb_contr_use.html (last visited Feb. 2, 2008) [hereinafter Contraceptive Use]
4 *See, e.g.* Roe v. Wade, 410 U.S. 113, 154, 163-67 (1973) (establishing a right to abortion found within the right of privacy); *see also* Planned Parenthood v. Casey, 505 U.S. 833, 854-55 (1992) (reaffirming the central holding of *Roe*); Stenberg v. Carhart, 530 U.S. 914, 948 (2000). *See generally* Laurence Tribe, Abortion: the Clash of Absolutes 150 (W.W. Norton & Company 1990) (1992) (recognizing the anti-choice movement as a small but powerful political force, working to "chip away" at abortion rights one law at a time).
5 *See generally* Webster v. Reproductive Health Services, 492 U.S. 490, 520 (1989) (upholding a Missouri law that prohibited the use of public funds, government employees, or public facilities for the performance of abortions); Harris v. McRae, 448 U.S. 297, 306-11 (1980) (authorizing the Hyde Amendment, which prohibited the use of Medicaid funds for abortions, even in circumstances where the abortion was considered medically-necessary by a woman's doctor); Maher v. Roe, 432 U.S. 464, 478-80 (1977) (finding that states

were not required to provide abortion services to low-income women through state Medicaid programs, unless the abortion was considered necessary to save the life of the woman, or medically necessary).

6 *See Facts on Induced Abortion*, *supra* note 1. *See generally* Judith Appelbaum & Jill Morrison, *Hospital Mergers and the Threat to Women's Reproductive Health Services: Applying the Antitrust Laws*, 26 N.Y.U. Rev. L. & Soc. Change 1, 10 (2000-2001).

7 *See* Marlene Gerber Fried, *Legal But Inaccessible*, *in* Abortion Wars: A Half Century of Struggle 208, 215 (Ricky Solinger, ed., 1998).

8 *See* Monica Sloboda, *The High Cost of Merging With a Religiously-Controlled Hospital*, 16 Berkeley Women's L.J. 140, 146 (2001).

9 *See id*. at 140.

10 *See* Leora Eisenstadt, *Separation of Church and Hospital: Strategies to Protect Pro-Choice Physicians in Religiously Affiliated Hospitals*, 15 Yale J.L. & Feminism 135, 138 (2003).

11 See *id.* at 138.

12 *See id*.

13 *See* Ethical and Religious Directives for Catholic Health Care Services, 4th ed. (2001), *available at* http://www.usccb.org/bishops/directives.shtml [hereinafter Directives].

14 *See* Appelbaum & Morrison, *supra* note 6, at 6-7.

15 *See id*. at 7.

16 *See generally id*. at 33-35 (describing how members of a community in the Hudson River Valley region of New York state fought a hospital merger of two secular hospitals merging with a Catholic hospital, that would have resulted in the three facilities being dictated by Directives, thereby prohibiting many essential reproductive health care services); Sloboda, *supra* note 8, at 147 (explaining that a woman in California with nine children was denied the right to be sterilized after giving birth to her tenth child because the hospital had recently merged with a Catholic institution).

17 *See generally* Susan Berke Fogel & Lourdes A. Rivera, *Saving Roe is Not Enough: When Religion Controls Health Care*, 31 Fordham Urb. L.J. 725, 739 (2004).

18 *See id*. at 734.

19 *See id*. 729.

20 *See id*.

21 *See id.* at 730.

22 *See* Sloboda, *supra* note 8, at 140.

23 *See* Appelbaum & Morrison, *supra* note 6, at 6.

24 *See id*. at 4.

25 *See id*. at 3-4.

26 *See* William Basset, *Private Religious Hospitals: Limitations Upon Autonomous Moral Choices in Reproductive Medicine*, 17 J. Contemp. Health L. & Pol'y 455, 463 (2001).

27 *See id*. at 464.

28 *See* Fogel & Rivera, *supra* note 17, at 731.

29 *See id*.

30 *See id*.

31 *See* Christopher Snowbeck, *UPMC-Mercy Deal to Test Antitrust Law; Studies Show Mergers Bring Higher Prices*, Pittsburgh Post-Gazette, Oct. 8, 2006, at D1.

32 *See id*.

33 *See* Fogel & Rivera, *supra* note 17, at 734.

34 When a fertilized egg implants outside of the uterus, usually in the fallopian tubes, creating a hazardous situation.

35 *See* Fogel & Rivera, *supra* note 17, at 734.

36 *See id*. at 734-35.

37 *See id*. at 735-36.

38 *See* Jane Hochberg, *The Sacred Heart Story: Hospital Mergers and Their Effects on Reproductive Rights*, 75 Or. L. Rev. 945, 955 (1996).

39 *See* Appelbaum & Morrison, *supra* note 6, at 7.

40 *See* The National Campaign to End Teen Pregnancy, General Facts and Statistics, *available at* http://www.teenpregnancy.org/resources/data/genlfact.asp (last visited Feb. 7, 2008); *see also*, Lawrence Finer & Stanley Henshaw, *Abortion Incidence and Services in the United States in 2000*, 1, The Guttmacher Institute, http://www.guttmacher.org/pubs/psrh/full/3500603.pdf.

41 The National Campaign to End Teen Pregnancy, General Facts and Statistics, *available at* http://www.teenpregnancy.org/resources/data/genlfact.asp. (last visited Feb. 7, 2008)

42 *See* Contraceptive Use, *supra* note 3.

43 *See* Directives, *supra* note 13, at 52.

44 *See id.*; *see also* Contraceptive Use, *supra* note 3 (stating that "natural family planning methods" have a 25 percent failure rate, compared to an eight percent failure rate for the Pill).

45 Fogel & Rivera, *supra* note 17, at 734.

46 *See id.* at 736-37; *see also* Hochberg, *supra* note 38, at 954.

47 *See* Hochberg, *supra* note 38, at 954-55

48 *See* Fogel & Rivera, *supra* note 17, 736-37.

49 *Facts on Induced Abortion*, *supra* note 1.

50 *See* Finer & Henshaw, *supra* note 40, at 10.

51 *See id*. at 11.

52 *See* Kathryn Kolbert & Andrea Miller, *Legal Strategies for Abortion Rights in the Twenty-First Centur*, *in* Abortion Wars: A Half Century of Struggle 95, 106 (Rickie Solinger, ed., 1998).

53 *See* Fried, *supra* note 7, at 214.

54 *See* Kolbert & Miller, *supra* note 52, at 96; *see also* Rust v. Sullivan, 500 U.S. 173 (1991).

55 *See Rust*, 500 U.S. at 173.

56 *See id*.

57 More than one in five pregnancies in the United States ends in an abortion.

58 *See* Finer & Henshaw, *supra* note 40, at 14-15.

59 *See* Appelbaum & Morrison, *supra* note 6, at 9-10.

60 *See* Bassett, *supra* note 26, at 457.

61 *See* Sloboda, *supra* note 8, at 146-47.

62 *See* Appelbaum & Morrison, *supra* note 6, at 1.

63 *See* Basset, *supra* note 26, at 472.

64 *See* Sloboda, *supra* note 8, at 149.

65 *See* Appelbaum & Morrison, *supra* note 6, at 1.

66 Sloboda, *supra* note 8, at 149.

67 *See id*.

68 *See* Jennifer Connors, *A Critical Misdiagnosis: How Courts Underestimate the Anticompetitive Implications of Hospital Mergers*, 91 Cal. L. Rev., 543, 547 (2003).

69 *See id*. at 547.

70 *See id*. at 548.

71 *See* Snowbeck, *supra* note 31, at D1.

72 *See* Connors, *supra* note 68, at 548.

73 *See id.* at 549.

74 *See generally id.* at 549 (noting that mergers give hospitals more power to control prices, allowing them to drive up prices to the detriment of women and the poor).

75 *See* Appelbaum & Morrison, *supra* note 6, at 16.

76 *See* Connors, *supra* note 68, at 558.

77 *See* Appelbaum & Morrison, *supra* note 6, at 15.

78 *See id.* at 17.

79 *See* Connors, *supra* note 68, at 550.

80 *See* Appelbaum & Morrison, *supra* note 6, at 17.

81 *See id*.

82 *See id*.
83 *See id*; *see also* Conners, *supra* note 68, at 555.
84 *See* Conners, *supra* note 68, at 555; *see also* Snowbeck, *supra* note 31, at D1 (referring to a Federal Trade Commission report that shows mergers actually increase costs for consumers, rather than decrease costs).
85 *See* Appelbaum & Morrison, *supra* note 6, at 36.
86 *See* Sloboda, *supra* note 8, at 149.
87 *See* Conners, *supra* note 68, at 576.
88 *See* Sloboda, *supra* note 8, at 150.
89 *See* Fogel & Rivera, *supra* note 17, at 728.
90 *See generally* Bassett, *supra* note 26, at 471 (arguing that "[i]f patients have little or no choice of hospitals, hospitals cannot retain a distinctive ethical autonomy to deny patients their rights to comprehensive medical care").
91 *See id*. at 464.
92 *See* Fogel & Rivera, *supra* note 17, at 739 (quoting Doe v. Bridge Memorial Hosp. Ass'n, 366 A.2d 641 (N.J. 1976)).
93 *See id*.
94 According to one study, religiously affiliated hospitals received $45 billion in 2002.
95 *See* Molly M. Ginty, *Dangers of Hospital Mergers,* Planned Parenthood Federation of America (2005) *available at* http://www.plannedparenthood.org/news-articles-press/politics-policy-issues/birth-control-access-prevention/hospital-mergers-6526.htm (last visited Feb. 7, 2008).
96 *See* Lemon v. Kurtzman, 403 U.S. 602, 612-13 (1971).
97 *See id*. at 612-13.
98 *See* Edwards v. Aguillard*,* 482 U.S. 578, 585 (1987) (quoting Wallace v. Jaffree, 472 U.S. 38, 56 (1985)).
99 *See* Ginty, *supra* note 95.
100 *See* Dina R. Lassow, *Hospital Mergers and the Threat to Women's Reproductive Health Services: Using the Establishment Clause of the Constitution to Fight Back*, 14, National Women's Law Center (2006) http://www.nwlc.org/pdf/EstablishmentClause_06.16.06.pdf.
101 *See* Bassett, *supra* note 26, at 471.
102 *See* Eisenstadt, *supra* note 10, at 140.
103 *Id*.
104 *See id*.
105 *See id*. at 141.
106 *See id*.
107 *See* Fogel & Rivera, *supra* note 17, at 741.
108 *See generally* Hochberg, *supra* note 37, at 957 (quoting a study conducted by Catholics for a Free Choice that found that over 40 percent of women polled were unaware that a Catholic hospital might not restrict reproductive health services).
109 *See* Fogel & Rivera, *supra* note 17, at 734.
110 *See id*.
111 *See* Hochberg, *supra* note 38, at 955.
112 *See* Sloboda, *supra* note 8, at 144.
113 *See* Kathleen M. Boozang, *Deciding the Fate of Religious Hospitals in the Emerging Health Care Market*, 31 Hous. L. Rev. 1429, 1482 (1995).
114 *See* Tribe, *supra* note 4, at 145.
115 *See* Sloboda, *supra* note 8, at 144.
116 *See* Fogel & Rivera, *supra* note 17, at 742.
117 *See* Bassett, *supra* note 26, at 484.
118 *See* Appelbaum & Morrison, *supra* note 6, at 3.
119 *See* Bassett, *supra* note 26, at 459.
120 *See* Sloboda, *supra* note 8, at 149.
121 *See id*. at 150.
122 *See* Cara Matthews, *Reproductive Care at Issue in Hospital Plan*, Gannett News Service, Dec. 8, 2006.
123 Sloboda, *supra* note 8, at 149.
124 *See* New Hampshire Att'y Gen. Report on Optima Health 1 (1998) [hereinafter AG Report].
125 *See id*.
126 *See id*. at 38.
127 *See* Sloboda, *supra* note 8, at 149.
128 AG Report, *supra* note 124, at 13.
129 *See id*. at 14 (quoting Articles of Agreement of Catholic Medical Center, Art. II. A) (capitalization in original).
130 *See id*. at 15.
131 *See id*.
132 *See id*. at 16.
133 *See id*.
134 *See id*. at 17.
135 *See id*. at 1.
136 *See id*. at 2.
137 *See id*. at 5.
138 *See id*.
139 *See id*. at 40, n. 93.
140 *See id*.
141 *See id*.
142 *See id*.
143 *See id*.
144 *See* Julia Eberhart, *Merger Failure: A Five-Year Journey Examined—Optima Health*, Healthcare Financial Management, Apr. 2001, *available at* http://findarticles.com/p/articles/mi_m3257/is_4_55/ai_73328480 9 (last visited Feb. 7, 2008).
145 *See* Sloboda, *supra* note 8, at 146.
146 *See* AG Report, *supra* note 124, at 40.
147 *See id*. at 41, n. 96
148 *See id*. at 42.
149 *See id*.
150 *See* Ebarhart, *supra* note 144.
151 *See* AG Report, *supra* note 124, at 39.
152 *See id*. at 9.
153 *See* Eberhart, *supra* note 144.
154 *See* AG Report, *supra* note 124, at 1.
155 *See id*. at 2.
156 *See id.*
157 *See* Sloboda, *supra* note 8, at 149.
158 *See* Appelbaum & Morrison, *supra* note 6, at 27.
159 *See id*. at 29.
160 *See* Connors, *supra* note 68, at 549.
161 *See* Hochberg, *supra* note 38, at 963.
162 *See* Bassett, *supra* note 26, at 464.
163 *See* Hochberg, *supra* note 38, at 965.
164 *See* Bassett, *supra* note 26, at 516.
165 *See* Appelbaum & Morrison, *supra* note 6, at 8.
166 *See id*. at 9.
167 *See* Fogel & Rivera, *supra* note 17, at 729.
168 *See id*.

Deafness: A Disability or a Difference?

*Erica R. Harvey**

I. Introduction

Depending on the source and time at which data is collected, between 28.6 million and 31.5 million people in the United States describe themselves as having "hearing difficulty."[1] These hearing difficulties range from age-related hearing loss to profound deafness. A smaller group of people within the group of individuals who are profoundly hearing impaired or deaf considers themselves to belong to a social minority group or subculture known as "Deaf Culture" or the "Deaf Community."

The inability to receive information through sound creates a group of people who appear the same as others, but who have additional needs because of their difference. This invisible difference creates a potential tension between physical appearance and actual needs.

The Deaf Community takes the seemingly paradoxical position that society (and individuals) should not define deaf people as impaired or as having a disability.[2] The Deaf Community believes that, rather than having a disability, its members are merely "different." Yet, at the same time, they want to receive the legal benefits and accommodations that persons who fit within the characterization of individuals with disabilities receive.[3] Thus, the Deaf Community desires to obtain the protections and benefits afforded to those with disabilities while rejecting the notion that members of the Deaf Community have a disability that gives rise to the legal protections and benefits that they seek to enjoy. This philosophy and other paradoxes that surround Deaf Culture lead to difficult issues, including the extent to which people who deny having a disability should be able to take advantage of laws designed to afford rights to persons with disabilities, and whether the government should modify or expand existing laws to accommodate the views of this minority group.

The Deaf Community should not be able to reject the views of individuals who do not subscribe to their belief system, create their own communities separate from the rest of society, and still expect society to willingly accommodate them on the same basis that it accommodates those persons who acknowledge having conditions generally considered to be disabilities. The Deaf Community's rejection of the label of disability and rejection of deaf persons who do view themselves as having disabilities, while demanding the protections and special rights granted to persons with disabilities, raises a difficult question of whether disability is defined by society or by the person who has a physical or mental condition. Federal legislation to date seems to opt for the former, while the Deaf Community advocates for the latter.

The approach taken by federal disability rights law is, on balance, the better approach. This approach avoids the potential abuse of individuals proclaiming themselves as having disabilities in cases where an individual has neither physical nor mental conditions that limit the ability to live and function in society, and where society as a whole does not view the individual as having a disability.[4] Also, since individuals with disabilities have historically suffered from discrimination in the general society, this approach links the rights afforded to the individual to the societal cause of the discrimination.[5] The Americans with Disabilities Act[6] (ADA), the landmark federal legislation in the field of U.S. disability rights law, adopts a three-pronged test which defines disability either as physical or mental conditions that interfere with an individual's daily life, a record of impairment, or physical or mental conditions other individuals perceive as a disability.[7]

Like other people with disabilities, individuals with hearing impairments[8] find themselves at a disadvantage when attempting to live and function in a society that does not automatically accommodate their needs. This disadvantage begins at birth for those who are born deaf, or who become deaf very shortly after birth, since babies learn speech largely through aural input.[9] Children who are born deaf, or lose their hearing shortly after birth, do not receive this critical input. Much of the information people receive comes though auditory channels such as everyday conversation, radio, television and other entertainment media, and warning sounds such as horns and sirens. Individuals with hearing impairments have limited or no access to information that comes through these media without special accommodations. To obtain auditory information, either the deaf must accommodate themselves to the society in which they live, or society must make accommodations for them.

Yet many individuals with impaired hearing often are otherwise physically indistinguishable from those without disabilities, making their disability invisible. The inability to receive information through sound creates a group of people who appear the same as others, but who have additional needs because of their difference. This invisible difference creates a potential tension between physical appearance and actual needs.

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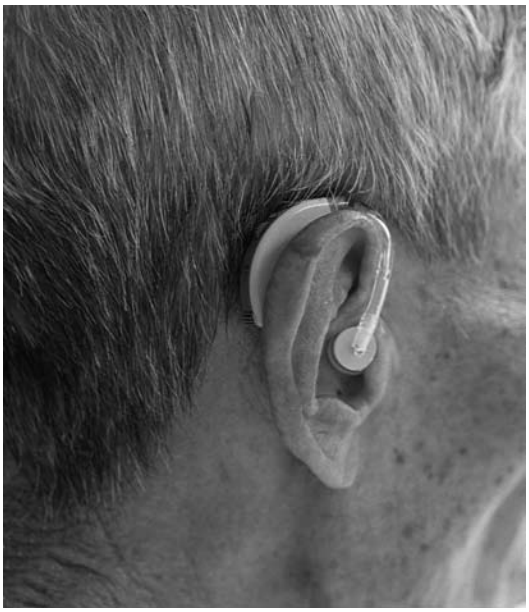


Deaf people find themselves subjected to what has been termed "unintentional barriers," meaning that the systematic design of features of modern life, such as the telephone, are inaccessible to the deaf without modification.[10]

Individuals who are deaf clearly fall within the definition of disability which entitles those individuals to the protections of U.S. disability rights laws, regardless of whether those individuals consider themselves as having a disability.[11] This makes the Deaf Community's position that deafness is not a disability irrelevant in the determination of the legal rights of the deaf. However, it is neither wise nor appropriate to adopt legislation granting separate and special treatment to the deaf that would separate their treatment from that given to other individuals with disabilities.

II. Background

A. The Evolution of Models for Understanding Disability

Individuals with disabilities have been subject to discrimination and mistreatment throughout history.[12] Until recently, society dealt with persons with disabilities under what is commonly referred to as the medical model. The medical model is a paternalistic model which focuses on attempting to "cure" disabilities rather than protect individual human rights.[13] Under this model, government or society viewed individuals with disabilities as objects who were acted upon, rather than as equals who participated in determining their own needs and enforcing their own rights. The medical model also views individuals with disabilities as exhibiting a deviation from what is considered normal.[14] This deviation makes them appropriate subjects for medical intervention and cure.[15]

In contrast, the social, or human rights-based model of disability, views a person's disability not as the individual's problem, but as a problem with the way that the society perceives of and treats the person who has a condition that society considers to be a disability.[16] The individual with perceived disabilities is empowered to be an active participant in determining how he or she is treated by society.[17]

The "equal opportunity" or rights model emphasizes the willingness and ability of individuals to assert their rights and establish their place in society.[18] Under the rights model it is the government's duty to assist individuals in asserting their rights and establishing their equal place in society.[19] However, the individual is empowered as a partner with the government to be an advocate for his or her own rights. This empowerment of the individual fits best if the individual subscribes to the societal view that he or she, in fact, has a disability.

At least in theory, under the medical model, if society views the individual as having a disability, the individual is an appropriate subject for "cure" regardless of his or her self-perception.[20] On the other hand, the situation is problematic if the individual does not believe that he or she has a disability. Generally, to gain the rights that legislation grants, an individual must openly accept society's perception that he has a disability, regardless of his own personal beliefs about his condition. On the other hand, if the government or advocacy groups assert the rights for an individual who denies that he or she has a disability, society has regressed to the medical model where the individual is an object that is acted upon.

The ADA represents a departure from the medical model since it is premised on a social or human rights model of disability. The ADA attempts to bring individuals with disabilities on to a level playing field with individuals without disabilities.[21] The goal of the ADA is to permit individuals with disabilities to share in the same opportunities in society to the maximum extent possible and on the same basis as individuals without disabilities.[22] Thus, individuals with disabilities become participants in the process rather than objects of treatment.

The ADA has attempted to adopt the rights model by permitting individuals with disabilities to avail themselves of the benefits of the ADA regardless of their subjective view of their physical or mental condition. However, the concept of disability in the ADA, which is based on impairment or society's view that the individual is impaired, still carries with it the medical model's concept that disability is a variation from "normal."[23]

> Section 504 empowered individuals with disabilities to become advocates for their own rights, rather than having to sit passively and wait for the government to act on their behalf.

B. Existing Legislation Affording Rights to the Deaf

The United States is often viewed as one of the first countries to adopt national legislation dealing with the rights of persons with disabilities.[24] The U.S. approach to granting these rights is a civil rights model, which attempts to assure that persons with disabilities enjoy the same rights and opportunities as other persons, and that in employment and areas that are considered public accommodations, physical facilities or systems are available to permit persons with disabilities to effectively use those public accommodations.[25] However, disability rights legislation in the United States is general in nature, focusing on assuring rights and access to all persons with disabilities in a given context, such as public accommodations, employment, or education, or assuring access or opportunity in a specific context such as air transportation or voting, rather that addressing the particular challenges faced by individuals with a specific disability. While the approach dictating equal access and opportunity established a general framework for disability rights, it is up to the individual with disabilities, or the government or an advocacy group acting as that person's proxy, to apply the general principles of U.S. disability law to the specific person and situation.

There are at least ten separate federal laws that seek to grant rights or protection to individuals with disabilities.[26] Many of these laws focus on specific activities and attempt to assure that persons with disabilities have the ability to fully participate in the activities on which the laws choose to focus. These focused laws deal with everything from access to air transportation,[27] to assuring that persons with disabilities can vote.[28] However, the Rehabilitation Act and the ADA are the key pieces of legislation relating to the rights of individuals with hearing impairments because of their historical contexts and broad implications for everyday life. These federal laws seek to prevent discrimination against those with disabilities, including the deaf, and assure them access to society in a broad range of activities and locations, both private and public.

i. The Rehabilitation Act

Although the Rehabilitation Act's primary focus is on discrimination in areas where federal funds are involved, its enactment was a significant step in the development of U.S. disability rights law.[29] Section 504 of the Rehabilitation Act prohibits discrimination against individuals with disabilities in activities and programs carried on by any federal executive agency, the Postal Service, or by any group or entity receiving federal financial support. Not only did the Rehabilitation Act facilitate access to areas such as employment and education for people with disabilities, it also empowered people with disabilities to enforce the rights granted to them as independent actors in the judicial system.[30]

The Rehabilitation Act forbids discrimination based on disability in federal employment (including those businesses which are working under federal contract), in programs receiving federal funds, or in programs sponsored by federal agencies.[31] Section 504 of the Rehabilitation Act prohibits discrimination and encourages non-discrimination by conditioning the receipt of federal funds on compliance with the statute.[32] Section 503 of the Rehabilitation Act goes beyond merely prohibiting discrimination and requires affirmative action by government contractors and certain subcontractors to include persons with disabilities.[33]

The Rehabilitation Act established the definition of disability used in other federal laws, including the ADA. Both acts adopt a three-prong definition of disability. When originally enacted, the regulations used the term "handicap." This obsolete and prejudicial term has since been changed to "disability" in describing individuals who are under its coverage. Both the ADA and the regulations adopted under it use the functional definition of an individual with a disability as an individual who: "(i) has a physical or mental impairment which substantially limits one or more of such person's major life activities; (ii) has a record of such an impairment; or (iii) is regarded as having such an impairment."[34]

The Rehabilitation Act was the first federal legislation that prohibited discrimination against persons with disabilities.[35] However, its scope was limited–it only prohibited discrimination by the Federal government and by other groups that either contracted with the Federal government or received federal funds.[36] Limiting the scope of the Rehabilitation Act to the Federal government and federally-connected groups excluded a large number of businesses and organizations from the Rehabilitation Act's coverage.[37] Despite this shortcoming, the Rehabilitation Act has had at least two further positive effects. First, Section 504 of the Rehabilitation Act is viewed as a model for drafting multiple employment policies dealing with the hiring and treatment of individuals with disabilities.[38] Section 504 of the Rehabilitation Act also created a private right of action under which individuals with disabilities are able to sue on their own behalf if they believe they were the subject of disability discrimination.[39]

While the Rehabilitation Act's focus on discrimination against people with disabilities in employment was a major step in eliminating discrimination in one aspect

of the lives of persons with disabilities, the creation of a private right of action for individuals with disabilities was even more significant since it opened up a means to effectively enforce rights of persons with disabilities in a broad range of activities. Section 504 empowered individuals with disabilities to become advocates for their own rights, rather than having to sit passively and wait for the government to act on their behalf.

ii. The Americans with Disabilities Act of 1990

The Rehabilitation Act served as the precursor to the ADA and provided a base from which the ADA expanded the rights it grants.[40] Although they were not always successful, individuals with disabilities used Section 504 of the Rehabilitation Act in an attempt to gain access to education[41] and to gain or retain employment.[42] Even after the Rehabilitation Act's enactment, persons with disabilities were subject to both conscious and inadvertent exclusion and discrimination, due to the limited applicability of the Rehabilitation Act and enforcement limitations within its sphere. As a result, people with disabilities and their advocates undertook a grass roots campaign and generated publicity to pass legislation that would assure broader application of the rights of individuals with disabilities.[43] The National Council on the Handicapped (now, the National Council on Disability) developed a draft law.[44] The proposed congressional bill was the subject of numerous hearings held in every state. Despite opposition from groups such as small business owners, insurance companies, and other special interest groups, Congress passed the ADA on July 26, 1990.[45]

The ADA purports to assure civil rights to individuals with disabilities.[46] It extends the prohibition on discriminating against individuals with disabilities into areas where no federal employment or funds are involved.[47] In addition to broadening the Rehabilitation Act's prohibition against discrimination, the ADA attempts to extend the obligation to accommodate those with disabilities in numerous public places where individuals with disabilities were otherwise excluded because of accessibility or other existing limitations.[48]

While the standards used in determining employment discrimination under Title I of the ADA are the same as those used under the Rehabilitation Act, Title I of the ADA prohibits discrimination on the basis of disability in employment by any covered entity or employer that regularly employs 15 or more employees.[49] Thus, the ADA broadened the prohibition against discrimination from only the Federal government and entities doing business with it to most medium-sized and large organizations. Title II of the ADA similarly extends the prohibitions on discrimination against those with disabilities to state and local governments and their instrumentalities and activities, as well as to certain forms of public transportation.[50] States and localities may adopt their own laws prohibiting discrimination against people with disabilities provided they are consistent with the ADA.[51] Title III of the ADA prohibits discrimination in public accommodations and certain commercial facilities.[52]

The ADA adopted its structure from Title VII of the Civil Rights Act of 1964.[53] It borrows provisions from and defines disability the same as it is defined under the Rehabilitation Act. Significantly, the ADA went one step further than previous laws, such as the Civil Rights Act of 1964, and extended coverage against discrimination in the private sector to prohibit not only discrimination, but to also affirmatively require accessibility in an effort to avoid indirect discrimination as a result of lack of physical access.[54]

The ADA adopted the three-pronged approach described above to define a disability that invokes the ADA's protections.[55] This definition was adopted from Section 706 of the Disability Act and, by reference, Section 504 of the Rehabilitation Act.[56] Courts also adopted this definition in applying the acts.[57] Deafness fits within this definition of disability. However, the definition of disability is not universal. Groups such as transvestites,[58] users of illegal drugs (other than former drug users who have completed rehabilitation),[59] homosexuals and bisexuals, and people who suffer from certain other psychological disorders[60] are not considered to be individuals with disabilities and, thus, do not receive protection under the ADA.

The ADA also contains enforcement mechanisms that go far beyond anything contained in the Rehabilitation Act. Courts interpreted Section 504 narrowly in line with its scope, which applies to federal programs and organizations receiving federal aid. Congress intended broader protections for persons with disabilities and incorporated these protections into the ADA. The Act designates specific federal agencies that have enforcement powers and responsibility for implementing the Act.[61] Further, the ADA prohibits discrimination or retaliation against an individual who has alleged a violation of the Act and creates a private right of action under Titles I and II.[62]

The ADA also loosens the standard of when an action may be brought under the ADA. A person may bring a proceeding under Title II of the ADA when he or she has "reasonable grounds for believing" that he or she will be discriminated against because of new construction or modification to public accommodations.[63] Thus, a person with disabilities need not wait until a public accommodation is constructed and he or she faces actual discrimination before seeking a remedy. If an individual has a reasonable basis to believe that the design of a public accommodation will discriminate against him or her, the person may intervene before construction begins to require modification to the facility.[64] This right potentially makes persons with disabilities active participants in the design and planning of public accommodations.

iii. Individuals with Disabilities Education Act (IDEA)

In order to ensure a "free appropriate public education" for all students with disabilities, Congress enacted the Individuals with Disabilities in Education Act (IDEA).[65] The IDEA requires public schools to provide children with disabilities appropriate learning environments and assistance to promote their education.[66] States, and more particularly school systems, are periodically required to work with students and their parents or guardians to develop an Individualized Education Program (IEP) for particular students with disabilities. The IEP is developed by a team of professionals, as well as the child's parents, the teacher, and where appropriate, the student with the disability. The IDEA provides a method by which parents of children

"...the ADA attempts to extend the obligation to accommodate those with disabilities in numerous public places where individuals with disabilities were otherwise excluded..."

with disabilities and schools can address disagreements over the terms of the IEP and concerns about the student and the program.

The IDEA requires periodic re-evaluation, allowing for changes and using different approaches to find the best way to help the individual student.[67] In the case of deaf individuals, assistance for children with disabilities may include hearing aids or interpreters for the student in class, since otherwise the child may not be able to participate or learn from class lectures and discussion.

The IDEA requires that children with disabilities (including those in institutions or care facilities) be educated with children without disabilities, when possible, in the least restrictive environment reasonable.[68] The least restrictive environment for an individual is the environment most identical or similar to that in which children without disabilities are educated which still enables the child with a disability to flourish. The environment includes the physical location and facilities where the child is taught, as well as the means and approaches used to teach the child. Further, if possible, children are to be taught and participate with children without disabilities in as many class activities as is reasonable.

Implementation of the IDEA has led to numerous disputes between parents and school systems since the IDEA does not, and cannot, contain hard and fast rules or explicit guidance on how to meet the IDEA's aspirational criteria.[69] Naturally, parents want maximum assistance and benefits for their children, while school administrators may view the child's needs or situation differently and may also be constrained by available resources and funds. Whether "mainstreaming" is reasonable and how much, or what activities the child will participate in are determined on an individual basis.[70] Often the type of placement for a student will depend on the child's individual disability. There is a wide continuum of what may be considered the least restrictive environment for a particular child. This environment may range from full-time participation in general education classes with supplemental aids to education in special educational facilities or schools.[71]

The Deaf Community appears opposed to the least restrictive environment when it is applied to place a deaf student in general education classes. The Deaf Community has exhibited forceful opposition to educating deaf children in general education classrooms and prefers, or insists, that deaf children be segregated into special schools only for the deaf in order to surround them with Deaf Culture.[72]

The Deaf Community has exhibited forceful opposition to educating deaf children in general education classrooms and prefers, or insists, that deaf children be segregated into special schools only for the deaf in order to surround them with Deaf Culture.

The IDEA is a complement to the Rehabilitation Act and the ADA. It is consistent with the approach of the other two acts because it permits persons with disabilities access to a "free appropriate public education"[73] so that the child has a chance to achieve the maximum educational benefit that the child's disability will permit.[74] Like the ADA, the IDEA permits the individual with a disability, or at least their parents in the case of children, to be a partner in advancing the interest of the person with a disability.

The Rehabilitation Act, the ADA, and the IDEA are important not only because of the rights that they create for persons with disabilities. The acts also reflect an underlying shift in the view or model by which society and government understand the individual with a disability and that individual's relation to society.[75]

C. The Emerging Movement of Deaf Culture Among the Deaf

The deaf do not have a uniform view of their condition. One deaf commentator has described the situation as, "[t]he world of deafness often seems Balkanized, with a warlord ruling every mountaintop."[76] At its simplest, the deaf fall into two basic groups characterized as the "deaf" and the "Deaf." The deaf view their condition as a physical or medical condition and as a disability or impairment.[77] The Deaf do not consider themselves to have a disability and view their condition as a label of a separate subculture to which they voluntarily subscribe as members.[78] They do not view themselves as medical cases and, instead of labeling themselves as individuals with disabilities, believe that the Deaf are "different."[79] Rather than finding this difference to be a negative factor, Deaf Culture aggressively asserts that the Deaf may be different but they are equal.[80] In its extreme form, this assertion leads to a desire to create a separate but equal classification for the Deaf. This clearly is at odds with the goal of current U.S. disability rights laws that seek to create equality for individuals with disabilities by integrating them into society.

Even within the group of individuals who classify themselves among the Deaf, there is a range of attitudes toward the deaf and the Deaf. The most extreme of the Deaf have been referred to as "absolutists" by I. King Jordan, the past President of Gallaudet College, the preeminent university for the deaf.[81] This group believes that a person either supports American Sign Language (ASL) or they are not Deaf.[82] This diversity in beliefs has led to friction within the Deaf Community. Recently, Jane K. Fernandes was ousted as President of Gallaudet College because of student and faculty opposition.[83] The opposition was based, in some quarters, on the fact

that she was not "deaf enough," having only learned ASL when she was in her twenties.[84] This controversy highlights the varying approaches to deafness within the deaf community.

Under the traditional medical model of disability, which views functional ability on a scale of normality, deafness was characterized as a disability.[85] Deafness was viewed as an individual shortcoming that needed to be corrected or cured. However, the Deaf Culture movement, or the Deaf Community, adopted the view of disability as a social construct.[86] Contrary to the medical model that mandates changing an individual or helping the individual to adapt, the Deaf Culture movement believes that mainstream society should modify social and environmental factors to allow the full participation of individuals with disabilities, including individuals with hearing impairments.[87] Yet, at the same time, it advocates self-segregation in educational facilities, such as Gallaudet College, and the avoidance of treatments or devices that may enable the deaf to regain some or all of their hearing.[88]

The Deaf Community goes one step further than the social model of disability. Deaf Culture rejects deafness as a disability in its entirety, viewing Deafness as a subculture existing within American culture. This Deaf subculture is entitled to exist as a recognized classification or minority similar to an ethnic or racial group. As a result, Deaf Culture is strictly opposed to "correctional" methods to improve hearing.[89] The Deaf Community views deafness as a characteristic that should be appreciated and valued,[90] and believe that deafness is only a different way of life.[91] Further, they believe that any effort to cure Deafness would be a repugnant attempt to eradicate a culture, with some individuals going so far as to consider it an attempt at genocide.[92]

Deaf Culture views discrimination against deafness, or audism, as a form of discrimination similar to racism, based not on perceived physical limitations of the individual, but rather based on the perceived difference in the characteristics of the individual.[93] While race is generally physically apparent, deafness is not necessarily visually apparent. Further, the Deaf differentiate themselves from individuals with other physical impairments such as blindness.[94] Advocates for the proposition that the Deaf are different from other individuals with disabilities assert that their Deafness makes them "ineradicably different" because of their inability to receive and process auditory signals and learn speech.[95]

This argument is weak, since the blind suffer from the same ineradicable difference since they cannot receive and process visual signals. The Deaf Community does not answer the question as to how auditory signals are different from or more important than visual signals, except by the implicit assumption that sound is more important than sight.[96] The only answer that the Deaf Community proposes to this argument is one that implies that a person must be Deaf to understand the difference. They point out that while an individual can simulate blindness, one cannot truly simulate deafness since a hearing person who simulates deafness still has the knowledge of what sound is.[97]

The language of Deaf Culture is sign language, and specifically American Sign Language (ASL) within the United States.[98] The Deaf Community views itself as a natural environment for not only deaf children, but all Deaf individuals. The Deaf Community not only welcomes those whose ability to hear is impaired, but also any individuals accepting their cultural beliefs and norms and associate themselves with the Deaf Community.[99] Not all individuals who are unable to hear are considered Deaf or members of the Deaf Community. Those individuals who have taken steps to assimilate within mainstream hearing society are not considered to be a part of the separate Deaf Culture.[100] In the recent past there has even been talk by some members of the Deaf Community of creating a Deaf Town.[101] This separate town would replicate deaf enclaves that existed in the past and would provide a home for what the advocates see as the unique Deaf Culture.[102]

While society has made great steps and advances towards "curing" deafness, the Deaf Community is adamantly opposed to taking steps to "correct" hearing impairments. One such technological advance is the cochlear implant, an electronic device that is surgically implanted in the ear to create electronic stimulation of hearing nerve fibers. Cochlear implants allow sound to be transmitted to the brain.[103] The Deaf Community is ardently opposed to such devices, calling them "the ultimate invasion of the ear, the ultimate denial of deafness, the ultimate refusal to let deaf children be Deaf."[104] The more extreme elements of Deaf Culture even oppose further research into cures for deafness.[105]

The Deaf do not believe that deafness is something that needs to be, or should be, cured.[106] Instead, they believe that deafness is a characteristic that should be embraced.[107] Deaf adults have the ability to make decisions for themselves as to whether they want treatments that may "cure" or lessen their deafness, such as cochlear implants. However, children who are born deaf, or become deaf, do not have this decision-making right. Parents generally make the decisions as to a child's health care and treatment. Since the vast majority of deaf children are born to hearing parents,[108] in many of these cases, the decision as to whether to attempt to treat a child's deafness will be made by parents who are not members of Deaf Culture. It is unlikely that courts will give standing to members of the Deaf Community who are not a child's parents in determining a child's medical treatment. Thus, the choice between being Deaf and deaf will be made for the individual.

II. Analysis

A. The Deaf Community's Denial of Deafness as a Disability Raises Issues

Deafness is clearly defined as a disability under the ADA, as major life activities include hearing,[109] and hearing impairments are clearly specified as a physical or mental disability.[110] While this resolves the issue for most individuals and entities, the Deaf Community takes a different view. The Supreme Court has highlighted ambiguities in the definition of disability under the ADA and its implementing regulations.[111]

The Deaf Community and its supporters feel strongly that being deaf is not a disability. Yet, consistent with the other paradoxes that surround the Deaf Community, it has been a leader aligning itself with the disability movement in supporting the passage of the ADA.[112] Historically, both those living with other disabilities and those who are deaf experienced the same oppression. In the United States, persons living with physical and mental disabilities, including the deaf, have been institutionalized and segregated from the rest of mainstream society, and have even been faced with attempts to be wiped out of the future through the eugenics movement.[113]

Undeniably, there are commonalities between those who support the disability movement and those in the Deaf Community. Both groups attempt to change the perception of what it means to live with a disability, moving away from the idea of impairment or the idea that an individual must conform to society, and instead, toward a concept that individual variability is desirable and worthy of respect.[114] Further, both groups believe in the right to self-determination.[115]

The Deaf Community takes pains to separate itself from other disability advocates and points out the differences between itself and those accepting the concept of their disability. Unlike other people with mental or physical disabilities, the Deaf often point out that simulations of being deaf are not the same because temporary loss of hearing is not the same as everyday life without hearing.[116] While the disability movement believes that persons with disabilities should be indistinguishable from the rest of society, the Deaf Community thrives on its "differentness" and attempts to segregate itself and exist as a separate group or minority within society.[117]

The dichotomy between the disability movement's efforts to integrate individuals with disabilities in society and the Deaf Community's efforts at self-segregation are clearly seen in their diverging views on education. The Deaf Community has created segregated education facilities for the deaf, establishing their own schools to teach ASL and reject audism. At the same time, the disability movement is a strong proponent of inclusive education and accommodations to allow individuals to be accepted in society.[118] The Deaf Community's goal of separate education goes far beyond deaf pride, since pride in deafness does not mandate that the deaf be separate from the general population.

The Deaf Community also has some striking similarities to groups that have faced past discrimination based on race or gender. Many ethnicities such as Hispanics and African-Americans have been in an inferior or minority position in American society. The Deaf Community compares itself to these groups. Like Hispanics, the Deaf Community identifies itself as a linguistic minority or subculture that ought to be honored.[119] Like characteristics of an individual's race and gender, deafness is an uncontrollable characteristic.

However, in *City of Cleburne v. Cleburne Living Center*,[120] the United States Supreme Court distinguished the category of persons with disabilities from race and gender when it comes to analyzing governmental action under the Equal Protection Clause. While governmental actions based on classifications of race received the highest scrutiny and gender classifications receive intermediate scrutiny, in reviewing governmental actions relating to people with disabilities, the Supreme Court declared that these actions need only to be analyzed to determine whether the governmental action is a rational means to serve a legitimate end.[121] This is a very low standard of judicial scrutiny because as long as the government demonstrates a legitimate state interest and the classification or treatment is rationally related to this interest, the classification is constitutional and passes muster.[122] Interestingly, although the Supreme Court granted great deference to governmental actions and established a very low standard of judicial scrutiny, the Court in *Cleburne* nonetheless invalidated the City of Cleburne's action denying the living center's application.[123]

This low standard of scrutiny affords states "wide latitude" in social and economic legislation.[124] It does not support affirmative action to level the playing field for deaf individuals or place them in a favored position to make up for past wrongs. While the *Cleburne* Court determined that persons with disabilities, namely individuals with intellectual impairment, had a "non-suspect" status, it acknowledged that physical disabilities often have a relation to an individual's "ability to perform or contribute to society."[125] The Court noted two factors that applied to the individuals with intellectual disabilities, but that are equally applicable to all individuals with physical or mental disabilities. The first factor is a "reduced ability to cope with and function in the everyday world."[126] The second factor is the variability among individuals who have the same disability.[127] Although *Cleburne* dealt with intellectual disability, the general principles are equally applicable to the deaf.[128]

This distinction between disability and race and gender in applying equal protection criteria also emphasizes two additional pragmatic points. First, it highlights the need for a thoughtful analysis of the applicable general legal standards to various groups of individuals in determining their similarities and differences when it comes to applying equal protection concepts.[129] Second, it argues against the Deaf position that the Deaf are a separate subculture. Based on the *Cleburne* analysis, Deaf Culture's claim to be a subculture or linguistic group becomes irrelevant. Courts are unlikely to grant any special consideration to Deaf Culture other than under the low standard of actions furthering a legitimate governmental interest.

Perhaps the Deaf Community is most similar to the homosexual community, in that deaf individuals, more often than not, do not share this distinct characteristic with their parents.[130] Therefore, both homosexuals and Deaf individuals may join their respective cultures later in life and do not learn the "ins and outs" of their community at home but rather at school or from others outside of their family.[131] Further, disability appears to receive similar judicial treatment to that given to the homosexual community. Classifications based on sexual orientation have only been given "rational basis" scrutiny and therefore, the treatment of homosexuals in courts has been very similar to that received by individuals with disabilities, including those individuals who are deaf.[132] But the ADA specifically excludes homosexuality as a disability that falls under the ADA's protection.[133]

To a large extent, the argument as to whether deafness is a disability and whether Deaf Culture is a subculture or minority is irrelevant. Because both the Rehabilitation Act and the ADA provide that a person is defined as having a disability if that person is generally perceived by others as having a disability, people who are deaf are able to obtain the protection of both acts based on society's perception of deafness as a disability independent of an individual's willingness to admit that he or she has a "disability."

Case law under the ADA validates the position that, if a person or organization covered by the ADA regards an individual as having an impairment, that belief, whether or not correct, is sufficient to bring the individual within the protection of the ADA.[134] The Equal Employment Opportunity Commission has interpreted this "regarded" test in its regulations to provide that impairment includes physical or mental conditions that do not substantially limit "major life activities" but are regarded as doing so by a covered entity. Impairments also include

conditions that limit major life activities only because of the attitudes of others, and conditions, outside of certain enumerated conditions under the regulations, that are treated by a covered entity as a "substantially limiting impairment."[135] This approach to the "regarded" test focuses not on the individual's self-perception, but on how others perceive the individual.

Under this analysis, the individual's perception of his or her condition is a sociological issue rather than a legal issue. This approach also has the added benefit (along with the logical paradox) of permitting individuals to determine both how they perceive themselves and whether they will choose to seek the protections and benefits granted by disability laws regardless of that self-perception.

B. The Conflict Between Self-Segregation and Integration: The Puzzle of Education

No area highlights the conflict between the goals of Deaf Culture and disability law better than education. The goal of the IDEA is to mainstream children with disabilities to the maximum extent consistent with their abilities and educational needs.[136] This reflects an underlying desire to provide both equality of opportunity and integration of children into society to the maximum extent feasible.[137] The prevalent theory is that children with disabilities placed in integrated classrooms will not only personally benefit, but children who do not have disabilities will also benefit by seeing human diversity and learning tolerance.[138] In this sense, mainstreaming under the IDEA is analogous to racial integration of schools.

Deaf Culture opposes this integration, however, it also wants to coexist within society as a separate subculture. In a movement that can be compared to resegregation, Deaf Culture advocates separate education for the deaf and exclusive reliance on ASL.[139] Members of the Deaf Community want their children to be like them. The Deaf Community seeks to liberate the Deaf from what it sees as oppression by setting up an alternative community and alternative education. It vigorously asserts the positive attributes of being deaf while largely denying the negative drawbacks. These values of the Deaf Culture are best preserved and passed on to future generations by teaching them to deaf children in an educational setting that is separate from the general population.[140] Rather than focusing on the problems that come from deafness in a hearing society, they often feel that since they have had the experience of being deaf, they will be able to assist their children.[141] The Deaf see separate, residential education as a way of preserving Deaf Culture.[142] They downplay the costs of separate schools, where it is dramatically more expensive to educate a child than it is to educate the same child in a mainstreamed environment.[143] Since funding for public education is limited, establishing separate schools and universities for the deaf reduces the funding available for all other children, whether or not those children are living with a disability.[144]

Parents make the educational decisions for their minor children.[145] The model under the IDEA is that, to the maximum extent feasible, children who are deaf will be given special assistance and mainstreamed with hearing children.[146] However, mainstreaming runs directly contrary to the position of Deaf Culture. Parents, educators, and specialists develop an IEP for the child. Unless the parents and the educators determine that segregated education in a special facility is in the best interests of the child, the Deaf Community's goal of separate education is unlikely to be achieved. In fact, the position of the Deaf Community likely will not be heard or considered in developing an IEP for the deaf child unless the parents subscribe to Deaf Culture. This is consistent with the general approach that parents have the right and power to make decisions for their minor children.

C. Evaluating Existing Disability Laws

Regardless of whether Deaf Culture chooses to view the Deaf as having a disability, a system of laws is in place that prohibits discrimination and requires a broad range of public and private parties to make reasonable accommodations for individuals with disabilities. Even if the Deaf choose to reject the position that the deaf suffer from a disability, they nonetheless seek the benefits of laws protecting persons with disabilities. Laws that prohibit discrimination against individuals with disabilities and that assure them rights to the facilities enjoyed by society as a whole also protect those who are deaf but who do not accept the positions taken by the Deaf Community. The key issue is whether the existing provisions of the ADA are sufficient to protect the deaf or whether further legislation is advisable.

Importantly, it is possible and feasible to enact federal and state legislation that requires or prohibits particular conduct. The ADA is a clear example of such legislation. The ADA both prohibits discrimination against persons with disabilities and requires broad classes of governmental bodies and private interests to make reasonable accommodations for people with disabilities, including individuals who are deaf. However, the modification of attitudes is a more gradual process, but by mandating conduct, legislation can modify attitudes over time. The Civil Rights Act of 1964[147] and subsequent civil rights legislation have generally modified societal attitudes. Similarly, the ADA

"The ADA both prohibits discrimination against persons with disabilities and requires broad classes of governmental bodies and private interests to make reasonable accommodations for people with disabilities, including individuals who are deaf . . . the modification of attitudes is a more gradual process . . . ."

has created societal changes that do not automatically create acceptance of persons with disabilities but that do facilitate the integration of those individuals with disabilities who do want to participate in society.[148] While these laws do not require participation, by requiring reasonable accommodations for people with disabilities and prohibiting discrimination based on disability, they facilitate participation in society.[149]

Evaluating the status of individuals who are deaf and determining whether they receive adequate protection under existing disability laws involves issues of both law and sociology. Disability laws focus on the ability of individuals to function within society on a basis that is equal with people without disabilities.[150] Further, American disability law adopts the rights model so as to empower individuals with disabilities to assert the legislative rights granted to them.[151] Deaf Culture takes the approach that the Deaf are a separate subculture and a minority group. The implication of this approach is that Deaf Culture is a group that is protected not just by the ADA but also by civil rights legislation. The initial determination is whether Deaf Culture is really a culture. The secondary determination is whether it is possible or desirable to treat the Deaf as a minority.

Regardless of whether Deaf Culture is a subculture or minority, existing disability laws provide certain protections for persons with disabilities. It is appropriate to evaluate whether existing provisions of these laws achieve the goals of preventing discrimination against the deaf because of their condition and facilitating their ability to function on equal footing with persons without disabilities. If existing disability law is not adequate to achieve these goals, it is appropriate to determine what legislative provisions would be necessary to do so. Finally, as a policy matter it is appropriate to ask whether adopting special laws or treating Deaf Culture as a culture is a regressive step toward the discredited doctrine of separate but equal.

D. Determining Whether Deaf Culture is a Subculture May Be Sociologically Useful, But is Legally Irrelevant

Deaf Culture is often seen as a response to society's "rejection" of deaf individuals, which leads these deaf individuals to establish their own unique subculture.[152] The Deaf Community believes that they are entitled to legal and social recognition as a minority linguistic culture based on their use of ASL.[153] The Deaf view their minority group as disadvantaged only relative to the rest of hearing society due to the construction and structure of majority society around the needs and abilities of people who are able to hear.[154]

Critics have disputed this identification of the Deaf Community as a subculture. These critics view Deaf Culture as a lifestyle choice that is adopted by the Deaf.[155] Therefore, these critics do not view the Deaf as a separate ethnic, religious, or racial group.[156] Deafness affects members of all ethnic, religious, and racial groups. Further, if the deaf are a minority linguistic group, there is ample precedent for meeting their needs. Spanish-speakers also comprise a linguistic minority that has been accommodated in the United States. Many of the materials that are supplied by the federal and state governments are made available in Spanish and other languages as an alternative to English. The same accommodations are made available to the deaf through the availability of facilities such as teletype, relay, assistive devices, and ASL interpreters.

Determining whether Deaf Culture is a culture or subculture or minority group starts with determining exactly what comprises a culture or subculture. Culture is a concept which mixes both legal and sociological concepts and has many definitions.[157] The sociological concept of culture may be useful as a starting point for developing a legal definition of a culture or subculture since it provides a framework for applying the concepts of what a culture is to the facts that relate to a specific group, such as the deaf. However, based on cases such as *Cleburne*, although the concept of culture may have some relevance in criminal law, it seems to have little value in the field of disability rights law.[158]

While the deaf share tendencies toward certain behaviors, deafness does not occur based on any one characteristic.[159] Clearly, deaf persons must rely more heavily on visual input than hearing persons do. To the extent that they cannot receive auditory signals, they must compensate through the use of sight. ASL also can provide a common characteristic.[160] Putting aside the opposition of Deaf Culture to their use, the availability of cochlear implants permits many people who otherwise would remain deaf to gain some form of hearing. Deaf persons also tend to marry other deaf individuals more frequently than they marry hearing individuals.[161] The current estimate is that 90 percent of deaf people marry other deaf people.[162]

Deafness occurs throughout all nations and cultures and is found in all races and religions and among both men and women.[163] Ninety percent of deaf children are born to hearing parents and 90 percent of deaf parents have hearing children.[164] Many deaf persons suffer from other societally-imposed disabilities that can subject them to multiple discriminations. Like other members of the racial group to which they

belong, members of minority racial groups may suffer from both audism and racial discrimination.[165] An African-American woman who is deaf may suffer from three forms of discrimination: racism, sexism, and audism.

One author has commented on the similarities between the negative stereotypic terms that the Belgians used to describe the Africans that they colonized and the stereotypic terms used to describe the deaf when training teachers, doctors and social workers to work with the deaf.[166] But negative stereotypes and discrimination do not create a culture or a subculture. They may be evidence of a suspect classification upon which legal protections are based, but not evidence of a distinct culture or subculture.

Despite the similarities shared by the deaf and the differences among them, the key question is whether a group of people "manufacture" a subculture by their conduct. An individual cannot elect to become African-American, Hispanic, or Italian-American. An individual acquires this racial or cultural status by birth. While the deaf may be born deaf or become deaf, this should not be seen as creating a subculture. While a person cannot change races, a person can either embrace or reject their cultural heritage. In the same manner, people may be born into a religious group but either choose to remain in that faith or leave it of their own volition. And while it is possible to embrace a culture even if an individual is not born into it, doing so does not create a new ethnic identity.

E. Deaf Culture Attempts to Create a New Subculture.

While it may be a cultural movement, Deaf Culture should not be considered a culture or subculture.[167] Deaf Culture clearly is a minority group within American society. Its members express a sense of solidarity, at least within a range of general attitudes. Deaf Culture embraces ASL as a medium of communication and rejects "curing" deafness by means such as cochlear implants.[168] It is difficult to consider ASL as a separate language instead of a means of communication based on American-English. Nor have the deaf universally adopted ASL as a means of communications.[169] Unlike other cultural or racial groups, the members of the Deaf Community do not share "communal characteristics" like race, national origin, or other commonly recognized cultural characteristics.[170] The Deaf may be subject to multiple characteristics that may potentially lead to discrimination, such as race, gender, or other physical or mental disabilities. Any one of these traits may be a basis for discrimination, but not all of these traits are communal characteristics. Physical impairment is fundamentally different from race or gender. The only universal trait that the deaf share is their deafness. Except for this one common trait, the deaf represent a cross-section of society as a whole. Acknowledging Deaf Culture as a culture is, in essence, acknowledging that any group of like-minded people can create a subculture.

However, Deaf Culture may be a movement within a larger group that is gaining recognition – disability culture. Persons with disabilities have been subjected to discrimination and, in some cases, persecution for all of recorded history.[171] Disability culture is difficult to define precisely, but one commentator has noted that it is a group identity that is based on a common history of oppression and common toughness that allows for the formation of cultural artifacts such as art, music, and literature which allow individuals with disabilities to express their life experiences.[172] This approach is sociological. Disability culture can also be viewed as a psychological phenomenon, because it is a psychological response by a minority population to the majority's treatment of that minority group manifestred in attitudes and responses.[173]

Classifying Deaf Culture or even disability culture as a subculture or culture is sociologically and psychologically relevant, but not necessary to assure that the deaf are afforded the protection of disability laws. The deaf fall within the definition of disability in the ADA. An individual has a disability when he or she have "a physical . . .impairment that substantially limits one or more major life activities . . . ."[174] Paradoxically, Deaf Culture rejects the notion that the Deaf have a disability because of their deafness, while they also want protection of disability laws so they have both protection from discrimination and accommodations for their condition.[175] Despite this logical inconsistency, Deaf Culture does have a legal basis for this position. The ADA definition of disability does not require that an individual acknowledges his or her disability. The ADA definition of disability includes individuals who are "regarded as having such impairment [that substantially limits one or more major life activities]."[176] Under the ADA definition of disability, the test is a dual-pronged one. An individual can have an objectively observed physical or mental condition that interferes with major life activities, or he or she can be perceived by others as having an impairment.[177] Deaf Culture does not argue that the non-deaf world does not perceive the Deaf as having a disability. Members contend that the Deaf do not perceive themselves as having a disability.

The other possible field in which the treatment of Deaf Culture as a culture or subculture may have relevance

Classifying Deaf Culture or even disability culture as a subculture or culture is sociologically and psychologically relevant, but not necessary to assure that the deaf are afforded the protection of disability laws.

is in international human rights law. If Deaf Culture could convince the international community that the use of devices such as cochlear implants and mainstreaming children into schools with hearing children amounts to eugenics, then they could make the argument that Deaf Culture is in danger of being eliminated and is being subjected to the same treatment as other repressed minorities.[178] This argument overlooks the fact that in most other situations, the repressed minority is distinguished by factors such as race, ethnicity, or religion.

Further, the United States historically has not ratified international human rights treaties.[179] Notably, the United States has announced that it will not adopt the pending U.N. Convention on the Rights of Persons with Disabilities.[180] This Convention would be most relevant to the rights of individuals with disabilities. However, given the U.S. position that it will not join in such international agreements, should Deaf Culture succeed in convincing even part of the international community of its position, international comment alone will not likely change to position of the U.S. Government.

Based on the current state of disability laws in the United States and the U.S. position on international human rights law, the concept of Deaf Culture is a legal irrelevance. Based on the Supreme Court's ruling in *Cleburne*, Deaf Culture will likely not receive special protection under civil rights law or an equal protection argument.[181] While the concept of Deaf Culture may have sociological relevance, it does not provide the basis for expanding the rights or protections of the deaf. Further, the position of the Deaf that they are different and not living with a disability, and the drive of some in the Deaf Culture for resegregation, does little to advance their political goals.

F. Additional Laws Applying to the Deaf Community are Not Necessary

Existing disability rights laws are not perfect, nor are they universally applicable. The ADA requires that public accommodations include reasonable accommodations for individuals with disabilities.[182] However, every location and facility is not a place of public accommodation, nor can all accommodations be considered reasonable.[183] Economics enters into the analysis of what is a reasonable accommodation.[184] Determining reasonable accommodation involves a complex analysis of the cost of modifications or an analysis of the financial ability of a small employer to provide such facilities. Nor does the ADA require that employers hire individuals with disabilities for jobs for which they are not qualified.[185]

There also may be a range of technological solutions to afford reasonable accommodation that are viable but which may be more or less attractive to owners and individuals with disabilities. For example, to permit deaf individuals to understand the audio portion of motion pictures, it is possible either to use open captioning (i.e. subtitles) or a rear-window captioning system.[186] However, some hearing moviegoers object to open captioning because they find it intrusive.

These sorts of issues illustrate that laws such as the ADA are imperfect. Accommodating persons with disabilities, including individuals who are deaf, involves compromises that respect the rights of individuals without disabilities, commercial and social interests, and individuals with disabilities. Also, individuals with disabilities, including the deaf, are not monolithic. They have individual needs and varying situations. The rights of the majority must also be considered when considering the rights of individuals with disabilities.

Despite the imperfections in laws such as the ADA, it is not advisable to adopt disability laws targeting people with specific disabilities unless there is a compelling reason to do so. Targeted disability laws create several risks. First, they will create even more regulations, litigation, and conflicting requirements than generic disability laws such as the ADA. Lawmakers must consider the interests of employers and owners along with the interests of people with disabilities. Multiple sets of requirements impose additional burdens on employers and owners. Second, singling out people with a specific disability creates the possibility that one group of people with disabilities will be pitted against another. Creating separate classes can only weaken the chances of unified action to further the rights of persons with disabilities. Advocates for the deaf were early supporters of the ADA and played a major role in obtaining its passage.[187]

In contrast, it is equally dangerous to adopt legislation that would codify the positions taken by Deaf Culture. The Deaf Community is a subgroup among the deaf and does not represent the positions of all deaf persons.[188] Adopting legislation that satisfies the desires of the Deaf Community would both undo federal disability law and create further fragmentation of the deaf. Requiring or encouraging separate deaf-only education and mandating use of ASL would go against the goals of the IDEA, which is intended to permit students with disabilities to participate in regular educational settings to the extent that they can benefit from being mainstreamed, even when this requires extra accommodations and cost. Giving representatives of Deaf Culture a role in the medical treatment and development of IEPs of deaf children other than their own would run against the existing general rights of parents to determine the health care and education of their children.

III. Conclusion

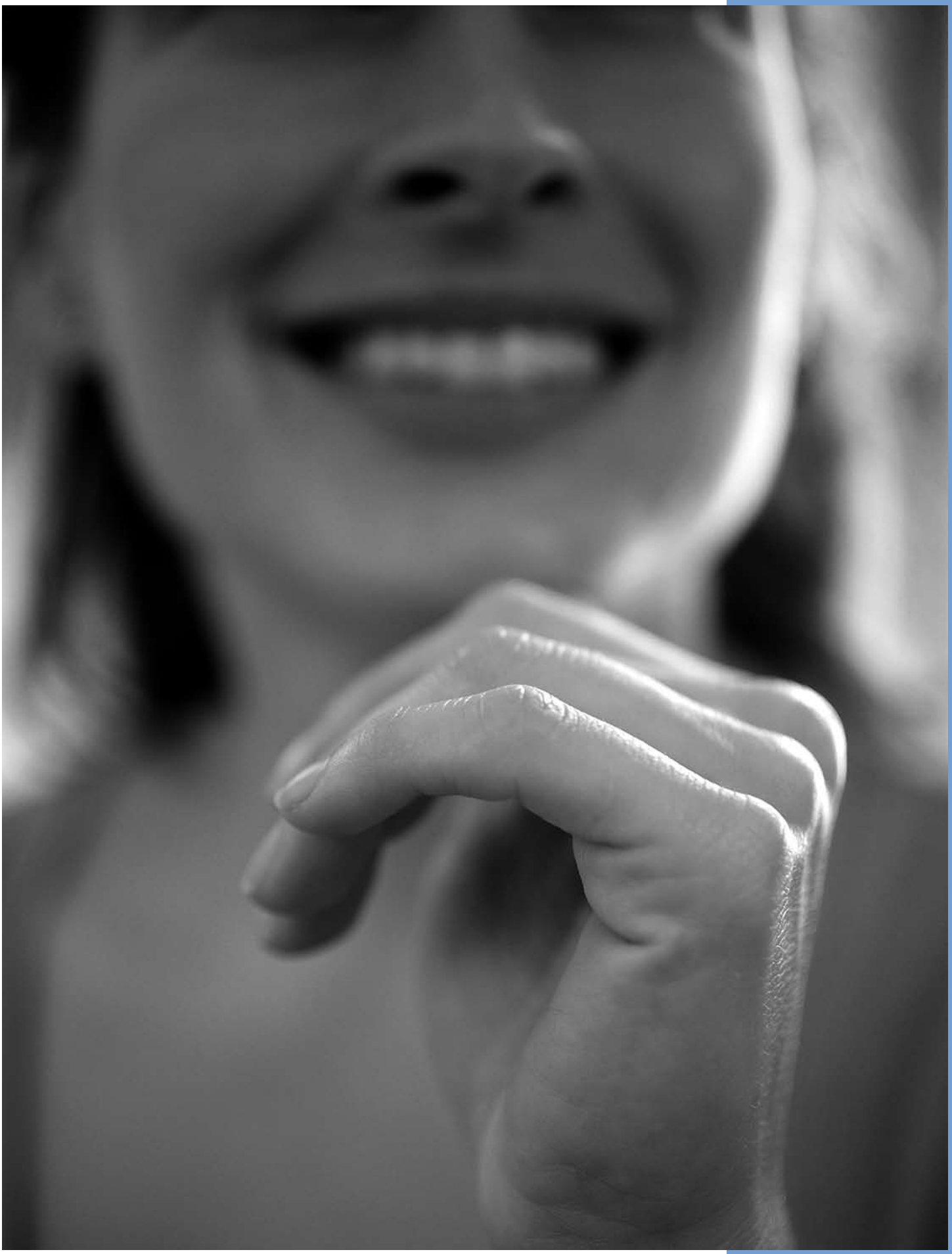
Whether deaf individuals consider themselves to be living with a disability or merely view themselves as being "different," as Deaf Culture advocates, these individuals still fit within the definition of having a disability under existing disability rights laws such as the Rehabilitation Act, the ADA, and the IDEA. Thus, they are entitled to the protections and benefits of these laws, if only because they are regarded by others as having a disability. While the question of whether Deaf Culture is a linguistic minority or a subculture raises debatable sociological issues, the answer to this question does not create any unique rights for the Deaf Community that set it apart from other individuals with disabilities. Based on present law, it is not advisable to adopt additional legislation granting different treatment or special rights to individuals who are deaf in addition to the rights and accommodations the law gives to all other people with disabilities.

1 U.S. Equal Employment Opportunity Comm'n., *Questions and Answers about Deafness and Hearing Impairments in the Workplace and the Americans with Disabilities Act*, http://www.eeoc.gov/facts/deafness.html (last visited March 26, 2007).
2 Bonnie P. Tucker, *The Americans with Disabilities Act: Social Contract or Special Privilege?: The ADA and Deaf Culture: Contrasting Precepts, Conflicting Results*, 549 Annals Am. Acad. Pol. & Soc. Sci. 24, 25 (1997) [hereinafter Tucker, *Social*]; *see also* Shelly Lane, *Deafness Shouldn't be Called Handicap*, Dallas Morning News, Mar. 5, 1995, at 6J (reporting that many deaf people say "'handicapped' doesn't apply to their cultural group").
3 *See* Tucker, *Social*, *supra* note 2, at 25.
4 *See infra* notes 174 -177 and accompanying text (discussing the definition of "disability," particularly in the Americans with Disabilities Act of 1990); *cf.* Mary Ellen Maatman, *Listening to Deaf Culture: A Reconceptualization of Difference Analysis under Title VII*, 13 Hofstra Lab. L.J. 269, 271 (commenting that "courts' norm-centered perspective prompt them to regard differences as unreasonable privilege-seeking").
5 *See* Tucker, *Social*, *supra* note 2, at 25 ("People with disabilities confronted virtually insurmountable discrimination . . . preclud[ing] their full participation in mainstream society").
6 The Americans with Disabilities Act, 42 U.S.C. §§ 12101-12213 (2000).
7 42 U.S.C. § 12102(2) (2000).
8 *See generally* Nat'l Ass'n of the Deaf, *Info & FAQs: What is Wrong with the Use of these Terms: "Deaf-mute", "Deaf and dumb", or "Hearing-impaired"?*, *available at* http://www.nad.org/site/pp.asp?c=foINKQMBF&b=103786 (last visited March 26, 2007) (explaining that many deaf people object to the term "hearing impaired" as they feel that it has a negative connotation, rather preferring to be called "deaf" or "hard of hearing").
9 *See* Edward Dolnick, *Deafness as Culture*, The Atlantic, Sept. 1993, at 37 (describing the difficulties deaf children have when learning to speak because they are unable to hear and mimic sounds).
10 *See* Tucker, *Social*, *supra* note 2, at 26 (explaining also that emergency broadcast warnings and televisions are other technologies unintentionally inaccessible to the deaf).
11 *See* EEOC Regulations to Implement the Equal Employment Provisions of the Americans with Disabilities Act, 29 C.F.R. § 1630.2(i) (defining major life activities, which must be limited to qualify as a disability, including "functions such as . . . *hearing*"). (emphasis added)
12 *See* Barbara J. McKee, *Disability Culture Timeline*, http://www.chairgrrl.com/Disability/Timeline/index.htm, *available at* (last visited May 8, 2007); *see also* Carol Padden & Tom Humphries, Inside Deaf Culture, 18 (Harvard University Press) (2005) (explaining how the increase in urbanization and socio-economic problems in the late 1800's led to the separation and institutionalization of citizens whom were deaf, blind, criminal, sick, or insane under the guise of "rehabilitation and education").
13 *See* Nat'l Council on Disability, A White Paper: Understanding the Role of an International Convention on the Human Rights of People with Disabilities 6 (June 12, 2002) [hereinafter NCD White Paper]; *see also* Aaron A. Dhir, *Human Rights Treaty Drafting through the Lens of Mental Disability: The Proposed International Convention on Protection and Promotion of the Rights and Dignity of Persons with Disabilities*, 41 Stan. J. Int'l L. 181, 191-92 (2005) (explaining that the medical model holds that individuals with disabilities show a deviation from the norm, making them appropriate subjects for medical intervention and cure).
14 Dhir, *supra* note 13, at 191.
15 *Id.* at 191-192; Gerard Quinn & Theresia Degener, *Human Rights and Disability: The Current Use and Future Potential of United Nations Human Rights Instruments in the Context of Disability* at 14, U.N. Doc. HR/PUB/02/1, U.N. Sales No. 02.XIV.6 (U.N. Off. High Comm'r of Hum. Rts.) (2002); Martha Minow, Making All the Difference: Inclusion, Exclusion, and American Law, 107 (Cornell University Press) (1990) (discussing what Minow terms the 'Rights Analysis Approach').
16 Quinn & Degener, *supra* note 15, at 27-28; *see also* NCD White Paper, *supra* note 13, at 28 (stating that, under this model, disability is a "social construction according to which *society, not* the person with a disability, requires adaptation.") (emphasis in original).
17 Quinn & Degener, *supra* note 15, at 27-28.
18 *Id.*
19 *Id.*
20 *See* Dhir, *supra* note 13, at 191-92 (explaining that under the medical model, individuals with disabilities deviate from normal and are appropriate subjects for cure).
21 *See* Sally Chaffin, *Challenging the United States Position on a United Nations Convention on Disability*, 15 Temp. Pol. & Civ. Rts. L. Rev. 121, 141 (2005) (remarking that the ADA is often viewed as "the most comprehensive civil rights law for people with disabilities that has ever been enacted by the United States [and] among the most protective in the world," and often serves as a model for legislation in other countries because of concepts such as "reasonable accommodation").
22 *Id.*
23 *See* 42 U.S.C. § 12102(2) (2000) (recalling that the ADA requires that in order for an individual to be eligible for assistance, or the difference or impairment must "substantially limit" the individual in at least one major life activity, which requires a comparison with other citizens considered to function "normally").
24 *See* Arlene S. Kanter, *The Globalization of Disability Rights Law*, 30 Syracuse J. Int'l L. & Com. 241, 249 (2003) (describing the history of national anti-discrimination laws focused on people with disabilities and identifying the United States as among the first countries to adopt such laws).
25 *See generally* 42 U.S.C. § 12101(b) (describing the purpose of the ADA as "to provide a clear and comprehensive national mandate for elimination of discrimination against individuals with disabilities.").
26 *See* U.S. Dep't of Just., A Guide to Disability Rights Laws (2005), *available at* http://www.usdoj.gov/crt/ada/cguide.pdf (listing and generally describing existing federal laws dealing with the rights of persons with disabilities) [hereinafter DOJ, Guide to Disability Rights Law].
27 Air Carrier Access Act of 1986, 49 U.S.C. § 41705 (2000).
28 National Voter Registration Act of 1993, 42 U.S.C. §§ 1973(gg) (2000).
29 29 U.S.C. §§ 791-794 (2000).
30 *See* 29 U.S.C. § 701(b) (stating the purpose of the Rehabilitation Act as "to empower individuals with disabilities to maximize employment, economic self-sufficiency, independence, and inclusion and integration into society.").
31 29 U.S.C. § 794(a) (2000).
32 29 U.S.C. § 794(a) ("No otherwise qualified individual with a disability in the United States . . . shall, solely by reason of her or his disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service.").
33 29 U.S.C. § 793 (2000).
34 42 U.S.C. § 12102(2) (2000); *see also* 29 C.F.R. § 1614.203 (2001).
35 *See* Bonnie P. Tucker, *The ADA's Revolving Door: Inherent Flaws in the Civil Rights Paradigm*, 62 Ohio St. L.J. 335, 341 (2001) [hereinafter Tucker, *The ADA*].
36 Center for Psychiatric Rehabilitation, Boston University, Reasonable Accommodations: The Rehabilitation Act of 1973 (1997), http://www.bu.edu/cpr/reasaccom/whatlaws-rehaba.html (last visited Mar. 26, 2007).

37 *See* Tucker, *Social*, *supra* note 2, at 25 (noting that a majority of employers and others were not covered by the Rehabilitation Act).
38 *Id.*
39 *Id.*
40 Tucker, *The ADA*, *supra* note 35, at 341.
41 *See* Southeastern Cmty. Coll. v. Davis, 442 U.S. 397 (1979) (rejecting the claim of discrimination under Section 504 made by a hearing impaired woman who was denied admission to nursing education where accommodations would not be effective and her disability might prevent her from effectively performing nursing duties).
42 *See* School Bd. of Nassau County v. Arline, 480 U.S. 273 (1987) (denying a claim under Section 504 by a teacher who had repeated relapses of tuberculosis because of the potential danger to students).
43 Lennard J. Davis, *Crips Strike Back: The Rise of Disability Studies,* 11 Am. Liter. Hist. 500, 507 (1999), *available at* http://alh.oxfordjournals.org/cgi/reprint/11/3/500.pdf.
44 Nat'l Council on Disability, Equality of Opportunity: The Making of the Americans with Disabilities Act xvii (1997), http://www.ncd.gov/newsroom/publications/1997/pdf/equality.pdf [hereinafter NCD, Equality of Opportunity].
45 *See* Tucker, *Social*, *supra* note 2, at 25-26 (describing steps leading to the proposal and the passage of the ADA).
46 *See* Tucker, *The ADA*, *supra* note 35, at 340.
47 *See, e.g.*, 42 U.S.C. §§ 12111(2), (5) (2000) (prohibiting employment discrimination by an employer with more than 15 full time employees, an employment agency, a labor organization, or a joint labor-management committee, and subjecting them to very narrow exceptions).
48 *See* 42 U.S.C. §12182 (2000) (forbidding discrimination against people with disabilities from benefiting through goods, services, facilities, privileges, advantages or accommodations, and requiring modification of policies, practices and procedures, removing barriers, and providing auxiliary aids and services).
49 42 U.S.C. § 12111 (2000). *But see* 42 U.S.C. §12209 (2000) (showing that although Congress chose to apply the ADA to "instrumentalities of Congress", *i.e.*, the General Accounting Office, the Government Printing Office, and the Library of Congress, it did not choose to apply the ADA to itself).
50 42 U.S.C. §§ 12131 (2000).
51 Cornell Law School, Legal Information Institute, *Disability Law -- Wex*, http://www.law.cornell.edu/wex/index.php/Disability_law (last visited March 26, 2006).
52 42 U.S.C. § 12181 (2000).
53 42 U.S.C. § 2000d (2000).
54 Tucker, *The ADA, supra* note 35, at 342.
55 *See* 42 U.S.C., *supra* note 34 and accompanying text.
56 29 U.S.C. § 794 (2000).
57 *See* Bragdon v. Abbott, 524 U.S. 624, 631 (1998).
58 42 U.S.C. § 12208 (2000).
59 42 U.S.C. § 12210 (2000).
60 42 U.S.C. § 12211 (2000).
61 *See* 42 U.S.C. §12206 (2000) (naming specifically the Attorney General, the Equal Employment Opportunity Commission, the Secretary of Transportation, the Architectural and Transportation Barriers Compliance Board, and the Federal Communications Commission to develop a plan to assist with understanding the responsibility of entities and agencies covered by the Act).
62 *see* 42 U.S.C. § 12203 (2000) ("No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this Act or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this Act").
63 42 U.S.C. § 12188(a)(1) (2000).
64 *See* 42 U.S.C. §§ 12183(a), 12188(a) (granting individuals a right to injunctive relief in certain cases where new facilities or renovations of existing facilities will discriminate against people with disabilities).
65 20 U.S.C. § 1400.
66 *See id.* (stating that this may include supplying necessary learning aids, testing modifications, and other educational accommodations).
67 *See* Reevaluation Regulations for IDEA, 34 C.F.R. 300.536 (2004) (mandating that each child will be re-evaluated at least once every three years).
68 DOJ, Guide to Disability Rights Law, *supra* note 26, at 15.
69 *See* Nat'l Council on Disability, Individuals with Disabilities Education Act Burden of Proof: On Parents or Schools? Position Statement 1 (Aug. 9, 2005), http://www.ncd.gov/newsroom/publications/2005/pdf/burdenofproof.pdf.
70 DOJ, Guide to Disability Rights Law, *supra* note 26, at 15.
71 *Id.*
72 Tucker, *Social*, *supra* note 2, at 33; Padden & Humphries, *supra* note 12, at 12 (citing that in 2002 only 27 percent of deaf children were enrolled in special schools centers).
73 20 U.S.C. § 1401(a)(9) (2000) (defining a FAPE as the "special education and related services that (A) have been provided at public expense, under public supervision and direction, and without charge; (B) meet the standards of the State educational agency; (C) include an appropriate preschool, elementary, or secondary school education in the State involved; and (D) are provided in conformity with the individualized education program.").
74 *See* Board of Education v. Rowley, 458 U.S. 176, 209-10 (1982) (holding that the Education of the Handicapped Act did not require states to maximize the potential of each child proportionate to the opportunity provided children without disabilities and that, insofar as a school was required to provide a FAPE, the school would provide personalized instruction with sufficient support services to allow the child to receive some educational benefit).
75 *See supra* notes 61-68 and accompanying text.
76 Dolnick, *supra* note 9 (quoting Henry Kisor).
77 *See id.*
78 *Id.*; Bonnie P. Tucker, *Deafness – Disability or Subculture: The Emerging Conflict*, 3 Cornell J.L. & Pub. Pol'y. 265, 270 (1993-1994) [hereinafter Tucker, *Deafness*].
79 Tucker, *Deafness*, *supra* note 78, at 270-74.
80 *Id.*
81 I. King Jordan. *Deaf Culture and Gallaudet*, Wash. Post, Jan. 22, 2007, at A19.
82 *Id.*
83 Susan Kinzie, Nelson Hernandez & David A. Fahrenthold, *Gallaudet Board Ousts Fernandes; As Protesters Cheer, Trustees Say Law-Breakers 'Will Be Held Accountable'*, Wash. Post, Oct. 30, 2006 at A01.
84 *Susan Kinzie & Michael E. Ruane, Gallaudet's Next President Won't Bow Out,* Wash. Post, May 5, 2006, at A01.
85 Maya Sabatello, *International Law Weekend: Panel Presentation – Disability, Cultural Minorities, and International Law: Reconsidering the Case of the Deaf Community*, 26 Whittier L. Rev. 1025, 1027 (2005).
86 *See* Dolnick, *supra* note 9 (describing how the Deaf now proclaim themselves as a subculture).
87 Sabatello, *supra* note 85, at 1028.
88 *See* Dolnick, *supra* note 9, at 43 (describing how the Deaf Culture views treatments for deafness, such as cochlear implants, as child abuse or even genocide); Tucker, *Deafness*, *supra* note 78, at 271 (quoting Roz Rosen: "Since '[h]earing is not a life or death matter . . . [it is] consequently not worth the medical, moral and ethical risk of altering a child.'").
89 Sabatello, *supra* note 85, at 1028-29 ("Members of the Deaf community rebuff technological advances such as hearing aids as medical attempts to 'cure' deafness").
90 *See* Tucker, *Deafness*, *supra* note 78, at 271 (indicating that supporters of Deaf Culture are proud of being deaf and claiming it is their own cultural right that should "be cherished rather than fixed and erased"); Sabatello, *supra* note 85, at 1028 ("'Deafness' is . . . a quality to cherish").
91 *Id.*
92 *See supra* notes 88-90.
93 *See* Jane K. Fernandes, Editorial, *Many Ways of Being Deaf*, Wash. Post, October 14, 2006, at A21 (discussing diversity among the Deaf Community and discrimination against the Deaf).
94 *See* Dolnick, *supra* note 9, at 39 (reporting that the Deaf view deafness as similar to ethnicity and distinguishing deafness from other disabilities such as blindness).
95 *Id.*
96 *See* Shelley Lane, *supra* note 2.
97 Dolnick, *supra* note 9, at 39.
98 Dolnick, *supra* note 9, at 37; Padden & Humphries, *supra* note 12, at 2-4.

99 *See* Monica Davey, *As Town for Deaf Takes Shape, Debate on Isolation Re-emerges*, N.Y. Times, March 21, 2005, at A1, *available at* http://www.nytimes.com/2005/03/21/national/21deaf.html (last visited May 7, 2007) (describing the plan for a town for sign language users in South Dakota that would welcome anyone who has "a commitment to live in a visually centered environment that supports manual as opposed to spoken language" often including the hearing relatives of deaf individuals).
100 Tucker, *Social*, *supra* note 2, at 31.
101 Davey, *supra* note 99.
102 *Id.*
103 U.S. Food and Drug Admin., Ctr. for Devices and Radiological Health, *Cochlear Implants – What is a Cochlear Implant?*, (Oct. 26, 2004) http://www.fda.gov/cdrh/cochlear/WhatAre.html.
104 Tucker, *Social*, *supra* note 2, at 33 (quoting Dolnick, *supra* note 9, at 43).
105 Tucker, *Deafness*, *supra* note 78, at 270-71 ("Supporters of this view do not *want* researchers to find a cure for deafness.") (emphasis in original).
106 *Id.*; Dolnick, *supra* note 9.
107 Dolnick, *supra* note 9, at 37-38 (comparing "Deafness" to ethnicities such as Haitian, Hispanic and Italian-Americans).
108 *See* Nat'l Inst. of Health, Nat'l Inst. on Deafness and Other Communication Disorders, *Statistics about Hearing Disorders, Ear Infections, and Deafness, available at* http://www.nidcd.nih.gov/health/statistics/hearing.asp#1 (last visited May 7, 2007) (reporting that in the United States, 9 out of every 10 children who are born deaf are born to hearing parents)[hereinafter NIDCD].
109 28 C.F.R. § 36.104 (1991) (defining "major life activities" under the *Disability* definition part (iv)(2)).
110 28 C.F.R. § 36.104 (1991) (defining "physical or mental impairment" under the *Disability* definition part (iii)).
111 *See* Sutton v. United Air Lines, Inc., 527 U.S. 471, 482 (1999) (dismissing a claim of hiring discrimination based on the determination that whether an individual has a disability that substantially limits a major life activity must take into account measures that the individual is taking to alleviate the impairment).
112 *See* Tucker, *Deafness*, *supra* note 78, at 271 ("[T]he the Deaf community, however, are among the strongest advocates for laws and special programs to protect and assist people with hearing impairments.").
113 Padden & Humphries, *supra* note 12, at 174-76 (discussing the eugenics movement, specifically in relation to movements to prevent procreation among deaf individuals).
114 Mairian Corker, Deaf and Disabled or Deafness Disabled? Towards a Human Rights Perspective 31 (1998).
115 *Id.*
116 *See* Dolnick, *supra* note 9 (describing the differences between simulating deafness and blindness); Lane, *supra* note 2; *see also supra* notes 94-97 and accompanying text (describing the Deaf community's effort to distinguish themselves from other disabilities such as blindness).
117 *See* Corker, *supra* note 114, at 31 (embracing the notion of minority group status, based on the strong believing in segregated education, the right to coexist as a separate subculture of society, and seeking liberation by creating alternative communities).
118 *Id.*
119 *See* Sabatello, *supra* note 85, at 1035-38 (comparing how both the Deaf Community and linguistic minorities experience "distinctive 'shared history, culture, and tradition'"); see Dolnick, *supra* note 9, at 37-38.
120 473 U.S. 432 (1985).
121 *Id*. at 440-42.
122 *See id*. at 442-43 (declaring that individuals with disabilities was a group too undefined and amorphous to allow intermediate or heightened scrutiny).
123 *Id.* at 448 (holding that the record failed to provide any evidence that the home for individuals with intellectual impairments posed a special threat to the City of Cleburne's legitimate interest, and therefore the ordinance involved was invalid).
124 *Id.* at 440 ("When social or economic legislation is at issue, the Equal Protection Clause allows the States wide latitude.").
125 *Id*. at 440-41.
126 *Id*. at 442.
127 *Id.*
128 *See generally* H.R. 6258, 109th Cong. (2006) (responding to *Cleburne*, Rep. James Sensenbrenner introduced H.R. 6258, The Americans with Disabilities Restoration Act, in the 109th Congress in 2006. The Act was intended to "restore the intent of the Americans with Disabilities Act of 1990 to more fully remove the barriers that confront disabled Americans." However, while the Bill was referred to four committees and two of their subcommittees, it went no further.).
129 *See* Sarah S. Geer, *When "Equal" Means "Unequal" – And Other Legal Conundrums for the Deaf Community*, in Sociolinguistics in Deaf Communities, 114-18 (Ceil Lucas ed., Gallaudet University Press) (2003) (discussing application of equal protection and suspect classifications to the deaf).
130 *See* Dolnick, *supra* note 9 (communicating that 90 percent of deaf children are born to parents who can hear and vice versa; Dolnick goes on to point out the similarity between deaf and homosexual children and their hearing or heterosexual parents by not sharing their cultural identity and instead acquiring cultural identity from peers). *Compare* Harlan Lane, The Mask of Benevolence: Disabling the Deaf Community, 21 (Vintage Books 1993) (1992) (noting that it is impossible for a child, homosexual, or heterosexual to procreate without the egg of a female and the sperm of a male (in other words, a heterosexual couple) and that the grouping of the deaf and homosexual communities is voluntary and the segregation or inability to participate with society is involuntary) *with* Tucker, *Social*, *supra* note 2, at 33 (explaining that, unlike the homosexual community, in many instances such as in education, the Deaf desire a segregated existence from mainstream society).
131 *See* Lane, *supra* note 130, at 21.
132 *See* Romer v. Evans, 517 U.S. 620, 631 (1996) (applying rational basis scrutiny to a State Amendment repealing all protections for homosexuals and finding it not rationally related to a legitimate government interest).
133 *See* Robert P. O'Quinn, The Americans with Disabilities Act: Time for Amendments, Cato Policy Analysis No. 158 (Cato Inst.) (Aug. 9, 1991), *available at* http://www.cato.org/pubs/pas/pa-158.html (explaining that the U.S. Senate amended Section 511 of the ADA to specifically exclude not only homosexuals, but also bisexuality, transvestites, transsexuals, pedophiles, individuals with gender identity disorders that are not the result of physical impairments, other sexual behavior disorders, compulsive gambling, kleptomaniacs, pyromaniacs, and disorders resulting from the current illegal use of drugs, in 1989).
134 Murphy v. United Parcel Serv., 527 U.S. 516 (1999) ("To be regarded as substantially limited in the major

life activity of working, one must be regarded as precluded from more than a particular job. The inability to perform a single, particular job does not constitute a substantial limitation in the major life activity of working one must be regarded as precluded from more than a particular job."); 29 C.F.R. § 1630(j)(3)(i).
135 29 C.F.R. § 1630(l)(2).
136 *See supra* notes 65-75 and accompanying text.
137 *See generally* Sacramento City Unified Sch. Dist. v. Rachel H., 14 F.3d 1398 (9th Cir. 1994) (illustrating how the conflicting goals of Deaf Culture and disability laws can create complex legal tests, such as the Ninth Circuit's four-factor test that requires balancing (i) the educational benefits of mainstreaming, (ii) the non-educational benefits of mainstreaming, (iii) the effect of the disabled child on the other children and the teacher in the class in which the child with a disability is placed, and (iv) the costs of mainstreaming.)
138 *See* Lane, *supra* note 130, at 237-238.
139 *See* Sabatello, *supra* note 85, at 1029 (explaining the Deaf Communities demand for an active role in the education of deaf children); *see also id.* at 1026 (explaining that the Deaf Communities point to the likelihood of hearing parents choosing an oral education and cochlear implants for pre-lingual deaf children and claim that these decisions impact the numbers of individuals associating with Deaf Culture and rather encourage deaf children to assimilate into the mainstream hearing culture).
140 *See NPR Talk of the Nation: As Deaf Culture Changes, So Do the Questions* (NPR radio broadcast Oct. 12, 2006) (transcript *available at* http://www.npr.org/templates/story/story.php?storyId=6189253) (describing need for schools like Gallaudet College as a place of deaf culture and the need to get to "folks younger").
141 Lane, *supra* note 130, at 20.
142 Tucker, *Social*, *supra* note 2, at 31 (advocating removal of deaf babies from their homes in order to immerse or raise these children in Deaf Culture and Communities).
143 *See id.* at 33-34 (giving facts about the costs of educating deaf children in segregated schools and regular classrooms).
144 Therese Caraparo, *Remembering the "Individuals" of the Individuals with Disabilities Education Act*, 6 N.Y.U. J. Legis. & Pub. Pol'y. 467, 494-95 (2003).
145 *See* Sabatello, *supra* note 85, at 1025-26.
146 Marjorie L. Baldwin, *The Americans with Disabilities Act: Social Contract or Special Privilege? Can the ADA Achieve Its Employment Goals?*, 549 Annals Am. Acad. Pol. & Soc. Sci. 37, 40 (1997).
147 Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (codified as amended in scattered sections of 42 U.S.C.).
148 Baldwin, *supra* note 146, at 40.
149 *Id.*
150 Quinn & Degener, *supra* note 15, at 27-28.
151 *See* Arlene S. Kanter, *The Globalization of Disability Rights Law*, 30 Syracuse J. Int'l L. & Com. 241, 249 (2003).
152 Carol J. Gill, *A Psychological View of Disability Culture*, Disability Stud. Q. (Fall 1995), *available at* http://www.independentliving.org/docs3/gill1995.html (last visited May 8, 2007).
153 Sabetello, *supra* note 85, at 1028
154 *See* Tucker, *Deafness*, *supra* note 78, at 270-71; Anna-Miria Muhlke, *The Right to Language and Linguistic Development: Deafness from a Human Rights Perspective*, 40 Va. J. Int'l L. 705, 722-23 (2000).
155 Sabetello, *supra* note 85, at 1039-40.
156 *See* Tucker, *Deafness*, *supra* note 78, at 273 ("deaf people do not comprise a cultural race in the same manner as Native Americans, Blacks, Haitians, or Hispanics . . . these cultural races . . . do not lack one of five critical sense necessary to function in society"); *see also* Muhlke, *supra* note 154, at 738 (detailing how it is difficult to include the deaf into the definition of an ethnic minority which usually not only share biological and genetic features but also residence in a certain area, name, origin, use of a minority language, and cultural custom).
157 *See* Kenneth B. Nunn, Foreword, *New Explorations in Culture and Crime: Definitions, Theory, Method*, 17 U. Fla. J.L. & Pub. Pol'y. vii, viii-ix (2006) ("Culture can be defined as the structure of social organization found in a distant society or unfamiliar ethnic group . . . [or it] can also be defined as familiarity with a system of social etiquette. Culture may mean the state of artistic production in a given place or time . . . According to Stuart Hall, one of cultural studies' leading figures, culture is 'the production and exchange of meanings . . . between members of a society or group.' Likewise, Naomi Mezey defines culture as 'any set of shared signifying practices-practices by which meaning is produced, performed, contested, or transformed.'").
158 *Id.* at vii-ix
159 *Documentary: Through Deaf Eyes* (PBS television broadcast Mar. 26, 2007) http://www.pbs.org/weta/throughdeafeyes/about/transcript.pdf [hereinafter *Through Deaf Eyes*].
160 *See* Dolnick, *supra* note 9, at 40 (estimating that 500,000 people use ASL).
161 *See* Lane, *supra* note 130, at 16-17 (noting that ASL is the common language among members of the Deaf Community and that it plays a significant role in passing Deaf Culture between generations).
162 *See id.* at 17; Dolnick, *supra* note 9.
163 *Through Deaf Eyes*, *supra* note 159.
164 *See* NIDCD, *supra* note 108.
165 Fernandes, *supra* note 93.
166 Lane, *supra* note 130, at 34-36.
167 Dolnick, *supra* note 9.
168 *Id*.
169 *Id.* (estimating that approximately 500,000 people use ASL, and groups of deaf individuals have different forms of sign language in different countries, such as French Sign Language and Canadian Sign Language).
170 Sabatello, *supra* note 85, at 1038.
171 McKee, *supra* note 12.
172 Steven E. Brown, Editorial, *What is Disability Culture,* Disability Culture – Indep. Living Inst. Newsl. 2001-12, *available at* http://www.independentliving.org/newletter/12-01.html (last visited May 8, 2007).
173 Gill, *supra* note 152.
174 42 U.S.C § 12102(2)(A) (2002).
175 Tucker, *Deafness*, *supra* note 78, at 270-72.
176 42 U.S.C § 12102(2)(C) (2002).
177 *Id.*
178 Tucker, *Social*, *supra* note 2, at 25.
179 *See* Chaffin, *supra* note 21, at 130 (noting that the United States has ratified only three of twenty-six international human rights treaties).
180 *See* Chaffin, *supra* note 21, at 121 (reporting a 2003 comment by Ralph Boyd, former U.S. Assistant Attorney General for Civil Rights to the Ad Hoc Committee drafting the U.N. Convention, that the United States would not join in the convention). *See generally* The Secretary-General, *Final Report of the Ad Hoc Committee on a Comprehensive and Integral International Convention on the Protection and Promotion of the Rights and Dignity of Persons with Disabilities*, U.N. Doc. A/61/611 (Dec. 6, 2006) [hereinafter Convention] (adopted by U.N. General Assembly Dec. 1, 2006, opening for signing by member nation states March 30, 2007).
181 *See supra* notes 119-126 and accompanying text.
182 42 U.S.C. § 12182 (2000).
183 *See* 42 U.S.C. §§ 12111(9)-(10) (2000) (defining reasonable accommodation and undue hardship).
184 *See* 42 U.S.C. § 12111(10) (2000) (defining undue hardship).
185 *See* 42 U.S.C. § 12112(a) (2000) (prohibiting discrimination in employment against *qualified* individuals with disabilities).
186 *See* MoPix Motion Picture Access, *Frequently Asked Questions*, http://ncam.wgbh.org/mopix/faq.html (last visited May 3, 2007).
187 *See* Tucker, *Social*, *supra* note 2, at 25; *see also* Tucker, *Deafness*, *supra* note 78, at 271.
188 *See* Dolnick, *supra* note 76 and accompanying text (describing the deaf as "Balkanized").



Mandating Health: Comparing Different State Approaches to the Distribution of the HPV Vaccine

*Jessica Kennington**

> States face the decision of whether to mandate a vaccine for a sexually transmitted infection or not to require citizens to receive a vaccine that prevents cancer.

I. Introduction

The American Cancer Society estimates that in 2008, over 11,000 women will develop cervical cancer and roughly 4,000 will die from the disease.[1] About 70 percent of cervical cancer cases result from human papilloma virus (HPV) types 16 and 18.[2] In 2006, the Food and Drug Administration (FDA) approved the first HPV vaccine, Gardasil, which prevents not only cancer-causing HPV, but also HPV types 6 and 11, which cause genital warts.[3] The Center for Disease Control and Prevention (CDC) estimated that 6.2 million people contract a genital form of HPV each year, infecting over half of all sexually active men and women at some point in their lives.[4]

While drug companies test the HPV vaccine to determine if it can provide protection for men, in the meantime, legislatures must determine what to do with a single-sex, sexually-related vaccine.[5] States face the decision of whether to mandate a vaccine for a sexually transmitted infection or not to require citizens to receive a vaccine that prevents cancer.[6]

This article analyzes and compares the different legislative approaches to Gardasil by examining traditional vaccination methodologies and exploring how state approaches expand upon and violate those methodologies.[7] The second part of this article examines the legal basis for mandatory vaccinations and the arguments against compulsory immunizations.[8] The third part of this article analyzes how Virginia, New Hampshire, and Texas have responded to Gardasil and determines how each state approaches the legal arguments for vaccination.[9] Finally, this article identifies one approach as being the most effective and responsible method of distributing Gardasil to a state's population.[10]

II. Background

A. Different State Approaches to the HPV Vaccine

States generally take one of three different approaches to vaccinating schoolgirls with Gardasil.[11] The first approach, taken by Texas, neither provides nor requires HPV immunization, leaving all vaccination decisions to parents.[12] The second approach, exemplified by Virginia, requires schoolgirls to receive the vaccination, but allows parents to opt-out of the vaccination for any reason.[13] New Hampshire introduced the final approach by not requiring vaccination, but providing the vaccine to all girls in the state free of cost.[14]

i. Texas

Texas exemplifies a conservative approach to Gardasil by not mandating, recommending, or arranging for the distribution of the vaccine.[15] The Governor of Texas signed an executive order, directing the state Department of Health and Human Services to adopt the required vaccination of 11-12-year-old girls.[16] In response, the state legislature immediately passed an amendment overruling the executive order, breaking from traditional immunization legislation by requiring parents to opt-in for their children to receive the vaccination, rather than requiring them to opt-out of mandatory vaccination.[17]

ii. New Hampshire

Taking the middle ground between Texas and Virginia, New Hampshire side-stepped the issue of mandating a controversial vaccine when the state Department of Health and Human Services (HHS) announced that it would distribute Gardasil free of cost.[18] New Hampshire has a comprehensive state immunization program to provide children with vaccinations for numerous diseases, including HPV, free of cost.[19] Because the inclusion of the HPV vaccine did not change the overall budget for the immunization program, the New Hampshire legislature had no role in approving the distribution of Gardasil.[20] Since the initial dispersal of Gardasil in January 2007, more than 14,000 doses have been administered in the state.[21]

iii. Virginia

Virginia introduced a new approach to vaccination by mandating the vaccination of schoolgirls, but allowing parents to forego the vaccine for any reason.[22] Beginning in October 2008, Virginia will require schoolgirls entering the sixth grade to receive a HPV vaccine.[23] The addition of this vaccine required the state legislature to amend the state vaccination plan, which currently allows families to opt-out of vaccinations if the vaccination would be medically detrimental to a child, or if families' strong religious beliefs prohibit the administration of a vaccine.[24] Traditionally, if a family

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claims a medical exemption, the school board must receive a statement from a physician or nurse practitioner verifying the reason for the exemption.[25] When Virginia begins to require the use of the HPV vaccine in October, parents and guardians will have the right to refuse that vaccination for their child on any grounds because HPV is not communicable in a school setting.[26]

B. The Legal Basis for Mandating Vaccines and Quarantine

States' authority to mandate vaccination originates in their police power, as vaccinations protect public health and public safety.[27] Airborne diseases, like smallpox once presented a serious health and logistical problem to cities and states when quarantine was the only option for combating the spread of the disease.[28] Using state police power, states could require widespread vaccination and quarantine.[29] The Supreme Court has defined "police power" as everything essential to public safety, health, and morals that the state has legitimate authority to remedy.[30]

In *Jacobson v. Massachusetts*, the Supreme Court held that states have a fundamental interest in preventing the spread of communicable diseases, and, as such, have the police power to mandate vaccinations and require

Implementing a National Mandatory Vaccination Campaign among Pre-teen Adolescent Females

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For a mandatory vaccination program to succeed, the partnership between the private and public sectors needs to work well so the clients as well as the providers become educated. Education is a vital part of any comprehensive vaccination program, particularly for something as new to the public as Gardasil. Acceptance among gynecologists and physicians is generally high, depending on factors such as a patient's gender, age, and sexual history, as well as efficacy of the vaccine.[1] A review of a research study regarding HPV and HPV vaccine acceptability also indicates that health care providers and professional health organizations play a large part in a parent's decision to vaccinate his or her child.[2] Parents are more likely to follow the recommendations and information put forth by health care providers, and health care providers are more apt to follow a professional health organization's endorsement of a vaccine.[3] Thus, health care providers will likely play a pivotal role in relaying information about HPV and HPV immunization in order to ensure the targeted population is vaccinated.

Surveys have shown that when the HPV vaccine is presented under the umbrella of sexually transmitted disease-protection, females are less likely to be inoculated.[4] Researchers at the University of Pennsylvania observed that the way in which the vaccine is represented by the media influences opinion toward vaccination among females. They surveyed 635 adults over the age of 18, about half of whom were females, assigning each to read one of three paragraphs about the vaccine (each emphasizing a different perspective):

a) The vaccine protects against cervical cancer.

b) The vaccine protects against cervical cancer and sexually transmitted infections.

c) The vaccine protects against cervical cancer, sexually transmitted infections and may or may not lead to increased sexual promiscuity among those vaccinated.[5]

More than half had heard of HPV, but 80 percent expressed that they had never spoken to a health-care provider about the virus. When females read that the vaccine protects only against cervical cancer, 63 percent explained they were "very likely" or "somewhat likely" to get vaccinated, compared with 43 percent of those who read the vaccine protects against cervical cancer and a sexually transmitted infection.[6] Doctor Susan Towns, head of the Department of Adolescent Medicine at the Children's Hospital in Westmead, Maine, explains that, "This is confronting because it's associated with sexual activity, which most parents aren't thinking of in their 11- and 12-year-olds. It's a hard one because you don't want to be framing it as though you're giving permission for early sex."[7] One possible effective way to approach the mandatory HPV vaccination campaign is to respect religious and cultural sensitivities and differences by promoting it to be an anti-cancer vaccine rather than as a STD-related vaccine.

Campaigns mandating the new vaccine holds great promise for millions of females. Not only can the HPV vaccination greatly reduce deaths and morbidity attributable to cervical cancer, but it also has the potential to reduce the economic, emotional, and psychological burdens that women may experience from the diagnosis through the progression of this chronic disease. The key to the success of this new vaccine will be in how policymakers, health care providers, community leaders, media, educators, parents, females, and the general public respond to ensure that all those who can benefit from this new technology have access to it and understand its value for society. The elimination of cervical cancer could be the first major medical and global health accomplishment of the 21st century. The HPV vaccine can save lives and improve the quality of life, both nationally and worldwide.

1 J.C. Raley, K.A. Followwill, G.D. Zimet, et al., *Gynecologists Attitudes Regarding Human Papilloma Virus Vaccination: A Survey of Fellows of the American College of Obstetricians and Gynecologists*. Infectious Diseases in Obstetrics & Gynecology 12(3–4):127–133. Sept–Dec. 2004, *available at* http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=Abstract&list_uids=15763912&query_hl=15&itool=pubmed_DocSum (last visited Mar. 22,2008).

2 *Id.*

3 J.M. Riedesel, S.L. Rosenthal, G.D. Zimet, et al., Attitudes About Human Papillomavirus Vaccine Among Family Physicians. Journal of Adolescent Health 18(6):391–8, December 2005, *available at* http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=16338604&query_hl=19 (last visited Mar. 22, 2008).

4 Jeanna Bryner, *Survey: Most Women Don't Know Virus Causes Cervical Cancer,* Foxnews.com - Science, *available at* http://www.foxnews.com/story/0,2933,229090,00.html (last visited Mar. 22, 2008).

5 *Id.*

6 *Id.*

7 Jacqueline Maley, *Cancer Vaccine For Girls Before Sex Life Starts,* July 16, 2005, *available at* http://www.smh.com.au/articles/2005/07/15/1121429359320.html (last visited Mar. 22, 2008).

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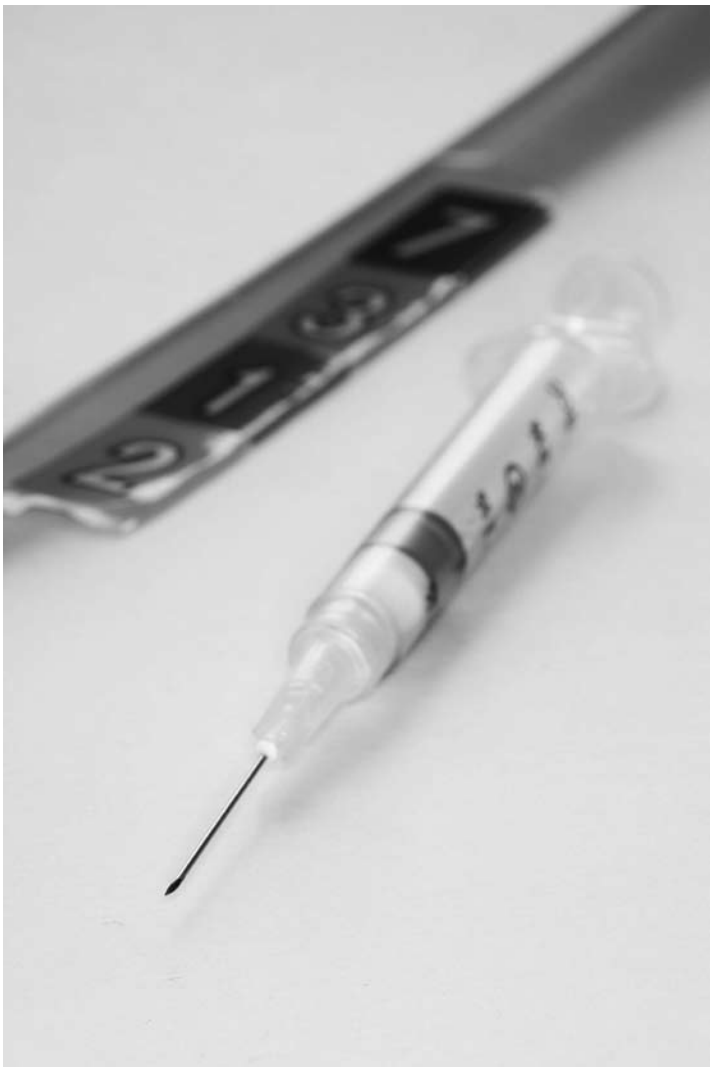

quarantine when vaccinations are not used.[31] Jacobson argued that required vaccinations were "unreasonable, arbitrary, and oppressive," and thus violate an individual's right to care for one's own body and health.[32] However, the Court rejected Jacobson's argument and mandated that states have the power to enact laws for the common good and welfare of their citizens, especially when the laws relate to health.[33]

C. The Balancing Test Between State Interest and Parental Control

Gardasil presents a unique situation because it protects against a sexually transmitted disease, which may conflict with traditional sexual education and religion.[34] The Supreme Court has consistently defended parents' right to determine the upbringing of their children without state interference.[35] In *Meyer v. Nebraska*, the Court ruled that a state government must respect the right of parents to determine the upbringing of a child.[36] In that case, the Court determined that Nebraska's ban on teaching children foreign languages was unconstitutional and had no reasonable relation to a legitimate state interest.[37] The Supreme Court used *Meyer* to clarify that under the Constitutional promise of "liberty," individuals have the right to establish a home and bring up children without undue interference from the state.[38]

In *Pierce v. Society of Sisters*, the Supreme Court extended its ruling in *Meyer* by overturning an Oregon law requiring compulsory public education for children between the ages of eight and sixteen.[39] The Court stated that although the state has an interest in educating children, Oregon could not require the standardization of upbringing because parents have the right and duty to prepare their children for society.[40]

In *Wisconsin v. Yoder*, the Supreme Court held that the Amish do not need to send their children to school after the eighth grade, in accordance with their religious beliefs.[41] The Court reasoned that because the First Amendment guarantees the freedom to practice religion, forcing Amish children to attend schools against their religious beliefs violated that fundamental freedom.[42] Additionally, the Court held that parents have the obligation to prepare their children for the future, which Amish parents do through education based on religious beliefs and practices.[43]

D. Equal Protection and Medical Treatment for Women

In addition to determining whether the state police power extends to mandating the distribution of Gardasil, a court must examine the validity of the vaccine as a single-sex medical treatment. The Supreme Court has ruled on the validity of single-sex medical coverage in past cases.[44] In *Geduldig v. Aiello*, the Supreme Court held that a failure to take into consideration differences between men and women does not necessarily constitute sexual discrimination.[45] In *Geduldig*, a California disability insurance plan failed to cover disabilities attributable to pregnancy, a condition that only affects women.[46] The Supreme Court held that the failure to provide coverage was not gender discrimination because there was no risk from which men were protected and women were not.[47]

III. Analysis

A. By Neither Changing Precedent Nor Ignoring Women's Health, New Hampshire's Approach to Gardasil Presents the Most Effective Public Health Measure

New Hampshire's approach to distributing Gardasil serves as the best model for the distribution of the vaccine.[48] Since New Hampshire provides the vaccination free of cost, but does not require anyone to receive the vaccine, this approach neither erodes the principles of mandatory vaccination nor ignores the value of the vaccine as an important medical advancement.[49] New Hampshire recognizes the difference between HPV vaccines and other immunizations by providing the inoculation, but not requiring it.[50] New Hampshire does have required vaccinations, but by leaving Gardasil off of that list, New Hampshire has recognized the fundamental differences between HPV and other diseases.

New Hampshire stays within the strictures of Supreme Court decisions by reserving parents' ability to make fundamental decisions about the upbringing of their children.[51] HPV differs from the other diseases prevented by vaccination because it requires intimate contact for contraction, making it distinctly different from the smallpox discussed in *Jacobson*.[52] Giving a child a vaccine to prevent a sexually-transmitted disease might be construed as condoning the child's sexual behavior, which may be related to religious beliefs states are precluded from infringing upon.[53] In *Wisconsin v. Yoder*, the Court decided that religious beliefs trumped state interest in education.[54] Like education, public health remains a state concern, but in the situation with HPV vaccines, religion and the issue of sexuality cannot be separated from health, creating a balancing test states must address.[55] By allowing parents to choose to vaccinate their daughters without forcing such a

decision, New Hampshire respects both the rights of families and the health of women.[56]

B. Public Health Police Power: Gardasil Fails the *Jacobson* Test

The *Jacobson* Court relied on the fact that smallpox is an airborne disease and to prevent the contraction of smallpox, the state needed to either vaccinate prior to infection or isolate the disease.[57] The smallpox vaccine could be given to every member of society through state planning, allowing the state to reduce the threat of a widespread smallpox outbreak until the threat ceased to exist.[58] HPV differs from smallpox as it requires intimate contact, raising the question of whether *Jacobson* would apply to HPV vaccinations.[59]

Whether a court would find that a state has inherent police power to protect against the spread of a sexually transmitted disease remains unclear. In *Jacobson*, the Court relied upon the principle of self-defense to hold that "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members."[60] Because cervical cancer threatens the health of members of society and is spread through human contact, HPV seems similar to the smallpox discussed in *Jacobson*.[61] However, an analysis based on *Jacobson* would most likely not recognize the police power of the state to require an HPV vaccine.[62] Unlike smallpox, HPV does not pose a traditional health risk: quarantine could not prevent against the spread of the disease because once a person contracts the disease, they can never be rid of it and over 50 percent of the population is infected.[63]

Jacobson also addressed the idea that strict quarantine and immunization would eradicate smallpox.[64] Neither Merck nor the CDC has expressed a belief that the strands of HPV targeted by Gardasil will cease to exist.[65] However, if all women were vaccinated, incidents of cervical cancer would decrease by 70 percent; since men are asymptomatic for the strands that cause cervical cancer, no method of prevention exists besides strict abstinence.[66]

Some states have held that vaccination laws can only be upheld when a disease is present or threatening in a community.[67] Due to the pervasive nature of HPV and the estimates that most adult Americans have some form of HPV, the disease satisfies the requirement of presence in a community.[68] However, HPV would probably fail to threaten a community because it cannot be deemed dangerous on an everyday level, such as polio or smallpox.[69] In states requiring that a disease threaten a community in order for vaccination laws to apply, the HPV vaccine laws would probably not receive enforcement.[70]

C. Equal Protection Claims Do Not Apply to Gardasil

The varying responses to the HPV vaccine also raise the issue of equal protection, as addressed by the Supreme Court in *Geduldig v. Aiello*.[71] Like the post-pregnancy treatments discussed in *Geduldig*, the HPV vaccine currently offers benefits only to women.[72] In *Geduldig*, the Supreme Court specifically noted that men did not receive any treatments that women could not receive, just as in the case of HPV, men do not receive attention that women do not receive as well.[73] The Court recognized that existence of medical treatment does not equate with a right to that treatment, meaning that failure to receive medical care does not equal discrimination.[74] Following this reasoning, any argument that a vaccine preventing against a disease that occurs only in women, but is not mandated for women, does not win an equal protection argument.[75]

If Merck or another pharmaceutical company discovers that Gardasil or other HPV vaccines can prevent against HPV and subsequently penile cancer in men, states that have refused to require or offer vaccinations will be precluded from later offering the vaccine.[76] If a state were to change a policy because the vaccine could prevent diseases in men, undoubtedly questions of equal protection would be raised.[77] While a state government could argue that requiring a vaccination for an entire population is fundamentally more equal than requiring it for a subset, it would appear that the government is worried more about the health of men than of women.[78] Nonetheless, a state government could again point to the decision in *Geduldig* and argue that at no point did the government require medical care for treatment that it did not require for women.[79]

D. Just as Parents Have the Right to Determine the Education and Religion of Their Children, So Too Should They Have Discretion Over Non-Necessary Medical Treatment

As parents have the right under *Yoder* to determine how to educate their child, it should follow that parents also have a right to determine which non-necessary medical treatment their child ought to receive.[80] In the case of Gardasil, vaccination and education are entwined, as girls who receive the vaccination are told that they are protected against a sexually transmitted disease, raising the issue of education and religion as discussed in *Yoder*.[81] Abstinence until marriage has a long-standing history in religion, as family education did for the Amish, and in both situations, religious principles clash with legitimate state interests.[82] Like in *Yoder*, where the Amish were deemed to have a legitimate religious interest that overrode a state law, other groups could

> Most state legislatures allow parents to opt out of vaccinating their child on the basis of religion or some philosophical belief so long as parents understand that their child cannot attend school during any kind of epidemic.

claim to have a legitimate religious interest in boycotting a vaccine that could be deemed to promote sexual behavior.[83] Unlike the polio vaccine, which prevents the contraction of all polio, the HPV vaccine only protects against certain strains of the disease, meaning that girls must continue to learn about and understand the dangers of engaging in behaviors that lead to the contraction of the disease.[84]

Similarly, in *Meyer*, the Court held that parents have a fundamental right to determine the upbringing of their own offspring.[85] Which vaccination a child receives could fall under *Meyer* because, like education and language, non-necessary medical procedures can involve fundamental and religious beliefs.[86] Even parents, who do not want their daughter to receive Gardasil for religious reasons believing that it might encourage loose morality, might not want to object to all vaccinations, as a religious exemption might otherwise call for.[87] A decision that involves morality relates directly to the parental duty of raising a child and is protected primarily under the *Meyer* and *Pierce* decisions.[88] In this situation, Texas, Virginia, and New Hampshire's approaches would all respect the parents' desire to refuse the Gardasil vaccination.[89]

Most state legislatures allow parents to opt out of vaccinating their child on the basis of religion or some philosophical belief so long as parents understand that their child cannot attend school during any kind of epidemic.[90] By doing this, states follow the dictates of *Yoder*, *Pierce*, and *Meyer* that reserve for the parents the right to determine the upbringing of their own child.[91] Legislation has been proposed in West Virginia to require an HPV vaccination for all schoolgirls entering the sixth grade, and as the state lacks a religious exemption to vaccinations, such legislation could inspire a court case addressing the right of the parent to determine non-necessary medical care.[92]

E. Texas Fails to Provide Protection Against Cervical Cancer

When Governor Rick Perry announced that he would mandate the inoculation of all school-aged girls in the state of Texas, the conservative state legislature viewed the immunization as unnecessary, effectively ignoring the health of women in favor of following a conservative agenda.[93] The Texas legislature adopted a policy of distributing information at the time of adolescent inoculation so that parents could decide whether or not to vaccinate their daughters.[94]

Some interest groups argue that Texas's failure to mandate the Gardasil vaccine does not matter, as the vaccine will still be available to those who desire it.[95] In Texas, Virginia, and New Hampshire, young girls and their parents have the option of vaccinating against HPV. Should their parents choose to inoculate, girls in Texas would receive the same vaccine as girls in New Hampshire and Virginia do.[96] However, with nine million uninsured children in the United States, it is naive to assume that all children receive the same medical treatment and inoculations, even within a single state.[97]

Texas does not outlaw the distribution of the vaccine and requires the distribution of information regarding vaccination to parents at the time of other vaccinations.[98] Additionally, on July 16, 2007, all 55 immunization projects in the country adopted the distribution of Gardasil, including centers in Texas.[99] This adoption means that all girls who are uninsured, on Medicaid, of Native American descent, or enrolled in the State Children Health Insurance Program (SCHIP) will receive the vaccine.[100] While the state will still not require the vaccination, many girls will receive it regardless, as states receiving federal money for the Vaccines for Children (VFC) program are required to implement the vaccine.[101]

Despite this step towards preventing cervical cancer throughout the state of Texas, VFC neither vaccinates all eligible children nor assists children with private insurance to receive the immunizations.[102] Even though parents will have the right to determine whether or not to vaccinate their child, those receiving the incentive of a free and recommended vaccination from VFC will face a different decision than those simply offered information.[103] Schoolgirls who cannot receive vaccines through the VFC program will lose out in this situation because, unlike the girls in the VFC program whose parents will have to opt-out of the vaccine, girls with private insurance will need their parents to opt-in to receive the vaccination.[104] The largest group of women who will fail to receive the vaccine will be adults without private insurance as few uninsured women will pay the $360 for the three shot plan.[105]

F. Virginia Reinvents Public Health Policy by Allowing a New Exemption

Allowing parents to opt-out of the administration of the HPV vaccine allows Virginia to remain within the framework of the *Meyer*, *Yoder*, and *Pierce* decisions, in that the parents have the primary position of determining non-necessary medical treatment for their children.[106] As in those cases where parents have the power to determine how to raise their child, the issue of a non-necessary vaccination against a sexually transmitted disease can be seen simply as an issue in rearing a child, and not a medical decision.[107] Virginia addressed this issue by distinguishing the HPV vaccine from other vaccines through changing the exemption rules.[108]

Virginia's immunization law requiring Gardasil, but providing parents with a simple method of refusing the vaccination, presents a radical change for immunization statutes.[109] By traditionally requiring an affidavit of waiver of recommended treatment, legislatures have ensured widespread vaccination.[110] The amended statute removes the physician's role in recommending medical treatment for minors, leaving decisions in the hands of parents, who, according to previous court cases, have the primary role in determining the upbringing of their children.[111]

Despite the Court's reluctance to limit parents' discretion, there remains a role for the state in decisions to immunize children.[112] In numerous Virginia cases regarding child abuse or determining custody, the issue of whether or not a child has received his or her immunizations and is up-to-date with the immunization schedule serves as a factor in the outcome of the case.[113] While not the most compelling proof of child abuse, the failure to immunize a child can be viewed as neglect, as in the case of *Welch v. Commonwealth.*[114] In *Welch*, a mother argued that she did not purposefully murder her child, but rather the child died from neglect because she failed to provide proper medical care.[115] *Welch* shows that failure to immunize a child can have legal ramifications, which will be weakened when the state implements varying levels of importance for vaccines because both the defense and prosecution will have to become familiar with a more complicated immunization scheme.[116]

By changing the state statute to allow for a new parental waiver of a vaccine recommended by the CDC, the state of Virginia set a dangerous precedent for the future of required immunization in the state.[117] Parents could make a logical argument that just as an HPV vaccine is not strictly necessary, neither is a vaccine for antiquated and rare diseases like polio and measles.[118] Essentially, the approach to vaccinations adopted by the new Virginia policy has never been the appropriate role of vaccinations.[119] Rather than weakening the entire vaccination program by allowing an opt-out to a "mandatory" vaccine for any reason, Virginia and states adopting Virginia's plan, like South Dakota and Washington, ought to think of a new procedure through which to vaccinate adolescent girls.[120] Mandatory vaccinations ought to remain for diseases that pose a serious health threat through which the state can exercise its police power.

IV. Policy Recommendations

A. Changing Public Health Tradition and Failing to Encourage the Prevention of Cancer are Questionable Public Policies

Many arguments remain for not requiring a vaccination of a non-airborne communicable disease. Since the introduction of vaccinations, people have had reservations about receiving immunizations.[121] Claims range from the argument that vaccines violate the Fourteenth Amendment and interfere with a parent's right to determine the upbringing of her own child, to the current belief that vaccinations cause autism.[122] However, the CDC has largely ruled out the argument that vaccinations cause autism, choosing to cite to the numerous research studies conducted to show the lack of a correlation between immunization and autism, rather than citing to the few showing a tenuous connection.[123]

The reason that the HPV vaccine ought to be freely offered to citizens lies in the fundamental reason for vaccinations: the more people who receive vaccinations, the more protected the community becomes from infection.[124] Studies have suggested that there is a significant difference in the rate of infection when only one percent of the population abstains from vaccinations versus when four percent of the population abstains of vaccinations.[125] By offering vaccinations to school-age children at the time they receive other vaccinations, the rate of children exempted from vaccinations remains at about one percent.[126] Evidence points to the fact that more people receive vaccinations when immunizations are required than when they are simply recommended. However, Virginia's policy of requiring a vaccination but allowing an opt-out for any reason could fail to serve as an effective means of vaccination because it threatens all vaccination by calling attention to exemptions.[127]

V. Conclusion

The invention of Gardasil presents an opportunity for the country to prevent needless deaths from cervical cancer. If every girl were to receive vaccinations before engaging in sexual activity, the incidence of cervical cancer would decrease significantly. New Hampshire has dealt with the threat of cervical cancer most effectively by not reinventing public health laws and recognizing the hope offered by the HPV vaccine. However, the vaccination of nine-, 10-, and 11-year-old girls for a sexually transmitted disease remains understandably contentious. Nonetheless, the states are attempting to successfully confront the advancement in medical technology.

1 *See* Am. Cancer Soc'y, What are the Key Statistics About Cervical Cancer, http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_cervical_cancer_8.asp (last visited June 24, 2007) [hereinafter *Key Statistics*] (stating that cervical cancer was once one of the deadliest forms of cancer among American women, occurring mainly in women between the ages of 35 and 55).

2 Merck, Gardasil, http://www.gardasil.com/ (last visited June 24, 2007) (writing that Gardasil protects against the strains of HPV that cause 70 percent of cervical cancer, the strains of HPV that cause 90 percent of genital warts).

3 *See* Ctr. for Biologics Evaluation and Research, FDA, Product Approval Information - Licensing Action, *available at* http://www.fda.gov/cber/products/hpvmer060806qa.htm [hereinafter *FDA Product Approval Information*] (discussing the FDA's approval for Gardasil because studies have shown Gardasil to be nearly 100 percent effective in preventing types of cervical cancer and has been deemed safe through various testing procedures).

4 *See id.* (stating that Gardasil is nearly 100 percent effective against the HPV types at which it is directed and the vaccine has limited adverse reactions).

5 *See* Davis Tuller, *New Vaccine for Cervical Cancer Could Prove Useful to Men Too*, N.Y. Times, Jan. 30, 2007 at F5 (explaining that Merck is currently researching whether HPV vaccines would work for men, specifically regarding the prevention of anal cancer).

6 *See* Gardiner Harris, *Panel Unanimously Recommends Cervical Cancer Vaccine for Girls 11 and Up*, N.Y. Times, June 30, 2006, at A12 (reporting the approval of the vaccine and giving an overview of the arguments against widespread distribution of the vaccine).

7 *See infra* Part II (examining current state policies regarding required vaccinations as part of school attendance).

8 *See infra* Part II (exploring the basis for modern vaccination and quarantine legislation).

9 *See infra* Part III (arguing that the approach taken by Texas to distributing literature about the HPV vaccine without requiring it or providing it free of charge offers a disservice to women).

10 *See infra* Parts III and IV (recommending that New Hampshire offers the

most appropriate response to the distribution of Gardasil for schoolgirls).
11 *See* Tex. Educ. Code Ann. § 38.001 (2007) (mandating certain vaccinations in order to attend school, but excluding HPV vaccination requiring the distribution of literature regarding the vaccination); Va. Code Ann. § 32.1-46 (2007) (requiring HPV vaccination for schoolgirls, but allowing parents to opt-out of the vaccination for any reason); Div. of Health and Human Serv., Immunization Program, N.H. , http://www.dhhs.nh.gov/DHHS/IMMUNIZATION/LIBRARY/Best+Practice/immunizations-info.htm (last visited June 24, 2007) [hereinafter *NH Immunization Program*] (including the HPV vaccine as one of the vaccinations included the state's in free vaccination program).
12 *See* Tex. Educ. Code Ann. § 38.001 (2007) (mandating vaccination against diptheria, rubeola, mumps, tetanus, and poliomyelitis prior to any person's admission to elementary or secondary school).
13 *See* Va. Code Ann. § 32.1-46 (2007) (noting that parents and guardians have the sole discretion over whether or not to vaccinate a child against HPV because the disease is not communicable in a school setting).
14 *See NH Immunization Program*, *supra* note 11 (including the HPV vaccine as one of the vaccinations included in New Hampshire's free vaccination program).
15 *See* Tex. Educ. Code Ann. § 38.001 (2007) (mandating that families receive unbiased, medically, and scientifically accurate, and peer reviewed educational materials about Gardasil at the appropriately scheduled time); *see also* Ralph Blumenthal, *Texas Legislators Block Shots for Girls Against Cancer Virus*, N.Y. Times, Apr. 26, 2007, at A16 (discussing the legislature's almost unanimous vote to overturn the executive order because of the "volatile" mix of under-age girls, cancer, and sex).
16 Exec. Order No. RP65, Office of the Governor (Feb. 2, 2007), *available at* http://www.governor.state.tx.us/divisions/press/exorders/rp65 (last visited June 24, 2007) (overturned by 2007 Tex. Sess. Law Serv. Ch. 94 (H.B. 1059)) (citing the 391 women who died in Texas of cervical cancer during 2006 and ordering the vaccination of girls up to the age of 18); Office of the Governor, Rick Perry, Text of Gov. Rick Perry's State-of-the-State Address, *available at* http://www.governor.state.tx.us/divisions/press/speeches/speech_020607 (last visited June 24, 2007) (arguing that the mandatory distribution of Gardasil would further conservative principles by protecting life by preventing needless deaths due to cervical cancer).
17 See Tex. Educ. Code. Ann. § 38.001 (2007) (mandating that children receive immunizations against diphtheria, rubella, rubella, mumps, tetanus, and poliomyelitis prior to attending elementary or secondary school in Texas, clearly not including HPV vaccinations in a mandate until at least 2011).
18 *See NH Immunization Program*, *supra* note 11 (attempting to reduce or eliminate all vaccine-preventable diseases by offering vaccinations to the roughly 342,000 children under the age of 19 in New Hampshire); s*ee also* Pam Belluck, *For One State, Soft Sell Eases Vaccine Fears*, N.Y. Times, May 12, 2007, at A1 (reporting that New Hampshire has donated 28 percent of its immunization budget of 4.9 million dollars on Gardasil).
19 *See* N.H. Rev. Stat. Ann. § 126-A:4 (LexisNexis 2008) (establishing the Department of Health and Human Services to protect and strengthen families, communities, and to develop the independence and self-sufficiency of the state); *NH Immunization Program*, *supra* note 11 (explaining that New Hampshire requires the vaccination against diphtheria, influenza, hepatitis B, measles, mumps, rubella, pertussis, polio, tetanus, and varicella before a child can attend school and day care).
20 *See NH Immunization Program*, *supra* note 11. (discussing the DHHS distribution scheme which allows the state DHHS to determine which vaccines will be provided for free without interference from the state legislature).
21 *See* Belluck, supra note 18 (reporting on the efficacy of the immunization program, including the HPV distribution, which provides vaccinations to much of the state's children free of charge, not only the poor or those lacking adequate insurance).
22 *See* Va. Code Ann. § 32.1-46 (2007) (mandating three doses of properly spaced HPV vaccine for females prior to entrance to the sixth grade).
23 *See id.* (stating that a parent can exempt his or her daughter from receiving the HPV vaccine without a religious or medical exemption after the parent reviews materials regarding the connection between HPV and cervical cancer).
24 *See id.* (stating that students can receive exemption from vaccination in the case of medical, religious, or philosophical reasons, and stipulating that an exemption from the HPV vaccine can occur for any reason approved by a parent).
25 *See id.* (ensuring the veracity of medical exemptions by requiring a statement from a physician or nurse practitioner licensed in Virginia stating that immunizing agents would detriment a child's health).
26 *See id.* (clarifying that unlike religious exemptions which can be overridden in the case of emergency or epidemic disease, HPV vaccine exemptions are not subject to such stipulations).
27 *See* Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11, 25 (1905) (holding that a Massachusetts law requiring immunization against smallpox did not violate the Fourteenth Amendment because states have the police power to enact "health laws of every description").
28 *See generally* Katherine E. Strong, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 Geo. Wash. L. Rev. 426, 432 (2007) (stating that the success of vaccination as a general public health measure relies in large part on widespread vaccination).
29 *See Jacobson*, 197 U.S. at 25 (stating that the police power serves as the basis for vaccination and quarantine to protect state interests because widespread disease threatens the security of the state).
30 *See* Lawton v. Steele, 152 U.S. 133, 136 (holding that New York properly exercised its police power when controlling a public nuisance because it protected a public interest).
31 *See Jacobson*, 197 U.S. at 25-27 (holding that the state of Massachusetts has the police power to require vaccinations because the government must legislate for the common good, and liberty must be regulated by law).
32 *See id.* at 26 (lambasting the argument that vaccinations violate the integrity or liberty of the individual because the Constitution does not impart an absolute right to the individual to exist free of law and restraint).
33 *See id.* at 28-29 (explaining that the basis of the police power in relation to mandatory vaccinations and quarantine lies in the necessity of the regulations to protect "life, liberty, health, or property").
34 *See* Stephanie Saul & Andrew Pollack, *Furor on Rush to Require Cervical Cancer Vaccine*, N.Y. Times, Feb. 17, 2007, at A1 (explaining that Gardasil has received opposition from religious and socially conservative groups believing the vaccine would promote sexual activity and promiscuity).
35 *See, e.g.,* Wisconsin v. Yoder, 406 U.S. 205, 236 (1972) (holding that it violates freedom of religion to force an Amish parent to send a child to parochial school); Pierce v. Society of Sisters, 268 U.S. 510, 536 (1925) (giving parents the choice as to which school their child would attend); Meyer v. Nebraska, 262 U.S. 390, 403 (1923) (allowing parents to teach children any language they choose as part of a fundamental right to bring up a child).
36 *See Meyer,* 262 U.S. at 403 (holding that the state cannot interfere with the upbringing of a child except when there is a legitimate state interest in protecting the child, as in a situation of danger to the child's health).
37 *See id*. at 398-99 (stating that the law can be unfairly applied as it restricts the parental interests of immigrants more than of parents born within the country, and such discriminatory application cannot be within the state interests).
38 *See id*. at 399-400 (applying a broad definition of "liberty" in the Fourteenth Amendment to ensure that parents have the right to determine the education and upbringing of their children).
39 *See Pierce*, 268 U.S. at 534-35 (stating that the injury to a Catholic school by an Oregon law requiring children to attend public school was very real and parents have a right to determine the upbringing of their own children according to the tenants of their religious beliefs).
40 *See id*. (expounding upon *Meyers* by arguing that parents have the right to nurture and direct the destiny of their own children with minimal state interference).
41 *See Yoder,* 406 U.S. 205, 229, 236 (1972) (finding a lessened state interest in requiring high school education for the Amish than for other students because of the strict Amish religious requirements, and holding that forcing the Amish to attend school would interfere with the practice of religion).
42 *See* U.S. Const. Amend. I (forbidding the government from impinging on the free practice of religion); *see also Yoder*, 406 U.S. at 221 (stating that the state has a legitimate interest in the education of it citizens, but the exercise of religion outweighs that interest as the children would continue to receive education from their parents and community).

43 See *Yoder*, 406 U.S. at 222 (holding that parental interest and religion outweigh the interest of the state because most Amish children take over family farms from parents and must learn how to run such a venture, that serves as informal education).
44 *See* Geduldig v. Aiello, 417 U.S. 484, 496 (1974), *superseded by statute*, Pregnancy Discrimination Act of 1978, 42 U.S.C. § 2000e (k), (holding that exclusion of normal pregnancy related disabilities failed to violate equal protection because insurance protection remained equivalent for all participating employees).
45 *See Geduldig,* 417 U.S. at 493 (stating that the cost of covering pregnancy related disabilities would be "so extraordinarily expensive" as to make it impossible for California to maintain the disability benefit program).
46 *See id.* at 485 (holding that with respect to social welfare programs, so long as the line drawn between who shall benefit from the program and who shall not remains rationally supportable, courts should not interpose judgment).
47 *See id*. at 497 (stating that both men and women received the same coverage because the policy divided between pregnant women and everybody else).
48 *See NH Immunization Program*, *supra* note 11 (stating that the New Hampshire immunization program also promotes immunization initiatives for adults to insure lifelong protection against preventable diseases); *see also* Press Release, N.H. Dep't. of Health and Human Serv. , DHHS Announces New Hampshire Will Offer Free Vaccine to Children for HPV (Nov. 29, 2006) *available at* http://www.immunize.org/express/issue634. asp#n2 (last visited June 24, 2007) (recommending all parents consider vaccinating their daughters because the HPV vaccine represents a significant step towards protecting the lives and health of women).
49 *Compare NH Immunization Program*, *supra* note 11 (stating that children in the state of New Hampshire can receive all necessary vaccinations free of charge) *with* Tex. Educ. Code Ann. § 38.001 (2007) (stating that only parents have the right to decide whether to vaccinate a child against HPV) *and* Va. Code Ann. § 32.1-46 (2007) (detailing Virginia's approach to requiring an HPV vaccine, which requires administration of the vaccination except in the case of parental refusal).
50 *See* N.H. Rev. Stat. Ann. § 141-C:20-a (LexisNexis 2007) (listing the required vaccinations for attending school in New Hampshire in the absence of medical or religious exemptions).
51 *See Yoder*, 406 U.S. at 235 (holding that it violates freedom of religion to force an Amish parent to send a child to parochial school because the religion dictates that children learn from their parents after completion of the eighth grade); *Pierce* 268 U.S. at 533 (giving choice to parents as to which school their child can attend because parents have the right to determine the upbringing of their own child); *Meyer* 262 U.S. at 401 (allowing parents to teach children any language they choose because parents have a right to instill certain values and beliefs in their children, including knowledge of foreign languages because family members do not speak English).
52 *See Jacobson* 197 U.S. at 27-29 (claiming that smallpox presented a large threat to the community of Cambridge and required state action to contain the threat); CDC, HPV Vaccine-Questions and Answers, *available at* http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm (last visited June 24, 2007) [hereinafter *CDC Questions and Answers*] (stating that sexual contact without sexual intercourse can lead to the spread of HPV).
53 *See* U.S. Const. Amend. I (denying the government the ability to establish or infringe on the free exercise of religion); *cf. Yoder*, 406 U.S. at 214 (holding that states must balance interest in education and the right of religious freedom).
54 *See Yoder*, 406 U.S. at 209 (holding that the Amish community that believed further education for their children would endanger their salvation had a right to educate their children outside of a traditional school system).
55 *See id.* at 214 (stating that religion and legitimate state interests require a delicate balancing test between infringing on the freedom of religion and legitimate state action).
56 *See* Belluck, *supra* note 18 (stating that the Secretary of Health and Human Services in New Hampshire pushed for the inclusion of HPV in the immunization scheme because of a desire to protect as many women as possible from cervical cancer).
57 *See Jacobson*, 197 U.S. at 38-39 (holding that the state does not have the police power to force a person to receive a vaccination when the vaccination would detriment the health of the individual).
58 *See generally* Strong, *supra* note 28, 432-33 (discussing the problems with vaccinating only in part, which can lead to new strains of disease resistant to treatment as well as widespread epidemics).
59 *See Jacobson*, 197 U.S. at 37-38 (theorizing that a different holding in this case would have lead to a tyranny by a minority of people who refused to receive vaccinations).
60 *See id.* at 28-29 (stating that so long as the vaccination scheme adopted by the State of Massachusetts failed to cause distress or inconvenience, it passed judicial scrutiny); *see generally* Wendy E. Parmet, *Informed Consent and Public Health: Are they Compatible When it Comes to Vaccines*, 8 J. Health Care L. & Pol'y 71, 71-72 (2005) (arguing that *Jacobson* places the public good above the rights of the individual, making it difficult for individuals to give informed consent when receiving vaccinations).
61 *See Jacobson*, 197 U.S. at 30-31 (discussing the health threat posed by smallpox as a matter for the state's police power).
62 *See id.* at 27 (stating that the board of health in Massachusetts only required smallpox immunizations when it became necessary for the public health and safety).
63 *See Key Statistics*, *supra* note 1 (explaining HPV can only be contracted through physical touching, meaning traditional quarantine would not work without preventing people with HPV from ever engaging in sexual contact).
64 *See Jacobson*, 197 U.S. at 35 (holding the state has the police power to enforce strict quarantine when confronted with a public health dilemma because the state has an obligation to protect its citizens); *see also* Public Health Service Act, 42 U.S.C. § 70 (2003) (giving the federal government the ability to quarantine people, animals, and plants suspected to be infected with a communicable disease).
65 *See* Tuller, *supra* note 5 (discussing the fact that men cannot currently prevent contraction of HPV except through abstinence because condoms do not prevent contraction and the vaccine has not been approved for men).
66 *See FDA Product Approval Information*, *supra* note 3 (stating 70 percent of cervical cancer cases are caused by sexual touching); CDC, HPV Vaccine-Questions and Answers, *available at* http://www.cdc. gov/vaccines/vpd-vac/hpv/vac-faqs.htm (last visited June 24, 2007) (explaining HPV is contracted by sexual touching, not necessarily sexual intercourse, so unlike other sexually

transmitted infections, condoms do not necessarily prevent the transmission of HPV from one sexual partner to another); *see also Lawrence v. Texas*, 539 U.S 558, 578-79 (2003) (holding that intimate sexual conduct is part of "liberty" as defined by the Constitution and, as such, abstinence could not be legislated).

67 See Lawbaugh v. Bd. of Educ., 52 N.E. 850, 850-51 (Ill. 1899) (holding that in the absence of a smallpox outbreak, lack of vaccination cannot be used to keep a student from school); Rhea v. Bd. of Educ., 171 N.W. 103, 105 (N.D. 1919) (holding that boards of education cannot legislate beyond their statutorily delegated authority); Adams v. Burdge, 70 N.W. 347, 351 (Wis. 1897) (holding that barring a child from school when there is no smallpox outbreak violates the child's right to education).

68 *See* CDC, Genital HPV Infection - CDC Fact Sheet, *available at* http://www. cdc.gov/std/HPV/STDFact-HPV.htm#common (last visited June 24, 2007) ("By age 50, at least 80 percent of women have acquired genital HPV.").

69 *See id.* (stating that people primarily contract HPV through genital contact).

70 *See* James G. Hodge, *School Vaccination Requirements: Legal and Social Perspectives*, 27 NCSL St. Leg. Rep. 3 (Aug. 2002), http://www.ncsl.org/programs/health/schoolvaccination.pdf (stating that courts in Illinois, Wisconsin, Utah, and North Dakota have state school vaccination laws when a disease "was present in or threatening a community").

71 *See* 417 U.S. 484, 488 (1974), *superseded by statute*, Pregnancy Discrimination Act of 1978, 42 U.S.C. § 2000e (k), (holding that a state disability insurance system that excluded from coverage certain disabilities resulting from pregnancy did not violate equal protection, which means that omission due to gender does not equal discrimination).

72 *See id*. at 490 (stating that men did not receive treatment women were precluded from receiving and vice versa; therefore, women were not discriminated against in the state disability scheme).

73 *See id*. (explaining that discrimination arises when one gender is denied a service granted to the other, and in the situation of post-pregnancy care, men did not receive that coverage).

74 *See* Kim Shayo Buchanan, *Lawrence v. Geduldig: Regulating Women's Sexuality*, 56 Emory L.J. 1235, 1270 (2007) (arguing that pregnancy and biological differences between men and women should not be used to reduce the level of equal protection scrutiny).

75 *See Geduldig*, 417 U.S. at 496 (stating that the selection of the risks insured by the disability program were selected so as not to discriminate against any definable group or class).

76 *See* Tuller, *supra* note 5 (discussing the studies that are underway to discover whether Guardasil can also prevent anal cancer in men because anal cancer has been linked to the same strains of HPV as cervical cancer).

77 *See Geduldig*, 417 U.S. at 499-500 (Brennan, J., dissenting) (stating that individuals receive compensation for disabilities from cosmetic surgery but not pregnancy related illnesses).

78 *See id.* at 503 (Brennan, J., dissenting) (arguing that the majority decision in *Geduldig* "threatens to return" to a time when legislative classifications treated members of society differently solely because of sex).

79 *See id*. at 487 (stating that so long as men and women are offered the same medical treatment, there is no equal protection violation even if a gender specific treatment is not offered).

80 *See Yoder*, 406 U.S. at 210 (stating that Amish parents can better select the proper education for their children than a parochial school system after the eight grade because of the interrelationship between belief and lifestyle).

81 *See* Denise Grady, *A Vital Discussion, Clouded*, N.Y. Times, March 6, 2007, at F5 (comparing HPV infections to the common cold in its prevalence and arguing that even with vaccination, prevention efforts will be needed for combating the disease).

82 *See Yoder*, 406 U.S. at 209-210 (stating that the Amish carried the burden of showing that the state interest in education violated the religious principles of the Amish).

83 *See* James Colgrove, *The Ethics and Politics of Compulsory HPV Vaccination*, 355 New Eng. J. Med. 2389, 2389 (Dec. 7, 2006) http://content.nejm.org/cgi/reprint/355/23/2389.pdf (stating that religious conservatives have protested the availability of the HPV vaccine as undermining abstinence-based prevention messages).

84 *See FDA Product Approval Information*, *supra* note 3 (stating that Gardasil protects against only four strands of HPV, while over 100 different strands of the disease exist).

85 *See Meyer* 262 U.S. at 400 (holding that a parent has a liberty protected by the Fourteenth Amendment of the U.S. Constitution to freely choose to have his child schooled in a foreign language without government interference).

86 *See Yoder*, 406 U.S. at 211 (stating that religious beliefs can outweigh the importance of state interest when the state interest violates tenants of a religion); *Meyer*, 262 U.S. at 400 (stating that the fundamental right to family includes the right to educate a child outside of school as a parent or guardian deems suitable).

87 *See* Grady, *supra* note 81 (citing parents who believe Gardasil will increase promiscuity, and that the only protection a daughter needs is abstinence until marriage).

88 *See Meyer*, 262 U.S. at 499 (stating that each individual is imbued with the liberty to raise a child in the dictates of a chosen religion); Pierce v. Soc'y of Sisters, 268 U.S. 510, 532 (1925) (stating that parents have the right to choose the school where their child will receive appropriate mental and religious training).

89 *See* Tex. Educ. Code Ann. § 38.001 (2007) (failing to require the HPV vaccination within the state); 2007 Va. Acts 922 (requiring the HPV vaccination, but allowing parents to opt-out for any reason; *NH Immunization Program*, *supra* note 11 (including Gardasil as one of the state's free vaccinations available to all children within the state).

90 *See* National Conference of State Legislatures (NCSL), States with Religious and Philosophical Exemptions from Immunization School Requirements, http://www.ncsl.org/programs/ health/2004exchart.htm (last visited June 24, 2007) [hereinafter *NCSL Religious and Philosophical Exemptions*] (listing which states allow a religious and a philosophical exemption from vaccination). *See generally* Linda E. LeFever, *Religious Exemptions from School Immunization: A Sincere Belief or a Legal Loophole?*, 110 Penn. St. L. Rev. 1047, 1067 (2006) (arguing that religious exemptions should be repealed and all states ought to implement a philosophical exemption to vaccination to protect the equal protection rights of the non-religious).

91 *See Yoder*, 406 U.S. at 235 (holding freedom of religion can trump state interest when it comes to education); *Pierce*, 268 U.S. at 533 (stating that education

in a religious institution can replace state sponsored schools, should the parent so desire); *Meyer*, 262 U.S. at 401 (stating that the right of the parent can trump that of the state because of the fundamental rights of liberty).
92 *See* Kaisernetwork.org, Daily Women's Health Policy: *Colorado, Kansas, West Virginia Introduce Legislation on HPV Vaccines, Abortion* (Jan. 18, 2007), http://www. kaisernetwork.org/Daily_reports/rep_index.cfm?DR_ID=42315 (last visited June 24, 2007) (citing the introduction of legislation in West Virginia to require the HPV vaccine and stating West Virginia has the second highest cervical cancer rate in the country, only behind Washington, DC).
93 *See* Blumenthal, *supra* note 15 (quoting a Texas legislator who lambasted the vote by referring to the girls who will eventually die for failure to receive the vaccination).
94 *See* Tex. Educ. Code Ann. § 38.001 (2007) (mandating that at the time of adolescent immunizations, families receive information regarding an HPV vaccine).
95 *See* Focus on the Family, Focus on the Family Position Statement: Human Papilloma Virus Vaccines, http://www.family.org/socialissues / A000000357.cfm (last visited June 24, 2007) (stating that Focus on the Family supports the availability of HPV vaccines, but vehemently opposes making such vaccines mandatory as parents ought to be the primary decision maker regarding sexual education for their child).
96 *Compare NH Immunization Program*, *supra* note 11 (providing free Gardasil to girls in the state of New Hampshire) *with* Tex. Educ. Code Ann. § 38.001 (2007) (allowing the purchase of Gardasil in the state of Texas should parents chose to vaccinate their child) *and* VA. Code Ann. § 32.1-46 (2007) (demanding Gardasil vaccines for schoolgirls unless otherwise indicated by parents).
97 *See* Children's Defense Fund, Who are the Uninsured, http://www. childrensdefense.org/site/PageServer?pagename =healthy_child_backinfo_whouninsured (last visited June 24, 2007) (discussing the breakdown of uninsured children, many of whom do not receive adequate health care); *see also* Texas Dep't of State Health Serv., Texas Immunzation Survey, *available at* http://www.dshs.state. tx.us /immunize/coverage/tis.shtm (last visited June 24, 2007) (providing statistics on Texas immunization levels, putting children who qualify for government immunizations at a much lower rate of immunization than children with private insurance coverage, and children of color at lower rates of immunization than whites, with only 67 percent of Hispanic children receiving mandatory vaccinations).
98 *See* Ector County Health Dep't, Texas Vaccines for Children Program, Texas Department of Health and Human Services, *available at* http://www. co.ector.tx.us/ health_dept/texas_vaccines_for_children_prog.htm (last visited June 24, 2007) (stating that the Texas immunization program was introduced by the CDC to improve the rate of immunization throughout the country).
99 *See* Lewis Krauskopf, *Merck Vaccines Adopted in Kids Immunization Plan*, Reuters, July 19, 2007, *available at* http://www.reuters.com/article/ health-SP/idUSWNAS603820070716 (reporting that Gardasil has been adopted for distribution to eligible children throughout the country, even in states where the vaccine has not been mandated).
100 *See* Incorporation of Vaccines into the VFC Program, CDC, http:// www.cdc.gov/vaccines/programs/vfc /projects/faq-general.htm#inc (last visited June 24, 2007) (stating that all states receiving federal funds for the state vaccination program must provide the vaccinations recommended by the Advisory Committee on Immunization Practices).
101 *See id*. (explaining that even though Texas will not mandate the distribution of Gardasil, the state must provide vaccinations for girls eligible to receive them).
102 *See* Texas Dep't State Health Serv., News Release: *Texas Increases Immunizations 11% in National Survey*, Sept. 14, 2006, *available at* http:// www.dshs.state.tx.us/news/releases/20060914.shtm (stating that the entire immunization rate in the state of Texas in 2005 was 76.8 percent, ranking twenty-fourth in efficacy in the United States).
103 *See* Tex. Educ. Code Ann. § 38.001 (2007) (offering only information on HPV vaccinations to parents, and not a free vaccination).
104 *See* Tex. Educ. Code Ann. § 38.001 (2007) (mandating that parents choose the HPV vaccination for their child by requesting it, and not by opting out of an offered vaccine).
105 *See* Geo. Wash. Univ. Sch. Pub. Health and Health Serv. Rapid Public Health Policy Response Project, *HPV Vaccine, Should it be Recommended or Required?* 2, Jan. 2007, http://www.gwumc.edu/sphhs/about/rapidresponse/ download/HPV_Vaccine_Paper_(January_2007).pdf [hereinafter *Recommend or Require?*] (arguing that the HPV vaccine should be required because it would increase the immunization rate, and decrease the rate of HPV contraction and resulting deaths from cervical cancer).
106 *See Meyer*, 262 U.S. at 400 (stating that the natural duty of a parent involves imparting education suitable to the family's station in life); *Yoder*, 406 U.S. at 235 (emphasizing the longevity of Amish religious beliefs and traditions as related to the requirement for a particular type of education); *Pierce*, 268 U.S. at 534 (reiterating the power of the state in regulating all schools, teachers, and pupils in order to ensure nothing taught can endanger the public welfare).
107 *See Meyer*, 262 U.S. at 392 (holding that teaching a language is a fundamental part of child-rearing); *Yoder*, 406 U.S. at 210 (seeing education as an issue of religion central to raising a child); *Pierce*, 268 U.S. at 536 (holding the manner of education as an essential factor for parents to decide).
108 *See* VA. Code Ann. § 32.1-46 (2007)(to become effective on Oct. 1, 2008) (mandating HPV vaccinations, but allowing an exemption for any reason).
109 *Compare* 2007 Va. Code Ann. § 32.1-46 (stating that HPV vaccinations will be required as of Oct. 1, 2008) *with* R.I. Gen. Laws § 16-38-2 (1956) (stating that a child can only be excused from receiving vaccinations for medical or religious reasons), S.C. Code Ann. § 44-29-180 (1976) (mandating that a child can receive special exemption from immunization for 30 days, but thereafter must have either an authorized medical exception certificate or a state certificate of religious exemption), *and* S.D. Codified Laws § 13-28-7.1 (2006) (allowing the schools to exclude from attendance any unvaccinated child without a medical exemption, religious exemption, or a signed statement requesting the local health department to pay for unaffordable vaccinations for the child).
110 *See* Alicia Novak, *The Religious and Philosophical Exemptions to State-Compelled Vaccination: Constitutional and Other Challenges*, 7 U. Pa. J. Const. L. 1101, 1123 (2005) (discussing the need for documentation of valid exemptions and the dangers presented by allowing students to attend public schools when unvaccinated).
111 *See Yoder*, 406 U.S. at 211 (holding that parents have power to determine the religious upbringing of their child); *Pierce*, 268 U.S. at 534-35(allowing parents the freedom to determine how and where their children receive their education); *Meyer*, 262 U.S. at 403 (overturning a state law that violated the parents right to educate their child outside of school by hiring a foreign language teacher).
112 *See* Novak, *supra* note 110, at 1121-22 (discussing the danger in a school or public environment with unvaccinated people as a compelling interest for the state to intervene and erase exemptions).
113 *See* Abbitt v. Lynchberg Div. of Soc. Serv., No. 1202-06-3, 2006 Va. App. LEXIS 484 at *6 (Va. App. Oct. 31, 2006) (holding that a father's parental rights were properly terminated because he failed to keep physicians appointments, among other factors); Welch v. Commonwealth, No. 3152-03-4, 2005 Va. App. LEXIS 264, at *24-*25 (Va. App. July 12, 2005) (deciding that a mother who tried to prove that there was no evidence of premeditation, only negligence as she was unaware of proper medical care for a child failed to show she acted without criminal malice).
114 *See* 2005 Va. App. LEXIS 264, at *20 (arguing neglect rather than premeditation).
115 *See id.* at *25 (holding that there was proof that the defendant acted with criminal malice, but there was no evidence of premeditation).
116 *See* Va. Code Ann. § 32.1-46 (2007) (to become effective on Oct. 1, 2008) (complicating immunization legislation by allowing exemption for any reason).
117 *See id.* (to become effective on Oct. 1, 2008) (noting the changed precedent through the inclusion of the HPV vaccine and specific exemption procedures only applicable to that vaccine).
118 *See Jacobson* 197 U.S. at 23-24 (stating that immunizations only work if everyone is immunized to prevent the resurgence of a disease); *see also* LeFever, *supra* note 90 at 1048 (discussing parents who hide behind the religious exemption to refuse to immunize their children, despite the lack of a real religious belief).
119 *See Jacobson*, 197 U.S. at 34-35 (stating that law requires that everyone be vaccinated in order to prevent a new outbreak in the community).

120 *See* Va. Code Ann. § 32.1-46 (allowing parents to opt-out of an HPV vaccinations without providing a religious or medical affidavit explaining the reason for the exemption).

121 *See, e.g.,* Itz v. Penwick, 493 S.W.2d. 506, 506 (Tex. 1973) (mandating that a father refusing to vaccinate his child for religious reasons must sign an affidavit to those reasons, or a child can rightfully be banned from attending school); State v. Drew, 192 A. 629, 630 (N.H. 1937) (holding that a father could not send his child to school without vaccinating him or providing a valid reason for the lack of vaccination); *City of* New Braunfels v. Waldschmidt, 207 S.W. 303, 304-05 (Tex. 1918) (stating that compulsory immunization does not violate the Constitution, or the Constitution of Texas, and that cities have lawful authority to enact their own immunization schemes); Bissell v. Davison, 32 A. 348, 348-49 (Conn. 1894) (holding that the legislature has the right under the police power to regulate who can attend a public school with regards to immunization and can keep pupils from attending who have not complied with local statute).

122 *See* Immunization Action Coalition, *MMR Vaccine Does Not Cause Autism Examine the Evidence!*, Aug. 2007, http://www.immunize.org/catg.d/p4026.pdf [hereinafter *Does MMR Cause Autism?*] (citing studies for and against the belief that the common and mandatory vaccination for measles, mumps, and rubella causes autism); Andrew Zoltan, *Jacobson Revisited: Mandatory Polio Vaccination as an Unconstitutional Condition*, 13 Geo. Mason L. Rev. 735, 752-58 (2005) (discussing the dangers of vaccinations as well as the constitutional violations and unreasonableness of continued vaccination).

123 *See Does MMR cause Autism?*, *supra* note 122 (citing 10 studies against a correlation between vaccination and autism, and only three supporting such a connection).

124 *See Recommend or Require?, supra* note 105, at 3 (arguing that vaccinations serve a public health service and any decrease in vaccinations would serve to increase infections).

125 *See* Colgrove, *supra* note 83, at 2389 (arguing that even though issues of religion and morality have dominated the discussion on HPV vaccines, the main conversation ought to be about how to protect women against contracting cervical cancer).

126 *See* Hodge, *supra* note 70, at 1 (arguing that vaccinating prior to the beginning of the school year provides the most consistent means of vaccination).

127 *See* Va. Code Ann. § 32.1-46 (encouraging HPV vaccines by saying the vaccinations are required, but also allowing a broad exemption for any reason).

Patient-Physician Relationships in the Military

*Harlye Maya**

The essence of military service "is the subordination of the desires and interests of the individual to the needs of the service."[1]

"While military personnel maintain many of the same rights and burdens as members of the civilian community, there is simply not the same autonomy within the military as there is in the larger civilian community."

I. Introduction

Military law and custom prohibit many acts that most civilians would categorize as normal human behavior under the catch-all justification "for the good order and discipline of the military."[2] Internal orders and the Uniform Code of Military Justice (UCMJ) alike impose restrictions on dress and personal appearance,[3] speech,[4] homosexual activity,[5] and even everyday relationships.[6] While military personnel maintain many of the same rights and burdens as members of the civilian community, there is simply not the same autonomy within the military as there is in the larger civilian community.[7] However, should that fact hold true when it comes to one's medical decisions and the relationships between patients and physicians in the military?

When the law enters the field of bioethics, it provides a rich language for exploring bioethical issues and provides the tools for action and the means for dialogue.[8] As the environment surrounding the meeting of the physician and patient in the military changes, so does the dynamic of the relationship and the parties' options for action. This article begins with an overview of the patient-physician relationship and how it functions in both the civilian and military world. Next, it discusses the military health care system and how members of the military are barred from initiating malpractice suits against the U.S. Government and individual military physicians, and the possible impact this restriction has on the patient-physician relationship. It then discusses how the patient-physician relationship changes due to the varying importance of the stakeholders and interests present under different specific circumstances.

Throughout this article, the phrase "military patient" is used as the generic term applying to a sick, injured, or wounded member of the military who receives medical care or treatment from medically-trained personnel who make medically substantiated decisions based on medical military occupational specialty (MOS) specific training.[9] The term "physician" refers to the medically-trained personnel who administer treatment and make medical decisions based on their medical MOS training.[10]

II. The Patient-Physician Relationship in the Civilian and Military Worlds

A. The Patient-Physician Relationship in the Civilian World

Generally, a few main principles comprise the relationship between physicians and their patients – or patients and their physicians, depending on your perspective. These issues include veracity and disclosure of information, privacy, confidentiality, and fidelity.[11] The first, veracity, is important in a patient-physician relationship because it is a part of the respect physicians owe to their patients. Consent is not informed unless it is based on truthful communication, and it invokes obligations of

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fidelity and promise-keeping, and the trust necessary for successful interaction and cooperation.[12] Veracity is not absolute, however as nondisclosure, deception, and lying will occasionally be justified when veracity conflicts with other obligations.[13]

The second principle, right to privacy, refers to protection against unauthorized access to and reports about a person.[14] The rule of privacy can often conflict with concerns for the safety and welfare of others.[15] For example, physicians are concerned with issues of privacy when an HIV-positive patient refuses to inform family members or lovers of his or her condition.[16] The third principle, confidentiality, is related to privacy in that while patients lose some of their privacy when they grant physicians access to their bodies and personal histories, they maintain some degree of control of the information generated about them through the confidentiality of their physicians.[17] When one person divulges information to another with the implicit promise that the receiver will not reveal that information to any other person, the receiver should respect that implicit promise.[18] The difference between a breach of confidentiality and a breach of privacy in the medical setting is that an infringement of confidentiality occurs when a physician with the duty to protect information fails to protect that information or deliberately discloses it without the consent of the patient.[19] A breach of privacy, on the other hand, would occur if someone merely broke into the hospital and stole the information.[20]

Lastly, rules of fidelity or promise-keeping are rooted in respect for autonomy, and provide a strong warrant for an individual's obligation to keep promises.[21] Upon making a promise, one creates an expectation on the part of others who then rely on the promise and have a valid claim to its being kept.[22] Promises, such as the promise to think of the patient's welfare and the related promise that the physician will not abandon the patient, are important to the patient-physician relationship.[23]

There is another extremely important aspect of the civilian patient-physician relationship: the tort. One of the law's oldest aims is to resolve disputes. American law fulfills this aim partly through the law of torts, settling the dispute between the injurer and the victim and restoring the victim to his or her prior well-being.[24] Building on tort doctrines, courts have developed the principle of informed consent, which serves three bioethical goals: (1) to help resolve disputes over injuries caused by a doctor's failure to inform a patient adequately; (2) to recompense – however crudely – the injured patient; and (3) – more ambitiously – to improve the way doctors treat patients.[25] Tort law's loftiest goal in the medical realm should be to improve the way doctors treat their patients.[26] The possible consequences for neglectful or reckless acts give doctors an incentive to provide patients with the best care possible.

B. Military-Specific Challenges of Patients and Physicians

Even in the civilian world there is an inherent imbalance of power between the patient and the physician. Within the military, unique pressures only accentuate this imbalance of power, as the military is a hierarchical organization and its operation is based on the presumption of obedience.[27] Because of this, both military physicians and patients face challenges different from their civilian counterparts.

i. Military Patients

The discipline and "order-centric" nature of the military inherently reduces a military patient's autonomy in comparison to a civilian patient's autonomy. Like the physician, a military patient must answer to the military command which has its own set of expectations for the cooperation of the soldiers on medical matters. A soldier on active duty will usually be required to accept medical care considered necessary to protect his own life or the life of those around him.[28] Additionally, unlike their patient counterparts in a civilian setting, patients in a military setting may suffer from numerous psychological illnesses, which can occur from the stresses of combat or from the guilt associated with a medical evacuation from the combat zone.[29] There is also a pre-existing reduced state of autonomy when it comes to medical decisions involving vaccinations, as the President of the United States may mandate vaccinations despite the patient's refusal.[30] The level with which the command and nation's interests come before that of the patient varies depending on the stage of military life.

ii. Military Physicians

The Manual for Courts-Martial defines the term "medical officer" as "an officer of the Medical Corps of the Army, an officer of the Medical Corps of the Navy, or an officer in the Air Force designated as a medical officer."[31] Health care professionals serving in the military play a variety of roles, including, for example, pathologists, primary care physicians and nurses, battlefield clinicians, and advisors to interrogators.[32] However, what separates military from civilian physicians is that once he or she is a member of a military branch, the physician is subject to the same chains of command, rules, restrictions, and bodies of law as all other members of the military, including criminal consequences for failing to follow orders.[33] These competing interests give rise to the issue of "dual loyalty," which transpires when the physician feels

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caught between the obligation to help another human being under his or her care and a demand (formal or informal, explicit or implicit) to act on behalf of some other entity.[34] This dual loyalty conflict between the practice of medicine, the interests of the patient, and pressures from the military and command produces the majority of biomedical issues and highlights the inherent conflict between patients and their doctors throughout different stages of one's military career.[35]

iii. Military Patient-Physician Interaction

Many challenges of the military patient-physician relationship present themselves differently as the military setting around the meeting of the patient and physician change. For example, on one hand, the military patient may not be as eager for the physician to release him as a civilian would be if it meant a swift return to the battlefield. On the other hand, a patient may be more inclined to lie about symptoms and pains if he is eager to perform his duties and wants to return to the battlefield. Depending on which interests the patient holds highest – either his own interests or those of the patient's unit, mission, or nation – the patient may make medical decisions and requests that a civilian in the same situation would not make. These include decisions such as requesting release to return to battle before medically-ready or asking to remain in the hospital after fully healing to avoid the same result. In turn, the issues put pressure on the military physician that he would not face in the civilian world. It is not likely that a determination of whether to release a patient or not has such drastic consequences on the lay patient in a civilian hospital. Outside of certain medical conditions that require extra attention from the doctor after the patient leaves, the possibly extreme character of the location of the release has an impact on both the military patient and the military physician in their relationship and decision-making.

> "Patients in the military are bound to follow orders, and certain federal provisions make it lawful to put the needs of the nation before those of the patient."

C. Bioethical Issues

In the study of bioethics there are a few recurring terms and, arguably, four main principles: Autonomy, beneficence, nonmaleficence, and justice.[36] Autonomy is the principle usually assigned to the patient, indicating that independent actions and choices of the individual should not be constrained by others.[37] To act autonomously, the patient must act intentionally, with understanding, and independently of controlling influences.[38] Autonomy is the foundation for rules relating to disclosure of information on the side of the physician, and consent on the side of the patient.[39] Paternalism on the part of the physician is in constant conflict with the autonomy of the patient, and may include actions such as withholding information from the patient or going forward with a procedure despite the wishes of the patient if the doctor believes it is in the patient's "best interest." Informed consent is important to the promotion of autonomy in medical decision-making,[40] and requires the doctor to disclose material information to the patient such as risks, discomforts, benefits, side effects, alternatives, risks if left untreated, and personal interests unrelated to the patient's health prior to treatment.[41] Additional–and equally important –concepts are the related non-maleficence and beneficence. Non-maleficence is the principle that one has a duty not to inflict evil, harm, or risk of harm on others while beneficence is the principle that one has a duty to help others by doing what is best for them.[42]

D. Stakeholders and Competing Interest

Those who exercise command authority over military personnel have an obligation to protect the rights, dignity, and autonomy of their subordinates to the greatest extent possible without jeopardizing the military mission or the welfare of military personnel as a whole.[43] That said, in addition to conflicting bioethical principles, a physician in the military will confront the simultaneously competing interests of multiple stakeholders throughout his career. First, the physician has a duty to the patient. Depending on the circumstances that bring the soldier into contact with the physician, the physician may experience varying relationships with the soldier. These can range from peace time to on the battlefield, and even in the courtroom.[44] Additionally, not only does the military physician see the soldier as his patient, but also as his or her fellow soldier. Second, the physician has an obligation to the medical community's general standards and practices. Despite the military physician's – at times – special circumstances, the medical community has standards and practices that it does not feel are ever appropriate to compromise.[45] Third, the physician has a duty to the military command and superior officers. Command is the authority that a commander exercises over his subordinates by virtue of his rank or assignment.[46] One cannot become a military doctor unless he or she is in the military and accepts the obligations that come with it. This subjects the physician to the same rules and laws as any other soldier; physicians face the same consequences for failing to follow orders. Fourth, the physician has a responsibility for society, as a whole, and the state's dependence on the proper functioning of the military for safety and order. Because of the special nature of the military and the importance of maintaining good order, the military has its rules, regulations, and disciplines to provide for a proper defense of the nation. By joining the military, the doctor makes a promise to put the needs of the command and society before his or her own.[47]

From the patient's point of view, his or her autonomy is already compromised for the sake of the armed forces and national security. For example, "the [Department of Defense], through administrative,[48] legislative,[49] and executive[50] action obtained its own exception to the consent requirement, which has been upheld despite constitutional challenge."[51] Under civilian standards, consent to a drug or treatment is of the utmost importance. A person of adult years of sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment.[52] Patients in the military are bound to follow orders, and certain federal provisions make it lawful to put the needs of the nation before those of the patient.

III. Health Care in the Military

A major selling point for the military is its well-known and highly regarded health care system.[53] Congress took steps to create and maintain high morale in the uniformed services by providing an improved and uniform program of medical and dental care for members and certain former members of those services and their dependants.[54] The health care program serving active duty service members, retirees, their families, survivors, and certain former spouses is called TRICARE.[55] On its website, the TRICARE program states that it "brings together the health care resources of the uniformed services and supplements them with networks of civilian health care professionals, institutions, pharmacies, and suppliers to provide access to high-quality health care services while maintaining the capability to support military operations."[56] The program covers a wide range of services, including medical, dental, vision, mental health and behavior, and life events[57] using both military and civilian physicians.

A. Malpractice Suits Generally

As previously mentioned, the law of torts is an important aspect of resolving disputes which stem from claims of medical malpractice and negligence between patients and their physicians.[58] The medical malpractice system has two primary goals: to compensate injured patients, and to deter physicians from careless behavior.[59] Allowing patients to seek redress for the negligence of their physicians has forced changes in the attitudes and behaviors of physicians, and led them to become more accommodating to the needs of their patients. Knowing that their actions could produce a liability has even led some hospitals to manage risk by setting policies.[60] Furthermore, while in traditional negligence cases, the duty not to act negligently applies among all persons regardless of their relationship to one another, the idea behind medical malpractice liability is that by undertaking the voluntary role of physician, the doctor creates a special relationship between him or herself and the patient.[61] In the medical profession, the relevant standard of care is objective and looks to whether the practice conforms to the standard of care practiced by another member of the medical profession.[62]

B. Relief Barred Against the United States: The *Feres* Doctrine

Military doctors are different from most civilian doctors in that they are not private individuals but employees of the federal government. In fact, perhaps no relation between the government and a citizen is more distinctively federal in character than that between the government and members of its armed forces.[63] While the Federal Tort Claims Act mandates that the government shall be liable to the same extent as a private individual under similar circumstances,[64] the statute also makes certain exceptions that take away this privilege from members of the armed forces. The Supreme Court in *Feres v. United States* held that the U.S. Government is not liable under the Federal Tort Claims Act for injuries to servicemen where the injuries arise out of or in the course of activity incident to service.[65] This means that a soldier has no means for redress from the negligence of his or her military physician if the injury arises from activity incident to service.[66] In *Feres*, the Court held that the service members fail the test for applicable claims against the government because: (1) the plaintiffs could not point to the liability of a "private individual" even remotely analogous to their claims; and (2) there is no liability "under like circumstances."[67] The Court's analysis for the first reason said there was no analogous private individual because the Court "knew of no American law which ever has ever [sic] permitted a soldier to recover for negligence against either his superior officers or the Government he is serving."[68] As for the second reason, the Court said that there are no like circumstances because "no private individual has the power to conscript or mobilize a private army with such authorities as the Government vests in echelons of command."[69] It is important to note that in the *Feres* opinion, the Court did not mention the patient-physician relationship or the standard for a medical breech, two factors typically discussed in medical malpractice cases in civilian realm.

A key aspect under the *Feres* doctrine is that the outcome of the case varies according to the status of the member of the military at the time of the alleged injury. For example, in *Madsen v. U.S. ex rel. U.S. Army, Corps of Eng'rs*,[70] the plaintiff was a Captain in the regular Air Force who was on terminal leave expecting to retire in a month.[71] He sustained injuries in a motorcycle accident and sued the United States for the negligent acts of Army medical personnel.[72] The suit was barred under the *Feres* doctrine because the court concluded that the treatment was incident to military service and that the plaintiff was on active duty status.[73] The court looked to the fact that during his terminal leave and while on medical hold status, the plaintiff was, in fact, on active duty status because he received active duty pay, accrued annual leave, and accumulated credit for active duty time later used in computing his military retirement pay.[74] It did not matter that the plaintiff was on terminal leave because, like other forms of military leave, it could have been cancelled at any time and the service member could have been ordered to return to duty.[75] Correspondingly, the active duty service member under medical care remains subject to the orders of the hospital commander and the Uniform Code of Military Justice.[76] These are some of the factors considered by courts when determining the status of the plaintiff and whether a negligence suit should be barred under the *Feres* doctrine.

In *United States v. Johnson*, the Supreme Court upheld the *Feres* doctrine and articulated three of the doctrine's underlying factors:[77]

> First, the relationship between the Government and members of its Armed Forces is 'distinctively federal in character'; it would make little sense to have the Government's liability to members of the Armed Services dependent on the fortuity of where the soldier happened to be stationed at the time of the injury. Second, the Veterans' Benefits Act establishes, as a substitute for tort liability, a statutory 'no fault' compensation scheme which provides generous pensions to injured servicemen, without regard to any negligence attributable to the Government.[78]

Of note is the third factor, "the peculiar and special relationship of the soldier to his superiors, the effects of the maintenance of such suits on discipline, and the extreme results that might obtain if suits under the Tort Claims Act were allowed for negligent orders given or negligent acts committed in the course of military duty . . . ."[79] The third factor carries the most weight, as the Supreme Court specifically stated that the first two rationales are "no longer controlling."[80] This makes the strongest justification for the *Feres* doctrine consistent with the UCMJ's rational for many of its laws – "for the good order and discipline of the military."[81]

Congress and the military made their priorities clear by barring medical malpractice suits for the good order and discipline of the military. Essentially, the military holds barring suits on superior officers and good order and discipline above the two main reasons for allowing medical malpractice suits: redress for victims and maintaining proper standards for medical personnel. If one looks at the two rationales side by side, they do seem to conflict. On one hand, if the military wants efficient military functioning, it cannot allow soldiers to question, second guess, and bring suit against superior officers. On the other hand, if society wants the medical community to maintain the utmost standards of medical practice possible and provide redress for those who are injured, it must allow patients to sue for negligence. Faced with these two rationales for and against malpractice suits, the Court in *Feres* chose the option that ensured the good order and discipline of the military.

C. Relief Barred Against the Individual Military Doctor Under 10 U.S.C. § 1089

In case there were any questions left regarding whether a member of the military could collect a remedy alleging medical malpractice, in 1976 Congress enacted 10 U.S.C. § 1089(a). The Act's purpose is to fully protect medical personnel from any potential personal financial liability that might arise from the performance of official medical duties.[82] Its effect is to provide complete immunity for individual military doctors, even where it leaves servicemen without remedy.[83] It protects against suits for personal injuries, including death caused by a negligent or wrongful act or omission, and protects the following persons: physicians, dentists, nurses, pharmacists, and paramedical or other supporting personnel, including medical and dental technicians, nursing assistants, and therapists if they are in the armed forces, National Guard (under specified times), the DOD, the Armed Forces Retirement Home, or the Central Intelligence Agency.[84]

The plaintiff in *Howell v. United States*, outlined the "Catch-22" situation in how 10 U.S.C. § 1089, when combined with the *Feres* doctrine, left her without the possibility of a remedy.[85] She made this argument on the basis that 10 U.S.C. § 1089 makes the Federal Tort Claims Act action against the United States the exclusive remedy for negligence of military medical personnel, yet *Feres* bars suits by servicemen against the United States.[86] While she argued that this contraction indicated Congress could not have intended such a result and urged for an alternate interpretation of 10 U.S.C. § 1089, the court ruled that the interpretation she sought was not persuasive when viewed in light of the case law developed prior to the enactment of the statute.[87] Furthermore, aside from wanting to maintain the good order and discipline of the military by preventing military personnel from suing for medical malpractice, there was also a more practical reason why Congress enacted 10 U.S.C. § 1089, which was to eliminate the need for personal malpractice insurance for all government medical personnel.[88]

IV. The Fluctuating Patient-Physician Relationship

A. Peacetime

Peacetime is when the nation is not at war[89] and the soldier and physicians have no notice of an impeding deployment. Times of peace are the instances when a military patient-physician relationship most closely mimics that of the patient-physician relationship in the civilian world. While the military physician still has duties to the command and nation, those interests are lower than what they might be during a time of war which, in turn, means peacetime indicates the heightened interests and autonomy of the patient. Some of the situations that may cause a military physician to compromise principles for the good of the nation, such as confidentiality or privacy in disclosing medical information to superiors, are not present, and forced vaccinations or treatment are not as necessary as they might be if a soldier were preparing for war. The environment is more stable and the soldier likely goes to the medical officer on the base or near vicinity to where he or she is stationed. While the nature of the military requires military personnel to travel and move often, during peacetime it is possible for the patient and the physician to maintain a relationship that extends beyond a passing check-up, and it is more likely that they can build a long-lasting, trusting relationship.

The *Feres* doctrine and 10 U.S.C. § 1089 still bar medical malpractice suits for soldiers, even during peacetime, so long as the soldier is acting in the course of duty. However, the lack of a hectic situation may reduce the need for such suits in the peacetime environment. During peacetime there are less immediate needs, fewer

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battlefield injuries, and fewer excuses for proceeding with treatment without informed consent or for acting with negligence. Yet, these same reduced stressors may also be the reason that lifting the bar on malpractice suits may be more appropriate at this stage. The lack of hectic situation, the reduced interests of the command and nation, and the raised autonomy of the military patient make it less necessary to hold the physicians to a different standard than their civilian counterparts. It is more reasonable that a military physician working in a hospital, while still subject to chains of command and orders, could be held to the same objective standard of care to which civilian doctors are held. Granted, allowing malpractice suits in this peacetime setting could result in a snowball effect of suits. Even in peacetime, it is not in the nation's best interests to allow soldiers to sue superiors because of orders. However, it is worth considering that many of the factors that justify overriding a military patient's autonomy in a battlefield or pre-deployment stage are not present during peacetime, so a suit may be more justified. While these reasons to lift the bar make sense in the civilian world because of the goals of malpractice law (i.e. redress and upholding proper medical standards), it still would not override the interests of the military and the rationale behind the *Feres* doctrine and 10 U.S.C. § 1089's enactment – avoiding suits against superiors for negligent orders.

B. Pre-Deployment

The pre-deployment setting lasts from when the soldier is alerted that he or she will deploy to the date of deployment. As a nation moves closer to war, the interests of the command and nation begin to rise and, as a result, the interests of individuals fall. One example of this is the Military Selective Service Act,[90] which signs certain qualified individuals up for military service and possibly war whether or not they consent; it is the means by which the United States administers military conscription. These actions on the part of the government are constitutional,[91] and the government sees service in the Army as duty owed to the state.[92] At these times a soldier can undergo treatment he or she does not desire, be given vaccinations he or she does not consent to, or receive unapproved drugs that he or she did not know about nor give consent to receive. The ever-conflicting paternalism of the military physician rises and the autonomy of the soldier-patient falls.

Informed consent for vaccinations and treatments is one clear principle of autonomy that the government will compromise to achieve military success. For example, prior to commencing Operation Desert Storm, the combat phase of the Persian Gulf War, the DOD sought and obtained a one-time waiver of informed consent requirements, known as Rule 23(d), to permit the use of investigational drugs and vaccines on American Forces serving in the Persian Gulf.[93] In persuading the Food and Drug Administration (FDA) to waive their requirements on the use of investigational agents without obtaining consent from the soldiers, the DOD argued that obtaining soldiers' informed consent was "not feasible" in the exigencies of war."[94] By following the orders of the command and administering these vaccinations without the informed consent of the soldiers, the physicians showed increased paternalism, and the military patients were subject to decreased autonomy.

Additionally, it is arguable whether the physicians were upholding or contradicting the important principles of beneficence and nonmaleficence. On one hand, if the vaccination saved a soldier's life, then the physician may feel that he acted for the good of the patient while simultaneously feeling that he harmed the patient by administering the vaccine without the soldier's consent. This is likely in contradiction with the Hippocratic Oath, which every doctor must take, and is another pressure exerted onto the military physician. If the situation arose where the patient was demanding that the physician not administer the vaccine, but the physician received orders to administer the vaccine – adding in the fact that it is a lawful order due to the waiver obtained by the DOD – the physician would likely have to administer the vaccine. This would tarnish the autonomy of the soldier and, depending on how much the military authorized the physician to reveal about the vaccination, it may diminish the truth and veracity principles for the physician.

In the civilian world, if a doctor performs a surgery without the informed consent of a patient, it is considered an assault, an unlawful touching, and the patient would be able to seek redress through the court system. In the military setting, however, there are two issues that run contrary to the interests of the patient. First, it is not always unlawful for a military physician to administer treatment to a patient without his or her informed consent as seen through the directives, orders, and statutes enacted by Congress and the Executive Branch. The military allows and sometimes orders its physicians to administer vaccines, treatments, and experimental drugs without the informed consent of the patient or any consent at all from the soldier-patient under certain narrow circumstances, in effect making it a lawful touching. In the pre-deployment stage, many of the environmental factors discussed in the next section about the battlefield are not present, decreasing the military necessity for such actions. However, since the interests of the military and society are still in heightened state and because the soldier is likely deploying to a battlefield environment, the command

> The knowledge that a doctor is safe from a tort action may further make it easier for him to administer non-censual treatment or vaccinations, which further keeps the physician and patient from achieving a well-balanced relationship.

could still argue that it was militarily necessary to administer the compulsory treatment.

Second, even if the touching was considered unlawful, the military patient would still be barred from bringing suit because of the *Feres* doctrine and 10 U.S.C § 1089. While the soldier is in a pre-deployment position there is little room to argue that the soldier is not on active duty or acting within the course of military duty while receiving compulsory treatment. Therefore, the courts and Congress have effectively barred all personal injury suits in order to maintain the discipline the military so heavily relies upon to achieve the success of the mission. The knowledge that a doctor is safe from a tort action may further make it easier for him to administer non-censual treatment or vaccinations, which further keeps the physician and patient from achieving a well-balanced relationship.

C. Battlefield

On the battlefield, it is common for the greatest medical ethical dilemmas to arise.

Indeed, it is impossible to imagine a more challenging environment in which to practice medicine than on a battlefield. It is the antithesis of the ideal medical setting. It is violent. It is noisy. It is chaotic. It is in a constant flux. And it is unpredictable. Lack of creature comforts is the least of the problems faced. Noise levels prevent normal aspects of patient care. Rapid movement, often on little or no advanced notice, requires treatment facilities to be set up and taken down very quickly. Patients can arrive before preparations are completed. Medical personnel, as well as patients, suffer from the fatigue and filth. [95]

In addition to the challenging physical environment surrounding physicians and patients, the physician has the legal obligation to place the interests of society (and the military mission of protecting and defending that society) above those of the military patient.[96] In situations of military necessity, such as on a battlefield, military physicians must give absolute priority to military needs, and therefore, will also give priority to protecting and defending society when not doing so would greatly sacrifice society's interests.[97] In fact, the Secretary of the Army may direct the medical care of any individual on active duty and may determine that the needs of the Army are so significant that they must override those of the soldier-patient.[98] At this point, it is likely that the strength of the autonomy of the patient is at its lowest and the paternalism of the physician is at its highest. This reduction in patient autonomy is in direct correlation to the heightened interests of the command and society during this time of war.

> "Oftentimes, due to the extreme nature of the battlefield setting and the injuries brought to the attention of the military physician, the physician may make risky decisions to help save the soldier's life without his or her first thought turning towards the military mission or society as a whole."

On the battlefield, the military physician faces issues such as battlefield triage,[99] limited supplies, injured enemies, questions of whether to administer euthanasia, and return-to-duty considerations.[100] For almost all of these issues, the doctor must make decisions with the interests of the military command and society in mind first, and the individual soldier second. This is not to say that the physician is not without any guidance. On the battlefield, the physician applies the following rules, listed in order of precedence, when priorities are in conflict: (1) maintain medical presence with the solider; (2) maintain the health of the command; (3) save lives; (4) clear the battlefield; (5) provide state-of-the-art care; and (6) return soldiers to duty as soon as possible.[101] Military physicians have the duty to be as concerned with the success of the military mission as they are with their patients, and although returning soldiers to duty as soon as possible is the lowest priority, there are likely times when national interest may allow the military to require soldiers to undergo life-saving or other medical care to return to the front lines.

It does not always follow that it will hurt the military patient if the military physicians obey their orders. Oftentimes, due to the extreme nature of the battlefield setting and the injuries brought to the attention of the military physician, the physician may make risky decisions to help save the soldier's life without his or her first thought turning towards the military mission or society as a whole. For example, in Iraq, Army surgeons have become aggressive users of a controversial drug called Factor VII, which promotes clotting in cases of severe bleeding.[102] Like in the pre-deployment stage where soldiers may have to take vaccines that the FDA has not yet approved, Factor VII is still in a trial stage.[103] However, the urgency of saving a soldier's life in Iraq takes priority over possible ethical conflicts.[104] Furthermore, to improve the trauma care which is a leading cause of death in war zones and is the third leading cause of death in the Untied States,[105] top trauma surgeons strongly advocate conducting clinical trials to improve trauma.[106] These trials can be ethically tricky "because trauma research can involve trying novel treatments on severely injured patients who cannot give informed consent."[107] However, the dire situation in which many of the physicians find themselves often justifies the use of risky, potentially life-saving treatment.

Military physicians in a battlefield setting can also go the opposite route with their paternalism and send soldiers home using medical reasons as an excuse if they feel that they can save a soldier's life by getting him or her out of harm's way. This is most common with combat stress disorder and was often experienced during the latter stages of Vietnam.[108] A physician's willingness to

send soldiers home early could result in the physician diagnosing a soldier with a more serious psychological disorder, and further leave the soldier with a sense of guilt for leaving his comrades because of the questionable diagnosis.[109] Furthermore, knowing of the existence of this less-than-truthful option may leave the physician with a sense of guilt if he chooses not to exercise that option.

The battlefield stage is also where the *Feres* doctrine and 10 U.S.C. § 1089 likely affect the patient-physician relationship most. Due to the loud and hectic nature of the administration of medical care on the battlefield and in clinics near the front lines, there is already a compromised relationship between the military patient and the physician. It is possible to see how an injured military patient would desperately look to the physician to save his life or ease his pain with any means available. However, without the time and opportunity to become familiar with one another, it is more likely that the physician will also have to make snap decisions without consulting as carefully with the military patient or the medical community as would be expected in the civilian world. As a result, issues such as the administration of treatment with less than perfect trial results, without informed consent, or with a reduced standard of care could occur more easily. Congress has already barred the ability of soldiers to seek redress from the government and individual health care administrators for medical malpractice for the good-order and discipline of the military. It has also made clear that if a physician has orders to act a certain way in certain situations that may impede the autonomy of the military patient, he or she must do so to avoid violating orders and may do so without the fear of a medical malpractice suit.

At the same time, in this setting, the *Feres* doctrine and 10 U.S.C. § 1089 restrictions may make the most sense from the physician's standpoint. After all, it seems unfair to hold the same objective standard of care to military physicians with conflicting orders in a hectic, dangerous, and often dirty battlefield environment as is held to civilian doctors in hospitals and office buildings. In this situation, it may be more appropriate to hold the doctors to a "reasonable-under-the-circumstances" standard. It is also in this situation when it is the most important for military personnel, both soldiers and physicians, to follow orders immediately and without question. Therefore, it is more likely that a physician on the battlefield will need to follow standing orders to perform a certain operation or administer a certain drug without receiving the informed consent of the military patient. Here, the physician should feel the most secure that her actions are for the good of society and the command, and further, that she does not have to face a possible malpractice suit in the future. The thought that following an order under these circumstances may eventually cause the physician to face a malpractice suit would likely dampen the resolve of the physician to follow that order and may compromise the success of the mission. This would produce negative consequences for the physician, the command, and society.

D. Post-Deployment

The fourth setting is in a post-deployment stage, which is arguably very similar to the peacetime setting in terms of the levels of autonomy and the importance of the interests of varying stakeholders. In comparison to the battlefield setting, in post-deployment, there is likely an increased level of autonomy of the military patient due to the diminished immediate concerns of the command and nation. There is also a reduced opportunity for paternalism on the part of the doctor as compared to the battlefield because the post-deployment setting lacks the immediate and stressful nature that was present on the battlefield. Unless the physician is working in an emergency room setting, many of the hectic theater-of-war elements are not present. For instance, the physician does not have to make immediate decisions regarding whether the soldier can and should return to the front lines.[110] There is more time to sit and discuss options with the military patient, and at this stage, the doctor has the opportunity to listen more closely to the needs and desires of the soldier who has just returned from the battlefield. There are many resources available to post-deployed soldiers, and the military and medical communities are sensitive to the issues that a returned soldier may face.[111]

In this stage, however, there are also additional needs and concerns that are not present in the previous settings because the soldier has just returned from a high stress and dangerous situation. There is a substantial possibility that the soldier is dealing with injuries in this quiet and not-urgent setting – both physical and mental injuries – that the physician did not have to deal with in the previous stages except when on the battlefield.[112] One example is post-traumatic stress disorder (PTSD) that, by definition, occurs after a stressful event. PTSD is a unique diagnosis in that use of the term requires determination of an external gatekeeping condition: exposure to an event through "direct encounter or witness that involves actual or threatened death or serious injury combined with a response involving intense fear, helplessness, or horror."[113] At this stage, the relationship between the patient and his physician would likely depend on trust, veracity, privacy, and open communication.

There is also the possibility of the issue arising that the soldier returns from the front lines to be treated by a physician who had never deployed. In this case, a soldier may not have the same trust in the physician that he might have if the physician had been at battle and experienced the same stresses and injuries as the military patient. It is possible that the military patient feels he has more answers and experience than the physician, which may make it more difficult for the soldier to accept the advice of the physician, resulting in a conflict in their relationship. This is especially likely in the cases of PTSD where the soldier may feel more comfortable with the person administering his mental health plan if he or she has experienced the same issues that the military patient is currently feeling.[114]

It is in this post-deployment stage that the most mental harm could result from a barred medical malpractice suit. After all, if a physician is negligent in the treatment of an injured military patient who just returned from a battlefield, the resulting injury may compound the stresses already experienced by the military patient. She may feel that she did her part by following orders, doing her job, and returning safely from enemy lines. It would likely be mentally devastating for a soldier to have an injury with no chance of recovery occur due to the negligence of her physician once she made a safe return. In post-deployment, the soldier, in most cases, remains on active duty, so the same concerns and desires for good order and discipline still override the needs of the individual soldier and enforcement of medical standards when in reference to the *Feres* doctrine and 10 U.S.C. § 1089's bar against medical malpractice suit.

In this stage, the physician should take the care and time to understand the difficulties experienced by the military patient. There is a high chance

that the soldier just returned from the hectic situation described in the "battlefield" section where her autonomy was at its lowest ebb. While it is in the nature of the military for personnel to rotate duty stations every so often, physicians and patients in this stage should do everything in their power to maintain a stable atmosphere, as post-deployment is likely a "healing" stage which requires consistency. In the post-deployment phase it is important for the physician to understand the desires and concerns of the patient to best meet those needs and develop a trusting and truthful relationship.

V. Conclusion

This article outlines the bioethical issues facing the patients-physician relationship in the military. Both parties have challenges and pressures that are foreign to those in the civilian world. While military physicians must be as equally qualified to practice medicine as their civilian counterparts, they are subject to different standards and have loyalties not only to the patient, but also to the military command, society, and the medical community. Military physicians should be cognizant of the fact that military patients' level of autonomy rises and falls depending on the state of the military and nation, and adjust his or her treatment behavior accordingly. In the cases where the interests of the military override the wishes of the individual soldier, the physician should do everything in his or her power to, at the minimum, fully explain the treatment the soldier is about to receive. Barring the ability of members of the military to collect damages from instances of medical malpractice lowers the autonomy of the military patient even further, and could possibly compromise the patient-physician relationship. While the brunt of the responsibility falls on the physician to ensure the welfare of the patient, the military physician is not the only party here that should take extra precautions. Military patients should remember that, while limited at times, they still have a say in their medical future. It should be the goal of both the military patient and physician to discuss issues of autonomy, paternalism, and conflicting loyalties, and to promote an open dialogue about these sensitive issues.

1 Orloff v. Willoughby, 345 U.S. 83, 92 (1953).
2 10 U.S.C. § 934. The Uniform Code of Military Justice (UCMJ) Art. 134. ("Though not specifically mentioned in this chapter, all disorders and neglects to the prejudice of good order and discipline in the armed forces... shall be punished at the discretion of that court.").
3 *See, e.g.*, U.S. Dep't Of Army, Reg 670-1, Wear And Appearance Of Army Uniforms (3 Feb. 2005); U.S. Dep't Of Navy, Uniform Regs. (Jan. 2005); U.S. Dep't Of Air Force, Force, Instr. 36-2903, Dress and Personal Appearance Of Air Force Personnel (2 Aug. 2006); U.S. Marine Corps, Order P1020.34G, Marine Corps Uniform Regs. (31 Mar. 2003).
4 *See, e.g.*, 10 U.S.C. § 888, UCMJ Art. 88 (prohibiting contempt towards officials); 10 U.S.C. § 889, UCMJ Art. 89 (prohibiting disrespect towards a superior commissioned officer).
5 10 U.S.C. § 654; *see* Able v. United States, 155 F.3d 628, 636 (2d Cir. 1998) (reversing the district court and holding that 10 U.S.C. § 654, the prohibition on servicemen engaging in homosexual conduct, does not violate the Equal Protection Clause of the United States Constitution).
6 10 U.S.C. § 943, UCMJ Art. 143 (prohibiting fraternization).
7 *See* Parker v. Levy, 417 U.S. 733, 751 (1974) (upholding a service member's conviction for making public statements criticizing the Vietnam War and Special Forces personnel, and for refusing to train Special Forces aide men).
8 Carl Schneider, *Bioethics in the Language of the Law*, 24(4) Hastings Center Rep. 16 (1994).
9 Field Manual 8-55, Planning for Health Service Support (U.S. Dep't of the Army 1994).
10 *See id.* (using a variation of the same definition that defined 'patient').
11 Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 307 (3rd ed. 1989).
12 *Id.* at 308.
13 *Id.* at 309.
14 *Id.* at 321.
15 *Id.* at 317.
16 *Id.*
17 Beauchamp, *supra at 11,* at 329*; see* Trammel v. United States, 445 U.S. 40, 51 (1980), (stating that the. The physician and patient privilege is rooted in the imperative need for confidence and trust, and that the physician must know all that a patient can articulate in order to identify and to treat disease because barriers to full disclosure would impair diagnosis and treatment).
18 Barry R. Furrow, Thomas L. Greaney, Sandra H. Johnson, Timothy S. Jost & Robert L. Schwartz, Bioethics: Health Care Law and Ethics 4 (5th ed. 2004).
19 Beauchamp, *supra* note 11, at 329.
20 *Id.* at 329.
21 *Id.* at 341.
22 *See* Henry Sidgwick, The Methods of Ethics 304, (7th ed. 1907) ("The essential element of the Duty of Good Faith seems to be not conformity to my own statement [i.e. veracity], but to expectations that I have intentionally raised in others.").
23 Code of Medical Ethics §§ 8.11-8.115 (Am. Med. Ass'n Council on Ethical and Judicial Affairs 2001) ("Once having undertaken a case, the physician should not neglect the patient, nor withdraw from the case without giving notice to the patient, the relatives, or responsible friends sufficiently long in advance of withdrawal to permit another medical attendant to be secured.").
24 Schneider, *supra* note 8, at 16-22.
25 Schneider, *supra* note 8, at 16-22.
26 *See, e.g.*, Beauchamp, *supra* note 11, at 311 (stating that an increased level of disclosure is another example of improvement, and one documented reason for an increase in the level of disclosure to cancer patients is fear of malpractice suits).
27 Thomas E. Beam, & Edmund G. Howe, *A Proposed Ethic for Military Medicine*, 2 Military Med. Ethics 851, 854 (2003) [hereinafter *A Proposed Ethic*].
28 Army Regulation 600-20, Army Command Policy § 5-4(a) (U.S. Dep't of the Army 2006) ("A Soldier on active duty or active duty for training will usually be required to submit to medical care considered necessary to preserve his or her life, alleviate undue suffering, or protect or maintain the health of others.").
29 Field Manual 8-55, Planning for Health Service Support (U.S. Dep't of the Army 1994) (stating that combat stress behavior is the generic term which covers the full range of behaviors in combat, from highly positive to totally negative.).
30 Army Regulation 40-562, Immunizations and Chemoprophylaxis § 8-3 (U.S. Dep't of the Army 2006) ("The FDA may decide that potential recipients of a drug under a[n Emergency Use Authorization] should have the option to refuse it. The President may waive this option for military personnel.").
31 R.C.M. 103(20) (2005 ed.)
32 Mildred Solomon, *Healthcare Professionals and Dual Loyalty: Technical Proficiency is Not Enough*, Medscape General Medicine (2005), http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1681654.
33 10 U.S.C. § 890, UCMJ Art. 90 (prohibiting willful disobedience).
34 Solomon, *supra* note 32.
35 *See* Peter A. Clark, *Medical Ethics at Guantanamo Bay and Abu Ghraib: The Problem of Dual Loyalty*, 34 J.L. Med. & Ethics 570, 571 (2006). ("Military medical personnel, especially in a time of war, are faced with the most ethically difficult dual loyalty of doing what is in the best interest of their patient and doing what is in the best interest of their government and fellow soldiers.").
36 Avraham Steinberg, *The Foundations and the Development of Modern Medical Ethics*, 12 J. Assisted Reproduction & Genetics 473 (1995).
37 Furrow, *supra* note 18, at 4.
38 Beauchamp, *supra* note 11, at 69.
39 Beauchamp, *supra* note 11, at 308.

40 Alan Meisel & Mark Kuczewski, *Legal and Ethical Myths About Informed Consent*, 156 Arch. Internal Med. 2521, 2521 (1996).
41 *See* Moore v. Regents of Univ. of Cal., 51 Cal. 3d 120, 129 (1990) (holding that in soliciting the patient's consent, the research physician had the obligation to reveal to the patient his financial interests in materials harvested from the patient).
42 *Moore*, 51 Cal. 3d at 129.
43 Michael E. Frisina, *Medical Ethics in Military Biomedical Research*, 2 Military Med. Ethics 533, 551 (2003) [hereinafter *Military Biomedical Research*].
44 *See* Stephen A. Saltzburg, Mil. R.Evid. Manual § 313.04 (2003) (quoting Analysis, Mil. R. Evid. 313(b)) ("Compulsory urinalysis, whether random or not, made for appropriate medical purposes, *see* Rule 312(f), which and the product of such a procedure if otherwise admissible may be used at a court-martial.").
45 *See* Navy Medical Corps Recruiting Brochure (The military is not inclined to have its physicians stray from accepted medical practices either. For example, in order to join the Navy Medical Corps an applicant must: (1) have graduated from an eligible medical school accredited by the American Medical Association (AMA) or the American Osteopathic Association (AOA); (2) have completed one year of graduate school in a program approved by the AMA or AOA; (3) have a current state medical license within one year of entering the Navy Medical Corps; and (4) be able to complete 20 years of active service prior to age 60.).
46 Field Manual 8-55, Planning for Health Service Support (U.S. Dep't of the Army 1994). Command also includes the authority and responsibility for effectively using available resources and for planning, organizing, directing, coordinating, and controlling military forces for the accomplishment of assigned missions. It includes responsibility for health, welfare, training, and discipline of assigned and attached personnel.
47 Orloff v. Willoughby, 345 U.S. 83, 92 (1953) (subsequently overruled on other grounds); "[T]he very essence of compulsory service is the subordination of the desires and interests of the individual to the needs of the service" referring to how a conscripted doctor may have to perform services other than his first choice depending on the needs of the Army.) *see also* Stephen A. Saltzburg, Mil. R.Evid. Manual § 313.04 (2003) (quoting Analysis, Mil. R. Evid. 313(b)) ("[I]t may be appropriate to test – by compulsory production of urine – persons whose duties entail highly dangerous or sensitive duties. The primary purpose of such tests is to ensure that the mission will be performed safely and properly. Preserving the health of the individual is an incident – albeit a very important one – of that purpose.").
48 *See* 21 C.F.R. § 50.23(d) (2006), ("Under 10 U.S.C. § 1107(f) the President may waive the prior consent requirement for the administration of an investigational new drug to a member of the armed forces in connection with the member's participation in a particular military operation. The statute specifies that only the President may waive informed consent in this connection and the President may grant such a waiver only if the President determines in writing that obtaining consent: Is not feasible; is contrary to the best interests of the military member; or is not in the interests of national security.").
49 *See* 10 U.S.C. § 1107(f)(1) (2000) ("In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(i)(4)) may be waived only by the President. The President may grant such a waiver only if the President determines, in writing, that obtaining consent is not in the interests of national security.")
50 *See* Exec. Order No. 13,139, 64 Fed. Reg. 54,175 (Sept. 30, 1999)("Before administering an investigational drug to members of the Armed Forces, the Department of Defense (DoD) must obtain informed consent from each individual unless the Secretary can justify to the President a need for a waiver of informed consent in accordance with 10 U.S.C. § 1107(f). Waivers of informed consent will be granted only when absolutely necessary.").
51 Ashley R. Melson, *Bioterrorism, Biodefense, and Biotechnology in the Military: A Comparative Analysis of Legal and Ethical Issues in the Research, Development, and Use of Biotechnological Products on American and British Soldiers*, 14 Alb. L.J. Sci. & Tech. 497, 514 (2004).
52 Bouvia v. Superior Court, 179 Cal. App.3d 1127, 1137 (Cal. Ct. App. 1986).
53 Marine Corps Website, http://www.marines.com/page/usmc. jsp?flashRedirect=true (last visited Feb. 24, 2008) ("As long as you remain in the service of the U.S. government, you and your family are covered by medical insurance. If you remain in the Marine Corps through retirement age, your medical benefits will extend throughout your lifetime and that of your spouse.").
54 *See* 10 U.S.C. § 1071 (discussing the purpose of chapter 10 U.S.C. §§1071 et seq.).
55 TRICARE military health plan overview, *available at* http://www.tricare.mil/mybenefit/home/overview/WhatIsTRICARE (last visited Feb. 24, 2008).
56 *Id*.
57 TRICARE military health plan homepage, http://www.tricare.mil/mybenefit/index.jsp.
58 *See* 61 Am. Jur. 2d *Physicians, Surgeons, and Other Healers* § 287 (2004) ("An action for injuries or wrongful death sustained while under the care and control of a medical practitioner may proceed on a medical malpractice theory, based on three component duties which a physician owes a patient: (1) a duty to possess the requisite knowledge and skill such as is possessed by the average member of the medical profession; (2) a duty to exercise ordinary and reasonable care in the application of such knowledge and skill; and (3) a duty to use best judgment in such application.").
59 Allen Kachalia et al., *Physician Responses to the Malpractice Crisis: From Defense to Offense*, 33 J.L. Med. & Ethics 416, 417 (2005).
60 Beauchamp, *supra* note 11, at 234.
61 Kyle Miller, *Putting the Caps on Caps: Reconciling the Goal of Medical Malpractice Reform with the Twin Objectives of Tort Law*, 59 Vand. L. Rev. 1457, 1459 (2006).
62 *See* Adkins v. Ropp, 105 Ind. App. 331, 334 (Ind. Ct. App. 1938) (stating "[w]hen a physician and surgeon assumes to treat and care for a patient, in the absence of a special agreement, he is held in law to have impliedly contracted that he possesses the reasonable and ordinary qualifications of his profession and that he will exercise at least reasonable skill, diligence and care in his treatment of him.").
63 *See* United States v. Standard Oil Co., 332 U.S. 301,

305-6 (1947) (superseded by statute on other grounds) ("To whatever extent state law may apply to govern the relations between soldiers or others in the armed forces and persons outside them or nonfederal governmental agencies, the scope, nature, legal incidents and consequences of the relation between persons in service and the Government are fundamentally derived from federal sources and governed by federal authority.")' ;*see also* Tarble's Case, 80 U.S. 397 (1871); Kurtz v. Moffitt, 115 U.S. 487 (1885).
64 28 U.S.C. § 2674. ("The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances . . . .")
65 Feres v. United States, 340 U.S. 135, 146 (1950).
66 *Id*. at 136-137 (dismissing two of the claims which were medical in nature: in the first one, the *Jefferson* Case, the plaintiff underwent an abdominal operation, and eight months later, in the course of another surgery, a towel thirty inches long by eighteen wide, marked "Medical Department U.S. Army," was discovered and removed from his stomach; in the second case, the *Griggs* case, Griggs' executrix alleged that Griggs died while on duty because of the negligent and unskillful medical treatment by Army surgeons.).
67 *Id.* at 141.
68 *Id.*
69 *Id.* at 141-42.
70 841 F.2d 1011 (10th Cir. 1987).
71 *Id*. at 1012.
72 *Id*.
73 *Id.* at 1014.
74 *Id.* at 1013.
75 *See* U.S. Department of the Air Force, 7 August 1981, Reg. 35-9, para. 1-32.
76 *See* U.S. Department of the Army, *Army Medical Treatment Facilities General Administration*, Washington DC: DA, Army Reg. 40-2, para. 2-1(a) (change 1, 15 July 1981).
77 United States v. Johnson, 481 U.S. 681 (1987).
78 *Id.* at 684 n.2.
79 *Id.* (citing *Stencel Aero Engineering Corp. v. United States*, 431 U.S. 666, 671-672 (1977)).
80 United States v. Shearer, 473 U.S. 52, 58 n.4 (1985)); *c.f.* United States v. Atkinson, 825 F.2d 202, 206 (9th Cir. 1987) (barring the claim of a female service member who gave birth to a still-born baby due to the negligence of her military doctor and stating, "[a]lthough we believe that the military discipline rationale does not support application of the *Feres* doctrine in this case, the first two rationales support its application").
81 *See* 10 U.S.C. § 934 UCMJ Art. 134.
82 Hernandez v. Koch, 443 F. Supp. 347, 349 (D.D.C. 1978) (citing S. Rep. No. 94-1264, 94th Cong., 2d Sess. at 9 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4443, which states: "The bill is intended to provide, through application of the Federal Tort Claims Act, protection from individual liability to certain medical personnel while acting within the scope of their official duties. In short, defense medical personnel would be immunized from malpractice suits. The bill would eliminate the need of malpractice insurance for all such medical personnel, including physicians, dentists, nurses and other medical support personnel.")
83 Howell v. United States, 489 F. Supp. 147, 149 (D. Tenn. 1980).
84 10 U.S.C. § 1089(a).
85 *Howell*, 489 F. Supp. at 147 (discussing how the plaintiff alleged that as a result of the negligence of the Navy physicians that treated her back, her Navy career was irreparably damaged and she was forced to be discharged for health reasons, receiving only 10 percent temporary disability award or severance pay and not medical retirement).
86 *Id.* at 149.
87 *Id.*
88 Hall v. United States, 528 F. Supp 963, 965 (D.N.J. 1981) *aff'd without op.* 688 F.2d 821 (3d Cir. N.J. 1981) (citing S. Rep. No. 94-1264, 94th Cong., 2d Sess. at 9 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4443.
89 Merriam-Webster Online Dictionary (2005).
90 50 U.S.C. Appx 451.
91 United States v. Murray, 452 F.2d 503, 504 (8th Cir. 1971) *cert. denied*, 405 U.S. 935 (1972).
92 *See* Butler v. Perry, 240 U.S. 328, 333 (1916) (upholding a Florida statute requiring able-bodied men to do work on a road and declaring that it did not violate the Thirteenth Amendment's restriction against slavery or involuntary servitude. The Court stated that "[it] was not intended to interdict enforcement of those duties which individuals owe to the State, such as services in the army, militia, on the jury, etc.").
93 *Military Biomedical Research*, *supra* note 43, at 549.
94 *See id.* (quoting a letter, sent from Assistant Secretary of Defense for Health Affairs to the Assistant Secretary for Health of the Department of Health and Human Services, 30 October 1990).
95 Thomas E. Beam, *Medical Ethics on the Battlefield: The Crucible of Military Medical Ethics,* 2 Military Med. Ethics 369, 371 (Dave E. Lounsbury ed., Office of the Surgeon General, Department of the Army, United States of America, 2003) [hereinafter *Medical Ethics on the Battlefield*].
96 *Id.*
97 *A Proposed Ethic*, *supra* note 27, at 853.
98 *Id.* (citing 10 U.S.C. § 3723) ("The Secretary of the Army may order the hospitalization, medical and surgical treatment, and domiciliary care, for as long as necessary, of any member of the Army on active duty . . . .")
99 Merriam-Webster's Collegiate Dictionary, Springfield, Mass: Merriam-Webster (10th ed. 1999) ("Triage is the screening and classification of wounded, sick, or injured patients during war or another disaster to determine the priority needs and thereby ensure the most efficient use of medical and surgical manpower, equipment and facilities. It could also be a system to allocate a scarce commodity such as food, only to those capable of deriving greatest benefit from it.")
100 *Medical Ethics on the Battlefield*, *supra* note 95, at 372 (describing the tension that is faced by nearly all deployed physicians, which is the issue of returning a minimally injured patient or one suffering from combat stress disorder, to combat.).
101 U.S. Department of the Army, *Planning for Health Service Support*, Washington DC: DA; 9 September 1994, Field Manual 8-55.
102 Alex Berenson, *Army's Aggressive Surgeon is too Aggressive for Some*, N.Y. Times, Nov. 6, 2007, *available at* http://www.nytimes.com/2007/11/06/health/06prof.html?emc=eta1 (last visited Feb. 24, 2008).
103 *Id.*
104 *Id.* ("With soldiers severely injured every day in Iraq, the military cannot afford to wait for a definitive answer [from the trials].").
105 *Id.* (discussing what is behind heart disease and cancer).
106 *Id.* (describing top surgeons such as Col. John Holcomb, head of the Army's Institute of Surgical Research and Dr. John R. Hess, a professor of pathology and medicine at the University of Maryland and a physician at the Shock Trauma Center in Baltimore).
107 *Id.*
108 *Medical Ethics on the Battlefield*, *supra* note 95, at 373-74.
109 *Id.* at 374.
110 At the same time there still may be the possibility of a future deployment.
111 Dep't of Defense Post-Deployment Health Reassessment Program, *available at* http://fhp.osd.mil/pdhrainfo/sm_fam/faq_sm.jsp (last visited Feb. 24, 2008) (making resources available through the Post Deployment Health Reassessment provided by the Department of Defense where a primary health care provider will review the soldier's health concerns and discuss and deployment-related health questions the soldier may have).
112 One can still differentiate the battlefield and this post-deployment stage by the fact that the physician may give the patient more say and time with the lack of environmental stressors and with the diminished interests of the command and society.
113 Karl Kirkland, *Post-Traumatic Stress Disorder vs. Pseudo Post-Traumatic Stress Disorder: A Critical Distinction for Attorneys*, 56 Ala. Law. 90, 91 (1995) (citing American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders,* 4th ed. (Washington, DC: 1994)).
114 *See*, *e.g.*, *National Institute of Mental Health*, http://www.nimh.nih.gov/health/publications/anxiety-disorders/how-to-get-help-for-anxiety-disorders.shtml (last visited Nov. 30, 2007) ("You should feel comfortable talking with the mental health professional you choose. If you do not, you should seek help elsewhere. Once you find a mental health professional with whom you are comfortable, the two of you should work as a team and make a plan to treat your anxiety disorder together.")

Compensation for Egg Donations to Stem Cell Research: Coercion or Choice?

*Diana M. Santos**

I. Introduction

In local newspapers, university publications, private websites, and even on airplane banners, advertisements seeking egg donors abound, each advertisement offering higher compensation than the next.[1] In exchange for giving the "gift of life," egg donors can receive upwards of $50,000.[2] Egg donors to In Vitro Fertilization (IVF) clinics may be compensated handsomely without having their altruism questioned. In contrast, women seeking to donate their eggs to stem cell research centers are prohibited from receiving compensation in a few states. Currently, California, Connecticut, and Massachusetts have laws prohibiting compensation beyond direct expenses for women donating their eggs to stem cell research facilities, while not even placing a ceiling on how much IVF clinics can compensate egg donors.[3]

The stated purpose of these statutes, banning compensation for women seeking to donate eggs to stem cell research, is to protect women from being coerced into undergoing a painful, medically unnecessary procedure.[4] Accordingly, women can be reimbursed for medical, travel, and miscellaneous expenses, but cannot receive compensation beyond those expenses when donating to stem cell research facilities. This dichotomy in compensation is motivated by the rationale that paying women to donate their eggs to stem cell research facilities is coercive while paying women for donating eggs to IVF clinics is apparently not. This article argues that the opposite is true. Given the "repronormativity of motherhood"[5] that exists in our society, if women who donate to IVF clinics are considered altruistic, what prevents healthy, young women from being pressured into donating their eggs to help an infertile friend or family member conceive?

What motivates the assumption that when a woman donates to an IVF clinic and gets compensated beyond the expenses she incurred, she acted out of altruism, yet if a woman undergoes that same medical procedure[6] in order to donate to a stem cell research facility, her donation is deemed the product of coercion or ignorance? Alternatively, is this differential compensation scheme a reflection of the social value placed upon IVF versus stem cell research? The dichotomy in compensation seems to presuppose that egg donors, and society as a whole, should or in fact do believe that the utility of IVF clinics is far greater than that of stem cell research. Accordingly, this article posits that while a woman's right to receive compensation for the time and inconvenience of egg donation might not be a constitutionally protected privacy right, this differential compensation scheme is nevertheless void under the Equal Protection Clause of the Fourteenth Amendment.

"The dichotomy in compensation seems to presuppose that egg donors, and society as a whole, should or in fact do believe that the utility of IVF clinics is far greater than that of stem cell research."

Section II of this article discusses the framework of these various state statutes. Section III examines the social utility of stem cell research, focusing first on the potential benefits that stem cell research could provide for people suffering from genetic diseases ranging from juvenile diabetes to Parkinson's disease. This article also examines the potential financial benefits of attracting private companies to invest in stem cell research and discuss the fact that everyone involved in stem cell research, with the exception of egg donors themselves, are compensated for their time. Finally, this article contends that in light of the expected social and financial benefits associated with embryonic stem cell research,[7] egg donors should be compensated for their donations. Since the current ban on federal funding for any stem cell research facility using embryos leftover from IVF treatments limits the availability of embryos available, and given the importance of egg donations for stem cell research, there is no reason that women should not be compensated for their time.[8]

Section IV focuses on the potential drawbacks of IVF of which egg donors, patients, and the public at large may be unaware. This Section analyzes the eugenic underpinnings of IVF clinics since fertility clinics can cherry-pick patients according to criteria such as sexual orientation, marital status, race, and ethnicity, and then use pretext for such discrimination in order to avoid liability.[9] Moreover, through mechanisms such as pre-implantation genetic diagnosis (PGD) and sex-selection, patients themselves can select character traits of their children-to-be. Section V discusses the actual process involved in donating eggs and the short and long-term side effects of the procedure. Section VI uses a feminist lens to critique this differential compensation scheme, discussing the "repronormativity of motherhood" and the value and definition of motherhood. Lastly, this article examines whether these statutes violate a woman's right to privacy and whether the statutes violate the Equal Protection Clause of the Fourteenth Amendment.

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II. States' Statutory Schemes

A. California

California allows egg donors to be reimbursed for direct expenses if women are donating for stem cell research purposes, but does not prohibit compensation for egg donors seeking to donate their eggs to IVF clinics, or even for sperm donors seeking to donate to stem cell research.[10] In addition, Proposition 71 provides $3 billion in funding for stem cell research and creates a state agency, California Institute for Regenerative Medicine (CIRM).[11] Looking at the legislative intent of this statute reveals that state legislators hope to promote embryonic stem cell research while promoting women's health and ensuring that women are not coerced into donating their eggs for stem cell research purposes. The California statute does not provide criminal sanctions for either institutions or individuals engaging in the selling or purchasing of human eggs.

B. Connecticut

Though Connecticut also prohibits payment to egg donors seeking to donate for stem cell research, unlike California, they similarly prohibit compensation for sperm donors when donating to stem cell research facilities.[12] Moreover, Connecticut has authorized $10 million in funding each year from 2006 to 2015 for grants-in-aid to eligible institutions conducting embryonic or human adult stem cell research.[13]

C. Massachusetts

Massachusetts, like California, includes a preamble explaining its intent to promote regenerative medicine and acknowledging the considerable chance regenerative medicine has of yielding advancements in biological knowledge that could lead to therapies to relieve disease and injury.[14] The statute explicitly states that no such compensation prohibition applies to donors seeking to donate to IVF clinics, and that the legislature does not intend to regulate IVF clinics.[15] Moreover, it carries criminal sanctions that provide for imprisonment for no less than one year, and no more than two years in jail, or imprisonment in state prison for no more than five years, or a fine of not more than $100,000.[16]

III. Potential Benefits of Somatic Cell Nuclear Transfer Research

Somatic Cell Nuclear Transfer (SCNT) is a form of embryonic stem cell research that requires a ready supply of human eggs.[17] In order to understand the implications of these state prohibitions on compensation for egg donation, it is necessary to first explain the potential medical benefits of SCNT. Second, this article will explicate the reason that ova are required in order for SCNT to realize these potential benefits. Third, this article will discuss the anticipated financial gains of SCNT research, examining the disparities of a no-compensation rule for egg donors while virtually all other research participants are compensated for their time.

A. Anticipated Medical Benefits of SCNT

SCNT has great potential to cure genetic and neurodegenerative diseases. Unlike adult stem cells and other cell types, human embryonic stem cells can develop into any type of cell in the human body.[18] In fact, human embryonic stem cells can multiply without differentiating[19] for a significant period of time, allowing scientists to investigate the process by which human beings develop into healthy adults. Because of this special ability to postpone differentiation, human embryonic stem cells provide scientists a unique opportunity to discover the causes of many diseases, including heart disease, juvenile diabetes, Lou Gehrig's Disease, Parkinson's disease, and Alzheimer's disease, to name a few.[20] In addition to finding the causes for many of these diseases, embryonic stem cells could potentially provide their cure. According to the preamble of the Maryland Stem Cell Research Act of 2006, an estimated 128 million Americans currently suffer from these chronic, degenerative diseases.[21] Unlike other types of stem cell research, SCNT allows scientists to target specific diseases to increase knowledge of genetic diseases, develop new treatments, create cell-based therapies, and grow immuno-compatible transplant tissues.

i. SCNT Procedure

In SCNT, two cells are combined in order to grow one cell with particular genetic characteristics. Scientists remove the nuclear DNA from an oocyte, leaving an "ovaplast."[22] Scientists then extract the nucleus of a specialized somatic cell and insert it into the ovaplast, creating a genetically reconstructed ovum. Instead of creating an embryo, this ovum is programmed to create somatic cells. Once scientists stimulate this ovum, it begins dividing cells, forming a blastocyst.[23] In contrast to blastocysts formed when a sperm fertilizes an egg, a blastocyst created by SCNT is genetically identical to the somatic cell from which nuclear DNA was extracted earlier in the process. Once the ovum has developed into a blastocyst, scientists then interrupt further development in order to use the blastocyst for research.[24]

Because ova are pluripotent,[25] largely capable of self-renewal, and can proliferate extensively, there are currently no adequate substitutes for human egg use in SCNT. While scientists have proposed using eggs from other animals, eggs created by the manipulation of stem cell lines, or using eggs derived from fetal cadavers, each of these alternatives present their own problems. First, eggs from other species would cause an interspecies mixture of DNA which scientists have been unable to resolve.[26] Second, creating human eggs by manipulating human stem cell lines is not yet scientifically feasible.[27] Third, because abortion would constitute at least one source of fetal cadavers, this procedure would likely cause more controversy than the use of human eggs.[28] Since no feasible alternative to human egg donation exists, these compensation prohibitions will greatly impede the progress of SCNT and the promise of treating and curing numerous genetic diseases.

B. Anticipated Financial Benefits of SCNT Research

While indicating that the benefits of embryonic stem cell research are "uncertain," thus justifying a no compensation rule for egg donations made to stem cell research centers, both California and Connecticut have pledged significant state funding for stem cell research. In 2004, California committed to donating an astounding $3 billion in state funding for embryonic stem cell research.[29] Connecticut has promised to donate $10 million a year from 2006 until 2015, a total contribution of $ 1 billion.[30] The fact that Connecticut and California have contributed such a considerable sum belies the rhetoric that egg donors should not be compensated because they would be coerced into donating in exchange for uncertain returns.

In addition to expected improvements in regenerative medicine, states also anticipate receiving a share of the prospective profits of embryonic stem cell research. For example, in California, besides authorizing $3 billion in funding, Proposition 71 created the CIRM to, among other things, "make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries."[31] Non-profit institutions receiving CIRM funds own any resulting patents.[32] However, for revenue over $500,000 generated from any ensuing patents, California can claim a share of the profits.[33] Moreover, states are interested in placing as few restrictions on stem cell research as possible to attract biotechnology companies to create new jobs and help stagnant economies.[34]

Virtually the only participants that would not have a financial interest in stem cell research would be the egg donors themselves. Besides state governments, researchers, universities, biotechnology companies, the pharmaceutical industry, lawyers, and health care providers all stand to profit from stem cell research and regenerative medicine.[35] "Only the providers of the necessary tissues, without which the research cannot be done and new medical treatments cannot be developed, who are singled out for remuneration prohibitions."[36] No vocal opposition seems to exist in regard to anyone else being compensated for their time.

When asked about a doctor's prerogative to decide who is a fit parent, 56 percent polled responded that they thought doctors had a right to determine who is fit for parenthood.

IV. Hidden Pitfalls of In Vitro Fertilization

Because approximately 12 percent of all IVF procedures performed in the United States use donated eggs,[37] it is important to examine the problems inherent in IVF clinic procedures. Although the rhetoric behind in vitro fertilization clinics is that egg donors are helping infertile women create loving and caring families, donors may not know who is actually benefiting from in vitro fertilization. In a survey conducted by Fertility and Sterility, 122 prospective egg donors were given various scenarios. Some of these scenarios include having a donor's eggs be given to recipients of different ethnic backgrounds, recipients who are HIV positive, and women over 50.[38] Once informed of the various possible destinations of donated eggs, a significant number of prospective donors were ambivalent.[39] Furthermore, six percent of those surveyed were unwilling to proceed altogether.[40] This section explores the eugenic undertones of IVF clinics, both at the hands of clinics themselves, and at the behest of patients.

A. Discrimination in Access to In Vitro Fertilization

Presently, only seven states mandate that health insurance companies cover IVF treatments.[41] At the average cost of $12,400 per cycle of IVF, and at an average total cost of $100,000,[42] only wealthy, middle class women can afford to undergo IVF treatment.[43] In addition to being prohibitively expensive, fertility clinics are also selective as to whom they sign up as patients based on a variety of criteria that runs the gambit from age and marital status to sexual orientation. For example, when Guadalupe Benitez and her partner Joanne Clark attempted to obtain in utero insemination[44] from North Coast Women's Care, located in California, they were rejected because they were lesbians and the director of the clinic thought it morally reprehensible to help lesbians beget children.[45] Ms. Benitez sued the clinic claiming discrimination on the basis of her sexual orientation and won at trial. However, on appeal, the clinic successfully argued that it refused to treat Ms. Benitez on the basis of her marital status, not on the basis of her sexual orientation.[46] Although the clinic was motivated by the fact that Ms. Benitez was a lesbian, it was nevertheless able to avoid liability by providing an alternate justification for refusing to treat her.[47]

In an interview with Dr. Geoffrey Sher, the founder and medical director of the biggest chain of fertility clinics in the world, the Sher Institute of Reproductive Medicine, Dr. Sher was asked the following questions:

"How much selecting is going on?"

"A lot."

"How much is a lot?"

"A lot."[48]

During this interview, Dr. Sher admitted that a great deal of screening and selection takes place behind closed doors. A study conducted by *Fertility and Sterility* showed similar findings.[49] When asked about a doctor's prerogative to decide who is a fit parent, 56 percent polled responded that they thought doctors had a right to determine who is fit for parenthood.[50] Moreover, when asked whom specifically doctors would object to having as patients:

> Forty-eight percent of responding directors said they were very or extremely likely to turn away a gay couple seeking a seeking a surrogate, 38 percent said they would turn away a couple on welfare who wanted to pay for ART [Assisted Reproductive Technology] with Social Security checks, 20 percent said they would turn away a single woman, 17 percent would turn away a lesbian couple . . . . 5 percent said they would turn away a biracial couple.[51]

Both the interview with Dr. Sher and the results of this survey demonstrate the prevalence of impermissible discrimination. So long as fertility clinics can provide legitimate reasons for their illegitimate preferences, these organizations can continue to discriminate against prospective patients freely.[52]

B. Eugenics-Based Practices of Patients

Selection of character traits of future offspring by patients receiving IVF treatment allows patients to practice "positive eugenics" in addition to the "negative eugenics"[53] practiced by some IVF clinics. Because the IVF industry is not federally regulated[54] and due to the dearth of statutory and case law regulating egg donation,[55] clinics can honor requests by patients to create offspring with specific character traits which can be accomplished by selecting egg donors with a specific eye color, hair color, height, IQ, etcetera. Egg donors can either be recruited directly by the patients, through independent fertility clinics, or by private egg brokerage firms catering to medical centers associated with fertility centers.[56] In California and New York, egg brokerage firms have flourished in order to meet the demand for "'desirable' donors."[57]

To illustrate this point further, the profile of a typical woman using IVF is a white, upper-middle class woman in her late 30's who is college-educated.[58] The typical profile of an egg-donor at one of the nation's leading fertility clinics is that of a young, white woman with some college education.[59] This is no coincidence. If women are unable to conceive their own biological children, they at least want to have children who resemble them and have similar phenotypes. However, nothing prevents these women from taking it a step further and attempting to create super babies.

i. Sex-Selection

In in vitro fertilization, three different procedures for sex selection are available in which the sex can be selected or determined before fertilizing the egg, once an embryo is formed, and once the embryo has been successfully implanted in utero and has developed into a fetus.[60] Spinning sperm in a centrifuge can separate Y-bearing sperm from X-bearing sperm, allowing patients to choose which sperm to use in fertilizing the egg.[61] Moreover, pre-implantation genetic diagnosis (PGD) allows doctors to test an embryo's chromosomes for sex. Finally, selective reduction allows a woman to terminate a fetus or fetuses on the basis of sex.[62]

Why do patients choose to engage in sex-selection? Some patients have genetic diseases which are only transmitted to a specific sex. Others are lesbian or gay couples who believe it would be easier to raise children of their same sex.[63] Some families want to strike a balance between the number of boys and girls they have.[64] Still, others are motivated by cultural perceptions of gender. Dr. Mark Evans, an obstetrician-geneticist shares, "[f]or years . . . the majority of sex-selection requests came from Asian and Indian parents, who tended to want to keep the boys."[65] Though Dr. Evans refuses to honor such requests motivated by clear gender bias, he will nevertheless honor requests for gay and lesbian couples seeking to have boys and girls, respectively.[66]

Still, other clinics will honor all requests for sex-selection and even go so far as to advertise sex-selection services in upscale magazines.[67] Sex-selection, when used in order to prevent passing on genetic anomalies to offspring, may not seem like a troubling use of sex-

selection, but this too raises serious concerns about creating "designer babies."

Clearly, in some places around the globe, the preference for male children is so strong that the use of ultrasound and other technologies for sex-selection has strongly skewed the usual ratio of boys to girls. It is not uncommon for American and European specialists in fertility and reproductive technology to point with horror at the declining numbers of girls in China and India. *We*, the Westerners claim in righteous tones, use the technology for good, medical reasons; *they* use it for bad, social reasons.

Activists and others concerned about disability rights are less clear about the difference. Do Western parents who are given the option already decide not to have children who would be mildly retarded, need a wheelchair, or be blind? Like being a girl in a culture that values boys, is being disabled a handicap that is best overcome through changes in society?[68]

Choosing to create or implant an embryo or terminate a fetus solely on the basis of sex in order to avoid creating offspring with genetic anomalies or due to gender perceptions or gender bias raises concerns about creating "desirable" children.

> Women donating their eggs to IVF then must go a more arduous and dangerous procedure than women donating their eggs to stem cell research centers.

ii. Pre-Implantation Genetic Diagnosis

Pre-implantation genetic diagnosis allows patients receiving IVF treatments to test chromosomes of embryos for potential genetic defects. PGD involves extracting a single cell from the embryo and performing laboratory tests on the nuclear DNA for any genetic anomalies. Despite the risk that PGD might damage the embryos when a cell is extracted, patients nevertheless elect to run these tests to avoid transferring embryos with genetic defects.[69] Through the use of PGD, doctors can now detect the following afflictions: "hemophilia; fragile X syndrome; neuromuscular dystrophy; cystic fibrosis; Tays-Sachs; Down syndrome, and hundreds of other genetic disorders, some of them fatal, some of them fatal after months, even years, of suffering."[70] In addition, PGD can also detect embryos carrying diseases that are not apparent until adulthood, such as a predisposition to breast cancer or Alzheimer's disease.[71] While prevention of human suffering is an honorable function of PGD, when a genetic anomaly does not cause suffering or fatality, but instead causes dwarfism, for example, PGD could be used as a tool to create a superior breed where differences are marginalized.

Although there is currently no technique which enables parents to genetically enhance an embryo, advancements in PGD technology could have profound implications for the future. The following quotation from Philosopher Gregory Pence demonstrates the potentially disastrous consequences of allowing market forces, unregulated by government, to create designer babies:

> Some day soon, when the opportunities arise, we will see the wisdom of allowing parents maximal choice about their future children. This is not state-controlled eugenics (which attempted to take away such choices from parents) but its opposite. If a child can be given an extra decade of life by an artificial chromosome, or 50 percent more memory through a therapy in utero, then I personally would feel *obligated* to give my future child such benefits.
>
> What I fail to understand is how other people—or the federal government—could think it just to prevent a parent from benefiting her future children in this way—for example by banning such enhancements. I see no difference between such a ban and a similar ban on parents sending their children to computer camps in the summer: both are intended to better children, both will be done most by people with money.[72]

Leaving aside the ethical implications of genetic enhancement, the difference between banning genetic enhancement of embryos and sending children to computer camp has its roots in the history of eugenics in this country. If the only people who have this "choice" are upper-middle class families, then the privilege of being a white child would take on a whole new meaning, while births of non-white children would be further marginalized.

V. Procedure Involved in Egg Donation

Women donating eggs to both stem cell research facilities and to IVF clinics must first undergo a screening process in which donors are medically and psychologically evaluated.[73] Donors are then subjected to hormone injections for seven to ten days in order to stimulate the ovaries. These hormones typically cause stimulation of five to 15 eggs.[74] The progress of donors in both scenarios is monitored by ultrasound.[75] Once the eggs have matured, donors receive an injection of human chronic gonadotropin (HCG). Subsequently, these matured eggs are removed during an out-patient procedure in which donors are given anesthesia. Doctors remove the eggs by inserting a needle through the vagina and into the ovaries, where eggs are suctioned in the needle and deposited into test tubes.[76]

A. Risks and Side Effects

Short-term side effects of egg donation can include mood swings, headache, bloating, nausea, fatigue, breast tenderness, problems sleeping, body aches, problems with vision, and compulsory abstinence.[77] Long-term side effects of egg donation include, among others, the risk of decreased fertility in the future, ovarian cancer, and ovarian hyperstimulation.[78] Women who receive the highest doses of fertility drugs in order to donate eggs are only now reaching an age where cancer becomes more common.[79] Therefore, studies have not found any conclusive evidence regarding the risks of ovarian cancer or decreased fertility.[80]

B. Differences in Procedure between Egg Donation to IVF versus Stem Cell Research

Unlike egg donors to stem cell research facilities, egg donors for IVF are usually phenotypically matched to recipients so that the donor has a "similar look and background as the female recipient of the oocyte."[81] An additional step involved in the egg donation process that is peculiar to the IVF context is that a donor's menstrual cycle must be matched with the recipient's cycle.[82] Accordingly, egg donors to IVF must receive an additional ten days of hormone injections with concentrated drugs such as Lupron in order to suppress the function of the donors' ovaries.[83] Women donating their eggs to IVF then must go a more arduous and dangerous procedure than women donating their eggs to stem cell research centers.

VI. The Coercion of the Repronormativity of Motherhood and the Constitutional Safeguards of Choice and Equal Protection

Given the drawbacks of IVF and the potential benefits of stem cell research discussed above, and given that the risks involved in egg donation exceeds the risks inherent in donations to stem cell research, the policy rationale behind this differential compensation scheme seems questionable at best. This section examines the underlying presumptions that prompt the no compensation rule. The first presumption is that payment can constitute a form of coercion in and of itself. The second presumption is that women are defined by their fertility and, therefore, donating eggs to an IVF clinic is inherently altruistic, regardless of how sizeable the compensation received. This analysis also evaluates whether these statutes violate a woman's fundamental right to choose, and concludes that these statutes are likely unconstitutional pursuant to the Equal Protection Clause of the Fourteenth Amendment.

A. Compensation as Coercion

Black's Law Dictionary defines coercion as "[c]onduct that constitutes the improper use of economic power to compel another to submit to the wishes of one who wields it."[84] The position of state legislators is that paying women to donate their eggs to stem cell research facilities would be coercive. However, the very compensation schemes California, Connecticut, and Maryland have created coerce women to donate to IVF clinics. Since compensation to women donating eggs to IVF clinics is unregulated, women who otherwise wish to donate to stem cell research centers might be coerced into donating for IVF clinics simply for the financial gain. According to Dr. Mark V. Sauer, the director of the assisted reproduction program at Columbia-Presbyterian Medical Center, his list of prospective egg donors has recently doubled to over 500.[85] Dr. Sauer and other fertility doctors believe the surge in interest is correlated with a recent jump in the amount paid for the services of egg donors.[86] If the aim of state legislators is to decrease coercion in egg donations to stem cell research, then legislators should provide that egg donors to IVF and stem cell research be compensated similarly. Furthermore, to allay concerns of undue influence resulting from exorbitant compensation, legislators could place a ceiling on the amount that egg donors may receive for their time and inconvenience.

B. The "Repronormativity of Motherhood"[87]

In addition to the coercive compensation scheme which favors egg donation to IVF, the repronormativity of motherhood also places pressure on women to donate eggs to IVF centers. By stating that the benefits of embryonic stem cell research are uncertain, whereas the benefits of IVF are clear (helping an infertile woman be able to conceive), state legislators reinforce the notion that a woman's worth is at least partially connected to her fertility.[88] For example, conceiving biological offspring[89] is seen as a social good whereas adoption is only considered as a last resort. "Reproduction has been so taken for granted that only women who are not parents are regarded as having made a choice—a choice that is construed as nontraditional, nonconventional, and for some, non-natural."[90] Because motherhood is considered "society-preserving," altruistic work, to refuse it seems a selfish lifestyle choice. Motherhood is so sacrosanct in our society that legislators seem afraid to regulate in this area, afraid to question the health risks associated with egg donation in IVF, and afraid to consider whether the exorbitant compensation to egg donors in the IVF context is coercive.

C. Compensation as Choice

Having established that payment for egg donations to stem cell research is not coercive *per se*, the question remains whether these differential compensation schemes violate a woman's constitutional right to privacy, or right to choice. *Roe v. Wade* is primarily associated with the holding that the Due Process Clause of the Fourteenth Amendment protects a constitutional right to privacy.[91] More importantly, however, *Roe* held that fetuses and earlier stages of development up to fertilized eggs are not "persons" within the meaning of the Constitution.[92] Additionally, it held that the state has an important and legitimate interest in protecting potential human life.[93] Because the state has a recognized interest in the development of potential human life, the Supreme Court balanced a woman's right to privacy against a state's interests in the potential for life. During the first trimester, a woman's constitutional right to liberty and privacy are the strongest, and a state's interests are at their weakest.

In *Lawrence v. Texas*, the Court confirmed a prior Court holding "that our laws and tradition afford constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing and education."[94] In this context, privacy rights are primarily understood as respecting a person's autonomy in their sexual lives. Similarly, in *Eisenstadt v. Baird*, the Court referred to one's privacy rights as essential to protect single and married individuals from unwarranted government intrusion into one's decision whether or not to "bear or beget a child."[95]

Framed in this manner, the question then becomes whether the doctrine of privacy will apply in the context of new reproductive and scientific technologies, much the same way that courts have asked whether the First Amendment applies to the Internet.[96] The strongest argument in favor of applying the right to privacy in the context of embryonic stem cell research is that by donating eggs to stem cell research facilities, women are contributing to researchers' understanding of the replication of human cells. The very goal of SCNT is to develop therapeutic cloning in the future. Therapeutic cloning involves replicating fragments of an individual's DNA in order to replace diseased cells. Since cloning is a form of asexual reproduction similar to the process involved in reproduction of offspring, interpreting an egg donor's right to privacy depends upon the Court's rationale for recognizing a right to privacy from unwarranted government intrusion into the decision to have offspring. Like the decision to have genetic offspring, the decision whether or not to donate one's eggs for any reason (whether motivated by compensation, furthering therapeutic cloning, or a combination of both) involves an individual's conception of the meaning of life. Accordingly, the Supreme Court should find a woman's fundamental right to privacy encompasses her right to donate her eggs freely, whether in the context of stem cell research or in vitro fertilization.

D. Equal Protection

If the Court finds that a fundamental right to privacy applies to a woman's decision to donate her eggs, these state regulations would be unconstitutional unless the state can demonstrate a compelling state interest.[97] Although these states might argue that they have a compelling state interest in regulating egg donations in order to preserve potential life, this argument is flawed for several reasons. The predominant view is that at the earliest, human life begins at conception. Therefore, the state has an interest in protecting an embryo as a potential person. However, in SCNT, no embryos are created. Although SCNT is considered a subcategory of *embryonic* stem cell research, this is a misnomer because the eggs are not fertilized by sperm. Moreover, if one believes that conception occurs in the womb, then embryos created outside the womb may not be considered potential human beings. States eager to promote embryonic stem cell research would have no incentive to pass legislation that defines conception in any other manner.

Even if states defined human life as beginning with a mature egg or before fertilization of an egg, states would still not be furthering a compelling interest in prohibiting compensation to egg donors of stem cell research while leaving compensation to egg donors of IVF clinics unregulated. The argument that states are protecting human life is tenuous because, in the context of IVF, excess embryos are frequently created and are frozen or discarded. Moreover, because in vitro fertilization is an emerging field, researchers do not yet know how many transferred embryos are implantable in a woman's uterus. This has led to high order multiple pregnancies which cause complications to both mother and child. Thus, patients often undergo selective reduction in which one or more fetuses is terminated. [98] If one has a fundamental right to privacy in donating eggs, the differential compensation schemes in California, Connecticut, and Massachusetts would be an unconstitutional violation of that right.

Regardless of whether or not the Supreme Court finds a privacy interest in the donation of eggs, California's regulation is likely an unconstitutional as a means of gender-based classification. Unlike Connecticut and Massachusetts, California allows sperm donors to be compensated for donations made to stem cell research, while prohibiting egg donors from receiving any compensation beyond direct expenses. Since all sperm donors are males and all egg donors are females, the differential scheme necessarily implicates gender. Gender classifications trigger heightened scrutiny of state regulation and will only be upheld if the government provides "an exceedingly persuasive justification."[99] The purpose of the statute is clear: the process of egg donation is invasive and can cause serious side effects, therefore the prohibition on compensation is meant to protect women. So long as prospective egg donors provide informed consent of the potential health risks involved, they can decide whether the risks of donating outweigh the benefits. By "protecting women," this statute assumes that women cannot make informed decisions about their own bodies, a view that is paternalistic, patronizing, and unconstitutional.

VII. Conclusion

At first glance, the rationale behind statutes that create differential compensation schemes are concerned with women's health. By prohibiting compensation, state legislators reason that women will not be coerced into donating their eggs to stem cell research. However, if concern that compensation will coerce women were indeed the rationale behind these statutes, legislators would not leave compensation for egg donations to IVF clinics up to market forces, where women can be compensated upwards of $50,000.[100] A compensation scheme favoring egg donations to IVF clinics is even more coercive in light of the repronormativity of motherhood in this culture. Because motherhood is viewed as altruistic, potential egg donors will more likely be coerced into donating for IVF clinics because

their donation will be viewed as altruistic and they also will be compensated generously for their time.

Depending on how the Supreme Court interprets reproductive privacy rights involving technology and cloning, these statutes, besides being questionable as a policy matter, potentially infringe on the constitutional right to privacy. Because privacy rights are in a state of flux after *Gonzalez v. Carhart*,[101] it is difficult to know whether the Court will apply reproductive privacy rights in the context of reproductive and biomedical technologies such as therapeutic cloning. *Carhart* involved a woman's right to privacy in the third trimester, when a woman's interests are much weaker in comparison to a state's interests in regulation.[102] Since egg donation precedes even the first trimester framework, *Carhart* does not necessarily indicate how the Court would decide privacy rights in egg donation.[103] However, new reproductive technologies challenge the whole trimester framework in *Roe* and potentially call for an entirely new approach to reproductive privacy rights.

1 *See* Jim Hopkins, *Egg-donor Business Booms on Campuses*, USA Today (2006), *available at* http://www.usatoday.com/money/industries/health/2006-03-15-egg-donors-usat_x.htm (last visited February 29, 2008); *The High Cost of Eggs: Donors at Risk*, U.S. News & World Report (Jan. 5, 2003); Liza Mundy, Everything Conceivable: How Assisted Reproduction Is Changing Our World 21 (Knopf 2007).
2 *See The High Cost of Eggs*, *supra* note 1; Mundy, *supra* note 1, at 331.
3 Indiana and Maryland also place restrictions upon compensation for egg donations for stem cell research. Indiana allows women to be paid up to $3,000 beyond expenses incurred in the process of donating, but leaves compensation for egg donors to IVF unregulated. Maryland prohibits state funded stem cell research facilities from providing compensation for egg donations. However, the scope of this prohibition appears to be limited to excess eggs harvested for IVF treatment. *See* Cal. Health & Safety Code §§ 125118, 125119, 125119.3, 125119.5, 125300, 125330-123853 (Deering 2006); Conn. Gen. Stat. § 19a-32d (2006); 105 CMR 960.006; Ind. Code 35-46-5-3; Md. Ann. Code Art. 83A, §§ 5-2b-10, 5-2b-12.
4 *See* Cal. Health & Safety Code §§125118 (Deering 2006); Conn. Gen. Stat. § 19a-32d (2006); 105 Mass. Code Regs. 960.006 (2008).
5 See Katherine M. Franke, *Theorizing Yes: An Essay on Feminism, Law and Desire*, 101 Colum. L. Rev. 181 (2001) (coining the term "repronormativity" and refering to social influences that provide incentives for women to become mothers.)
6 As discussed in Section V, the medical procedure involved in egg donation to stem cell research and IVF clinics is similar. However, egg donations to IVF clinics are more time intensive and carry greater risks than associated with egg donations for research purposes.
7 Throughout the paper, I use the term "embryonic stem cell research" and "somatic cell nuclear transfer" interchangeably since somatic cell nuclear transfer is a subcategory of embryonic stem cell research.
8 *See* 2002 H.R. 3061 § 510 (a); 45 C.F.R. 46.208 (a)(2); 42 U.S.C.A. § 298g(b) (West 2002).
9 Elizabeth Weil, *Breeder Reaction: Does Everybody Have the Right to a Have a Baby? And Who Should Pay When Nature Alone Doesn't Work?*, Mother Jones, July/August 2006, at 33
10 Cal. Health & Safety Code §§ 125118, 125119, 125119.3, 125119.5, 125300, 125330-123853 (Deering 2006).
11 2004 Cal. Legis. Serv. Prop. 71 (West).
12 Conn. Gen. Stat. § 19a-32d (2006).
13 Conn. Gen. Stat.. § 19a-32e (2006).
14 Mass. Gen. Laws 111L, § 1 (West, 2005)
15 105 Mass. Code Regs. 960.008 (2008).
16 105 Mass. Code Regs. 960.009 (2008).
17 Sarah B. Angel, *The Value of the Human Egg: An Analysis of Risk and Reward in Stem Cell Research*, 22 Berkeley J. Gender L. & Just. 183, 187 (2007).
18 Comm. On Guidelines for Human Embryonic Stem Cell Research & National Research Council, Guidelines for Human Embryonic Stem Cell Research (National Academy of Sciences 2005 at 29), *available at* http://nap.edu/catalog/11278.html (last visited Feb. 24, 2008) [hereinafter NAS Guidelines].
19 NAS Guidelines, *supra* note 18, at 15 (Differentiation is the "process whereby an unspecialized cell acquires specialized features, such as those of a heart, liver, or muscle cell.").
20 President's Council on Bioethics, Human Cloning and Human Dignity: An Ethical Inquiry 129 (2002), *available at* http://www.bioethics.gov/reports/cloningreport/index.html (last visited Feb. 24, 2008).
21 2006 Md. Legis. 19 (2006).
22 Ann A. Kiesling, *What is an Embryo?*, 36 Conn. L. Rev. 1051, 1090 (2004) (discussing the term "ovaplast" which indicates that the cell is incapable of developing into an embryo).
23 Angel, *supra* note 17, at 191. (defining a blastocyst as a "primitive and undifferentiated structure comprising between 100 and 200 cells with no specialized tissues or organs.)
24 President's Council on Bioethics, Human Cloning and Human Dignity: An Ethical Inquiry, *supra* note 20, at 16 (citing National Institutes of Health, Human Embryo Research Panel, 1994).
25 Stedman's Medical Dictionary Online, http://www.stedmans.com (last visited Feb. 29, 2008)
26 Chen et al., *Embyronic Stem Cells Generated by Nuclear Transfer of Human Somatic Nuclei into Rabbit Oocytes*, 13 Cell Research 251 (2003) (embryonic stem cells were produced using SCNT involving human nuclear DNA and ova from rabbits) (During the SCNT procedure, mitochondrial DNA of the egg cell remains even though its nuclear DNA has been extracted. Therefore, this mitochondrial DNA would mix with the human nuclear DNA, potentially causing significant growth and safety risks.).
27 NAS Guidelines, *supra* note 18, at 38.
28 42 U.S.C. § 289(g) et. seq. (prohibiting modification of abortion procedure to aid fetal donation and requiring that the decision to donate fetal remains be made after the decision to have an abortion).
29 2004 Cal. Legis. Serv. Prop. 71 (West).
30 Conn. Gen. Stat. § 19a-32e (2006)..
31 2006 Cal. Legis. Serv. Ch. 483 (S.B. 1260) (West).
32 Erika Check, *Stem-Cell Researcher's Move Attracts Funding*, 448 Nature 398 (July 26, 2007).
33 *Id*.
34 *See* 2006 Md. Legis. 19 (stating that as the fourth-largest sector for biotechnology, Maryland wants to maintain a "favorable research climate" to draw biotechnology companies).
35 Russell Korobkin, *Buying and Selling Human Tissues for Stem Cell Research*, 49 Ariz. L. Rev. 45, 46 (2007).
36 *Id*.
37 Mundy, *supra* note 1, at 21.
38 Natalie Adsuar, et. al., *Assessment of Wishes Regarding Disposition of Oocytes and Embryo Management Among Ovum Donors in an Anonymous Egg Donation Program*, 84 Fertility and Sterility 1513 (2005)
39 *Id*.
40 *Id.*
41 Mundy, *supra* note 1, at 222.
42 Weil, *supra* note 9, at 33.
43 Reprogenetics 99-100 (Lori P. Knowles & Gregory E. Kaebnick eds., Johns Hopkins Univ. Press 2007)
44 Although in utero insemination is a separate and distinct infertility treatment than IVF, this narrative is meant to demonstrate that fertility clinics generally screen and cherry-pick their patients.
45 Weil, *supra* note 9, at 33.
46 *Id*. at 35. California does not recognize marital status as a protected class.
47 *Id*.
48 *Id* at 34.
49 *See id*. at 36.
50 *Id.*
51 *See.* Weil, *supra* note 9, at 36.
52 *See* Weil, *supra* note 9, at 34 (discussing Kijuana Chamber's case in which a single blind woman was allegedly turned away from a fertility clinic because she was "prone to emotional outbursts; she had dirty underwear").
53 *See* Reprogenetics, *supra* note 43, at 3-4. Negative eugenics refers to policies intended to prevent or discourage reproduction by people deemed

socially undesirable. Positive eugenics, by contrast, signifies policies aimed at encouraging "social desirables" to reproduce.
54 *Id.*
55 Kari L. Karsjens, *Boutique Egg Donations: A New Form of Racism and Patriarchy?* 5 DePaul J. Health Care L. 57, 59 (2002).
56 *Id* at 61-62.
57 *Id*. at 65.
58 Dorothy E. Roberts, *Race and the New Reproduction*, 47 Hastings L. J. 935, 938 (1996) (stating that most couples using IVF are white and that the images IVF clinics use are usually that of a baby with blonde hair and blue eyes, "as if to emphasize her racial purity").
59 Genetics and IVF Institute, Summary of Selected Donor Characteristics (available from 3015 Williams Drive, Fairfax, VA 22031, (703)-698-7355, (800)-552-4363).
60 Mundy, *supra* note 1, at 260.
61 *Id*.
62 *Id*.
63 *Id*.
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65 Mundy, *supra* note 1, at 260.
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67 Barbara Katz Rothman, *The Consequences of Sex Selection*, 52 Chronicle of Higher Education, Feb. 24, 2006, at B16.
68 *Id*.
69 Mundy, *supra* note 1, at 229.
70 *Id.* at 319.
71 *Id.* at 320.
72 Reprogenetics, *supra* note 43, at 8 (emphasis in original).
73 *See* American Society for Reproductive Medicine, Guidelines for Oocyte Donation, 82 Fertility & Sterility S13-15 (Sept. 2004); Natalie Adsuar, Julianne E. Zweifel, et. al., *Assessment of Wishes Regarding Disposition of Oocytes and Embryo Management Among Ovum Donors in an Anonymous Egg Donation Program*, 84 Fertility and Sterility at 1513-1516 (Nov. 2005) (explaining that the psychological evaluation involved is meant in part to ensure that the donor is not acting under coercion).
74 Carl T. Hall, *Stem Cell Panel Ponders Hazards of Egg donation*, The San Francisco Chronicle, Sept. 29, 2006, at B1.
75 Kenneth Baum, *Golden Eggs: Toward the Rational Regulation of Oocyte Donation*, 2001 B.Y.U. L. Rev. 107, 118 (2001).
76 *Id*.
77 *See generally id.* (Since donors receive fertility drugs to stimulate production of mature eggs, sexual activity during this process carries a greater risk than average pregnancy. Also since these fertility drugs trigger the production of multiple mature eggs, there is also an increased risk of multiple pregnancies.).
78 *See* Jennifer Swift, *Donated Eggs Don't Come Cheap*, New Scientist, Dec. 8, 2007. Ovarian hyperstimulation syndrome occurs when the ovaries swell and retain fluid with symptoms varying from minor abdominal pain to kidney failure and even death. Studies estimate that about six percent of donors may contract ovarian hyperstimulation syndrome.).
79 *Id*.
80 *Id.* (Studies estimate that about 6 percent of donors may contract ovarian hyperstimulation syndrome.).
81 Sarah B. Angel, *The Value of the Human Egg: An Analysis of the Risks and Rewards in Stem Cell Research*, 22 Berkeley J. Gender L. & Just. 183, 198 (2007).
82 Jesse McKinley, *The Egg Woman*, N.Y. Times, May 17, 1998, at 14 (describing a New York University's film graduate student's experience donating eggs to a fertility clinic).
83 *Id*.
84 Black's Law Dictionary (8th ed. 2004)).
85 McKinley, *supra* note 82, at 14.
86 *Id.* (citing a compensation hike from $2,000 to $5,000 as responsible for the sudden increase in prospective egg donors).
87 *See* Franke, supra note 5, at 183.
88 Elaine Hoffman Baruch & Amadeo F. D'Adamo, Embryos, Ethics, and Women's Rights 217-21 (Joni Seager ed.1988).
89 *Id.* at 135-9 (When IVF patients use egg donors, although the recipient's resulting offspring might not be genetically related to a woman giving birth, offspring may nevertheless be genetically related to a spouse or partner.).
90 Franke, supra note 5, at 181.
91 Roe v. Wade, 410 U.S. 113, 114 (1973).
92 Jack M. Balkin, *How New Genetic Technologies Will Transform Roe v. Wade*, 56 Emory L. J. 843, 843 (2007).
93 *Id.* at 844.
94 Lawrence v. Texas, 539 U.S. 558, 574 (2003).
95 Eisenstadt v. Baird, 405 U.S. 438 (1972).
96 Balkin, *supra* note 92 at 856.
97 *See* Planned Parenthood v. Casey, 505 U.S. 833, 871 (1992).
98 *Id.* at 847.
99 United States v. Virginia, 518 U.S. 515 (1996).
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101 *See generally* Gonzales v. Carhart, 127 S. Ct. 1610 (2007).
102 *Id*.
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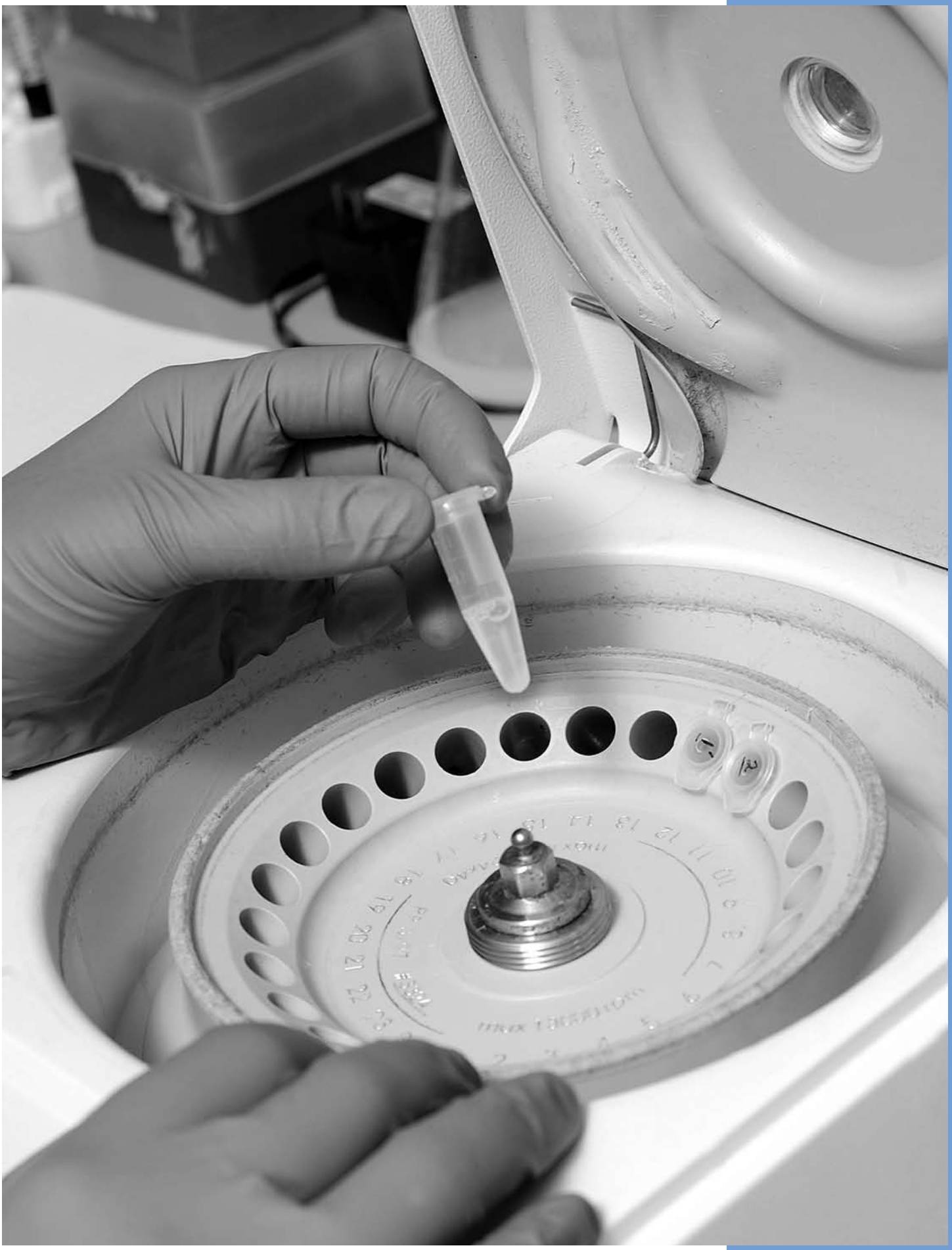

In The News

No Standards to Test for Drugs in Water

Until recently, the government and physicians advised consumers to flush expired pharmaceuticals down the toilet. However, experts now note that this recommendation was ill-advised. Recent studies have shown that this practice has resulted in the prevalence of medications, such as antibiotics, anti-convulsants, mood stabilizers, and sex hormones in the nation's water supply. Despite this phenomenon, the Environmental Protection Agency (EPA) does not require utility companies to test for the presence of pharmaceuticals in the water supply. Due to the lack of regulations, many communities do not test for the presence of drugs in drinking water, and most fail to inform their customers when these pollutants are detected. Experts express concern that these pollutants potentially threaten the health of humans, wildlife, and the natural environment.

In response, the U.S. Senate has scheduled hearings to address these concerns, however, many cities plan to take action before rulings are made in the federal government. In response to growing public outcry about the issue, the pharmaceutical industry has teamed up with the U.S. Fish and Wildlife Service to devise a strategy to inform Americans about ways in which to dispose of unused pharmaceutical products. Experts emphasize the need for the EPA to expand the list of contaminants for which utilities are required to test to include pharmaceuticals.

Heparin Contamination Raises Questions About the Safety of U.S. Drug Supply

Contamination of the blood thinner heparin, which led to drugmaker Baxter to recall its heparin in early in 2008, has been linked to the source of the supply in Chinese workshops. The associated deaths are estimated to include more than 60 people and the contamination is spread among all manufacturers of the drug. The recall raises questions about drug regulation in an increasingly global market, when drug supply originates from provinces that do not fall under the jurisdiction of the FDA's Good Manufacturing Practices. Indeed, China's State Food and Drug Agency responded to the contamination by releasing a notice requiring producers of heparin to obtain their supplies only from registered suppliers. Questions about the FDA's capacity to adequately inspect the United States' food and drug supply first arose in 2007 after spinach was contaminated in California, and will undoubtedly continue to be a concern for policymakers.

Celebrity Confidentiality Breaches in Health Care Records

With a public apology, the UCLA Medical Center in Los Angeles, California has promised to work closely with state health officials to investigate privacy breaches of over 30 high profile patients, including Britney Spears, Farrah Fawcett, and California first lady Maria Shriver. More than several employees have been implicated, disciplined, or fired for snooping into the electronic health records of celebrity patients in violation of state and federal laws, including thirteen individuals who were involved in probing into Britney Spears's medical file. At least one employee may face criminal charges under the Health Insurance Portability Accountability Act of 1996 (HIPAA). Questions have arisen regarding the time lapse between when the hospital became aware of the breaches and when it notified the celebrities. This breech has reinvigorated discussions about the possibility of strengthening state and federal medical privacy laws.

FDA To Issue Decision on the Safety of Cough and Cold Medications for Children

The over-the-counter drug industry is awaiting a decision from the Food and Drug Administration (FDA) as to whether it will allow the continued marketing of cough and cold medicines to children under the age of six. The FDA has issued two public health advisories since August 2007, warning that, "serious and potentially life-threatening side effects" can occur from use of the products. The adverse effects include death, convulsions, rapid heart rate, and decreased level of consciousness. The FDA recommends that the products not be given to children under two years of age "unless given specific directions to do so by a healthcare provider."

Prior to the FDA's Nonprescriptions Drugs Advisory Committee public meeting, the makers of oral infant cough and cold medicines sold under the Dimetapp, PediaCare, Robitussin, Tylenol, and Triaminic brands voluntarily recalled their products from store shelves.

As the industry awaits the final decision, stakeholders are debating whether labeling changes are an adequate solution, or whether the products should be removed from the market altogether. A Citizen's Petition filed with the FDA by several health professionals in early 2007 requests that the agency require nonprescription cough medications be labeled with the following statement: "(a) These products have not been found to be safe or effective in children under six years of age for treatment of cough and cold. (b) These products should not be used for the treatment of cough and cold in children under six years of age."

The Consumer Healthcare Products Association (CHPA), a trade group representing the nonprescription drug industry, has told the media that entirely removing these products from the market could have negative consequences, cautioning that if cough and cold medications are not available for children, parents may give their children adult medication and attempt to adjust the dosages. One study revealed that 74 percent of parents reported they would use whatever medication they had around the house to treat their children. Rather than eliminating all children's over-the-counter cough and cold products from the market, CHPA advocates for keeping the products on the market and educating parents on administering medicines to their children in safe and proper doses.

The Citizen's Petition asserts that the FDA has never formally concluded that the medications are "generally recognized as safe and effective" for the pediatric population. The agency has acknowledged that there is a paucity of data about the safety and efficacy of pediatric cold medications.

Funding to Develop Blood Substitute

As the blood-donor shortage in the United States worsens, demand for a suitable blood substitute increases. Aside from the shortages, problems with traditional blood transfusion include transfusion-transmitted diseases, the problems and expense of collecting and storing donated human blood, and the demand for compatibility testing.

According to estimates by the World Health Organization, there are not enough blood donations to meet the worldwide need of 100 million units (45 million liters) per year. Thus, a viable blood substitute could save the lives of millions, and has practical applications in military, homeland security, emergency medicine, and traumatic brain injury. "Creating an effective substitute for human blood has been an elusive dream for many decades," says Dr. Jan Simoni, associate research professor in Texas Tech Health Sciences Center's surgery department and HemoBioTech Inc.'s acting vice president for research and development.

To this end, the Office of Naval Research has awarded four grants to the Virginia Commonwealth University Reanimation Engineering Shock Center (VCURES) for research using the blood substitute Oxycite. VCURES is Virginia Commonwealth University's critical injury and illness research group. The $3.5 million funding will be used to support studies which focus on the use of Oxycite in decompression sickness, embolisms, traumatic brain injury, and blast injuries.

Bridget Behling and Rebecca L. Wolf contributed to this column.

WASHINGTON UPDATE:

The Presidential Race in Health Care

As of mid-April 2008, Senators Hillary Clinton and Barack Obama are still competing for the Democratic Presidential Nomination, while Senator John McCain is the Nominee-in-Waiting for the Republican Party. All three of the candidates have put forth their opinions and proposals for health care reform with varying degrees of complexity. Each generally advocates for raising the quality of patient care and chronic disease management, creating health care cost transparency, broadening the implementation of electronic health information technology, and ensuring drug costs and health care coverage are less tied to an individual's employer. However, this is where many similarities end.

Hillary Clinton has taken the position that affordable, accessible, and adequate health care is everyone's responsibility. Her plan would mandate that individuals buy into some form of health insurance with subsidies and tax credits tied to income to assist those who are otherwise unable to afford coverage on their own. Large employers would be required to either provide coverage or contribute to coverage for their employees. Small employers would be given tax credits, enabling them to provide coverage to their employees. Senator Clinton's plan would allow insured individuals either to maintain their current insurer or choose another insurance provider. Those who elect to obtain new coverage would be able to choose between new plans with private options modeled after the Federal Employee Health Benefit Program (FEHBP) and a public plan modeled after Medicare.

Barack Obama advocates towards the same goal of universal health care for all Americans. However, his plan only requires that children receive full coverage. His plan would also allow individuals to participate in their parents' health care plan until reaching 25 years of age. Senator Obama would further create a "new national health plan" with guaranteed eligibility for all Americans that would include benefits based on FEHBP. For individuals with lower incomes, Obama would seek to expand Medicare and the State Children's Health Insurance Program (SCHIP). His plan would also provide additional subsidies for those with higher incomes which would otherwise disqualify them from Medicaid and SCHIP. Senator Obama also advocates for more flexibility for states to institute reform and for federal health care initiatives targeting areas such as HIV/AIDS, autism, mental health care, and lead poisoning.

John McCain has been advocating for health care reform that provides for "personal . . . and economic freedom for everyone." McCain's plan includes tax credits of up to $2,500 for individuals and $5,000 for families, which will enable them to purchase insurance coverage independent of their employers. His plan also advocates for medical liability reform, especially to protect those physicians who follow clinical and safety protocols when treating patients. McCain has emphasized that families should have autonomy over medical decisions, so that they may genuinely consider financial constraints and the individual needs of their family members. Further, he advocates for health care cost transparency and the use of vehicles such as tax-exempt health savings accounts. Senator McCain's proposed individual responsibility would be bolstered by the increased competition created through the freedom for individuals to seek and for insurers to provide health care across state lines via the internet and other means.

The national elections are still many months away, and the candidates' diverse health care platforms will undoubtedly continue to develop as Election Day draws nearer.

Court Rules in Favor of FDA Preemption in Medical Devices

Preemption by Food and Drug Administration's (FDA) regulations has been a prominent issue before the Supreme Court in 2008. Specifically, this issue has arisen in the context of litigation against manufacturers of pharmaceuticals and medical devices. In Riegel v. Medtronic, 128 S. Ct. 999 (2008), the Court issued a decisive 8-1 decision ruling in favor of allowing FDA regulations to preempt certain state tort actions based on defective medical devices. Justice Scalia, writing for the majority, concluded that,if a medical device has passed the FDA's preapproval regulatory process, then it should not be subject to any further litigation in state courts for subsequent defects. The Court held that the Medical Device Amendments (MDA) of 1976 give the FDA exclusive power over the premarket approval process, and thus bar plaintiffs' from initiating common law negligence and strict liability claims in state courts which may impose duties of safety and effectiveness on manufacturers that exceed the scope of the FDA regulations. The Court relied on the FDA's administrative expertise in making final determinations on medical devices after weighting the associated risks and benefits, and reasoned that jurors cannot be trusted to accurately assess the same risks and benefits.

To date, the Court has not reached a consensus on whether FDA regulations should also preempt all common law personal injury suits against pharmaceutical manufacturers, The Court reached a 4-4 split in Warner-Lambert v. Kent, 128 S. Ct. 1168 (2008), the case addressing this issue. The decision did not issue an opinion, but essentially affirmed the Second Circuit's view that FDA regulations did not preempt this particular Michigan personal injury lawsuit against the allegedly defective drug Rezulin®. Notably, this may not be the ideal test case as it involved a rather narrow preemption issue.

The Court has expressed its interest in deciding the issue of whether FDA regulations preempt all pharmaceutical litigation, including defective design, inadequate warnings, and manufacturing defects. Indeed, in October of this year, the Court will hear the landmark case of Wyeth v. Levine, 128 S. Ct. 1118 (2008), and possibly preempt the entire realm of personal injury lawsuits against pharmaceutical manufacturers. In January 2006, the FDA issued a strong statement in the Federal Register supporting the preemption of all conflicting state

laws. The ultimate holding of Levine may well hinge on the amount of deference the Court is willing to yield to the FDA's expertise.

The Third Circuit's ruling in Colaccio v. Apotex Inc. in April 2008, a case brought by the families of two people who committed suicide while on antidepressants, provided a possible preview of the treatment of preemption in the drug industry. The court held that the drug manufacturer was shielded from liability under state law for failure to warn because of the preemption of established FDA rules.

Proposed Change to Physician Education about New Drugs

On March 12, 2008, the U.S. Senate Special Committee on Aging Chairman Herb Kohl (D-WI) held a hearing to propose changes to the current practice of pharmaceutical companies educating physicians about their own pharmaceuticals. Chairman Kohl and Senator Dick Durbin (D-IL) plan to introduce legislation this spring which will seek to ensure that physicians receive unbiased information about new pharmaceuticals. The bill will include the provision of grants to fund the dissemination of neutral information to physicians through educational materials and medical professionals' personalized visits to physicians' offices.

This proposed legislation may negatively affect the pharmaceutical industry's current marketing strategy since an integral component of many companies' marketing schemes relies upon the company's direct distribution of product information to physicians. Nonetheless, in the hearing, Chairman Kohl emphasized the importance of academic detailing, and stated that, "[w]ithout academic detailing, physicians may not have access to information about the full array of pharmaceutical options, including low-cost generic alternatives. However, research has shown that when they do, doctors prescribe the best drug – not just the newest one – and health care spending is lowered."

The March 2008 hearing was conducted as follow-up to a hearing held in June 2007 in which the Committee evaluated the current relationships between physicians and drug companies. During the preceding hearing, Chairman Kohl and Finance Committee Ranking Member Senator Charles Grassley (R-IA) proposed the Physician Payment Sunshine Act (S. 2029), which requires manufacturers of pharmaceuticals, medical devices, and biologics to provide information about money they spend marketing their products to physicians. The pharmaceutical industry has opposed the Physician Payment Sunshine Act, claiming that it impedes the industry's ability to provide information to physicians about these medical resources.

Updating the Family and Medical Leave Act

The Family and Medical Leave Act (FMLA), enacted in 1993, allows eligible employees to take up to 12 weeks of unpaid leave due to a serious medical condition or to care for a new child. After the fifteenth anniversary of the law's enactment, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing on February 13, 2008 to discuss the future of FMLA. Senator Chris Dodd (D-CT), Chairman of the HELP Subcommittee on Children and Families and drafter of FMLA, discussed a new bill that would provide paid leave to employees and new FMLA regulations recently proposed by the Department of Labor (DOL).

The DOL has proposed several regulations to amend FMLA. One proposal would reverse the current provision allowing employees the leeway to call their employers for up to two days after an absence, eliminating a provision which protects employees facing unpredictable and sudden family medical emergencies. The new regulations would also allow employers to ask for documentation regarding the medical conditions of their employees twice a year, regardless if the employees' medical conditions are chronic or permanent.

In addition to the proposed changes related to employees, the DOL also seeks public comments on a new bill related to veterans (H.R. 3556). This bill would amend the FMLA to allow eligible employees to take up to 26 weeks of leave to care for an ill or injured family member who is on active duty or has active duty status. The proposed changes also include at least one pro-employer provision, which would allow employers to deny perfect attendance awards or benefits to employees that utilize FMLA leave days.

Proposed Legislation Aims to Provide "Sunshine" in Industry Relationships

House and Senate bills titled the "Physician Payments Sunshine Act of 2008" appear to be moving swiftly through Congress. The legislation (H.R. 5605 and S. 2029), sponsored in the Senate by Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI), require quarterly reporting of all transfers of value in excess of $25 between manufacturers of drugs and devices, including compensation, gifts, speaking and consulting fees, and physician ownership or investment interests. The bills make an exception for product samples that are intended for a patient. The legislation provides for delayed reporting of clinical trials. Penalties for noncompliance include a fine between $10,000 and $100,000. Some manufacturers, such as device maker Zimmer, have provided support for the bills. The legislation is partly a response to recent media attention to industry sponsored drug studies where compensation reports have not been properly disclosed. Senator Grassley believes that "a little bit of sunshine will go a long way" in promoting the best interests of patients in a fair market health care sytem.

Biswajit Chatterjee, Chandana Kolavala, Thomas B. Sparkman, and Rebecca L. Wolf contributed to this column.

WCL Health Law Project Announc

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

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

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

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

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

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

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

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Introduction to Health Care and Life Sciences Fundamentals

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

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

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