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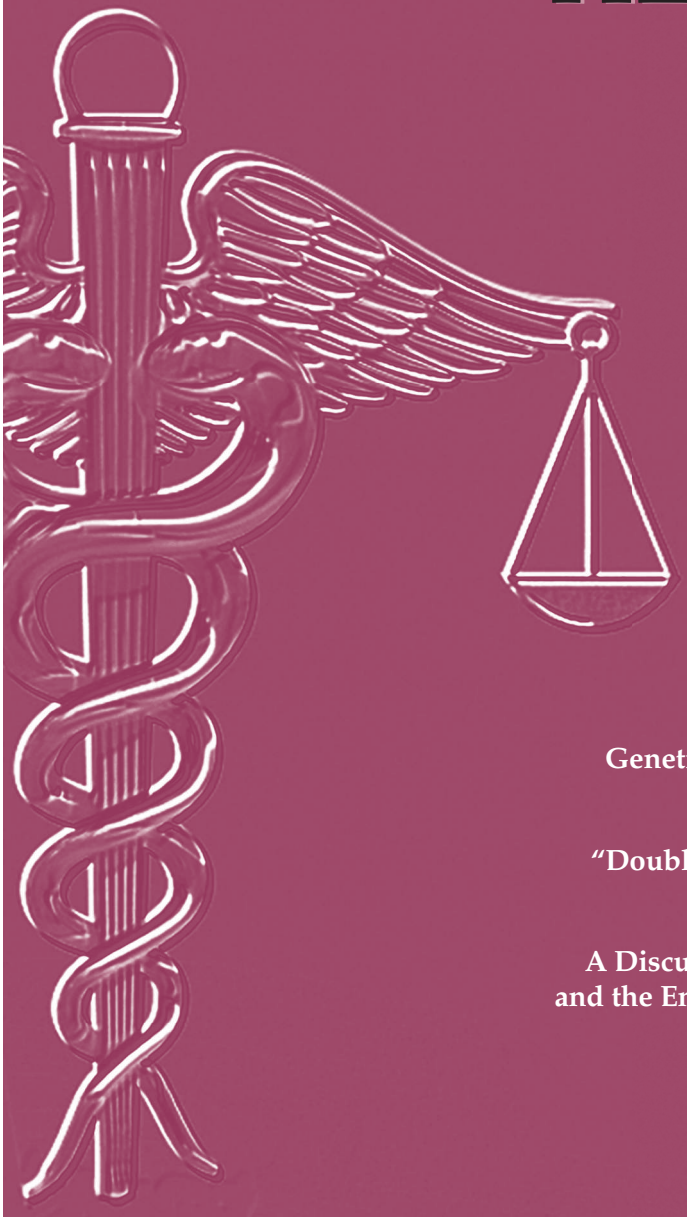
HEALTH LAW & POLICY



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AMERICAN UNIVERSITY

Health Law & Policy

Fall 2008 Staff

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

Letter from the Editors

Dear *Health Law & Policy* Reader:

On behalf of the Editorial Board and staff, we proudly present this issue of *Health Law & Policy*. Now in our fourth issue, we continue to strive to produce a publication that will both inform our readers of new developments in the ever-changing field of health care and help students at the Washington College of Law (WCL) discover an interest in health care law.

During this election year, universal health care was at the forefront of the presidential candidate debates. We open this issue with a transcript of a health care panel given at WCL that presented the presidential candidates' health care platforms. Following the discussion of the candidates' health care policies is an article presenting a discussion on regulations of medical resident work hours. This issue also addresses the controversial topics of genetic testing and anti-kickback statutes. Finally, this issue includes two student-written articles that explore ERISA and the "Double Jeopardy" facing New York's medical patients.

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

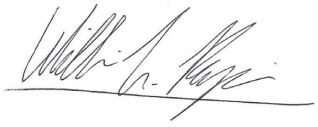
Currently, FSC Certification is one of four methods a publisher can employ to ensure its publications are being produced using the best sustainable practices. It is also the method practiced by our printer, HBP, Inc. (FSC Chain-of-Custody Certification: SW-COC-002553). *Health Law & Policy* is printed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

We extend our sincere gratitude and thanks to our advisor, Professor Corrine Parver, Esq. for her dedication and guidance. Further, we would like to thank our staff members for their tireless efforts during the production of this issue. We hope that you enjoy this issue as much as we enjoyed putting it together.

Sincerely,

Chandana Kolavala
Editor-in-Chief

Rebecca L. Wolf
Editor-in-Chief



William N. Papain
Editor-in-Chief

The Future of Health Care in America: A Panel on the Presidential Candidates' Health Care Reform Plans*

September 23, 2008

Heide Bajnrauh, Gwendolyn Majette, and Richard Teske

Corrine Parver: Welcome everyone to the second in a series of debates on the presidential candidates' health policy platforms. We held this same type of program before the elections in 2004. I am pleased that you all have a chance to come and listen, and participate in what will be a very exciting and energizing hour. I am the Executive Director of the Health Law Project at American University Washington College of Law (WCL). There are representatives here from the WCL Health Law and Justice Initiative, which is the student health law association, as well as editors and staff members from the *Health Law & Policy Brief*, which is the biannual student publication of health law and policy articles.

It is my great pleasure today to welcome our guest speakers. We have representatives from the supporters of the campaigns of Senators Barack Obama and John McCain, and Richard Teske, who was a Department of Health and Human Services official in the administrations and of President Ronald Reagan and George H. W. Bush. After his government service, Mr. Teske held positions advising pharmaceutical and medical device companies and, more recently, he has advised state governments on making their Medicaid State Health Programs more robust.

Gwendolyn Majette is a Global Health Law Scholar at Georgetown University's Law Center. She has had significant experience working on health law issues, including the analysis and review of Medicare policy as a Fellow with the Health Subcommittee of the House Ways and Means Committee. She currently serves on Senator Obama's Volunteer Health Policy Committee.

Heide Bajnrauh began her health career working for Senator John McCain on legislative issues in the late 1990s. She is a public policy advisor at Patton Boggs in Washington D.C., which is one of the major law and lobbying firms in the Nation's capitol. She consults with clients in biotech, pharmaceutical and medical device fields on payment issues, reimbursement processes, and health policy regulations. She is currently advising the McCain-Palin presidential campaign on health care issues.

We are going to begin the discussion with Gwen Majette, who is a supporter of Barack Obama.

Gwendolyn Majette: Good afternoon everyone. It is a pleasure to be with you this afternoon. I am a lawyer so I do have a disclaimer: I am not an official spokesperson for the Obama campaign. My presentation today is based upon my own personal views and should not be attributed to the campaign.

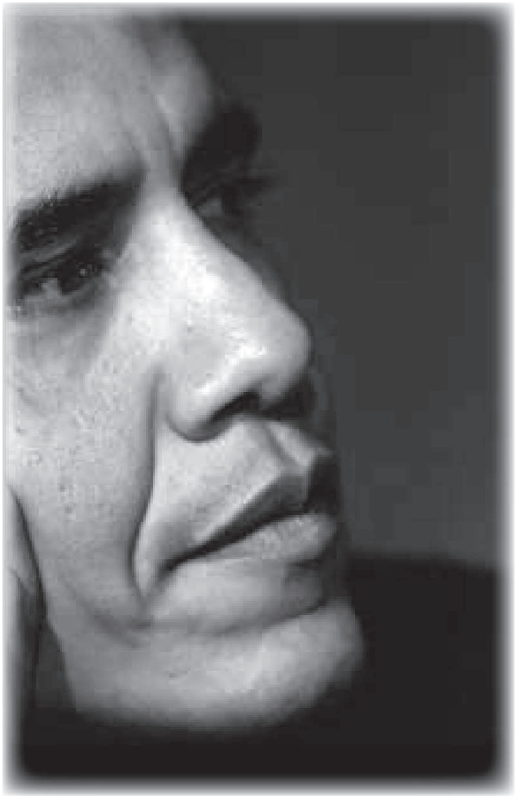
Barack Obama's plan or strategy to provide health care to all Americans includes three key components that his plan focuses on: affordability, quality, and portability. By this I mean that Obama's plan is designed to provide affordable, quality health care, as well as affordable, quality health insurance. Health insurance will be portable, meaning that as individuals change their jobs they will have access to affordable, quality health care.

Obama's proposal is designed to build upon our current system using those things that work well, so those individuals who are currently satisfied with their health insurance plan can continue with those plans. Obama's plan is also designed to expand coverage to the 46 million uninsured individuals in the United States, and to increase the value of the American health care system.

What does our current system looks like? Our current system of health care insurance coverage is primarily provided by two groups. The first and the largest is employer-sponsored health care. A Kaiser Family Foundation report shows that 54% of the people currently receiving health insurance receive it through their employers. I have seen some numbers today that suggest that two-thirds of the adults that have coverage receive it through their employer.

The other large provider of health insurance coverage is the government. Medicaid and other public programs like SCHIP provide 12% of coverage; another large portion of people are covered through Medicare — 14%. So, if you combine the employer-sponsored

* This panel took place prior to the November 4th, 2008 election. This transcript reflects a discussion of both candidates' health care platforms before Barack Obama's election.



coverage of 54% with the government-sponsored coverage of 26%, you will see that 80% of people are covered through employer-sponsored plans and the government plans.

Now, how specifically will Obama achieve coverage for all? President Obama will sign, in his first term, a universal health care plan that has five core attributes.

First, he will create a National Health Plan for individuals and small businesses to obtain affordable, quality coverage. This type of coverage will be comparable to what federal employees are currently receiving. He will also establish a National Health Insurance Exchange, which would allow individuals who choose to purchase private insurance to have a place to go where they can find affordable, quality, comprehensive plans to purchase. It will also moderate and provide fair rules of operation to make sure that insurance companies are treating insured consumers fairly.

The third attribute of Obama's plan is to preserve employer-sponsored health insurance. As I said before, two-thirds of adults have employer-sponsored coverage, so Obama's plan preserves that coverage by having an employer mandate. This mandate basically says that employers will be required to make a fair contribution to the health coverage costs of their employees, either by continuing to provide the insurance coverage that they provide or by paying some type of assessment toward their employees' insurance costs. Today, small employers and very small businesses do not provide coverage at the same level as larger employers. The Obama plan is designed to give them some incentives to provide coverage in the form of a small business tax credit. Small businesses and entrepreneurs who cannot afford it will be exempt from this employer mandate.

The fourth attribute of the Obama plan is to expand Medicaid and SCHIP. Some of you might not know, but during the most recent years as the number of uninsured has been increasing, it has been Medicaid and SCHIP that have been providing more coverage to those individuals. SCHIP specifically covers more children. The fifth aspect of the Obama plan is to leave Medicare intact for seniors and others (primarily individuals with disabilities).

Now, how is the Obama plan going to increase the value of the money that is currently being spent on health care? Well, there are several core components that the Obama plan uses to get more value from the system. According to the economists working with the campaign, individual families should be able to save $2,500 with their health care coverage costs under Obama's plan.

The Obama plan is going to focus on prevention. This is very important. There will be a shift towards providing more care via primary care providers. Many other industrialized countries in the world use primary care providers as the bulk of the providers of health care; and in those other countries, their health care costs are lower than ours and they also have higher value and better outcomes. This idea of focusing on primary care is not something new. The World Health Organization since 1978 has had a "health for all" agenda and has viewed primary care as a way to make sure that more people have access to affordable health care. When we are thinking about prevention, it is not only primary care, but we are also thinking about public health initiatives, such as focusing on tobacco cessation and the obesity problem.

Obama's plan will also focus on chronic disease management. Some of you might be aware that the incidence of chronic disease is increasing in the United States. The cost of care for people who have chronic diseases, especially multiple chronic diseases, is very expensive. So the Obama plan is designed to help screen for these diseases early and to help teach people how to better manage their care. Early intervention prevents complications that lead to expensive health care, like hospitalization.

The Obama plan is also going to emphasize Health (IT) as a way to reduce unnecessary and wasteful spending, medical errors, duplicate testing, and inefficient

billing. Health IT will also help identify who the best providers are, what the best treatments are, and what the best patient management tools are. The Obama plan proposes to invest $50 billion in Health IT. Other countries use Health IT more. Because of the high costs of Health IT, some type of financial contribution from the federal government will be needed to facilitate broad adoption of Health IT. Financial assistance is especially important for the many small physician practices that constitute the bulk of our physician practice in the United States.

The Obama plan also will have and encourage increased competition. The National Health Exchange is going to set standards for insurance companies and provide an environment for insurance companies to compete. The Obama plan will also increase competition in the drug markets by doing things like encouraging generic use of drugs.

Additional tools that will be used to add value in the Obama plan include transparency of cost and quality data. Here we are talking about what health care providers are doing, and getting data to make sure that they are providing quality, cost-effective health care services. We can require health care providers to give us data about medical errors; we can require hospitals to give us data about nurse staffing ratios; we can require hospitals to give us data about their hospital infection rates; and we can require them to give us data about health disparities. The data will help us decide who we want to use in our health care system, who are the best providers, and how can we get the most value for what is being spent. We are also going to impose disclosure obligations on insurance companies. We want to make sure that insurance companies are using the bulk of our premium dollars to provide medical care and not on administrative costs and, again, disclosure is the way that we can do that.

A core component of the Obama plan is the idea of comparative effectiveness. An institution will be established with the purpose of determining what medical treatments do not work. The medical literature shows that we do not currently know the effectiveness of many of the medical treatments that are provided today.

Another core reason why comparative effectiveness is important is because the chief driver of costs in the U.S. health care system, according to many reports, is the use of and adoption of new technology. We need to make sure that that new technology is cost-effective before it is adopted. This is something that we see in other countries. For example, England has an organization called the National Institute for Clinical Excellence (NICE), whose job is to advise the government about which health care treatments are cost-effective.

Another core component of the Obama plan is performance-based payment for physicians. You might have heard the term "pay for performance." The Obama plan will use this payment methodology. According to a large insurance carrier, using pay for performance and redesigning how it pays physicians is going to be the primary method to control costs. Physicians will no longer be paid based upon volume — the more volume, services, and procedures they provide the higher the pay. Instead, we are going to provide incentives to physicians to focus on the types and quality of care that will improve the health outcome of their patients so that we pay for better health outcomes.

The final feature that I want to emphasize is that the Obama plan will have a federal reinsurance plan. Essentially, what this will do is enable employers to continue offering affordable health care coverage when they have an individual employee in the group who has high health care costs. Under our present system, insurance companies typically raise the premiums for such employers; this results in everyone's premiums going up. Consequently, the employer may eventually be forced to drop the coverage or all of the healthy people leave the pool. The Obama plan will offer a federal reinsurance pool to help the employer cover those costs. Access to federal reinsurance is permitted as long as the employer promises that the savings will be used to lower the costs for their employees and continues to provide coverage. Those are some of the core features that I wanted to talk about with respect to the Obama plan.

In contrast, I want to talk about some of the features of the McCain health care reform plan. The design of the McCain plan will erode the employer-based health insurance that we talked about, which effectively pools group risk. It is going to do this by taking away the benefit that many employees receive by not being taxed on the contributions that their employers provide to employees for their health insurance coverage. Now, economists talk about this and they say that employees really do not benefit from the receipt of employer-provided health insurance because their wages are reduced by the amount of money that their employers pay for the insurance. What we do not know is that if we take away the benefit that encourages employers to buy it, whether they will use the savings to continue to provide coverage. Under the McCain plan, there is nothing to ensure that this occurs, but under the Obama plan there is an employer mandate. By unraveling group-provided health care that occurs through

employer-sponsored plans, the number of uninsured will not be reduced even minimally. In the articles that you read, it looks like the number of uninsured will be reduced by one-million individuals.

The McCain plan will provide individuals a $2,500 tax credit and families a $5,000 tax credit. The problem with this is that the cost of a family insurance plan today is $12,000. That is a $7,000 shortfall that individuals are now going to be required to pay. Because individuals only have $5,000 to go out into the marketplace, under the McCain plan, they are going to be looking for cheaper plans — "bare bones plans" — and they are not going to have the same level of comprehensive coverage.

Another impact of the McCain plan is that people will probably be forced into high-deductible plans. In those plans, the deductible and the cost sharing for individuals are much higher. They are basically designed to pay for catastrophic costs, so people are going to have higher co-payments and deductibles. People who are less healthy are going to have a very difficult time finding affordable coverage. The reason that this occurs under the McCain plan is that, in the unregulated market insurance, companies are going to be able to risk adjust premiums. This means that the insurance company can look at those less healthy people and say, "Okay, you are using this amount of health care coverage, we are going to charge you this premium." Obama's plan prohibits insurance companies from charging people more or excluding them because of health problems.

The levels of those premiums are exorbitant. Currently, less healthy individuals have difficulty obtaining coverage. McCain's solution to providing care to high-cost individuals is to build upon a model using high-risk pools. The problem with the high-risk pools is that the premiums are two times the premiums of the healthy individuals and the pools are financially unsustainable. For example, Maryland started a plan and within five years, that plan essentially went bankrupt because the high costs led to large payouts. So use of high-risk pools can be troubling.

I want to continue to talk about the financial consequences of either being uninsured or being underinsured. A poll conducted by the Kaiser Foundation showed that these individuals experienced adverse financial consequences as a result of medical bills. People were contacted by collection agencies; they had difficulty paying other bills; they were unable to pay basic necessities; they borrowed money; and they declared bankruptcy.

In 2001, half of the people who filed for bankruptcy cited medical causes as the reason for filing. These people were not primarily uninsured; they were probably underinsured or suffered from insurance companies dropping their coverage. So, 76% of the people had insurance at the onset of illness, yet one-third who were privately insured lost their coverage.

A more recent Kaiser survey analyzes the problems that people are currently facing because of the recent downturn in the U.S. economy. An August 2008 survey shows that 24% of the people surveyed said that they had problems paying for health care and health insurance. These health care related financial difficulties are likely to be exacerbated under the McCain plan.

Additionally, McCain's plan would increase taxes on some individuals. Because people no longer have the tax exclusion for the value of their employer-provided health insurance, one survey from the Kaiser Foundation and the Center for American Progress showed that couples making $60,000 in Maryland and Virginia would not only have to pay that $7,000 shortfall that was discussed earlier, but would also have to pay a tax — in Maryland and Virginia $1,500; and in D.C., $3,100.

Under the McCain plan there are weaker regulatory protections for consumers. The plan provides for an unregulated insurance market or a less regulated insurance market. Some of the protections that people currently have would be eliminated. In states that mandate certain benefits, such as cervical cancer screening or colorectal screening, insurance companies will no longer be required to offer them. If women are diagnosed with breast cancer, the insurance plans do not have to cover breast reconstruction surgery. So the mandates will be eliminated or plans will go to the states that have the least amount of regulation — either way it is not good for the consumer.

Other consumer protections came into existence because of problems that we had with managed care. Managed care has both positive and negative attributes. Under the McCain plan, some of the procedural protections from managed care's negative attributes may no longer be in place or they will be avoided — things like expedited review. Basically, if an insurance company decides that it is not going to pay for care that your physician has said that you need, you would no longer have the right to have that decision evaluated.

In summary, I think that the Obama plan is the better health plan for Americans. It provides access to affordable health care as well as affordable health insurance. Insurance coverage is portable because features like the National Health Insurance Exchange, as well as the national plan for small groups and individuals, facilitate the provision of coverage to individuals who no longer have access to group coverage. Obama's plan lays the groundwork for a high-performance health care system.

Heide Bajnrauh: I had the pleasure of working for Senator McCain on Capitol Hill for a few years. I worked for him in his state office, as well as in D.C., so he gave me an incredible opportunity. He actually was the one who pushed me into health care. I would like to thank the American University Washington College of Law for putting on this informative program. I think it is really important to hear different aspects of the health care reform plans so that you can make your own informed decision.

Senator McCain sees many of the problems with the U.S. health care sector as rooted in the encroachment of regulation and bureaucracy. I am sure everyone here has been to the DMV or any other place where you have to stand in a really long line and wait to get any sort of benefit that you think that you should have gotten first-hand without having to go through the whole slow process. I, as a D.C. resident, have encountered that quite often.

McCain wants to unleash incentives to create more competition in the private health care sector that would give people more choices and more affordable care and coverage. The senator has pointed out numerous times, and I quote, "The real key to reform is to restore control over our health care system to the patients themselves." John McCain's vision for America's health is based on four pillars of reform: affordability, portability and security, access and choice and, finally, quality.

I'll begin with affordability. John McCain believes in making health care more affordable for all Americans by ensuring that drug companies, doctors,

insurance companies, hospitals, and every other aspect of the health care system competes vigorously to respond to their needs. By rewarding quality, promoting prevention, and delivering health care more effectively and efficiently, we can ensure that every American can afford the health care coverage of their choice. Rising costs represent the greatest threat to achieving all of these goals. As we all know, and hear in the news every day, it is really the cost that is the issue. It makes it difficult for families and businesses to afford private coverage and puts increasing pressure on taxpayer dollars, which are paying the bill for these public programs like Medicare, Medicaid, and SCHIP. Cost puts health insurance out of reach for tens of millions of uninsured Americans.

Senator McCain would begin by creating a new and fairer tax subsidy that gives everyone equal help in purchasing coverage and that would unleash the power of the competitive marketplace to bring down costs. He proposes a tax credit of $2,500 for individuals and $5,000 for families to obtain basic health insurance. The credit would be refundable, meaning that people would get the full amount even if their tax bill is less than that. People who have job-based insurance today would see little change and could keep their current coverage. Nothing would change with the employer. They could still offer you the same health benefits that you receive today, but the credit would provide help to people shut out of the job-based insurance system. They could choose an insurer or other health care arrangement. Let us say a few years from now you decide that you would like to take some time off, either to help raise your children or to start your own business. You would be able to receive that tax credit to purchase health insurance — keeping yourself insured and your family insured.

This leads to the portability and security pillar. The tax break would be available whether people get their health insurance at work, as a great majority of people do, or whether they purchase coverage on their own or through new groups. This means that health insurance could be portable from job to job. People would have the security of coverage that they can own and keep with them over time, leading to better coordinated care. How often have you changed doctors yourself and had to go over your whole entire medical history all over again? This would actually alleviate that problem. You would be able to continue seeing the same doctor that perhaps you have seen for the last ten years, or maybe see somebody new and get your medical records over there so that care is coordinated — again, eliminating excessive testing and keeping costs down. You would not have to change from one doctor or one network to another when your employer changes insurance companies or when you change jobs, leading to better continuity of coverage and care.

What about those who have high health care costs? Senator McCain would create a new non-profit, Guaranteed Access Plan (GAP) to help those who have trouble getting insurance, usually because of preexisting conditions. He would provide new funding and guidance for the states to create GAP plans that allow people who are currently denied coverage to buy policies at affordable prices. This would not be another unfunded mandate to the states or a new federal entitlement program, but rather a partnership between the federal government, the states, insurance payors, and the medical community. There would be reasonable limits on premiums and additional assistance would be available to help people with lower incomes.

Senator McCain also wants to make premiums more affordable for tens of millions of others and he believes that the key lies in greater competition. As a result of that belief, he would allow people to purchase health insurance across state lines. Opening the health insurance market to nationwide competition would give people many more choices of policies that are not burdened by expensive state regulations that drive out competition and drive up prices. People could choose the best plan for them and their families, and through their choices would put pressure on companies to wring out excessive executive compensation and overhead costs.

For example, I am sure now many of you receive your insurance either through your employer or through the university, or perhaps some of you are still on your parents' insurance. McCain's plan would allow you the opportunity to go across state lines to see if there is a better plan for you. For example, if you got a job at a firm in California, that insurance policy would go with you so you would not have to change insurance.

The fourth pillar of quality, which is similar to Senator Obama's plan, really focuses on the coordinated care that I spoke about earlier, but also focuses on transparency, Health IT, and comparative effectiveness reform. But we have to improve quality of care. So this means providing new incentives for the medical profession to provide better care at lower costs. The biggest public programs, Medicare and Medicaid, can lead the way by paying for outcomes, not just for doing procedures and tests. Transparency is crucial so people can know the

outcome records of doctors and hospitals and what type of tests can be done and what those tests cost.

How many here can tell me what their doctor charges an hour for an evaluation and management visit? Some general practitioners charge $150 an hour, some $220 an hour, and some $95 an hour, depending on what community you live in. Without that knowledge you have no idea what the actual cost of treatment is. Perhaps there is a different doctor that you would like to see that would actually save you money in the long-run.

McCain also believes that it is essential to bring the health sector into the information age and supports providing incentives for doctors to provide better coordinated care through secure health records that not only protect patient privacy, but also make sure that doctors have access to their patients' medical histories so that they can provide the best care.

He also believes that individual responsibility in health care is crucial — giving people better incentives to take care of their own health. Rather than paying for procedures as we do today, he says we need to institute a new generation of chronic disease prevention, early intervention, and new treatment models to help patients stay healthy. No amount of money we spend on health care in the future will be enough if we do not get control of the epidemics of obesity, heart disease, diabetes, cancer, and other chronic conditions.

McCain also believes that health costs can be reduced by minimizing needless costs from lawsuits and the threat of lawsuits. He would protect doctors from lawsuits if they follow clinical guidelines and adhere to patient safety protocols.

Some criticism has been leveled against Senator McCain for the boldness of his tax credit idea, with some saying that it would spell the end of the employment-based health insurance system that provides health coverage to nearly 160 million Americans. The plan would be little more than an accounting change for the great majority of people with job-based coverage, moving the current invisible tax exclusion for job-based insurance to a more visible and more portable tax credit.

You heard Gwendolyn say that the average costs for insurance for families is something like $12,000. So where do you get the additional $7,000 after tax credit to pay for your premiums? The answer is the same place you do now. If you already have employer insurance, nothing changes — they can still provide the same wages and insurance. The tax credit is equivalent to the existing tax break on a $15,000 policy. If the policy is cheaper, then the worker comes out ahead. If the worker was buying his or her own insurance, then the premium was coming out of his or her pocket anyway; it still will, but the tax credit will offset some of the cost and make it more affordable. If the worker ends up dropping out of employer insurance and choosing one of the many options that will be available, they will have additional cash equal to the premiums they were paying, typically 25% of the total cost, and you will have cut the employer's cost so he or she will be able to raise your wages. Importantly, the tax credit does not exist in isolation. Competition between insurance companies will allow you to buy better, more affordable, and more customized insurance, which will reduce health care costs for everyone and make insurance cheaper to purchase.

The foundation of Senator McCain's health plan is the belief in the ability of Americans to make the best decisions about their health care and coverage they and their families need, with new subsidies and market reforms to help make that care and coverage more affordable, more accessible, and higher quality. Senator McCain does not want to force anyone to have health insurance or pay for health insurance. Of the 47 million people that are uninsured today, many of them choose to be uninsured.

Senator McCain says that the future quality of health care in the United States and around the world depends upon continued innovation, which is another one of his pillars. The goal, after all, is to make the best care available to everyone. The McCain health plan focuses on working with businesses and insurance companies to widely employ common sense approaches, like smoking cessation programs, promoting healthier eating habits, and encouraging a more active lifestyle. These do not only reduce incidents of cancer, but also of chronic diseases like diabetes and hypertension. By the way, the tobacco tax was the billing mechanism for the children's health insurance bill that Senator McCain did not vote for, but Senator Obama did. I just want to raise this point because that is often brought up — why Senator McCain did not vote for the extension of SCHIP — it is because he did not feel it should be funded by encouraging people to smoke more.

Most importantly, John McCain believes that no American, simply because of a preexisting condition like cancer, should be denied access to quality and affordable coverage. This is a very important priority in his health care plan — to make sure that people get the high quality coverage they need. The GAP plan will come into play to actually bring together industry and state, creating higher-risk pools so that people with preexisting conditions can have the insurance that they deserve.

Something that was mentioned to me prior to this talk was how these candidates' health care reforms will change health care in the future. As I mentioned before, health care is not on a good path — the costs are just unsustainable. Medicare and Medicaid cannot go on. Who knows — it may not even be there when you are 65. At this time we really need to come up with other ways.

One thing that Senator Obama has brought up in the past is the federal employee health insurance benefit plan, which is offered to members of congress, senators, and government workers. Well, I happened to have been on that plan when I worked for the Senate. That plan is also a private market plan and each year insurance companies contract out and vie for that opportunity to cover those government workers. Even in a plan that you think is an all-inclusive insurance market and everyone is going to have insurance, there is still going to be a need for some sort of contracting out. Everyone knows that when you contract out and you send out your proposal, you lower costs as a result of competition.

One of the issues that I think needs to change overall is included in McCain's plan, as well in Obama's plan. This is lowering drug prices. Senator McCain is in favor of a safe re-importation of drugs and making sure that generic drugs get to the market faster because brand name medicine is very expensive.

Also, chronic conditions account for about three-quarters of the annual health care bill. So through prevention and early intervention, healthy habits, screenings — those types of things — we can lower costs using health information technologies. McCain would like to focus on promoting and coordinating care, expanding access to health care, Medicaid and Medicare

reform, and transparency. Right now, you have no idea what your employer pays for your health insurance. You have no idea what your doctor charges. You have no idea what Blue Cross Blue Shield has contracted out with your preferred provider organization. The public needs to have that information to make good health care choices.

Richard Teske: Good afternoon. My role today is to comment on the two presentations you have just heard. I will try to be as fair and balanced in the jargon of today as I can be. In terms of jargon, you have just been subjected to a blizzard: insurance jargon, health care jargon, government jargon. Anybody who gets immersed in health care public policy will tell you that it will take you years to figure out what the jargon means. Once you figure out what the jargon means, putting it together into a cohesive whole is really difficult because only then can you start making policies. A lot of the policies in health care, once made, have a lot of very bad, but unintended, consequences. That is what we are talking about in health care. We are talking about one-sixth of the country's economy. If you make a mistake on your health care policy, you could actually destroy your entire economy.

The three papers that you have in front of you are excellent. The two papers critiquing each health plan are very good.[1] The Mark Pauly paper is also extremely good.[2] His paper is trying to take the best elements of both plans and come out with a solution. In the last page of Mark Pauly's paper, he says, "In the short run, such a system with income-targeted neutral tax credits replacing all or a major part of the employment-based exclusion could greatly reduce the number of uninsured people."[3] Fine. But the parenthetical is what I want you to look at: "the amount of reduction depending on the generosity of the subsidy and the specifications of minimum qualifying coverage."[4] Those are the two issues that we are really talking about here. We are talking about the generosity of a subsidy and the structure of the minimum qualifying benefit package. Those are the two elements that you have to concentrate on.

The major problem in reaching the goal of universal coverage or covering the uninsured and the uninsurable is: Where do you get the money? There are really only four places you can get the money. There is Medicaid at about 12%; Medicare, at 14%; private insurance, which is split between employees and employers, which is just over half at about 54%; and individual plans, at about 5%. The fourth area is out-of-pocket — you just pay for it when you need it. A lot of the uninsured and uninsurable are in that out-of-pocket category. When I talk in front of groups like this somebody always stands up and says, "You know you people in Washington, you just do not get it . . . the solution to health care is very simple" and they give me an X, Y, Z solution. Usually it is a pretty good solution. The problem in Washington is not that we do not have solutions. The problem is that we are awash in good solutions. But the difficulty lies in the fact that you are taking this system from here and going to there — it is the transition period. How do you get from here to there, without incredibly increasing your costs or making structural problems?

My wife tells me that my chief talent in life is blazing flashes of the obvious. Using that, let me just try and put these two Senators' plans into context. There are three things that all insurance policies and programs have in common. The first is eligibility: Who is eligible? Second is the benefits package: What do you get? And third, the cost. Obviously, they are all related, but those are the three, very simply. There are basically two philosophies in providing health care. One is a government-run system; the second is primarily a consumer- or market-driven system. The first one, the government-run system, is a defined-benefits program, like Medicare and Medicaid. What does that mean? It means that you have your eligibility fixed. You know exactly who is eligible for the plan. Your benefit package is fixed. These are the benefits you will get and the cost is variable. Why is that? Because the way it works when there is a defined-benefits program is that, if you are eligible for the program, you are entitled to all the benefits regardless of cost. That is why it is called an entitlement program. This essentially is the Obama plan. He is working off a defined-benefits structure because he's saying, "this is the program I want."

The McCain program is the opposite: it is a defined-contribution program. What does that mean? Again, eligibility is fixed. You are the people we are going to cover. Costs are fixed. McCain will give a set dollar amount to you — no more, no less. You do with it as you please, so the cost is fixed. The variable is the benefits package. That is where the competition comes in. Different employers, like under the federal employee health benefits program, will offer different benefits packages, and you choose the benefit package that you like. It is the benefit package that varies.

In government, you regulate the variable. Look at Medicare and Medicaid: defined-benefits programs.

In the last forty years, 90% of the regulations have been based on cost containment and relatively few have been based on quality or access. Under the McCain program, the cost is pretty much controlled because it is a set amount, but the benefits are where you get the regulation. You look at quality and information; things like that would impact your decision as a consumer.

This pithy example also isolates the problem with both plans. For the Obama plan to work, you need a good benefits package to attract the people to use it. He is not using an independent or an individual mandate. He is not forcing you to buy it. If he forced you to buy his plan, then he could have a low benefit package because everybody would at least have that. But the benefit package has to be rich enough to attract participation in the plan. If you have a really rich benefit package, then what happens? Obama's plan relies on preserving the employer system. Employers would either have to pay or play. The richer the benefit package the more employers will opt out of the plan — pay rather than play. Think of all the paperwork, all the negotiation, all the headaches that come with playing rather than paying. So you have that tension in the Obama plan.

As part of my eclectic career, for a couple of years I advised the Business Roundtable's health policy. There was not a single corporation on that committee that would not drop health care coverage tomorrow if they could. Why? Ask GM, Ford, and Chrysler. Pension and health benefits programs are the single most non-competitive element of their cost structure vis-à-vis Toyota and everybody else. This is another problem with the Obama plan.

The problem with the McCain plan is costs. You are getting a set amount, but that amount is not indexed for your income; nor is it indexed for health care inflation. If it is indexed, that is the first thing that is going to be on the table in front of Congress, namely: indexing the amount that your refundable tax credit would be under the McCain plan. Well, if you index it to health care inflation, which usually runs two-to-three times general inflation, again you have costs going out of control. Now, what does this do?

When I joined the Reagan Administration in 1981, I was the de facto head of the Medicaid program and I, like most young political appointees, had two qualifications for the spot. One was arrogance and the other was stupidity. Armed with those two qualities, I knew all the answers to the health care solutions. I was working with a group of officials and I said, "You know the problem with these bureaucrats is they cannot think out of the box. Where is the creativity? They only see this limited way." Well after a couple of years, I started to learn about the programs and I realized that I was wrong. The problem was not thinking outside of the box: the problem was the box. It is the structure of the programs themselves — not the benefits, not how many tax credits you get, and not how many IT elements you have for "hot gizmos" in the system. The structure of the program itself is the problem. If there is one criticism I would make of both plans, it is that they do not make any structural change.

The Obama plan is resting on employer-based insurance and that is going away. Employers are fleeing that; they do not want to provide insurance. You will find the traditional pension and health benefits in ten years only in one place, for public employees. Otherwise, it is going to be all gone.

The McCain system also does not do anything about containing the costs of the entire program. There are a couple of bells and whistles in there but essentially the costs will run away because of the structure. It is built into the structure of how we provide health care.

The Pauly paper comes close to analyzing these deficiencies. If we are talking about structural change, what would it look like? Remember what I said when I began: Washington is awash in good ideas. It is how you get to your idea that counts. But let's say that I wave a magic wand and eliminate that problem. What we have now is a health insurance system that covers middle dollar coverage. What do I mean? It means that you have a deductible up to a certain point, then the insurance kicks in, and then if you use a lot of that insurance, your lifetime limits kicks off and you are exposed again. So it is that middle band that insurance covers. That is stupid. That is not the way insurance should work. Catastrophic insurance should cover both acute- and long-term care with no lifetime limits. In other words, if you have catastrophic diseases, costing millions of dollars a year, it never knocks out. To afford that, you pay like McCain does — through refundable tax credits. Everybody would get catastrophic, long-term, and acute care coverage. Of course, if you are going to do that, you are going to have a high deductible right there. For the rich, a $10,000 deductible is fine as long they get this to cover their assets, so to speak. But what about the poor? What about the people who cannot cover a $10,000 or $15,000 deductible? That is what you call Medicaid and you do it based on income. Now that is as simple as I can put the ultimate system. This is a huge structural change.

There is one other thing about the McCain program that you have to note. Only five percent of the insurance today is provided to individuals. That means that we really do not know how that market works. I can tell you this, when I met with the health insurance industry and pitched the tax credit program based on individual policies, I debated somebody who wanted national health insurance. I said this can be a piece of cake. I am going to win this one easy. I lost. Why was that? Because the health insurance company marketing departments do not want to sell individual policies. It is a lot easier to go into Ford Motor Company with one guy and sell 500,000 policies in a day rather than sell them one at a time. The cost to the system under individual policies with tax credits is not to be underestimated. We really do not have a good picture of what it would be like given the present market penetration with these policies. That is a quick rundown simplistically of the two plans and their approaches.

In summary, both plans have a lot of good elements. Again, look at the Pauly paper, because he tries to combine them. The two other papers are excellent critiques of the plan but they are not about structural change. I do not think either plan will get us out of the hole of increasing health care costs in the long term. Thank you.

1 Joseph Antos, Hanns Kuttner, & Gall Willensky, *The Obama Plan: More Regulation, Unsustainable Spending*, Health Affairs, Sept. 16, 2008, at 462, *available at* http://content.healthaffairs.org/cgi/content/full/hlthaff.27.6.w462/DC1. Thomas Buchmueller, Sherry A. Glied, Anne Royalty, & Katherine Swartz, *Cost And Coverage Implications Of The McCain Plan To Restructure Health Insurance*, Health Affairs, Sept. 16, 2008, at 472, *available at* http://content.healthaffairs.org/cgi/content/abstract/hlthaff.27.6.w472v1.

2 Mark V. Pauly, *Blending Better Ingredients For Health Reform*, Health Affairs, Sept. 16, 2008, at 472, *available at* http://content.healthaffairs.org/cgi/reprint/hlthaff.27.6.w482v1.

3 *Id.* at 490.

4 *Id.*

Medical Resident Maximum Hour Regulations: Overcoming Institutional Resistance for Real Reform

*Braham Boyce Ketcham**

I. Introduction

The Accreditation Council for Graduate Medical Education (ACGME), an institution "responsible for the [a]ccreditation of post-MD medical training programs within the United States,"[1] faced rising pressure in 2001 to address the long hours worked by medical residents. Public concern for patient safety and residents' attempts to invite government intervention forced ACGME to respond. ACGME convened a work group to address medical resident duty hours and issued a report the following year which recommended that hospitals restrict the long hours that medical residents worked.[2] These measures were implemented on July 1, 2003, negating the need for federal intervention. The graduate medical education community waited to observe the manner in which new restrictions would be implemented.[3]

Since then, however, the ACGME standards have fallen short of their goal to bring resident duty hours down to a level that is safe for resident physicians and their patients. ACGME's self-regulation only forestalled discussion for a few years. Non-compliance, underreporting, and other weaknesses of their approach have renewed the controversy and calls for external regulation.[4] Federal legislation was reintroduced two years after the ACGME regulations took effect,[5] and several states have also taken steps to regulate resident hours.[6] The task is not straightforward, however, as regulators must address both institutional resistance to any cutbacks and understaffing caused by restricting hours. Current proposals do not meet this need.

This article makes the case for a new alternative to ACGME's regulation of resident duty hours, arguing for incentives to overcome stubborn internal resistance. Section II provides background information on the issues involved, including the role of residents in medical education, the history of long work hours, and the dangers posed by such extended hours. Section III details the history leading up to ACGME's decision to assume the regulator's role for itself, including legislation passed in New York State and residents' non-legislative efforts to reduce the number of hours worked. Section IV addresses the shortcomings of the current regulatory systems, focusing on the current ACGME standards. Section V examines state and federal legislation which has been offered as an alternative to the ACGME standards. Finally, Section VI recommends changes which will reduce resident work hours while avoiding the shortcomings of current proposals.

> "While popular television shows glamorize the lives of residents, the reality of their excessive schedules is far from glamorous. Their chronic sleep deprivation endangers both themselves and their patients."

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II. Background Resident Duty Hours

Unsurprisingly, it is no secret that hospital residents routinely work long hours. While popular television shows glamorize the lives of residents,[7] the reality of their excessive schedules is far from glamorous. Their chronic sleep deprivation endangers both themselves and their patients. Nevertheless, the educational culture embraces its tradition of long hours, and stubbornly resists change.

A. The Role of Residents in Medical Education

Medical residencies play a vital and important role in graduate medical education. After completing their four-year MD programs, aspiring doctors complete a multi-year residency, choosing a specialty and learning the practice of medicine hands-on.[8] These years are viewed as some of the most formative and essential in a physician's training.

i. History and Development of Residency

The modern residency program has developed over the last century to become an integral part of graduate medical education. In 1893, Johns Hopkins University built and operated a hospital as part of its program in medical education.[9] There, "the term 'residency' was first used to describe advanced specialty training following an internship."[10] This program became the American model, as graduate medical education shifted away from a system of apprenticeships to a hospital-centered learning process.[11] Dr. Kenneth M. Ludmerer describes the creation of the modern internship and residency in the early 1900s:

> Even a superior experience in medical school could no longer prepare a person for private practice. Accordingly, a period of hospital education following graduation — the "internship" — became standard for every physician. In addition, further training was necessary for those who wished to enter specialty practice or pursue academic careers. For those purposes the "residency" — a several-year hospital experience following internship — became the accepted vehicle.[12]

These "house-staff" physicians, or "house officers," were referred to as residents because they actually lived in the hospital and, thus, were always available. They "lived, worked, and slept in the hospital in order to follow the evolution of the illnesses of patients who were hospitalized for extended periods."[13] This "complete immersion" was seen as the best way for doctors to learn the craft.[14]

As an additional note on terminology, the first year of residency is often called an internship, though ACGME no longer recognizes this distinction and considers all post-graduate training programs to be residencies.[15] Nevertheless, first-year residents are still often called interns.

ii. Residents are Placed Through the Match Program

Each spring, graduating MDs participate in the National Resident Matching Program (the Match Program), a private non-profit corporation founded in 1953.[16] The Match Program matches residents with teaching hospitals based on surveys of participants' preferences. Around 16,000 U.S. medical school graduates compete with roughly 18,000 independent applicants for the approximately 24,000 residency positions.[17] On Match Day, the third Thursday in March, these results are announced publicly.[18] The Match Program was created to replace a hodge-podge of conflicting deadlines and offers that "forced students to make rash decisions" before they heard back from all the programs they had applied to.[19]

Applicants for a residency are informed on the Monday before Match Day whether they have been matched.[20] If not, they must scramble to find an alternate program by the next day, forgoing the typical research and thought that would ordinarily accompany such a decision, even causing some applicants to switch their specialty.[21] The Match Program has also come under criticism because some residents claim that participation prevents them from bargaining over wages or hours.[22]

iii. A Tradition and Culture of Long Hours

Before the ACGME proposals to shorten hours took effect, the traditional resident work schedule imposed extraordinary demands. "[C]ompleting all the tasks of a trainee routinely required 100 hours of work a week or more."[23] A 1999 study found that 25% of residents reported that they worked more than 80 hours per week even when averaged over the entire year.[24] Typical work hours range from 60 to 136 hours per week.[25]

To attain those hours each week, residents must work long overnight shifts, known as being "on-call." A study of residents just before the ACGME guidelines took effect reported: "Most interns in our study routinely worked more than 30 consecutive hours. . . . [T]here were 275 reports from interns who worked more than 40 continuous hours." Extrapolating nationwide "suggests that physicians in training worked approximately 20,000 extended shifts that exceeded 40 consecutive hours while caring for patients" in 2002–03.[26]

In contrast, the 2003 ACGME proposal limits residents to 80 duty hours per week, averaged over a four-week period, but certain programs may petition to increase to 88 hours per week. Residents must have one free day per week and cannot be on-call more often than every third night. These limits are also averaged over a four-week period. The proposals also restrict shifts to 24 hours, with up to 6 hours allowed for transfer and debriefing. Residents must be given 10 hours off between shifts. Finally, if a resident is called from home, any time spent in the hospital counts towards their limit.[27]

B. Long Hours Pose a Public Health Danger

Their work schedules push residents' bodies to their functional limits. The dangers associated with excessive and long-term sleep deprivation have long been known.[28] In the context of patient care, the potential for harm is extreme. Patients are at risk when they receive treatment from sleep-deprived residents, who are more prone to make medical errors.[29] Furthermore, the residents themselves are at a much higher risk of hospital and automobile accidents from chronic sleep loss.[30] These dangers raise the issue of resident work hours to the level of a public health risk.

Regulations are common in other industries where sleep-loss brings public risk. For instance, in 2002 Gaba and Howard noted that "[t]he levels of continuous duty and work hours for health care personnel are much greater than those allowed in the transportation and nuclear-power industries."[31] The long hours required of residents harm the national healthcare system. Kenneth Shine, a former president of the Institute of Medicine said, "We have house officers working enormous hours. We would never do that if we were designing a good system in terms of quality of care."[32] The problem is widespread, as 70% of residents report having seen colleagues work while impaired, most often due to lack of sleep.[33] More than a simple labor dispute, excessive resident hours demand public attention.

i. Residents' Sleep Deprivation is Dangerous for Their Patients

As a result of their work schedules, hospital residents are frequently sleep-deprived, especially during overnight call shifts. Being awake for extended periods of time impairs residents' efficacy. One study found that psychomotor performance after being awake for 24 hours was equivalent to performance with a blood alcohol level of 0.10%, higher than the legal limit for driving a vehicle.[34] If alcohol were a problem in hospitals, the public surely would not tolerate drunk doctoring. Sleep deprivation deserves the same level of scrutiny.

Under such circumstances, higher rates of error are unavoidable. A study by the Harvard Work Hours, Health and Safety Group published in 2004 compared "rates of serious medical errors made by interns while they were working according to a traditional schedule with extended (24 hours or more) work shifts every other shift (an "every third night" call schedule) and while they were working according to an intervention schedule that eliminated extra work shifts and reduced the number of hours worked per week."[35] The study found that the traditional schedule led to a 35.9% increase in serious medical errors, "including 56.6% more nonintercepted serious errors."[36]

These problems are effectively addressed by reducing the number of hours worked. In a parallel study, the Harvard group also found that residents on an intervention schedule of less than 80 hours per week slept more and "had less than half the rate of attentional failures while working during on-call nights."[37]

ii. Sleep Deprivation Endangers the Residents Themselves

Sleepy residents are not just more likely to commit medical errors that harm their patients; they are also more likely to harm *themselves* due to their impairment. A study published in 2005 found that sleep-deprived residents were at a significantly higher risk for motor vehicle crashes when their schedule included extended work shifts.[38] These residents were more than twice as likely to report a crash and nearly six times as likely to report a near-miss after working an extended shift than after working a shift of less than 24 hours.[39] In addition, "every extended work shift that was scheduled in a month increased the monthly risk of a motor vehicle crash by 9.1% and increased the monthly risk of a crash during the commute from work by 16.2%."[40]

Tired residents are also more likely to injure themselves in the hospital. A 2006 study published by the *Journal of the American Medical Association* examined the way in which extended shifts for interns affect the odds of accidental needle sticks and laceration injuries, finding that the most common contributing factors were loss of concentration and fatigue.[41] Injuries of this type were 1.61 times more frequent during extended shifts.[42] Furthermore, the stress of long hours can take an emotional toll. Dr. Ludmerer observed that "[o]verwork and exhaustion did perverse things to caring individuals who entered medicine to serve . . . . Not surprisingly, stress-related depression, emotional impairment, and alcohol and substance abuse were well-documented phenomena among house officers."[43]

> "Since the primary purpose of residency is education, many doctors believe that the long hours are justified by the ability to watch patients' progress through the course of a shift."

C. Resistance to Changes in Resident Duty Hours

Despite the risks of long work hours, reformers confront serious and nontrivial resistance from within the graduate medical education community. Many doctors believe in the virtues of long hours — that continuity of care provides benefits to residents and their patients. Other doctors point to the costs of reducing hours in a system where all available employees are already working at their limits.

i. Long Hours Viewed as Essential to the Educational Purpose of Residency

Teaching hospitals view their residents as students first and employees second,[44] as reflected in their salaries. The average starting pay rate for residents is $43,266 per year.[45] For those residents working over 80 hours per week this totals less than $11 per hour, meager compensation for a position requiring so much work and responsibility, as well as a four-year postgraduate degree.[46] Moreover, the average medical graduate carried a debt of $110,000 in 2003.[47] Since the primary purpose of residency is education, many doctors believe that the long hours are justified by the ability to watch patients' progress through the course of a shift.Residents also reap "benefits resulting from assuming total responsibility for one's patients."[48]

The residency is a unique time in a physician's career, "fundamental in shaping the way a physician thinks, works, and acts."[49] Doctors see themselves as being servants to their patients' health above all else, so they cannot control what hours they work. In that vein, they view the residency as a time to learn under particularly grueling conditions. Michael Sutherland, a thoracic surgeon and Vice Chair of the American College of Surgeons' Resident and Associate Society commented, "I've always been taught that you should train at a level harder than what you're expected to do in private practice. It prepares you to work under adverse conditions."[50]

Perhaps most importantly to many critics of regulation, residents who work fewer hours have less first-hand experience when their education is complete. They argue that long hours bring educational benefits that cannot be replaced: "The long hours on duty have come at a cost, but they have allowed trainees to learn how the disease process modifies patients' lives. Long hours have also served to teach a central professional lesson about personal responsibility to one's patients, above and beyond work schedules and personal plans."[51] Even the residents themselves may feel that they are missing out on educational opportunities when they work shorter hours.[52] Participants in one

study on reduced resident hours acknowledged that their learning had been compromised by the shorter work hours.[53]

Some doctors express the opinion that medical professionalism can be forged only in the flames of experience: "Limits on hours on call will disrupt one of the ways we have taught young physicians [the] critical value" of personal responsibility to patients.[54] Without this understanding, many fear the soul of the profession could be lost, "exchanging out sleep-deprived healers for a cadre of wide-awake technicians."[55] The idea of low pay, the older doctor[s] say, is to impress on the beginning doctor that his duty is to patients, and not just to make money."[56]

ii. Attitudes toward Long Hours

In addition to its educational benefits, many doctors look on the residency as a sort of hazing ritual for young physicians. Residents put up with the long hours to meet expectations, and their supervisors demand long hours almost as a rite of passage. The Director of Residency at one teaching hospital also recognized an attitude that, "Hey, we made it through. So should you."[57] After a 1975 strike in New York City yielded shorter weeks, one doctor griped that "When I was a boy, . . . we worked two out of three nights, and now they're only working one night of three."[58] Those residents who cannot cope with the pressures are often dismissed from their positions.[59]

Nearly all current doctors have passed through the residency program with its traditional demands for long hours. The experience is frequently described in military terms, "like basic training in the Army that toughens up a soldier."[60] One surgeon commented that the ACGME standards have "made [residents] weak and inexperienced. Look at the military. They train for war. They don't say, oh, this is training; let's only make them work 80 hours a week. You have to be sharp. You do it through practice."[61]

iii. Monetary Costs of Restricted Work Hours

Reducing hours for residents is not simply a matter of imposing restrictions. Hospitals must either hire additional support staff to perform tasks previously done by residents or reduce their level of care. A 2002 study estimated that compliance with the ACGME hours proposal would cost hospitals between $1.4 billion and $1.8 billion each year in additional labor costs.[62] Teaching hospitals with limited resources would have the most trouble making up for work lost to restricted hours. Ingrid Philibert, Director of Field Activities for ACGME, noted that "[i]f an institution can't afford to replace a resident, you may hurt patient care by reducing resident hours."[63] The alternative that hospitals face is simply to ignore any new regulations.

Because graduate medical education is primarily concerned with patient care, the "major source of support for residency and fellowship programs came from patient care revenues."[64] This requires that residents must be, to an extent, their own support staff, performing "extraneous duties . . . such as drawing blood and inserting intravenous lines. At a number of teaching hospitals, it was estimated that house officers spent roughly one-quarter of their time at these activities."[65] Labor-saving technologies have benefited hospitals, but not residents, "for telephone calls, scheduling chores, dictations, and time spent charting increased even as the time consumed by manual procedures decreased."[66]

This tends to undercut arguments that the long hours are educationally necessary. Dr. Ludmerer notes that "the amount of service actually required for learning was far less than that which hospitals typically extracted from house officers. The tradition of the economic exploitation of house officers persisted as hospitals continued to rely on trainees for an extraordinary range and amount of ancillary responsibilities."[67]

III. Attempts at Regulation Lead to the ACGME Guidelines

Even before 2003, several attempts were made to regulate resident work hours. New York State acted first, implementing legislation in 1989 after a high profile case found that resident error was a factor in a patient's death. In the face of mounting evidence of the risks associated with sleep deprivation, residents began to push for national changes. Eventually, ACGME implemented its own restrictions, obviating at least temporarily the demand for federal legislation.

A. New York State is the First to Regulate

New York State passed the nation's first restrictions on resident duty hours after a patient's death exposed the potential for sleep-deprived residents to make avoidable medical errors.

i. The Libby Zion Case Brings Public Pressure to Impose Regulations

In 1984, Libby Zion, an eighteen-year-old woman was admitted to New York Hospital with fever after having a tooth removed.[68] During the course of an overnight stay, her condition worsened, and she died only hours after arrival.[69] Amid controversy over her death, Libby's father, Sidney Zion, a columnist for the *New York Times* and a former prosecutor, pressed for a grand jury investigation to investigate the death.[70]

The grand jury did not return any indictments, but "criticized the residency system for permitting patient fatigue resulting from long work hours and lack of supervision in the emergency room."[71] Mr. Zion eventually filed and won a malpractice suit against several of the doctors involved.[72]

ii. The Bell Commission Proposes Standards for New York

In response to the publicity surrounding the Zion case, the State Health Commissioner convened a commission to address excessive resident hours.[73] Headed by Dr. Bertrand Bell, a professor of medicine, the commission was informally known as the Bell Commission. When the Bell Commission released its proposals, they included:

> (1) an 80-hour work week, averaged over four weeks; (2) a 24-hour limit per work shift; (3) eight hours between work shifts; and (4) at least one 24-hour period per week not on call. Surgical residencies would be exempt from the 24-hour limit on work shifts under the following circumstances: (1) residents, while on call at night, are generally resting with infrequent interruptions for patient care; (2) residents are on call no less than every third night; (3) resident receive rest periods of 16 hours after on-call shift; and (4) residents may be relieved of duty if fatigued while on call.[74]

The legislature enacted the Bell Commission's recommendations, which took effect on July 1, 1989[75] as part of the New York Health Code.[76] Recognizing that the new regulations would require hospitals to hire additional ancillary staff, the legislature provided $200 million in funding.[77]

Penalties for noncompliance with the new law were modest, however, at only $2,000 per citation.[78]

iii. Later Reforms in New York State

The years following enactment were marked by poor compliance. A 1994 report found that "violations were widespread and directly compromised patient care."[79] A follow-up report in 1997 claimed that "hospitals were avoiding investigations by underreporting adverse incidents."[80] After this second report, the Department of Health made surprise visits to twelve hospitals and found violations at all twelve.[81]

Public outcry grew too loud to ignore in 1999, when a cardiology resident was killed in an automobile accident after a night on-call.[82] New York enacted the Health Care Reform Act of 2000, which included additional funding for enforcement and increased fines for hospitals found in violation.[83] The State may now issue fines of up to $50,000 for repeat violations. The new law, however, did not change the original Bell Commission regulations.[84]

B. Residents' Labor Organization Efforts

In 2002, a coalition of residents took a different approach to reduce duty hours and filed a class-action suit against the national medical organizations that sponsor the National Resident Matching Program and other medical institutions. They argued that the Match Program monopolized the market for medical residencies, preventing residents from bargaining for their wages or hours.[85] This was not the first attempt for residents to gain bargaining rights, but it has been the most significant action in recent years.

i. Early Activism Seeks Collective Bargaining Rights

The 1970s were an era of student activism, and medical residents were no exception. In protests seeking collective bargaining rights, student activists "concentrated mainly on training concerns, particularly levels of pay and hours of work."[86] The Committee of Interns and Residents (CIR), formed in 1958, took the "initial steps at unionization."[87]

Through a March 1975 strike in New York City, CIR sought and won 80 hour work-weeks. Just as with national efforts, "[h]ospital officials decried this demand as demonstrating a lack of professionalism and a move toward a 'shift mentality.'"[88] In response to the strike, Dr. S. David Pomrinse, a hospital medical director, echoed the familiar concerns, describing the long hours as "a way of building the stamina that doctors must have."[89]

This era was brought to a close in 1976 with the *Cedars–Sinai Medical Center* decision in which the National Labor Relations Board (NLRB) ruled that residents are "primarily students,"[90] not employees. Therefore, they were "ineligible to engage in union organization under the jurisdiction of the National Labor Relations Act."[91]

In 1999, the NLRB revisited that ruling, and held that residents had a dual role as both students and employees, and that hospitals could not resist organization because they considered residents to be students.[92] This decision overruled *Cedars–Sinai* as "erroneous."[93] In contrast to the earlier decision, the NLRB no longer believes that "the fact that house staff are also students warrants depriving them of collective-bargaining rights."[94] Today, residents can and do form unions in some places, though this practice is not common.[95]

ii. The *Jung* Case Alleges that the Match Program Violates Antitrust Laws

Despite the recent NLRB reversal, residents still face considerable difficulties when attempting to organize. The complaint in *Jung v. Association of American Medical Colleges* stated that the defendants "contract, combine, and conspire to restrain competition in the recruitment, hiring, employment, and compensation of resident physicians by regularly exchanging among themselves competitively sensitive information on resident compensation and other terms of employment."[96] Noting that the Match Program assigned over 80% of hospital internships in 2000,[97] the plaintiffs claimed that the Match Program "eliminated competition for resident services,"[98] allowing hospitals to "exploit resident physicians by routinely requiring 60 to 100 hours of work per week, or more, often including 36-hour and 48-hour shifts."[99] Medical school graduates "sign binding work agreements with residency programs the minute they file their applications, before most hospitals have announced the wages."[100]

iii. Congress and the Courts Side Against the Plaintiffs

After the district court denied the defendants' motion to dismiss,[101] the case appeared to be headed to trial.

At the same time, Congress passed a law which contained findings that describe the Match Program as a "highly efficient, pro-competitive and long-standing process."[102] Further, the law specifically exempted the Match Program from antitrust regulation in an attempt to "derail" the pending lawsuit.[103] This residency provision was passed as part of a broader bill which offered relief to companies providing traditional pension plans. The bill won bipartisan support and carried the residency provision into law.[104]

This provision was attached to the pension bill without debate or hearings in either house of Congress. The language was instead inserted while the bill was in conference committee.[105] When the bill was returned from the conference committee, it quickly passed in the House of Representatives, but the antitrust exemption drew debate on the floor of the Senate. Senators Russ Feingold (D-WI), Jeff Bingaman (D-NM), and Herb Kohl (D-WI) expressed their reservations about the antitrust exemption; however, they eventually supported the bill because they supported the pension reforms.[106] These senators protested the way the language had been inserted without hearings, evidence, or debate. Furthermore, the relevant committee chairs did not receive notice of the insertion. Finally, they suggested that the underhanded nature of the proposal raised constitutional concerns because the provision would have been enacted without due process of law. Senators Feingold and Bingaman both noted the relevance of the pending lawsuit. They also suggested that the language of the exemption might not apply to price-fixing, which had been alleged in the *Jung* case. In rebuttal, Senator Judd Gregg (R-NH), who sat on the conference committee, claimed that the new language would indeed apply to the pending case.[107]

The provision was inserted "at the behest of" Senator Edward Kennedy (D-MA) and Senator Gregg, and it was also supported by "the Association of American Medical Colleges and other medical associations."[108] Lobbying records for the AAMC and the American Hospital Association, sponsors of the Match Program, reveal that they directly lobbied Congress in support of the exemptions.[109] Not only does this reveal the lengths to which the graduate medical education community would go to prevent outside influence over the Match Program and resident compensation, but it also suggests that this community has a considerable level of influence in Congress. This could make enacting more sweeping federal legislation difficult, if not impossible, without their support.

In light of the new law, the Federal District Court sustained a motion for judgment on the pleadings in favor of the defendants.[110] The judge addressed and dismissed the concerns raised during the Senate debate. The plaintiffs appealed this decision, but again lost at the appellate level.[111] Finally, the Supreme Court refused to hear their case in 2007,[112] ending the legal battle over the Match Program.

iv. No Likely Relationship between the Match Program and Resident Wages

Given the result of the case, the effect of the Match Program on residents' bargaining power was left unanswered. To address the question of whether the Match Program depresses wages, Niederle and Roth analyzed "similar markets for postgraduate medical fellowships that operate with and without a match."[113] They found no relationship between match programs and wages, suggesting that "eliminating the resident match would not necessarily increase residents' wages."[114] This implies that in order to be effective, future organizing efforts should not focus on the Match Program.

C. Attempts at Federal Regulation

Residents have also made several attempts to convince the Federal Government to regulate work hours. These efforts, so far, have been unsuccessful.

i. Residents' Petition to OSHA

In 2002, the Public Citizen Health Research Group presented a petition to the Occupational Safety and Health Administration (OSHA) to recommend that OSHA restrict and monitor resident hours.[115] "Signers of the petition included: Public Citizen, a consumer and health advocacy group; the Committee on Interns and Residents; a house staff union; the American Medical Student Association; Dr. Bell [of New York's Bell Commission]; and Kingman Strohl, MD, director of the Sleep Disorders Research Center at Case Western University."[116]

OSHA rejected the petition and noted the regulatory system already in place in New York and the soon-to-be-implemented ACGME regulations. OSHA deferred to these regulations, claiming that "the ACGME and other entities are well-suited to address work-duty restrictions of medical residents and fellows."[117]

ii. Proposed Legislation Ties Restriction to Medicare Funding

The American Medical Student Association (AMSA) drafted the Patient and Physician Safety and Protection Act to implement federal resident hours regulation,[118] which was first introduced by Representative John Conyers (D-MI) in November 2001.[119] The legislation imposes regulations on hospitals as a condition of participation in Medicare, ensuring the broadest possible federal application. The proposed restrictions are similar to restrictions enacted by New York State. The Department of Health and Human Services would track violations, which residents could report anonymously. Reporting residents would have whistleblower protection from retaliation. Hospitals that fail to comply with these provisions could face fines up to $100,000 for each program in a 6-month period. Further, these violations would be publicly disclosed. Congress would also provide funding to help hospitals pay for changes necessary to comply with these new provisions.[120]

D. ACGME Self-Regulates

Under the threat of federal regulation, and with other states also considering legislation, ACGME took action to regulate the graduate medical education field. A spokeswoman for ACGME expressed the view that "ACGME is the best organization to develop duty hour regulations."[121] Dr. Jeff Kempf, Pediatric Program Director of Residency, recalled that "There was great concern that if the ACGME didn't act, there would probably be an act of federal legislation," and hospitals wanted to avoid government regulation and fines.[122] After ACGME took action, the bills in Congress died in committee.

i. The ACGME Regulations

The regulations imposed by ACGME were based on the Bell Commission recommendations and included: a maximum of 80 hours per week, averaged over four weeks, with possible exemptions up to 88 hours per week; a maximum of 24 hour per shift, with up to 6 additional hours for non-patient

> A hospital in violation may be put on probation, but the only meaningful punishment that ACGME may impress upon hospitals is to revoke accreditation.

care duties such as paperwork and patient transfers; a minimum of 10 hours between daily shifts; mandatory 24 consecutive hours off every week, averaged over four weeks; and overnight on-call shifts no more than every third night, averaged over four weeks.[123]

ii. Methods of Enforcement

ACGME monitors resident hours through surveys sent to residents to complete anonymously. A hospital in violation may be put on probation,[124] but the only meaningful punishment that ACGME may impress upon hospitals is to revoke accreditation. This drastic penalty is excessively harsh, and has yet to be used.

IV. Shortcomings of Current Regulation Plans

While the proposals of the Bell Commission shaped the current regulatory system in New York and influenced the ACGME restrictions, there are still many areas where the current regulations fall short of their goals.

A. Noncompliance in New York State

Compliance levels in New York were poor throughout the 1990s.[125] Today, inspectors from the Island Peer Review Organization (IPRO), on contract with the New York State Department of Health (NYSDOH), "conduct interviews with residents and other appropriate hospital staff, observe resident working conditions, and review medical records, operating room logs and other documentation to determine each hospital's compliance."[126]

Surveys of hospital compliance before and after the implementation of the ACGME standards seem to show significant improvements in compliance over the last several years. In 2002, the NYSDOH reported that of 82 teaching hospitals surveyed after November 2001, 54 were cited for resident hour violations. This represents a 64% noncompliance rate.[127] By 2005, the NYSDOH reported a drastic change in the rate of noncompliance, to just 12%.[128]

The sudden change in compliance levels could be an indirect result of misreporting under the more recent ACGME standards. As residents and teaching hospitals fear losing their accreditation, they may be far less likely to record resident work-hour violations.

One additional problem with the New York State regulations may be that, on their own, they simply do not provide enough of a deterrent against violations. The Health Care Reform Act of 2000 increased fines for teaching hospitals, but these fines are still not large enough to be meaningful. For example, the NYSDOH reported in 2002 that for a "recurring resident work hour violation," New York University Hospital had been fined just $24,000.[129] A fine this minimal does not dissuade hospitals from overworking their residents. Hospitals do not incur any extra labor costs for excessive hours because residents have a fixed salary.

B. Shortcomings of the ACGME Regulations

The ACGME regulations face many of the same difficulties with compliance as the regulations in New York State. The problems of the ACGME regulations are compounded, however, by one significant difference: the penalty for noncompliance is revocation of accreditation. This extreme penalty harms teaching hospitals and their residents and creates perverse incentives to cover up hour violations.

i. ACGME's Monitoring Efforts

ACGME does not monitor hours directly. "Because most residents do not punch time clocks, hospital administrators who employ them often have no real-time knowledge of the hours their residents are working. Responsibility for monitoring work hours lays with the institutional- and program-level directors of some 8,000 residency and fellowship programs in about 750 hospitals across the nation."[130] As an accrediting institution, it is unrealistic to expect ACGME to establish a monitoring apparatus on par with government regulation; instead, ACGME relies on surveys and residents' reports of violations.

ii. The Harsh Penalty Leads to Noncompliance and Underreporting

A study published in 2006 by the Harvard Work Hours, Health and Safety Group found that noncompliance was far higher than reported by ACGME.[131] "In the year following implementation, 1,068 (83.6%) of 1,278 participating interns reported work hours that were noncompliant with the ACGME standards during at least one month."[132] Furthermore, although ACGME surveys residents anonymously, there are no whistleblower protections for those residents that do report their hospital's violations. Thus, residents are reluctant to report violations for fear of personal consequences.

ACGME's sole penalty of revoking accreditation is disproportionate to the problem and actually discourages reporting by residents. While accreditation is technically voluntary for teaching hospitals, it is vitally important to medical education programs. Those hospitals that lose their accreditation are disqualified from receiving federal funds, which total about $8 billion each year. Furthermore, residents

from those programs cannot sit for their board certification exams.[133] This provides a strong disincentive for residents to report any hour violations in their programs. Dr. Simon Ahtaridis, President of the Committee of Interns and Residents, said that reporting hour violations makes residents uncomfortable because they do not want to harm their careers by risking dis-accreditation.[134]

iii. ACGME Does Not Provide Funding to Replace Lost Work

Unlike the regulations in place in New York State and the proposed federal legislation, ACGME provides no additional funding to "remove the burden of non-educational activities from residents and medical students."[135] Due to this shortfall, "[medical] students are sometimes being asked to perform duties previously handled by residents during the clinical rotations that usually make up the third year of medical school."[136] This includes finishing paperwork or clinical work for residents limited by ACGME's hour limits. The medical students, in turn, are "reluctant to report being overworked because of peer pressure and the fact they are graded by their residents."[137] As with residents, some doctors resist the idea of tougher restrictions on student work for fear that learning opportunities might be lost.[138]

iv. Case Study: The University of Iowa Hospitals and Clinics

As a case study, the author interviewed a student at the University of Iowa familiar with the residency program, who spoke on the condition of anonymity.[139] The University of Iowa Hospitals and Clinics follow the ACGME regulations in their guidelines for resident hours.[140] The experience of this student, at least anecdotally, confirms that, while the residency program complies with the regulations on paper, it does not embrace the spirit or goals of the hour restrictions. This example is not intended to single out the residency program at the University of Iowa, but is offered merely to illustrate the problems faced by all teaching hospitals.

While most residents are limited by the ACGME standards to 80 hours per week, some specialties receive an exemption of up to eight additional hours per week. In this student's observation, surgical residents rarely work only 88 hours in a week.[141] They are only asked to record hours worked when they are directly involved in patient care, but do not include unavoidable time such as down-time between surgeries or time for meals. Most residents also arrive 30 to 60 minutes before their morning rounds to review their patients' status, write notes, and attend to other record keeping tasks. These times are not counted toward the work limit. Resident education programs not related to direct patient care are supposed to be counted towards the work hour limit, but are often left off.[142]

Residents report their own hours online at least once per month. They can report whatever hours they choose, but the trend is to underreport the actual number of hours worked. Faculty members review the reports, and residents are aware that working more than the hour limit reflects poorly on their department. They are also aware that working too many hours could even jeopardize the residency program if ACGME imposed sanctions. Thus, residents who work more than the limit tend to report only the maximum number of hours, rather than their actual hours worked.[143]

C. Validation for Those Who Say Restrictions Harm Education

Under a limited-hours regime, when residents are asked to perform the same tasks in less time without any additional support staff, they must either decrease their level of care or ignore the time restrictions. A study released in 2006 found that 80% of responding residents reported exceeding work-hour restrictions, with concern for patient care as the most important factor.[144] The study's authors concluded that "a significant number of residents feel compelled to exceed work-hour regulations and report those hours falsely."[145] This result reflects and validates certain attitudes against limiting resident hours. Robert O. Carpenter, who was a resident at Vanderbilt University Medical Center when the ACGME restrictions went into effect, reported that "there were a lot of [attending physicians] pressing you to work the old way, just look the other direction and write down the hours."[146]

Additionally, residents express sentiments that their education has been harmed by the new restrictions. A study of resident surgeons found that "Fifty-four percent of respondents believed that trauma education has worsened and 45 percent believed that patient care has worsened as a result of the work-hour restrictions."[147] Residents after the regulations took effect "showed a 40% decrease in technically advanced procedures, with a 44% increase in basic procedures."[148] Furthermore, resident surgeons were only able to follow their patients' progress after surgery half as often as they did before the time restrictions.[149] Volume and practice are undeniably

> "Volume and practice are undeniably important in a doctor's education, and they appear to have deteriorated under the work-hour restrictions.

important in a doctor's education, and they appear to have deteriorated under the work-hour restrictions. To address these problems, educationally unnecessary work should be delegated to support staff.

V. Alternatives to ACGME's Regulations

In the three years since ACGME's regulations took effect, a number of other alternatives have been proposed. Several states have considered legislation, and federal legislation has been revived.

A. States' Efforts Since ACGME

Puerto Rico passed legislation that took effect at the same time as the ACGME regulations in 2003.[150] Several state legislatures have also proposed new legislation over the past few years, though none have passed into law.[151] All the proposals are similar, though several include whistleblower protections and do not allow residents to average hours over several weeks.[152] The Delaware Senate considered one proposal in 2003.[153] The New Jersey Assembly and Senate proposed bills in 2004.[154] The Massachusetts Senate considered a bill in 2005,[155] as did the Pennsylvania General Assembly.[156] Although these state proposals were not adopted, they reflect a growing dissatisfaction with the ACGME standards and a growing desire for outside regulation over resident hours.

B. Federal Legislation is Revived

Two years after the ACGME regulations took effect, the Patient and Physician Safety and Protection Act (the Act), drafted by the American Medical Student Association, again appeared before Congress. Representative John Conyers (D-MI) introduced the Act in the House of Representatives on March 10, 2005,[157] and Senator Jon Corzine (D-NJ) introduced the Act in the Senate on June 23, 2005.[158] Reintroduction of the Act signified dissatisfaction with the ACGME standards and represented the hope that the additional provisions of the federal legislation would prove more effective. These provisions included whistleblower protection, fines, and funding for hospitals to hire additional staff. Nevertheless, the bill again died in committee.

In 2006, Clark J. Lee proposed in the *Journal of Health Law and Policy* that the federal government should impose regulation. He further proposed that the Department of Health and Human Services (HHS) should have discretion to set work-hour limits, and suggested ways that HHS would implement and monitor the regulations.[159]

VI. Recommendations for Improved Compliance

Although the dangers of long resident work hours are clear, resistance to change remains strong. Previous attempts at regulation have been met with noncompliance, underreporting, and a sense that the educational goals of residency were being undermined. The proposed federal solutions are an improvement, but they do not address the biggest issues: internal resistance and the desire for professional self-determination. A successful regulation regime must confront these problems.

A. Professional Autonomy Supported by Government Funds

One of the greatest shortcomings of the ACGME regulations is that ACGME does not provide hospitals with adequate funding to enable them to hire support staff for replacing lost work performed by residents. The federal government can provide this funding, but the currently proposed legislation removes professional autonomy. When faced with that prospect, the graduate medical education community has fought to protect itself from external influences: forestalling federal legislation by implementing the ACGME regulations and lobbying Congress for a law that protected the Match Program. The paradox here is that in regulating itself, the graduate medical community cannot provide additional funds to replace lost hours. Thus, it must resist its own regulations.

A compromise would allow an industry coalition to establish resident hour standards set to any desired level, keeping the creative energy behind regulation within the field. With a condition of anonymous reports and open reporting data, the government could subsidize replacement staff while assuring transparency. Furthermore, the size of the subsidy for hiring could depend upon how many additional staff members would be required, creating an incentive for hospitals to impose lower hour requirements. This would eliminate the disincentives that residents have against reporting their actual work hours. Openly published work statistics could provide them with some of the bargaining power lost to the Match Program.

With additional funding available, the graduate medical education community would be free to reshape residency programs to better accomplish its educational goals within the constraint of fewer duty hours. Paperwork and support tasks could be delegated to new hires, while residents could concentrate their time on valuable hands-on experience.

"The paradox here is that in regulating itself, the graduate medical community cannot provide additional funds to replace lost hours. Thus, it must resist its own regulations."

i. Hospitals Have Accepted Similar Arrangements in the Past

Although hospitals fiercely defend their autonomy,[160] Congress has successfully regulated other aspects of graduate medical education in the past. In the 1960s, "federal appropriations for medical schools began to come with strings attached."[161] Congress used so-called "capitation" grants to entice medical schools to increase their enrollment, causing "considerable consternation."[162] However, "the lure of funds that could be used in an unrestricted fashion was too great. No school turned down the opportunity, whatever misgivings about enlarging class size it may have had."[163] In the 1970s, the grants were expanded "to modify the geographic and specialty distribution of physicians."[164]

In this example, we find a model that could be adapted to the problem of resident duty hours. Congress could provide unrestricted funds, set at or above the level required to hire additional support staff. These funds would be provided to schools that limit resident hours; however, participation in the government grants would be voluntary. Unlike current proposals, this plan would not punish hospitals that choose not to participate; instead it would offer an incentive that hospitals would find hard to resist.

B. An Alternative Enforcement Role for ACGME

The current ACGME regulations are detrimental because the penalty of dis-accreditation creates incentives to violate the rules it is supposed to enforce. A new regulatory scheme could still have a place for ACGME, but the conditions for dis-accreditation would have to be structural, reinforcing an external regulatory framework. ACGME might sanction only those hospitals that do not participate in any outside regulation program. Alternatively, ACGME could retain more control over the process by sanctioning those hospitals that, for example, do not publicize their work hour data or offer whistleblower protections.

VII. Conclusion

The problem of extensive medical resident hours is serious. Sleepy and overworked residents pose a risk to themselves and their patients. This problem cannot and should not be swept under a rug.

The proposals presented here are just one potential way to address this issue. The critical point to note, however, is that institutional resistance will undermine reforms that do not reinforce educational goals. Any further attempts at regulation must recognize that restrictions cannot simply be imposed on this industry. Regulations must respect the profession, and regulators must find a way to dovetail their interests with the educational purpose of residency programs. Only then will regulators overcome stiff resistance, and only then will America's resident physicians be able to meet the demands of their profession open and honestly, with time left for a good night's sleep.

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2 Accreditation Council for Graduate Med. Educ., Report of the ACGME Work Group on Resident Duty Hours 1 (2002), http://www.acgme.org/DutyHours/wkgroupreport611.pdf [hereinafter ACGME Report].
3 Patient and Physician Safety and Protection Act of 2001, H.R. 3236, 107th Cong. (2001); Patient and Physician Safety and Protection Act of 2002, S. 2614, 107th Cong. (2002); Patient and Physician Safety and Protection Act of 2003, S. 952, 108th Cong. (2003). These bills all died in committee.
4 *See, e.g.*, Clark J. Lee, *Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth*, 9 J. Health Care L. & Pol'y 162, 163 (2006) (summarizing the controversy and calling for federal regulation).
5 Patient and Physician Safety and Protection Act of 2005, H.R. 1228, 109th Cong. (Mar. 10, 2005); Patient and Physician Safety and Protection Act of 2005, S. 1297, 109th Cong. (June 23, 2005); Am. Med. Student Ass'n, *In Response to Unsafe Work Hour Data, Congress Reintroduces Patient & Physician Safety and Protection Act*, U.S. Newswire (July 1, 2005).
6 The Resident Work Hour Issue: State Efforts, Am. Med. Student Ass'n., http://www.amsa.org/rwh/efforts.cfm (last visited Sept. 27, 2008).
7 *See, e.g.*, *Grey's Anatomy* (ABC television series 2005–2008); *Scrubs* (NBC television series 2001–2008) (two popular television shows glamorizing medical resident work).
8 Jeffrey M. Drazen & Arnold M. Epstein, *Rethinking Medical Training — The Critical Work Ahead*, 347 New Eng. J. Med. 1271, 1272 (2002) ("The years of internship and residency are sandwiched between medical school and a first job as a 'real doctor.'").
9 Paul Starr, The Social Transformation of American Medicine, 115-16 (Basic Books 1982).
10 *Id.* at 116.
11 *Id.* ("Here were the glimmerings of the great university-dominated medical centers of the next century."); Kenneth M. Ludmerer, Time to Heal 19 (Oxford U.P. 1999) ("In the ensuing 15 years [after 1910], hospitals across the country . . . reconsidered their role in teaching and research, and the modern teaching hospital was born, with the Johns Hopkins Hospital as the model"); *see also*, Marc K. Wallack & Lynn Chao, *Resident Work Hours: the Evolution of a Revolution*, 136 Archives of Surgery 1426, 1426 (2001) ("The concept of surgical residency as we know it" was introduced at Johns Hopkins in 1897.).
12 Ludmerer, *supra* note 11, at 79.
13 Laura K. Barger et al., *Extended Work Shifts and the Risk of Motor Vehicle Crashes among Interns*, 352 New Eng. J. Med. 125 (2005); s*ee also*, Eric J. Cassell, *Historical Perspective of Medical Residency Training: 50 Years of Changes*, 281 J. Am. Med. Ass'n 1231, 1231 (1999).
14 Drazen & Epstein, *supra* note 8, at 1272.
15 Accreditation Council for Graduate Med. Educ. Glossary of Terms 4 (2008), http://www.acgme.org/acWebsite/about/ab_ACGMEglossary.pdf.
16 National Resident Matching Program, http://www.nrmp.org/about_nrmp/ (last visited Oct. 23, 2008) (The NRMP is sponsored by the American Board of Medical Specialties, the American Medical Association, the Association of American Medical Colleges, the American Hospital Association, and the Council of Medical Specialty Societies).
17 *Id.* ("Independent applicants include former graduates of U.S. medical schools, U.S. osteopathic students, Canadian students, and graduates of foreign medical schools.").
18 How the NRMP Process Works, National Resident Matching Program, http://www.nrmp.org/about_nrmp/how.html (last visited Sept. 27, 2008).
19 Kenneth M. Ludmerer, Time to Heal, *quoted in* Alexi Wright & Ingrid Katz, *A Job or More School? Young Doctors Take On 'the Match,'* N.Y. Times, Apr. 6, 2004, at F5.
20 Wright & Katz, *supra* note 19, at F5.
21 M.H. Klaiman, *Medical Education's Dirtiest Secret*, Nov.–Dec. 2003 Humanist, at 30; Wright & Katz, *supra* note 19, at F5; Residency Match FAQ, National Resident Matching Program, http://www.nrmp.org/res_match/faq/us_seniors_faq.html#new04 (last visited Sept. 28, 2008) ("The Scramble is the period of time during which unmatched or partially matched applicants attempt to obtain positions in unfilled programs. The Scramble begins at noon Eastern Time on Tuesday of Match Week after the Dynamic List of Unfilled Programs is posted to the NRMP Web site.").
22 *See Jung v. Ass'n of Am. Med. Colleges*, 339 F.Supp.2d 26, 31 (D.D.C. 2004).
23 Drazen & Epstein, *supra* note 8, at 1271.
24 Steven R. Daugherty et al., *Learning, Satisfaction and Mistreatment During Medical Internship: A National Survey of Working Conditions*, 279 J. Am. Med. Ass'n 1194, 1196 (1999).
25 Klaiman, *supra* note 21, at 30.

26 Barger et al., *supra* note 13, at 125.
27 ACGME Report, *supra* note 2, at 1.
28 *See, e.g.*, J.S. Samkoff & C.H. Jacques, *A Review of Studies Concerning Effects of Sleep Deprivation and Fatigue on Residents' Performance*, 66 Acad. Med. 687 (1991) (reviewing scientific literature on the topic).
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35 Landrigan et al., *supra* note 29, at 1838. For criticism of the Harvard study's methods, *see* Letters to the Editor, *Interns' Work Hours*, 352 New Eng. J. Med. 726 (2005) ("One effect not quantified in the study was the interns' learning, which we felt was compromised by the intervention schedule.").
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37 Steven W. Lockley et al., *Effect of Reducing Interns' Work Hours on Sleep and Attentional Failures*, 351 New Eng. J. Med. 1829 (2004).
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39 Barger et al., *supra* note 13, at 125.
40 *Id.*
41 Najib T. Ayas et al., *Extended Work Duration and the Risk of Self-reported Percutaneous Injuries in Interns*, 296 J. Am. Med. Ass'n 1055, 1055 (2006).
42 *Id.*
43 Ludmerer, *supra* note 11, at 320.
44 *See* Boston Med. Ctr. Corp. 330 N.L.R.B. 152, 152 (1999) (presenting arguments by hospital that residents were students and therefore could not be 'employees'); Ludmerer, *supra* note 11, at 246.
45 Div. of Health Care Aff., Ass'n of Am. Med. Colleges, 2006 AAMC Survey of Housestaff Stipends, Benefits and Funding 5, (2007) http://www.aamc.org/data/housestaff/hss2006report.pdf.
46 *See also* Klaiman, *supra* note 21, at 30.
47 Wright & Katz, *supra* note 19, at F5.
48 Ludmerer, *supra* note 11, at 249.
49 Drazen & Epstein, *supra* note 8, at 1271.
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51 Drazen & Epstein, *supra* note 8, at 1272.
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53 Letters to the Editor, *Interns' Work Hours*, 352 New Eng. J. Med. 726 (2005).
54 Drazen & Epstein, *supra* note 8, at 1272.
55 *Id.*
56 David Bird, *The Sleepless-Nights Syndrome*, N.Y. Times, Mar. 18, 1975, at 50.
57 *Lightening the Load*, Plain Dealer (Cleveland), Mar. 13, 2005, at 15.
58 Bird, *supra* note 56, at 50 (quoting Dr. S. David Pomrinse).
59 Klaiman, *supra* note 21, at 30.
60 Bird, *supra* note 56, at 50 (quoting Dr. Leonard S. Lustgarten).
61 Buckner, *supra* note 50 (quoting John Zelem).
62 Gaba & Howard, *supra* note 31, at 1249.
63 Buckner, *supra* note 50.
64 Ludmerer, *supra* note 11, at 317.
65 *Id.* at 319-20.
66 *Id.* at 320.
67 *Id*. Ludmerer also notes that the length of the average patient stay has decreased over time, further undercutting traditional arguments for the educational necessity of long hours, *Id.* at 358.
68 Lee, *supra* note 4, at 175.
69 Gregory S. Cherr, *The Origins of Regulated Resident Work Hours: New York and Beyond*, Bull. Am. C. Surgeons, Nov. 2002, at 23, 24.
70 Lee, *supra* note 4, at 177.
71 *Id.*
72 *Id.* at 179.
73 Cherr, *supra* note 69, at 24.
74 *Id.*
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76 N.Y. Comp. Codes R. & Regs. tit. 10, § 405.4 (1998).
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78 *Id.* at 1429.
79 *Id.*
80 *Id.*
81 *Id.*
82 Cherr, *supra* note 69, at 24.
83 N.Y. Pub. Health Law § 2803 (2008); Wallack & Chao, *supra* note 11, at 1429.
84 N.Y. Pub. Health Law § 2803 (2008).
85 *Jung v. Ass'n of Am. Med. Colls.,* 300 F. Supp. 2d. 119, 125-26 (D.D.C. 2004).
86 Ludmerer, *supra* note 11, at 244.
87 *Id*. at 245.
88 *Id*. at 247.
89 Bird, *supra* note 56, at 50.
90 Cedars–Sinai Med. Ctr., 223 N.L.R.B. 251, 251 (1976) ("[I]nterns, residents, and clinical fellows, although they possess certain employee characteristics, are primarily students."). The NLRB clarified this position the next year, emphasizing that residents at nonprofit hospitals are not entitled to collective-bargaining rights, St. Clare's Hosp. & Health Ctr., 229 N.L.R.B. 1000, 1000 (1977).
91 Ludmerer, *supra* note 11, at 248-49.
92 Boston Med. Ctr. Corp., 330 N.L.R.B. 152, 152 (1999) (finding that "the interns, residents, and fellows employed by BMC, while they may be students learning their chosen medical craft, are also 'employees' within the meaning of Section 2(3) of the [National Labor Relations] Act.").
93 *Id*. at 159.
94 *Id*. at 164.
95 *E.g.*, the Committee of Interns and Residents represents over 13,000 residents. *See*, Committee of Interns and Residents, *Who We Are*, http://www.cirseiu.org/about/Default.aspx (last visited Oct. 23, 2008).
96 (Compl. ¶ 73.), *Jung v. Ass'n of Am. Med. Colls*., 300 F. Supp. 2d. 119 (D.D.C. 2004), *available at* http://www.aamc.org/newsroom/jungcomplaint/jung-nrmp.pdf.
97 *Id.* at ¶ 71.
98 *Id.* at ¶ 92.
99 *Id.* at ¶ 96.
100 Wright & Katz, *supra* note 19, at F5.
101 *Jung v. Ass'n of Am. Med. Colls.,* 300 F. Supp. 2d. 119, 175 (D.D.C. 2004).
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103 Albert B. Crenshaw, *New Law Hands Teaching Hospitals an Antitrust Shield*, Wash. Post, Apr. 13, 2004, at A2.
104 The vote in the House was 336–69–28. 150 Cong. Rec. H2132 (2004) (Roll No. 117). The vote in the Senate was 78–19–3. 150 Cong. Rec. S3996 (2004) (Rollcall Vote No. 68 Leg.).

105 H.R. Rep. No. 108-457, at 1 (2004) (Conf. Rep.) (noting that the original House and Senate bills made no provision for the amendment).
106 150 Cong. Rec. S3979 (2004) (statement of Sen. Kohl); 150 Cong. Rec. S3981 (2004) (statement of Sen. Feingold); 150 Cong. Rec. S3991-92 (2004) (statement of Sen. Bingaman).
107 150 Cong. Rec. S3985 (statement of Sen. Gregg).
108 Crenshaw, *supra* note 102, at A2.
109 Lobbying Reports, *available at* http://soprweb.senate.gov/index.cfm?event=choosefields (search for "American Hospital Assn" and "Assn of American Medical Colleges" via client name). The AHA lobbied on this issue through diGenova and Toensing, LLP, beginning in the second half of 2002 and through Hogan & Hartson, LLP, beginning in the first half of 2003. The AAMC lobbied on this issue on its own behalf and through Covington & Burling, LLP, BKSH & Associates, and Hogan & Hartson, LLP, beginning in the first half of 2003.
110 *Jung v. Ass'n of Am. Med. Colleges*, 339 F.Supp. 2d 26, 46 (D.D.C. 2004) ("[I]n view of the enactment of Section 207 by Congress, the Court concludes that . . . it must grant [the defendants'] motion for judgment on the pleadings.").
111 *Jung v. Ass'n of Am. Med. Colleges*, 184 Fed.App'x. 9, 13 (D.C. Cir. 2006).
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159 Lee, *supra* note 4, at 213. Lee, a former law student at the University of Maryland, also holds a Masters degree in Public Health Administration.
160 Ludmerer, *supra* note 11, at 270 ("Medical schools, like their parent universities, had always fiercely defended their rights as educational institutions to determine their academic policies.").
161 *Id*. at 271.
162 *Id*.
163 *Id*.
164 *Id*. at 272.

State Anti-kickback Statutes: Where the Action is*

*Kathryn Leaman**

I. Introduction

A low-income, pregnant, drug addicted woman walks into her local health and rehabilitative services department seeking help. The counselor threatens the vulnerable woman that the state will take away her baby unless the woman enrolls in a specific drug treatment center. The frightened woman enrolls in the specific treatment center, but behind the scenes, the counselor receives a "kick-back" from the drug treatment center in the form of $250 for each woman referred.[1] In order to prevent these types of financial arrangements that may skew professional medical judgment to the detriment of patients, Congress, in 1972, passed the Federal Anti-kickback Statute and has since broadened the scope and increased the criminal liability for actions violating the statute.[2]

Following the federal government's lead, most states enacted their own Anti-kickback Statutes. States enacted these statutes to protect patients from medical referrals based upon the health care provider's financial incentives, rather than medical necessity.[3] Recently, in *State v. Harden*,[4] the Florida Supreme Court declared the state's anti-kickback statute unconstitutional under the Supremacy Clause because it imposed criminal liability where the Federal Anti-kickback Statute did not.[5] This article evaluates several state Anti-kickback Statutes, using *Harden* to determine whether constitutional challenges would be successful against other state statutes. Part II provides a general overview of the federal and state anti-kickback statute and an analysis of *Harden*. Part III assesses whether other state statutes could be declared unconstitutional using *Harden*'s reasoning and provides recommendations on how states could amend their anti-kickback statutes to circumvent constitutional challenges.

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II. Overview

This section provides a brief history of the Federal Anti-kickback Statue and compares various state anti-kickback statutes.

A. The Federal Anti-kickback Statute

In 1972, Congress passed the original Federal Anti-kickback Statute, which prohibited payment of kickbacks, bribes, or rebates for the referral of Medicaid or Medicare patients.[6] Congress declared that any conduct violating the statute would result in a criminal misdemeanor punishable by fines of up to $10,000 and/or one year in prison.[7] Confusion over what constituted a "bribe" or a "kickback" arose in the courts.[8] In response, Congress amended the Anti-kickback Statute in 1977, declaring that any remuneration offered, solicited, or received in exchange for Medicare or Medicaid referrals violated the Statute and constituted a felony.[9] Congress again amended the Anti-kickback Statute in 1980 to provide the requisite mens rea of "knowingly and willfully" to justify the heightened fines.[10]

Once the violation became a federal felony, health care providers lobbied Congress to provide greater clarity on what types of referrals, remunerations, or offers are prohibited by the statute. As a result, in 1987, Congress once again amended the Anti-kickback Statute providing the Office of Inspector General of the Department of Health and Human Services (OIG), along with the Department of Justice, authority to punish individuals who violated the Anti-kickback Statute.[11] This amendment also imposed a duty on the OIG to establish "safe harbors," which would provide guidance and protection to individuals engaged in the health care business.[12] Congress continued to tinker with the Anti-kickback Statute by broadening the scope of the statute to cover all federal health programs, except the Federal Employee Benefit Health Program (FEBHP), imposing more duties on the OIG, such as the requirement to issue advisory opinions, and by drafting more safe harbors.[13] Currently, the Federal Anti-kickback Statute provides that any person who:

> [K]nowingly and willfully offers or pays any remuneration (including any kick-back, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person [for referrals or] . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made . . . under a [f]ederal health care program.[14]

The statute contains many exceptions, including but not limited to: (1) properly disclosed discounts; (2) a bona fide employee-employer relationship; (3) specific waivers of co-insurances; (4) specific arrangements between vendors and vendees; (5) certain managed care arrangements; and (6) any other arrangements exempted in the regulations.[15] Thus, it remains to be seen how Congress might tweak the Anti-kickback Statute in the future to protect patients covered by federal health care programs and the Federal Fisc from fraud, abuse, and waste.

B. State Anti-kickback Statutes

Out of the seven states surveyed, their anti-kickback statutes appear to fall into three categories. The first group follows the language of the Federal Anti-kickback Statute, while some also include state statutory exceptions.[16] The second group of states provides that a person in violation of the statute would be guilty of a misdemeanor, unless certain elements are present, in which case the conduct will constitute a felony.[17] The final group of state anti-kickback statutes provides no intent standard and no exceptions, yet still classifies the violation as a felony.[18]

i. State Anti-kickback Statutes that Mirror the Federal Anti-kickback Statute and Provide Statutory Exceptions

Three of seven states surveyed mirror the Federal Anti-kickback Statute in their own unique way and provide statutory exceptions very similar to the Federal Anti-kickback safe harbors. Of these three, New Mexico's Anti-kickback Statute differs from the Federal Anti-kickback Statute the most, providing that any person who knowingly solicits, receives, offers, or pays remuneration directly, indirectly, overtly, covertly, in return for referrals or purchasing, leasing, ordering or arranging goods, facilities, or services for which payment is made in whole or in part with public money shall be guilty of a felony.[19] The state statute does not apply to properly disclosed discounts or to a bona fide employee-employer relationship.[20]

Virginia's Anti-kickback Statute conforms more closely to the Federal Anti-kickback Statute. The Virginia Anti-kickback Statute provides that any person who knowingly and willfully solicits, receives, offers, or pays remuneration directly, indirectly, overtly, or covertly for a referral under medical assistance or to purchase, lease, order, or arrange for any goods, facilities, or services "for which payment may be made in whole or part under medical assistance" shall be guilty of a felony.[21] The statute does not apply to properly disclosed discounts, bona fide employee-employer relationships, authorized group purchases, or any business arrangement allowed under the Federal Anti-kickback Statute.[22]

Minnesota's Anti-kickback Statute takes a more direct approach in demonstrating its conformity with the Federal Anti-kickback Statute by providing that the Commissioner of Health shall adopt rules restricting financial relationships within the health care industry.[23] Interestingly, however, the rules must be "compatible with, and no less restrictive than" the Federal Anti-kickback Statute, except that the rules may apply to "additional provider groups and businesses and professional arrangements."[24] Furthermore, until the Commissioner adopts such rules, the Federal Anti-kickback Statute shall apply to "all persons in the state, regardless of whether the person participates in any state health program."[25] The Statute also exempts properly disclosed discounts or remunerations for continued product use so long as certain elements are met.[26]

ii. State Anti-kickback Statutes that have Misdemeanor and Felony Classifications

Three of the seven states surveyed provide that a violation of their anti-kickback statute constitutes a misdemeanor, unless the value of the remuneration in question exceeds a certain amount, or if certain elements are met. If not, the violation constitutes a felony. Ohio's Anti-kickback Statute provides that it is fraudulent to solicit, offer, or receive any remuneration in connection with goods or services for which payment may be made in whole or part under the medical assistance program.[27] Ohio's intent standard requires either "with the purpose to commit fraud or knowing that the person is facilitating a fraud."[28] While Ohio's statute does not provide any exceptions, if the value of property, services, or funds obtained is under $500, the violation is a misdemeanor. Otherwise, the violation is a felony.[29]

The New York Anti-kickback Statute raises the punishment level from misdemeanor to felony at the threshold value of $7,500.[30] The statute criminalizes any "medical assistance provider"[31] who accepts, offers, receives, or solicits any payment or any other consideration for referrals or "to purchase, lease, or order any goods, facilities, or services which payment is made" by the State.[32] While the New York Statute does

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not contain a knowing or willful intent requirement,[33] it specifically declares that it shall not apply to any activity exempted by either the Federal Anti-kickback Statute or regulations.[34]

While Texas' Anti-kickback Statute differentiates between a misdemeanor and a felony violation, it does not take into account the value of remuneration obtained.[35] Instead, a person can be convicted of a felony for violating Texas' anti-kickback statute only if the person has previously been convicted of an offense or if he or she was an employee of the federal, state, or local government at the time that the offense was committed.[36] To violate the Texas Statute, one must "knowingly offer to pay or agree to accept, directly, indirectly, overtly, or covertly, any remuneration for securing or soliciting a patient or patronage for or from a person licensed, certified, or registered" by Texas' health care regulatory agency.[37]

iii. Pennsylvania's Anti-kickback Statute, Contains No Intent Requirement, but a Violation Constitutes a Felony

Pennsylvania's Anti-kickback Statute stands alone because it does not include an intent standard, nor does it provide for any exceptions. Nonetheless, it still characterizes any violation as a felony.[38] The statute provides that it shall be unlawful for anyone to offer, receive, or solicit any remuneration, directly or indirectly, to any person for referrals or "in connection with the furnishing of services or merchandise for which payment may be in whole or in part under the medical assistance program."[39]

C. *State v. Harden*

The Florida Anti-kickback Statute provides that it is unlawful to knowingly offer, pay, receive, or solicit any remuneration directly or indirectly, overtly or covertly, for referrals or for leasing, obtaining, ordering, or purchasing any goods, items, facilities, or services for which payment may be made in whole or in part under Medicaid.[40] In *Harden*, the state alleged that ten individuals either associated with or employed by Dental Express Dentists engaged in a "pay for patients" scheme where these individuals received "per head" payments in exchange for soliciting and driving Medicaid-eligible children to Dental Express for dental treatment.[41] The state argued this "scheme" violated Florida's statute because the defendants received money in exchange for rounding up children from poor neighborhoods and taking them to their employer for dental services and, in turn, billing Florida's Medicaid Program for the services rendered.[42] The defense argued that such an arrangement was protected by the Federal Employee Safe Harbor.[43] The defense further argued that since the Florida Statute criminalized behavior the Federal Anti-kickback Statute allowed, it was unconstitutional under the Supremacy Clause.[44]

Federal law may preempt state law under express preemption, implied field preemption, or implied conflict preemption.[45] Express preemption is when the federal statute explicitly states that it preempts state statutes; (2) implied field preemption is when the "scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it;" and (3) implied conflict preemption is when it is physically impossible to comply with both federal and state law or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[46] In dealing with the explicit preemption theory, the Florida Supreme Court looked to both the Federal Anti-kickback Statute and the OIG, determining that there was no explicit preemption provision within the Statute.[47] However, the court believed that this fact alone did not bar the preemption claim because the Florida Statute could still be preempted under the theory of implied conflict preemption.[48]

The court held that Florida's Statute failed under the implied conflict preemption theory for two reasons: (1) the Florida statute contained a lower intent requirement, which permitted a violation based on negligent behavior;[49] and (2) the Florida statute did not contain safe harbors or exceptions.[50] In addressing the intent requirement, the court looked to Congress' intent for increasing the mens rea, and found that Congress did not want to impose criminal liability on individuals whose conduct, while improper, was ultimately inadvertent.[51] Thus, Congress intended that only those individuals who acted "knowingly or willfully" should be criminally liable under the Federal Anti-kickback Statute, while Florida's Statute criminalizes individuals who knew or should have known their conduct was unlawful.[52]

In addition, Congress explicitly stated that any compensation received in an employee-employer relationship would be exempt from criminal liability under the Federal Anti-kickback Statute, thus exempting the compensation the defendants received from their employer in return for transporting Medicaid-eligible children to receive dental services from their employer.[53] Congress clearly intended to exempt this type of employee-employer compensation arrangement from criminal liability and only wanted to criminalize individuals with a heightened mens rea. Thus, the Florida Supreme Court found that the state's Anti-kickback Statute presented an obstacle to the accomplishments and purposes of Congress and of

the Federal Anti-kickback Statute.[54] Consequently, the court held that the Florida Statute was preempted by the Federal Anti-kickback Statute via the Supremacy Clause.[55]

III. Discussion

While it is unclear whether the Florida Supreme Court would have declared the Florida Anti-kickback Statute preempted if the intent requirement was heightened or if the statute contained exceptions, *Harden* provides an analytical framework under which to evaluate other state anti-kickback statutes' constitutionality.[56] *Harden* also demonstrates ways state legislatures can amend their anti-kickback statutes in order to avoid successful preemption challenges.[57]

A. State Anti-kickback Statutes that Expressly Exempt any Allowable Arrangement Under the Federal Anti-kickback Statue Should Not be Preempted

The Florida Supreme Court's primary problem with the state statute was that it posed an obstacle to the objectives and purposes of the Federal Anti-kickback Statute.[58] Applying this reasoning to the laws in Minnesota, New York, and Virginia, it appears unlikely that a court would find that these statutes frustrate the objectives and purposes of the Federal Anti-kickback Statute primarily because the state statutes explicitly exempt any conduct from criminal liability that the Federal Anti-kickback Statute allows.[59] Given this interpretation, anti-kickback statutes in these three states would likely survive a preemption challenge under the Supremacy Clause.

B. It is Unclear Whether State Anti-kickback Statutes Which Have Either Some Exceptions or Classifies a Violation a Misdemeanor Rather Than a Felony Will be Preempted

The two elements that the Florida Supreme Court relied on to declare the Florida Statute unconstitutional were that: (1) the state statute provided a lower intent standard of "knowingly" as compared to the Federal Anti-kickback Statute's intent standard of "knowingly and willfully;" and (2) the state statute did not provide for any exceptions similar to the safe harbor found in both the Federal Anti-kickback Statute and regulations.[60] It remains unclear whether the court would have reached the same conclusion had only one of the two elements mentioned above been present.

For example, New Mexico's statute provides a lower intent standard of "knowingly" as compared to the Federal Anti-kickback Statue's intent standard of "knowingly and willfully."[61] The state statute includes two exceptions found in the Federal Anti-kickback Statute, namely: the discount and bona fide employment exceptions, but fails to incorporate the remaining exceptions currently found in the Federal Anti-kickback Statute and regulations.[62] While New Mexico's statute appears to be better suited to defend a preemption challenge than Florida's statute, a court would likely find the New Mexico statute preempted because: (1) it provides a lower intent requirement than the Federal Anti-kickback Statute; (2) it only provides two statutory exemptions compared to the numerous federal safe harbors; and (3) the state statute provides that anyone found in violation with the law shall be guilty of a felony.[63]

While New Mexico's regulations incorporate any conduct that violates federal law into its definition of "provider misconduct," it does not provide for any other exceptions found in the federal regulatory scheme, and therefore frustrates the Federal Anti-kickback's purpose by criminalizing behavior specifically exempted by the federal government.[64] The analysis becomes more interesting when the state anti-kickback statute provides that anyone violating the law shall be guilty of a misdemeanor, rather than a felony. For example, Ohio's statute provides an arguably more stringent intent requirement than the Federal Anti-kickback's "knowingly and willfully" by requiring a person to act "with the purpose to commit fraud or knowing that the person is facilitating fraud."[65] In addition to the higher intent requirement, a violation of the Ohio statute equates to a misdemeanor, rather than a felony (unless the value of the property obtained is more than $500, which in that case would constitute a felony).[66] While Ohio does not include any exceptions, a court may be persuaded that the state statute does not frustrate the objectives or purposes of the Federal Anti-kickback Statute because: (1) fewer individuals would be found in violation of the law due to the higher intent requirement; and (2) even if the prosecution is able to prove the higher intent requirement, the person is guilty of only a misdemeanor unless the prosecution can prove that remuneration over $500 was actually obtained, rather than just offered, solicited, or agreed upon.[67]

Texas' statute falls somewhere in between, because it provides a lower "knowingly" intent requirement than the Federal Anti-kickback Statute's "knowingly and willfully" standard.[68] The state statute also provides no exceptions and only classifies a violation as a misdemeanor (unless previously convicted under the statute or the individual was a government employee at the time of the violation then it is a felony), as opposed to the federal law's felony classification.[69] Texas' regulations provide an exception for a "referral of a patient to another practitioner within a multi-specialty group or university medical services research and development plan for necessary medical services."[70] Arguably, the Texas Statute does not frustrate the objectives or purpose of the Federal Statute because it provides a lower intent requirement for a lower classification of punishment and provides at least one exception to common health care business practices.[71] Nonetheless, the statute still prohibits other common health care business arrangements or conduct, such as a bona fide lease of

> A court would be hard pressed to find two individuals guilty of a misdemeanor for "knowingly" offering and receiving remuneration in the form of a fair market value lease arrangement in exchange for reasonable space or equipment provides.

office space or medical equipment, which the Federal Anti-kickback Statute sanctions.[72] A court would be hard pressed to find two individuals guilty of a misdemeanor for "knowingly" offering and receiving remuneration in the form of a fair market value lease arrangement in exchange for reasonable space or equipment provides. This is how the U.S. economy operates. One must consider, however, whether this reasoning will be sufficient to appease the OIG.

In order to remedy the possibility of a successful preemption challenge, New Mexico, Ohio, and Texas should amend their statutes with a catch-all provision, providing that these statutes do not apply to any conduct sanctioned by the Federal Anti-kickback Statute or regulations adopted thereafter. These states will still be able to maintain their autonomy and uniqueness in combating health care fraud, waste, and abuse, while complying with the Supremacy Clause of the U.S. Constitution.

C. A Court will Likely Find the Federal Anti-kickback Statute Preempts Pennsylvania's Anti-kickback Statute Under *Harden*

Under *Harden*, the Federal Anti-kickback Statute appears to preempt Pennsylvania's statute because the state statute seems to be more of an obstacle to the objectives and purposes of the federal statute than the Florida Anti-kickback Statute.[73] Pennsylvania's anti-kickback statute does not provide any intent requirement for a violation classified as a felony.[74] Moreover, the Pennsylvania Statute fails to provide for any exceptions for normal health care business practices that the Federal Anti-kickback Statute exempts.[75] However, Pennsylvania's regulations provide two exceptions, namely a bona fide office space lease exception[76] and a properly disclosed discount exception.[77] While the regulatory exceptions help strengthen the argument against preemption of the Pennsylvania Statute, the lack an intent requirement along with any bona fide employment exception frustrates the purpose of the Federal Anti-kickback Statute. Thus, if the Florida's statute fails under the Supremacy Clause because it provides a lower intent requirement and fails to grant exceptions, then the Pennsylvania Statute will fail as well. Pennsylvania provides no intent requirement and only two regulatory exceptions, as compared to the numerous federal regulatory exceptions.[78] In order to remedy this defect, the Pennsylvania legislature should add a provision stating that this statute does not apply to any conduct sanctioned by the Federal Anti-kickback Statute or any regulations promulgated under it.

IV. Conclusion

The Federal and state anti-kickback statutes play a valuable and necessary role in combating fraud, waste, and abuse in the health care industry. As Congress realized, these statutes must be narrowed in order to allow normal and necessary business transactions to occur without fear of criminal liability. Without such exceptions, the health care industry would cease to exist, which would devastate not only our economy but also jeopardize the well-being of all U.S. citizens. Consequently, state legislators must reevaluate their anti-kickback statutes and ensure that they do not frustrate the objectives of the Federal Anti-kickback Statute. If the state finds that its anti-kickback statute may pose a problem, the state legislature should add a provision exempting all conduct sanctioned by the Federal Anti-kickback Statute and regulations adopted thereunder.

1 *See U.S. v. Starks*, 157 F.3d 833, 835-37 (11th Cir. 1998) (describing the true events that are the basis for this hypothetical, where the two counselors were found criminally liable for violating the federal Anti-kickback Statute).
2 *See* 42 U.S.C. § 1320a-7b (2006) (explaining conduct Congress criminalized with respect to all Federal health care programs, including knowingly and willfully making false statements in order to obtain a benefit, knowingly and willfully counseling or assisting someone to dispose of assets in order to become eligible for Medicaid, and knowingly and willfully receiving or soliciting remuneration in exchange for Federal health plan referrals).
3 *See, e.g.*, Minn. Stat. Ann. § 62J.23 (West 2006) (explaining that until the Commissioner adopts the final rules, the federal Anti-kickback Statute shall apply to all persons in the State regardless of whether the person participates in Minnesota's Medicaid program); Ohio Rev. Code Ann. § 2913.40 (West 2006) (stating that any person who knowingly solicits, offers, or receives any remuneration for services that are at least in part funded by the Ohio Medicaid program shall be guilty of a misdemeanor, unless the value of the property is between $500 and $5,000, then the person shall be guilty of a felony); Va. Code Ann. § 32.1-315 (2006) (declaring any person shall be guilty of a felony for knowingly and willfully receiving or soliciting remuneration for which payment may be made for any medical assistance, while also providing statutory Safe Harbors including discounts, bona fide compensation agreements, and leases). – I didn't see leases in statute, unless it falls under (C)(4)).
4 938 So.2d 480, 492-93 (Fla. 2006).
5 *See id.* (invalidating Florida's Anti-kickback Statute because the statute (1) contained a lower mens rea requirement, which criminalized negligent acts; acts, than the federal statute; and (2) criminalized conduct the federal statue specifically exempted by not providing for any exceptions or Safe Harbors).
6 *See* Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329 (1972).
7 *Id.* at 1419.
8 *See U.S. v. Porter*, 591 F.2d 1048, 1053-54 (5th Cir. 1979) (reversing the defendants' convictions under the 1972 Anti-kickback Statute because the fees the lab shared with doctors, who referred specimens to the lab, were not bribes or kickbacks since where the financial arrangement contained no element of corruption nor misapplied federal funds).
9 *See* Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1175 (1977).
10 *See* Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599 (1980).
11 *See* Medicare Budget and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 682680 (1987).
12 *See id.*
13 *See* Health Insurance Portability and Accountability Act, of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (requiring the OIG to provide more industry guidance by authoring Safe Harbors and issuing advisory opinions based on specific business arrangements proposed or already in place).
14 42 U.S.C. § 1320a-7b (2006).
15 *Id.*
16 *See, e.g.,* Minn. Stat. Ann. § 62J.23 (West 2006) (stating that the rules in this section must be "compatible with, and no less restrictive than, the federal [Anti-kickback Statute] and regulations adopted under it"); N.M. Stat. Ann. § 30-41 (West 2006) (enumerating that Provision One covers soliciting or receiving illegal remuneration, Provision Two deals with offering or paying illegal remuneration, and Provision Three provides two exceptions for discounts and bona fide employment relationships); Va. Code. Ann. § 32.1-315 (West 2006) (stating that section A covers anyone who knowingly and willfully solicits or receives illegal remuneration, section B covers anyone who knowingly and willfully offers or pays illegal remuneration, and section C makes four exceptions including discounts, bona fide employment relationship, group purchases, and any agreement not prohibited by the federal Anti-kickback Statute).
17 *See, e.g.,* N.Y. Soc. Serv. Law § 366-d (McKinney 2006) (providing that any person who solicits, receives, offers, or gives payments "or other consideration in any form" shall be guilty of a misdemeanor, unless the property obtained had a value of $7,500 or more, then the person will be guilty of a felony); Ohio Rev. Code Ann. § 2913.40 (West 2006) (stating that

any person who violates this provision knowingly, or with the purpose to commit fraud, is guilty of Medicaid fraud which is a misdemeanor, unless the "value of the property, services or funds obtained is $500 or more" because then the person is guilty of a felony); Tex. Occ. Code Ann. § 102.001 (Vernon 2006) (explaining that any person who knowingly offers or agrees to accept any illegal remuneration shall be guilty of a misdemeanor, unless the person has been previously convicted under the provision or was employed by the federal, state, or local government at the time, then they shall be guilty of a felony).

18 *See* 62 Pa. Cons. Stat. Ann. § 1407 (West 2006) (expressing that any person who solicits, receives, offers or pays any illegal remuneration shall be guilty of a felony).

19 *See* N.M. Stat. Ann. § 30-41.

20 *Id.*

21 *See* Va. Code. Ann. § 32.1-315.

22 *Id.*

23 *See* Minn. Stat. Ann. § 62J.23 (West 2006).

24 *Id.*

25 *Id.*

26 *See id.* (listing the following exemptions: (1) a health industry manufacturer or distributor that reduces the patient's fee for a needed prescribed product or item, or (2) a health industry manufacturer or distributor that provides the patient with a "trinket or memento of insignificant value," or (3) a tiered formulary with different co-payment or cost-sharing amounts for different drugs).

27 *See* Ohio Rev. Code Ann. § 2913.40 (West 2006).

28 *Id.*

29 *Id.*

30 *See* N.Y. Soc. Serv. Law § 366-d (McKinney 2006).

31 *See id.* (defining medical assistance provider as "any person, firm, partnership, group, association, fiduciary, employer, or representative thereof or other entity who is furnishing care, services or supplies" under the state medical program).

32 *Id.*

33 *Id.*

34 *Id.*

35 *See* Tex. Occ. Code Ann. § 102.001 (Vernon 2006).

36 *Id.*

37 *Id.*

38 *See* 62 Pa. Cons. Stat. Ann. § 1407 (West 2006).

39 *Id.*

40 *See* Fla. Stat. Ann. § 409.920(2)(e) (West 2000).

41 *See Harden*, 938 So.2d at 483-84.

42 *See id.* at 484.

43 *See* 42 U.S.C. § 1320a-7b(b)(3)(B) (2006) (exempting any amount paid in a bona fide employee-employer relationship for employment purposes from the criminal sanctions of the federal Anti-kickback Statute).

44 *See* U.S. Const. art. VI, cl.2 (declaring that federal law "shall be the supreme law of the land" and anything in a state constitution or statute to the contrary is not withstanding); *Harden*, 938 So.2d at 492-93.

45 *See Harden,* 938 So.2d at 486.

46 *See id.*

47 *See id.* at 487-90 (discussing the OIG's position that lawful conduct under the Federal Anti-kickback Statute may still be unlawful under the state Anti-kickback Statute, and vice versa).

48 *See id.* at 490.

49 *See id.* at 491-92 (explaining that the Florida Legislature amended the Anti-kickback Statute in 2004 in order to increase the intent requirement and remove negligent actions from criminal liability). However, the defendants in *Harden* were tried and convicted under the pre-amended statute and that is the version the court analyzed. *Id.*

50 *See id.* at 492.

51 *See Harden*, 938 So.2d at 493.

52 *See id.* at 491.

53 *See id.* at 493.

54 *See id*.

55 *See id.*

56 *See id.*

57 *See Harden*, 938 So.2d at 493.

58 *See id.*

59 *See* Minn. Stat. Ann. § 62J.23(1) (West 2006) ("the rules must be compatible with, and no less restrictive than, the federal [Anti-kickback Statute] and regulations adopted under it."); N.Y. Soc. Serv. Law § 366-d(2)(d) (McKinney 2006) ("this subdivision shall not apply to any activity specifically exempt by federal statute or federal regulations promulgated thereunder."); Va. Code. Ann. § 32.1-315(C)(4) (West 2006) (stating that the state Anti-kickback Statute shall not apply to "any remuneration, payment, business arrangement or payment practice that is not prohibited by [the federal Anti-kickback Statute] or by any regulations adopted pursuant thereto.").

60 *See Harden*, 938 So.2d at 493.

61 *Compare* N.M. Stat. Ann. § 30-41 (West 2006), *with* 42 U.S.C. § 1320a-7b (2006).

62 *Compare* N.M. Stat. Ann. § 30-41 (West 2006), *with* 42 U.S.C. § 1320a-7b (2006), *and* 42 C.F.R. § 1001.952 (2006).

63 *Compare* N.M. Stat. Ann. § 30-41 (West 2006), *with* Fla. Stat. Ann. § 409.920(2)(e) (2000).

64 *Compare* N.M. Code R. § 8.351.2.10 (West 2006), *with* 42 C.F.R. § 411.357 (2006), *and Harden*, 938 So.2d at 493.

65 *Compare* Ohio Rev. Code Ann. § 2913.40 (West 2006), *with* 42 U.S.C. § 1320a-7b (2006).

66 *Compare* Ohio Rev. Code Ann. § 2913.40 (West 2006), *with* 42 U.S.C. § 1320a-7b (2006).

67 *Compare* Ohio Rev. Code Ann. § 2913.40 (West 2006), *with* 42 U.S.C. § 1320a-7b (2006), *and* State v. Harden, 938 So.2d 480, 493 (Fla. 2006).

68 *Compare* Tex. Occ. Code Ann. § 102.001 (Vernon 2006), *with* 42 U.S.C. § 1320a-7b (2006).

69 *Compare* Tex. Occ. Code Ann. § 102.001 (Vernon 2006), *with* 42 U.S.C. § 1320a-7b (2006).

70 1 Tex. Admin. Code § 371.172137.1721 (2006).

71 *Compare* Tex. Occ. Code Ann. § 102.001 (Vernon 2006), *with* 42 U.S.C. § 1320a-7b (2006), *and Harden*, 938 So.2d at 493.

72 *Compare* Tex. Occ. Code Ann. § 102.001 (Vernon 2006), *with* 42 U.S.C. § 1320a-7b (2006), *and* 42 C.F.R. § 1001.952 (2006).

73 *Compare* 62 Pa. Cons. Stat. Ann. § 1407 (West 2006), *with* Fla. Stat. Ann. § 409.920(2)(e) (2000) *and Harden*, 938 So.2d at 493.

74 *Compare* 62 Pa. Cons. Stat. Ann. § 1407 (West 2006), *with* Harden, 938 So.2d at 493.

75 *Compare* 62 Pa. Cons. Stat. Ann. § 1407 (West 2006), *with* 42 U.S.C. § 1320a-7b (2006) *and Harden*, 938 So.2d at 493.

76 *See* Pa. Code § 1101.51 (2006) (stating that the provision does not preclude "a provider from owning or investing in a building which space is leased for adequate and fair consideration to other providers nor does it prohibit an ophthalmologist or optometrist from providing space to an optician in his office").

77 *See id.* (explaining that the provision does not "preclude discounts or other reductions in charges by a provider to a practitioner for services, that is, laboratory or x-ray, so long as the price is properly disclosed and appropriately reflected in the costs claimed or charges made by the practitioner").

78 *Compare* 62 Pa. Cons. Stat. Ann. § 1407 (West 2006), *and* 55 Pa. Code § 1101.51 (2006), *with* Fla. Stat. Ann. § 409.920(2)(e) (2000), *and* 42 C.F.R. § 411.357 (2006), *and Harden*, 938 So.2d at 493.

Genetic Testing: Its Challenges to Employment and Insurance

*Maureen A. McTeer**

Thank you for inviting me to speak to you this morning. As members of the Vocational Rehabilitation Association of Canada, you have set high standards for your work. In fulfilling your mandate, you collaborate on an ongoing basis with other professionals in your association to establish best practices for all of you working in the field of disability and employment. You strive continually to develop your personal and professional practices, while acting as experts and as advocates for your clients on a broad range of disability issues. This is no small task.

During the next two days, you will listen to experts and colleague practitioners speak about the diverse challenges of your work. Their experiences and advice will be shared so that you can better improve the chances of your clients returning to the workplace and picking up the severed threads of their daily lives and ambitions.

This morning, as your keynote speaker, I will try to capture the theme of your conference and sail you off in a new direction. As you know, I am a lawyer whose specialty is law, science, and public policy. I am fascinated by the many possibilities that genetics and reproductive technologies offer us; I have written a book on these and related issues.[1]

The growing field of human genetics, and the predictive tools that come with it, will have a profound impact on labor relations and workplace rules. In turn, this will affect your work and the lives of those whom you assist.

In speaking with your executives recently, they asked that I explore some of the future cutting-edge issues that science and technology will force you to face in your practices. They also asked that I speak about how these affect some of the ethical standards that your association and members follow. To meet their request, I have divided my remarks into two parts. I begin with the question of genetics and genetic testing, the challenges these will raise for you and your clients, and what your association might do to shape public policy debate and future legislation.

“The growing field of human genetics, and the predictive tools that come with it, will have a profound impact on labor relations and workplace rules. In turn, this will affect your work and the lives of those whom you assist.”

* Maureen McTeer is an author, expert in law, science, and public policy, and an Adjunct Professor in the Faculty of Law at the University of Ottawa in Canada. She is the author of Tough Choices: Living & Dying in the 21st Century (Irwin Law 1999).

We are living in one of the most exciting periods in medical-scientific history. No matter where you stand on any one issue, from stem-cell research to cloning, we all have a stake in science’s success. Each of us in this room has known illness directly, or through a family member or friend. When all is said and done, who among us would choose illness and ignorance over health and knowledge? If we were forced to make such a decision, who here today would deny the options that modern science and medicine give us?

Science and medicine offer us real and important policy and legislative challenges as well, with their cutting-edge research and technologies. Thanks to science, we can now create, manipulate, and alter human life in the laboratory. Infertile, even sterile, people can have a family. We can use genetic manipulation techniques to create new seeds, animals, and — one day — people. We can use cloning technologies, the modern-day living version of photocopying machines, to clone cells and to make new skin for burn victims or new cartilage for accident victims. We can use one person’s organs so another can live, and we can keep people alive on machines, in a state of living death.

In my book “Tough Choices: Living and Dying in the 21st Century,” I have raised these issues, and others, as I analyzed the legal and public policy issues science and technology force us to face at each stage of life’s cycles. Key among these are the issues surrounding genetics and genetic testing, with the potential for predictive medicine and therapeutic interventions, which have enormous impacts on human rights.

What do we mean when we speak of “genetics,” of “genetic information,” and “genetic testing”?[2] Genetics is the study of heredity and the way in which the characteristics we inherit can vary from one individual or group to another. This can be as simple as the variation of the color of our hair to the presence of cancer or other disease-causing genes.

At the molecular level, our genes tell a part of the story about each of us. This same genetic story is found and repeated in every cell of our body. This means that from a single drop of blood, skin, or saliva, we (and anyone with the right diagnostic tools) can learn what destiny is written in our genes about our future genetic health and well-being.

The study of genetics and its impact on our daily lives is about more than just disease and its medical treatment. It also raises at least three fundamental human rights issues of direct interest and importance to you and your profession. These include discrimination, privacy, and confidentiality. Implicit in these issues is the "right" to know medical information discovered about others that affects us. So let us address each of these in turn.

Discrimination

I begin with discrimination. In most countries we have human rights laws that both ensure positive protection of our human rights and ban discrimination on several grounds. These include race, religious belief, ancestry or place of origin, color, physical or mental disability, age, socio-economic status, marital status and, in some places, sexual orientation. With few exceptions, including France, Austria, and now the United States[3] in certain situations, laws prohibiting discrimination do not address discrimination on the basis of genetic predisposition.

Science moves ahead regardless. Take the Human Genome Project (HGP) as one example. Scientists have already completed the first phase of the identification of the human genome, the common treasure that we all share. From the knowledge acquired with the completion of the HGP, we are now developing genetic testing kits and methods to predict individual predisposition to disease. We hopefully can treat such diseases even before the symptoms manifest. Failing that, we hope to develop new drugs and therapies so we can alleviate (and maybe even end) some of the worst of the physical pain and suffering that afflicts those with genetic anomalies and disease.

This is the HGP's noble goal — one which I both applaud and wholeheartedly support. But as professionals, each with our own specific training and experiences, we all know that this noble goal will not be the only outcome of our mapping of the human and other genomes.

This information will not be released into a social, legal, or economic void. The HGP was not a stand-alone effort. Science cannot pretend that it somehow operates outside of society, with its cultural and other biases and human frailties. Used with other technological developments and practices, such as pre-natal or pre-implantation genetic diagnosis, the knowledge we acquire from the human genome is immensely important. It will lead us to finally learn what each gene does in our bodies.

This will also force us to make a myriad of choices that will have an impact on our collective interests and will affect our individual rights. We will know ourselves and others at the molecular level — a partial description, at best, of what each of us is or can become as human beings. Yet it will be at this molecular level that tough decisions will be made, especially for embryos from in-vitro fertilization (IVF) that undergo genetic testing at the pre-implantation stage.

We have always been able to access *some* of a person's medical story, however, having access to a person's genetic information is a sea of change from what we had known before. This hitherto hidden personal and family information will be used for many purposes. For society, genetic testing will help solve crimes and identify the remains of people who have died tragic or violent deaths. On a personal level, it will bring about all kinds of new issues. In contested paternity or maternity cases, for instance, it will confirm or deny a man or woman's biological relationship to a child.

Its most frequent and highly contested use will be in the employment[4] and health care sectors, where the knowledge that we carry a defective gene that might or will result in a chronic or fatal disease later on in life, will have real and long-term consequences on our choices, our options, and our opportunities. Thus, this information has the potential of fundamentally affecting our lives.

Almost a decade ago now, in 1999, the Supreme Court of Canada gave a context to the definition of discrimination in *Law v. Canada.*[5] The court found that a core value of our human rights principles was realizing that human dignity, when absent, led to discrimination. In its judgment, Canada's highest court found:

> [T]he purpose of s. 15(1) [of the Canadian Charter of Rights & Freedoms] is to prevent the violation of essential human dignity and freedom through the imposition of disadvantage, stereotyping, or political or social prejudice, and to promote a society in which all persons enjoy equal recognition at law as human beings or as members of Canadian society, equally capable and equally deserving of concern, respect and consideration. Legislation which effects differential treatment between individuals or groups will violate this fundamental purpose where those who are subject to differential treatment fall within one or more enumerated or analogous grounds, and where the differential treatment reflects the stereotypical application of presumed group or personal characteristics, or otherwise has the effect of perpetuating or promoting the view that the individual is less capable, or less worthy of recognition or value as a human being or as a member of Canadian society.[6]

"We have always been able to access *some* of a person's medical story, however, having access to a person's genetic information is a sea of change from what we had known before."

As practitioners, you often deal with such stereotyping on the basis of disability of all kinds. You see its impact on your clients and their sense of self-esteem. Discrimination of any kind is a scourge, not to be tolerated in any way in Canada. That is why I hope that future courts will find precedence in the *Law* decision and in other related cases. This will protect individuals from discrimination by governments on the basis of genetic predisposition where they carry a gene that may or may not one day manifest itself as a disease or serious physical or mental condition. If future courts do so, then the large and increasing group of people who have been popularly labeled as the "healthy sick" will find protection under our Canadian Charter of Rights and Freedoms (the Charter)[7] against this type of genetic discrimination.

So we see that the Charter may protect us, but what about our human rights laws? Do they protect us from discrimination on the basis of genetic predisposition? Under the Canadian Human Rights Act,[8] companies like banks, which are governed by federal law, cannot discriminate on the basis of disability. Unfortunately, despite calls to do so, the Charter has not been amended to include a predisposition to disability due to a defective gene.

At the provincial level, there are no direct or explicit statutory prohibitions of discrimination on the basis of genetic predisposition to a disease or condition that has not manifested. The human rights laws in some provinces, such as Ontario[9] and Nova Scotia,[10] extend protection from discrimination on the basis of perceived disability. Some authors argue that provincial courts generally may find as the Supreme Court of Canada did in *Law*.

Under our human rights laws, discrimination in employment on the basis of disability or handicap is prohibited. The exception to this anti-discrimination law is where a person applying for a job, due to a disability or handicap, cannot perform the job in question. Only then can an employer refuse to hire someone. Establishing that a specific qualification or training is a "bona fide occupational requirement" is a question of fact and is usually closely scrutinized by human rights tribunals when a person alleges discrimination in not hiring or in firing on the basis of disability. Case law has looked at these issues. An employer must meet particular criteria when claiming that something is indeed a "bona fide occupational requirement." We will have to see what happens in future cases where the discrimination alleged is based on a person's genetic predisposition to a disease or serious condition.

Privacy[11] and Confidentiality

The second area of concern is how we ensure (if not guarantee) our individual privacy and the confidentiality of personal health information in an era of genetic testing. It is difficult now to be private and to keep things in confidence; we pay a price for this. In a case 13 years ago, Madame Justice L'Heureux-Dube, then a member of the Supreme Court of Canada, wrote that where personal health information is made public, there are profound personal ramifications. She described it as ". . . an invasion of the dignity and self-worth of the individual, who enjoys the right to privacy as an essential aspect of his or her liberty in a free and democratic society."[12]

Yet most of us cling to the belief that it will be *our decision alone* whether or not to know and to share our personal health information — including genetic information. In reality, it is not that simple. Canadian case law has shown us that there is no right to privacy under the Charter, although privacy interests may exist under sections seven and eight as developed in some of the "search and seizure" cases under the criminal law. This protection only covers government action and not the private sector. A person must show that he or she had a "reasonable expectation of privacy." That is very difficult to prove in cases of employment where the health information, including the presence of a genetic predisposition to disease, is deemed necessary as a "bona fide occupational requirement."

Our privacy laws in Canada, which cover the public sector, do not explicitly include genetic information as personal information. The Federal Personal Information Protection and Electronic Documents Act (PIPEDA)[13] covers the private sector for data collection and storage of personal information, and accepts that health information is personal information that is covered under PIPEDA. Even though PIPEDA

does not use the words "genetic information" in the section 2(1) definition of personal health information, the definition in PIPEDA is so comprehensive that such information, I believe, could be considered included.

While it is a debate for another day, I note here that there is real cause for concern about the ability and the willingness of the private sector to take the protection of personal data seriously. In her annual report last year, Jennifer Stoddart, Canada's Privacy Commissioner, found that inadequate security protection of our personal data is common, and urged the government to make it mandatory for companies in the private sector to report any material data breach to her office.[14]

In an age in which privacy is so easily violated, and when laws do not protect us from discrimination on the basis of genetic predisposition, I believe we need stronger, not weaker, privacy laws governing personal, health, and genetic information to protect ourselves from discrimination and to protect our personal and family privacy. I have argued for some time that because genetic information is so sensitive, we should have it stored securely and separately from our regular health records. Access should be granted only with our permission and only to designated persons, such as our own doctor or on a need-to-know basis only.

Why is it important to guarantee privacy of health care records generally and records on genetic health in particular? Because health information (and genetic information even more so) carries with it the power to label us forever. In labeling us, it carries the power to marginalize us, to sideline us, to make us strangers in our own communities, even our own families. People who think this is an exaggeration need not limit themselves to genetic disease. Think what happened, indeed still happens, to people with HIV/AIDS. There are lessons for us to see, and options for us to choose to protect our privacy and that of our families.

Genetic Information and Access

The third area involves the question of whether there is a right to know a family member's genetic information. At its most basic level, genetics is about heredity. It tells not just our own story, but the story and most important secrets of our parents and grandparents, brothers and sisters, and about our children as well. The fact that medical conditions run in families means that the information we learn about the human genome will open a Pandora's Box over which, as yet, we have not even begun to craft legal safeguards. What kind of power does that give those with the technology and skills to identify our genetic make-up through genetic testing?

Right now, such testing is limited by cost and by our current state of knowledge about the role of individual genes. However, the practice of genetic testing can occur at any stage of life — from conception, in the womb, at birth, in childhood, and in adulthood. These modern diagnostic genetic technologies, now at our disposal, offer tools of potential and actual discrimination as powerful as any we have ever known. How will we handle this new situation? What rules should apply? As importantly, who will decide who has access to this information and for what purposes?

We do not know yet what each gene does, but researchers have had great successes. Hundreds of genes that are linked to a particular disease or condition, physical, mental and social, have been identified. Now, selectively at first, but more widely as our genetic testing capacities grow, we can learn what fate has written for us in our genes. Why is this important? How will it affect what you will have to handle in the future? We should be concerned because genetic testing allows us to identify, after as well as before birth, those among us who are predisposed to genetic diseases and conditions. Think what that will mean to many of your clients who cannot work or are in need of insurances or education or retraining options to return to work. Already the governments and companies that have laid claim to these genes through patents are planning genetic testing kits and further research. What happens then?

Should we encourage genetic testing? Who should we ask to be tested and for what conditions? What conditions are serious enough to warrant attention? Color blindness? Deafness? Alzheimer's? Who decides what genetic conditions will be tested for, and on what basis will be one of the most hotly debated questions of the coming decade?

These are tough enough questions for your clients who want to return to work and have perhaps already been labeled one way or another throughout their working lives. What if your client only carries a late onset condition that manifests itself, if at all, when he is older, likely after he is retired? Should he be able (or be required) to use genetic testing now, when he is younger, to find out what his fate might be when he reaches middle age? Should he be able to make that decision for his children? How do our rules governing consent apply here? How can children be protected from future discrimination on the basis of their genetic heritage by decisions taken now by their parents?

The answers to these questions are important — they are society's, not just science's, to make. The social and economic ramifications of this information on

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your clients are huge. You know, from your own counseling and work experiences and those of your clients, that knowing this information will label people (for good or for bad) by their family, their friends, and even by strangers in their own communities. Not all of their attitudes will be supportive and generous. It is easy to be open and inclusive when we are all healthy. But think about how society responds to conditions like HIV-infection, or cancers, or serious physical or mental disability. Are we as welcoming and generous then?

One very important question in all this is: "Who should have access to your genetic information and for what purposes?" We would probably agree that our doctor should, but what about life or private health insurance companies? Should they require a genetic test as part of the medical examination needed to qualify for these various insurances? What about banks? Should they be able to require genetic testing as a pre-condition to lending you money or providing you with a mortgage? What about teachers working with students in our schools? Should they be granted a privileged status when it comes to knowing the genetic make-up of their students? This has been heightened by suggestions that anti-social and destructive sociopathic behavior can have a genetic basis. Some are demanding access to testing as a way of protecting teachers and students alike when they are at school.

In all this, can our privacy laws meet the challenge? The answer is certainly not as they are now. I have argued, and will continue to do so, that Ottawa and the provinces have an obligation to amend their human rights laws to include "genetic predisposition" and "genetic condition" among the enumerated categories of discrimination. I find the U.S. model, passed in May of this year, to be of considerable merit. We will want to consider it as part of our own legislative responses.

The U.S. Genetic Information Nondiscrimination Act (GINA) prohibits genetic discrimination by employers, insurers, and unions. Under the new law, employers will not be able to hire, fire, promote, or compensate an employee on the basis of genetic tests. Health care insurers will not be able to determine their coverage, premium rates, or increases using genetic testing information that indicates a susceptibility to a genetic disease or condition. Unfortunately, though, long-term care and life insurance are not covered under this health care provision.

Several states in the United States have some legislative measures to protect genetic information in the employment and health insurance fields. This new law will set a national standard and show federal leadership on a problem that affects a growing number of Americans, many of whom have refused to have genetic testing done for fear that they or a member of their family, would suffer discrimination if they did. That fear has led to the rise of Internet genetic testing services, unregulated and offered without counseling.

All of you who are counselors would know what that means. Imagine being told that you carry the gene for a disease like Cystic Fibrosis, Duchenne Muscular Dystrophy, breast cancer or ovarian cancer, and being unable to seek counseling for fear that you would lose your job or your health, life, or other insurances. Unfortunately, for some reason, the GINA law does not cover the regulation of the genetic testing industry, which is a growing multi-million dollar industry. Canada must be sure to address this issue when we amend our own laws. The provinces must agree to cover the cost of actual genetic testing as part of our provincial health insurance plans.

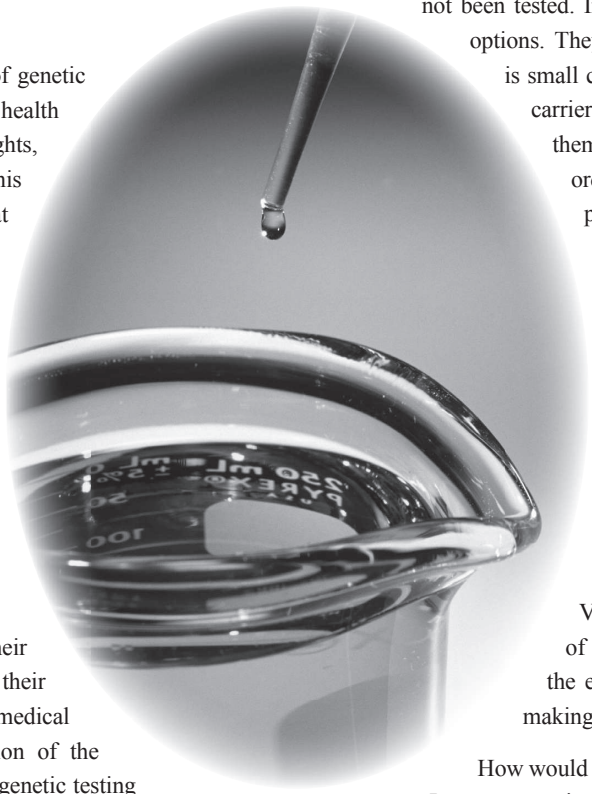
Finally, genetic information, no matter how it is gathered (by genetic tests or personal family medical histories) is special information that labels people who are well now and may become ill later in life. The purpose of acquiring and using this information has to be to benefit the person involved in an effort to ensure treatment for them. In a country like ours, there is no room for discrimination and exclusion based on genetic information.

We have seen how law and the courts address these issues, but what about your own profession? How would the concerns I have expressed this morning about genetic information and its special nature be treated in the context of your own code of ethics? I would like to conclude by looking at this question.

The word ethics has many meanings depending on the context. In the context of your work, it can mean "morally correct" or "honorable" behavior. It can refer to a "set of moral principles" fueled by religion or a noble secular code. Regardless of the exact definition you accept, the ethical rules of conduct are at the heart of your association's ethics code and professional mandate. Indeed, your own code of ethics states: "Codes of professional ethics identify those moral principles and standards of behaviour [sic] that professions, institutions, and organizations believe will assist them in distinguishing between right and wrong, and ultimately in making good moral judgments."[15] This will be our starting point. Ethical principles are not passive norms. They are dynamic and important tools upon which we guide our actions and decision-making. Indeed, I would argue that the the fundamental spirit of respect and caring, which is the philosophical basis of the Canadian Code of Ethics for the Vocational Rehabilitation Association of Canada, imposes specific obligations on all of you.

Take the first ethical principle of your professional association, namely respect for the dignity and autonomy of persons. Right now, you, as members of the Vocational Rehabilitation Association of Canada, agree to place this ethical principle of respect for the dignity and autonomy of persons at the top of the pyramid of ethical considerations in your decision-making and problem-solving with clients. You agree that this is such an important ethical obligation that you state clearly that it can only be set aside, "in circumstances in which there is a clear and imminent danger to the physical safety of any person." [16]

What does this mean in the current context of genetic testing, which risks affecting the long-term health and the current privacy rights, human rights, and everyday life of both your client and his or her family? How each of you answers that question or defines this respect for the dignity and autonomy of a person will have real repercussions on how you meet the second ethical principle of the VRA, which requires members to care responsibly "for the best interest of persons." What are their "best interests" when it comes to genetic testing in the employment and insurance context? Is it the fact that they will actually know whether or not they are genetically predisposed to a certain disease?



On the positive side, then, if they do learn their genetic information, then they can exercise their autonomous choices to accept or undergo medical therapies to cure or control the manifestation of the disease carried in their genes. In such a case, genetic testing would seem to be an ideal, perhaps even the best, solution for your client. Are there other equally compelling factors that you must consider when looking at whether or not a genetic test is in the "best interests" of your client? What about their privacy and need or desire for confidentiality about their genetic story? Genetic information is special information that can exclude your clients from future jobs, health and life insurance, educational, or financial opportunities.

Determining what the interests at stake are for your own client in terms of genetic testing is essential to help you meet your profession's first ethical commitment, which is to maintain "respect for the dignity and autonomy of persons." Even today, in all of your work, there are third parties to consider, including family members of a client who have their own worries and needs. Your code of ethics suggests that in situations involving third parties, "there is not one right or wrong answer, but rather the issue is how to manage the ongoing relationships in respectful and caring ways." [17]

That is a logical common sense approach. Family, after all, can give much-needed support to a client under your management. How does this help you counsel a client in situations where access to genetic information can affect the livelihood and career of innocent third parties in a real and detrimental way?

In your work, you know the importance of family support and encouragement. What happens when genetic information, its collection, identification, and use negatively affects the personal relationships your clients enjoy with other members of their families?

In genetic testing, this dilemma arises when one family member agrees to be tested while others in the family do not, either because they do not want to know or because they do not want to be specifically identified as being sick or predisposed to a genetic condition. Once this information is known, the reality is that there is nowhere to hide for family members who have not been tested. In these situations, there are not too many options. They can pretend they are unaffected, which is small comfort when the odds are they are indeed carriers as well. They can undergo genetic testing themselves, against their preference not to, in order to *prove* that they are not carriers of a particular gene.

What about children? Who decides for them? The question of who consents for children in these cases may seem unrelated to your work as vocational rehabilitation professionals. Is it? When you work in the future with clients who have agreed to genetic testing, you are automatically working with an entire family. These are some of the questions that genetic testing raises for you personally and for the Vocational Rehabilitation Association. All of these questions will challenge, in practice, the ethical principles that mark your decision-making and work.

How would I recommend that you address these issues? I spent a year in the United Kingdom recently studying and undertaking research in my field. In offering some suggestions for your group to consider, I refer you to a report by the British Human Genetics and Advisory Committee (HGAC).[18] Among its recommendations, the report proposed that the government and the public prepare for the day in which genetic testing in employment is possible and current. Even though such testing is not common among employers now, there is no doubt that the practice will develop as the science surrounding genetic testing and knowledge improves.

While not dismissing the possible use of genetic testing in the workplace, the HGAC insisted in its report that it be used restrictively and in very specific circumstances. What might these circumstances be? Genetic testing would be allowed if an employer were able to show that this would protect employees and workers. Such bona fide situations could include testing to detect any condition that may put the employee or others at risk in the workplace or to assess, whether a specific variation in an employee's or worker's genetic make-up affects his/her susceptibility to disease while working in a particular type of employment or environment. This, at the same time, has been shown to represent no hazard to most employees.

I agree with the HGAC's recommendation that genetic testing should not be used to provide information about a condition or a predisposition to a condition, which might lead to more absences for sickness. Other options will need to be found to ensure that employers are not overly burdened

financially as a result, and that the job is done regardless of the need for extended absences by an employee or worker. It would not result in fairness if preserving one person's rights in this case adversely affected the health and rights of colleagues who were required to take up the slack.

Finally, someone has to monitor all of this. I vote for an existing public agency with one caveat — the oversight body must be broadly representative of government, labor, and business. It would also be helpful to have access to health professionals and scientists working in the field of genetics and genetic testing, to offer guidance and to ensure that decisions are reasoned and based on sound medical and scientific evidence.

This week, you will have an opportunity to address your code of ethics in an attempt to make it more current to meet modern challenges that science and technology force us all to face. I hope that you will consider this aspect — that of genetic testing in the context of employment and insurance so that you will be ready to play the advocacy role essential to establishing fair and just rules for workers in this area. As you discuss future policy action the Vocational Rehabilitation Association of Canada will undertake in the months ahead, I urge you to consider lobbying both the federal and all the provincial governments to amend their human rights laws to expressly prohibit discrimination in the workplace and insurance on the basis of a genetic predisposition to an illness or disease that has not manifested itself — and perhaps never will.

Science and society must work in tandem to achieve real progress. This is why I have spoken out over the years to encourage greater involvement by the public in the discussion of the issues science raises for society. In this case, for instance, you and I must learn enough about what science is doing to be able to understand and review its developments and discoveries. Science does not operate in a social vacuum. Nowhere is that more so that in the area of human genetics. The legal, social, cultural, and ethical challenges will remain and become more complicated as science does what it does best — pushes back the frontiers of ignorance and superstition and discovers solutions to the toughest medical and scientific questions of our time. You and I may not be equipped to find the cure to deadly cancers or build whole organs from our individual cells, but we have other skills, experience and intelligence that we must add to the public debate and the crafting of public policy. We must use these to build public confidence and understanding of the nature of the challenges ahead of us as we balance science's potential and society's individual and collective rights.

"The legal, social, cultural, and ethical challenges will remain and become more complicated as science does what it does best — pushes back the frontiers of ignorance and superstition and discovers solutions to the toughest medical and scientific questions of our time."

1 Maureen McTeer, Tough Choices: Living & Dying in the 21st Century, Irwin Law (1999).

2 The following definitions are useful for the issues discussed in this speech. Genetic testing — testing to detect the presence or absence of, or alteration in, a particular gene sequence, chromosome or a gene product, in relation to a genetic disorder. Diagnostic genetic testing — use of genetic testing in a person with disease symptoms to aid in their diagnosis, treatment and management. Presymptomatic genetic testing — testing of healthy or asymptomatic individuals to provide information about that individual's future risk of certain specific inherited diseases. Such a test may indicate that the individual has a higher likelihood of developing a disorder. Presymptomatic genetic testing is most frequently offered to those thought to be at high risk of autosomal dominant disorders such as Huntington's disease. Carrier testing — testing of unaffected individuals to determine whether they are carriers of a gene for a recessively inherited disorder (e.g., cystic fibrosis) and are thus at risk of having an affected child. Susceptibility testing — testing which provides information about a genetic component in a multifactorial disorder. Multifactorial disorders are disorders whose genetic components are not the sole cause, but which work with other, often environmental factors, in determining a disease outcome. Multifactorial disorders include many cardiovascular diseases, most Alzheimer's disease of old age and most forms of diabetes. Genetic screening — a term used to denote the application of genetic tests to populations of people, who individually are not at particularly high risk. In contrast, genetic testing of individuals is undertaken when there is some specific prior reason to suspect that the person being tested may be at higher than average risk of carrying the gene change being tested for. *See* Human Genetics Advisory Commission Papers: The Implications of Genetic Testing for Employment, *available at* http://www.advisorybodies.doh.gov.uk/hgac/papers.htm. (defining a variety of genetic tests and terms cited in this speech).

3 In the United States, the Genetic Information Nondiscrimination Act of 2008 (GINA) was signed into law on May 21, 2008. See Pub. L. No. 110-233, 122 Stat. 881 (codified in scattered sections of 26, 29 & 42 U.S.C.), *available at* http://thomas.loc.gov/cgibin/query/D?c110:6:./temp/~c110qm5U1t: (last visited Oct. 5, 2008). The purpose of GINA is to protect Americans against discrimination based on their genetic information when it comes to health insurance and employment. The bill passed in the Senate unanimously and in the House by a vote of 414 to 1, 71 Cong. Rec. H2979 (Roll No. 234) (2008). *See also* http://www.genome.gov/24519851 (last visited Oct. 5, 2008) (detailing legislative efforts and NHGRI's proposals and policy recommendations). Prior to GINA, President Bill Clinton signed an executive order, "To Prohibit Discrimination in Federal Employment Based on Genetic Information," offering limited protection to all federal government employees, see Exec. Order No. 13,145, 65 Fed. Reg. 6877 (Feb. 8, 2000), *available at* http://www.dol.gov/oasam/regs/statutes/eo13145.htm. *See generally* http://www.genome.gov/10002077#2 (last visited Oct. 26, 2008) (providing details on U.S. legislation relating to genetic discrimination, reports on discrimination and recommendations by the NHGRI

on genetic discrimination in employment and insurance, a list of reports on genetics and discrimination and on recommendations by the NHGRI on discrimination in employment and insurance).
4 *See* The Ontario Ministry of Labour, http://www.worksmartontario.gov.on.ca (last visited Oct. 26, 2008) (providing other examples of provincial employment laws that protect workers).
5 1 S.C.R. 4977 (Can.) (1999).
6 *Id.* at 51.
7 *Constitution Act, 1982*, R.S.C. 1985 App. II, No. 44, Sched. B, Pt. I (Can.), *available at* http://www.solon.org/Constitutions/Canada/English/ca_1982.html (last visited Oct. 26, 2008).
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"Double-Jeopardy" of New York State Medical Patients

William N. Papain[*]

"A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights."[1] This is the number one principle of medical ethics adopted by the American Medical Association (AMA), which vicariously applies to all of its practicing professional members-physicians. In essence, the physician's sole responsibility is to preserve human life to the best of his or her abilities. In the past decade, this is where some New York physicians have fallen short of complying with these ethical standards. As a result of the irresponsibility of a few physicians practicing within the State of New York, the New York State Insurance Department and the Medical Society of the State of New York (MSSNY) claim that New York is submerged in a medical malpractice "crisis."[2]

On July 2, 2007, State Insurance Superintendent Eric R. Dinallo for the State of New York announced that the Insurance Department was implementing a 14% increase to medical malpractice insurance premium rates.[3] As a result, then Governor Eliot Spitzer directed Insurance Department Superintendent Dinallo to form a task force consisting of medical, insurance, and legal experts to investigate the reasons behind high medical malpractice costs.[4] This article will explore the legislative bills that were introduced by legislators of the New York State Senate and Assembly in response to the "crisis," as well as their impact on the civil justice system and on the supposed "crisis." In addition, the analysis will compare New York's proposed bills to the implementation of malpractice tort reforms in other states and their effectiveness in their respective forums.

First, this article gives an overview of what is entailed in a medical malpractice action in New York, as well as give a synopsis of previous medical liability reform in New York and the current statutes relevant to medical malpractice. Second, this article analyzes the proposed legislation that has been introduced in the New York State Assembly and Senate, which will affect a patient's right to bring an action for malpractice, and will alter the litigation of such claims.

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Third, this article focuses on responding to the claims of organizations such as MSSNY about the adverse affect that medical malpractice litigation has had on the practice of medicine in the State of New York. Finally, this article summarizes the points previously addressed.

I. Background

Due to the complexity and uniqueness of medical malpractice law in New York, it is essential to discuss the procedural process of a medical malpractice action in the state judiciary system, and to put into context the effect of tort reform on the process.

A. Cause of Action for Medical Malpractice in New York

As in any tort action for damages, a lawsuit for medical malpractice first begins with an alleged injured person who obtains counsel to file a claim against one or more tortfeasors. In New York, a plaintiff's complaint must have a Certificate of Merit declaring that the attorney for the plaintiff, after reviewing the facts and consulting with a physician who is licensed in the state and is knowledgeable of the relevant issues, has concluded that there is a "reasonable basis for the commencement of such action."[5] The attorney does not need to disclose the identity of the consulting physician.[6] The justification for such a requirement is to serve as evidence in the event of an action against the plaintiff for filing a frivolous lawsuit.

The plaintiff bears the burden of presenting and proving a prima facie case of liability in such actions by proving: "(1) the standard of care in the locality where the treatment occurred, (2) that the defendant breached that standard of care, and (3) that the breach of the standard of care was the proximate cause of the injury."[7] The locality standard of care has been upheld in New York case law for nearly a hundred years, from its inception in *Pike v. Honsinger*,[8] where the court ruled that a doctor should exercise the same reasonable degree of care practiced by physicians and surgeons in the locality where that doctor practices.[9] In other words, the plaintiff must prove that the defendant physician violated the standard of care in the geographic area of the practice, or in the specialty of the practice. As a result of the complexity revolving around proving this standard of care, courts require

expert testimony at trial in order to clarify issues of professional or technical knowledge which is beyond the knowledge of the jury.[10] Expert testimony is vital to the resolution of medical malpractice actions, and a plaintiff cannot prove its case without presenting such evidence, except in the rare instance where the issues are within the jury's competence to evaluate. Furthermore, after discussing facts and information relied upon in their analysis, medical experts must conclude within a reasonable degree of medical certainty, that the defendant did or did not commit malpractice which was or was not a substantial factor in causing the plaintiff's injury.[11]

In terms of discovery, CPLR § 3101 is the governing statute for disclosure of documents, information, witnesses and experts. In malpractice actions, parties are not required to disclose the name of their medical expert witness. However, they must disclose all other information, including a summary of the basis for their opinions, the facts and data that they relied upon, and their qualifications.[12] The thought behind such an exception is that the disclosure of the identity of medical experts may subject them to pressure and intimidation by their colleagues not to testify, since the expert is required to be from the same or similar locality as the defendant physician. Another possible purpose is to promote settlement, because the attorneys may not want to risk facing damaging expert testimony at trial. Notably, CPLR §§ 3101(d)(i) and (ii) are currently under consideration by the State Legislature to be amended.

With respect to presenting expert testimony at trial, there are instances where such testimony can be challenged by the opposing party through a *Frye* hearing.[13] At a *Frye* hearing, which occurs during pre-trial motions in limine, the party offering the expert testimony has the burden of proving that the science and opinions relied upon by its expert is 'generally accepted' by the relevant scientific community.[14] The proponent must prove three essential criteria: (1) the techniques generate results generally accepted as reliable within the scientific community; (2) the techniques satisfy a foundation inquiry on the evidence; and (3) the rate of error does not affect its trustworthiness, and is for the jury to decide.[15] In essence, the court lets the jury decide on the soundness of the evidence after it rules that the science passes the standards of *Frye*. However, in medical malpractice cases, courts have begun to rely less on the use of *Frye* hearings because of the belief that the jurors should be allowed to weigh the credibility of expert medical opinions. Courts fear that strict application of *Frye* hearings will deter people from suing.[16] Furthermore, if one takes into account the provisions in CPLR § 3101(d), it is difficult for an opposing party to challenge the opinions of an expert who has not given oral testimony prior to trial because a party is free to reject a request to have the expert deposed. See, CPLR § 3101(d)(ii).[17]

In medical malpractice actions, plaintiffs can recover economic damages (past and future medical expenses, loss of earnings and reduced earning capacity), and non-economic damages (pain and suffering, mental anguish, loss of consortium).[18] A plaintiff can also recover damages from a hospital where the physician responsible for the injury is an independent contractor if the hospital maintained control over the manner and means of the physician's work and the plaintiff reasonably believed that the treating physician was acting on its behalf.[19]

Complexity arises when multiple defendants are involved, which is quite common in medical malpractice cases. Issues arise as to a defendant's joint and several liability for a damage award in favor of the plaintiff. If there are multiple defendants, then the percentage of their respective culpabilities (or liabilities) dictates their responsibility for non-economic damages, unless a defendant is more than 50% liable, in which case that defendant is responsible for all of the non-economic damages.[20] In either case, the plaintiff can sue any of the liable defendants for the full amount of the economic damages.[21] For example, assume that there are three defendants: A, B, and C, and their respective liabilities are 50%, 30%, and 20%. If non-economic damages are $100,000, then A pays $50,000, B pays $30,000 and C pays $20,000. But if A was 51% liable, then the plaintiff could go after A for the full $100,000 of non-economic damages. In addition, the plaintiff could seek the economic damages from any of the three defendants — usually the one with the deepest pocket. The problem arises when there is a non-party tortfeasor, who plaintiff could have but failed to sue. In that instance, the defendants who are parties to the action are allowed to decrease their percentage of liability by the percentage of culpability of the non-party tortfeasor.[22] The status of joint and several liability is further discussed below regarding the proposed legislation. Currently, some of the statutes that are under consideration for amendment include CPLR §§ 3012-a, 3101(d)(i), 3101(d)(ii), and 1600-03.

B. Past Medical Malpractice Reform in the State of New York

In order to understand the current situation of medical malpractice law in New York, it is necessary to discuss past actions taken by the legislature in times of claimed "crisis," and the effect of such laws over time.

> "…the disclosure of the identity of medical experts may subject them to pressure and intimidation by their colleagues not to testify, since the expert is required to be from the same or similar locality as the defendant physician."

In 1974, the state enacted its first medical malpractice reform act in response to a perceived crisis due to the state's largest medical malpractice insurer withdrawing from the New York market.[23] Between 1974 and 1985, legislation for reform came about in piecemeal fashion, and was not effective. Such shortcomings included the lack of appropriate governing bodies to conduct and control a system of medical peer reviews, and a disciplinary network.[24]

One of the largest failures from the 1970's reforms was the creation of medical malpractice panels, which had the purpose of reducing congested court calendars and fostering settlement.[25] In 1980, the Ad Hoc Committee on Medical Malpractice Panels concluded, after an exhaustive study, that there was no real connection between panel findings and subsequent settlements.[26]

On July 2, 1985, then Governor Mario Cuomo signed into law a medical malpractice reform bill (the "Reform Act"), which had three principle objectives: (1) curtail the cost of malpractice insurance; (2) quicken the litigation of malpractice claims; and (3) reduce the incidence of medical malpractice.[27] The Reform Act increased hospitals' existing statutory duty to regulate the quality of medical care by implementing and installing a medical malpractice identification and prevention program.[28] However, the Reform Act oddly stops short of setting forth sanctions in the event of a hospital's failure to conduct such reviews or to implement the prevention program.

In terms of disclosing evidence during discovery, Section 4 of the Reform Act broadened disclosure by, among other things, requiring a party, upon request, to disclose "the substance of the facts and opinions on which each expert is expected to testify, the qualifications of each expert witness and a summary of the grounds for each expert's opinion."[29] This turned into CPLR § 3101(d), which also includes the medical expert identity exception discussed above. The exception seems counterintuitive to the general purpose of Section 4 of the Reform Act, which was to quicken litigation of malpractice claims by broadening disclosure, and thus facilitate settlement.

The Reform Act also attacked 'frivolous' lawsuits through section 10, which imposes sanctions for bad faith filing of claims, defenses, cross-claims, and counter-claims.[30] However, the courts have been wary to impose these sanctions under the belief that such penalties would severely inhibit the state's strong public policy of open access to the courts.[31] The Reform Act tackled this issue in another way: by creating a downward sliding scale for contingency fees for plaintiffs' attorneys. According to New York Judiciary Law § 474-a, a plaintiff's attorney receives 30% of the first $250,000; 25% of the next $250,000; 20% of the next $500,000; 15% of the next $250,000; and 10% of any amount over $1,250,000.[32] The rationale behind this law was that a plaintiff's attorney would lose incentive to try to go after higher damage awards because of their decreasing fee percentage.

In further attempts to reduce judgments against defendants, the Reform Act introduced the Collateral Source Rule, which allows defendants to enter into evidence plaintiff's receipt of compensation or benefit from a collateral source.[33] In order for the courts to implement this properly, juries must itemize the damages into past and future damages.[34] In addition, the Reform Act provided for the periodic payment of future damages rather than lump-sum payments for two reasons: it is arguably cheaper to make periodic payments, and it prevents alleged "windfall" awards to relatives if the plaintiff passes away before the period for which a particular award was intended to provide compensation expires.[35] There is the argument that such payments are unconstitutional and deprive the parties of their right to choose freely the use of the awards.[36]

In examining the Reform Act of 1985, the legislature appeared to be ready to implement new reforms and laws concerning medical malpractice litigation; however, at the same time there is a sense of hesitation of not going too far. For instance, the Reform Act failed to set forth sanctions for those hospitals that did not comply with Public Health Law § 2803. In addition, the courts intervened in a few instances, such as by imposing sanctions for frivolous lawsuits and medical malpractice panels, in order to preserve the strong public policy of open and unimpeded access to the courts. As discussed below, some provisions of the Reform Act of 1985 have lost their initial purpose, such as the non-disclosure of the medical expert's identity to prevent intimidation of potential testifying medical experts.

II. Analysis

Throughout 2007, the New York State Legislature was busy submitting and debating various bills concerning medical malpractice reform in order to respond to the supposed "crisis" in New York. The bills do not focus only on certain aspects of the litigation process but, instead, address the whole process from start to finish. The proposed legislation that is at the focal point of the current reform movement is Bill No.: A03139, which Assemblyman Robin Schmminger introduced on January 23, 2007.[37] This bill is entitled the "Medical Liability Reform Act," because it repeals

and amends several provisions in the Reform Act of 1985. Other bills target the collateral source coverage for physicians, as well as improve the oversight by the Department of Health–Office of Professional Medical Conduct (OPMC).

A. Bringing a Cause of Action — Statute of Limitations, Certificate of Merit, and Court of Claims Jurisdiction

Unlike other civil tort actions, medical malpractice cases are governed by separate procedural statutes regarding the period of limitations to commence a lawsuit and the prerequisites to filing a complaint. Jurisdictional issues for Court of Claims actions in New York are also unique to malpractice suits.

i. CPLR § 214-a: Statute of Limitations for a Medical Malpractice Action

Medical malpractice actions have a special statute of limitations provision under CPLR § 214-a, which was one of the provisions brought about by the Reform Act of 1985. The statute states that an action for medical, dental, or podiatric malpractice must be commenced within two years and six months from the act or omission that caused the injury.[38] In the case of a foreign object in the body, the statute runs either for a year from when the object is discovered or from when facts arise that would lead to discovery of the object.[39] The statute of limitations for medical malpractice actions is rather restrictive and can lead to harsh results because it does not take into account those plaintiffs who are not in a position to perceive the connection between the injury and possible medical error within the prescribed period. The statute relies solely upon when the act or omission that is the cause of the injury occurred, and not when the plaintiff should have reasonably known of it. The issue here, then, becomes the lack of transparency in the medical profession, which inhibits a plaintiff's ability to bring an action because the physician rarely communicates to the patient that a medical error occurred.[40] One reason patients file lawsuits is because they are not provided sufficient information from the health care system and do not know if their injuries are due to malpractice; they may file lawsuits to find out the cause.[41]

Harvey Finkelstein, M.D. is a pain management physician in Long Island, New York who reused syringe needles, thus putting nearly 628 patients at risk for contracting HIV and/or hepatitis.[42] Dr. Finkelstein did not disclose this practice and, the Department of Health, which investigated these incidents, did not direct Dr. Finkelstein to disclose this egregious conduct and the risk of infection to his patients until some three years after the fact.[43] Since the statute of limitations is 30 months, if any patient were infected, they would be barred from filing a lawsuit by CPLR § 214-a. The patients had no way of knowing what caused their illness, if they became infected, because the health system failed to provide them with the necessary information in a timely fashion.

Young v. New York City Health & Hospitals Corp exemplifies the harshness of the statute of limitations doctrine.[44] In *Young*, a female patient brought suit against her treating physicians and clinic for failure to diagnose breast cancer. The patient alleged that, in April 1990, she underwent a mammogram at the clinic which indicated a nodular density in the left breast; this result warranted a biopsy to rule out malignancy. However, these results were not communicated to the patient at that time. She received treatment at the clinic in June and September 1990 for unrelated conditions but was not told of the mammogram results. The patient first became aware of the results in November 1990, and underwent another mammogram in January 1991 that confirmed the diagnosis of cancer. She underwent a mastectomy and received postoperative care from the defendants until July 1991. The Court of Appeals affirmed the lower courts' decision to grant the defendants' motion to dismiss the plaintiff's claim as time barred regarding any acts or omissions amounting to medical malpractice which occurred prior to the accrual of the cause of action in November 1990.[45] The Court concluded that a course of treatment for the same condition which gave rise to the cause of action did not exist between April and November 1990.[46] Furthermore, the Court ruled that the patient failed to show that further treatment for breast cancer was contemplated by both parties in April 1990.[47]

On March 7, 2007, New York Assembly members Peter Grannis and Helene Weinstein proposed a bill to amend CPLR § 214-a. The bill states that an action for medical malpractice must be commenced within two years and six months of the "accrual of any such action."[48] The bill defines the accrual event as when "one knows or should have known of the alleged negligent act or omission and knows or should have known that said negligent act has caused an injury."[49] The bill would relax the harsh effects of the statute of limitations because the statute would not begin to run until information and facts are made available for the patient to realize that their injury may have been caused by medical malpractice. This more equitable statute of limitations would, in effect, combat the rampant lack of communication between physicians, such as Dr. Finkelstein, and their patients concerning injuries from medical errors.

"The issue here, then, becomes the lack of transparency in the medical profession, which inhibits a plaintiff's ability to bring an action because the physician rarely communicates to the patient that a medical error occurred."

In addition, the proposed amendment to CPLR § 214-a would help support the courts' public policy of open and uninhibited access to the judicial system. Under the original statute, the physician holds all the information that the patient needs in order to realize what occurred. Thus, the physician's and the healthcare system's failure to communicate information to patients inhibits the patient's ability to file a malpractice lawsuit within the requisite period of time. This scenario could possibly be a due process violation as well, since the failure to communicate prevents the patient from utilizing the civil justice system for a meritorious claim.

ii. CPLR § 3012-a: Certificate of Merit

In order to successfully file a complaint for a medical malpractice action, a plaintiff's attorneys must attach a Certificate of Merit to the complaint, as required by CPLR § 3012-a. Under the statute, a plaintiff's attorneys must declare that they have concluded that there is a reasonable basis for the lawsuit based upon their review of the facts, and their consultation with a physician who practices in the State of New York and is knowledgeable of the relevant issues.[50] The statute's main purpose is to prevent plaintiffs from filing frivolous lawsuits.[51] There are no sanctions for failure to comply with the statutory requirement, but case law indicates that courts will grant an extension of time to file the Certificate with the court.[52] The plaintiff is not required to disclose the identity of the consulting physician, except in the case where the plaintiff consulted with three physicians who failed to provide the information required to certify the complaint and the opposing party requests the names of those physicians.[53] The statute is a "bite with no teeth," because there is no disclosure of the consulting physician's identity, there are no sanctions or motions for dismissal allowed if the plaintiff fails to comply with the statute, and the requirements for the Certificate are somewhat general.

On January 23, 2007, an Assembly bill was proposed to amend, amongst other things, CPLR 3012-a. This bill requires a signed affidavit from the consulting physician, which concludes that "there is a reasonable basis for the commencement of an action."[54] In addition, the identity of the physician is disclosed, and an affidavit must address each cause of action where there are multiple defendants.[55] As such, more than one physician affidavit must be submitted.

This amendment would strengthen the statute and place a greater burden on the plaintiff in bringing a lawsuit. The burden could lead to the creation of a rather harsh deterrence, especially in the instance of a claim against multiple defendants. In such a claim, the plaintiff would need to procure multiple physician affidavits for each defendant physician, since the defendants' will have different specialties and claims against them. Not only does this appear to create an undue burden in terms of time and effort, but it also is a financial burden which may deter plaintiffs from even bringing such actions.

Plaintiffs may file lawsuits sometimes to find out what caused their injury because they received no information from the treating physicians or the healthcare system.[56] As a result of this lack of information, plaintiffs will often enjoin multiple defendants until they determine through discovery which one was more likely to have caused the injury.[57] This bill essentially infringes upon the plaintiff's legal right to file a claim on a good faith basis and to pursue the action through the civil justice system. It inhibits the plaintiff's access to the courts and places enormous burdens, including financial, in order to commence an action.

iii. New York Constitution, Article VI, § 9; Court of Claims Act § 8

In New York, whenever there is an action against the State, the action must be brought in the Court of Claims and not in any of the Supreme Courts.[58] In the Court of Claims, only a bench trial is permitted, with no trial by jury.[59] The State cannot be sued in any of the Supreme Courts of New York.[60] An action cannot be brought against a state employee in the Court of Claims unless their alleged negligence occurred during their official capacity as an Officer of the State.[61] A state agent or officer can be sued in the New York Supreme Court for tort damages because of a breached duty owed individually by them to the plaintiff; the State can be held secondarily liable under respondeat superior.[62]

In *Morell*,[63] the Court of Appeals rejected a narrow interpretation of the Court of Claims Act that would bar actions against State agents in Supreme Court.[64] The immunity of the State does not pass through to State employees in such actions merely because they are employed by the State.[65] Thus, the separation between the State and its employees in tort actions helps to preserve the injured party's constitutional right to trial by jury. In such a case, the injured party could have an

action against the physicians in the Supreme Court while also commencing an action against the State in the Court of Claims on the same matter. In a practical sense, the plaintiff's attorney would want to resolve the action against the physicians first — either by settlement or a jury verdict in their favor. One possible tactic would be to receive a favorable jury verdict in Supreme Court, and then attempt to use that evidence against the State in the Court of Claims to show the physician's percentage of culpability while alleging the doctrine of respondeat superior against the State.[66] Court of Claims judges would not likely look favorably on such an attempt since the State was not a party to the Supreme Court action.

The issue of distribution of liability amongst the defendants exists in the Supreme Court action. Defendants might allege that the State's liability should be factored into the judgment in order to lower the culpability percentages of the physicians. Plaintiffs cannot overcome this by proffering to the court that they are unable to obtain jurisdiction over the State in that Supreme Court. It is not an inability to obtain jurisdiction, but rather a result of a rule of substantive law based on sovereign immunity.[67]

On January 3, 2007, an Assembly bill was introduced to amend the jurisdiction of the Court of Claims. The bill amends the New York City Health and Hospitals Corporation (NYCHHC) Act Ch. 1016(1)(20) by extending the Court of Claims' jurisdiction to the NYCHHC, its officers and employees for actions that arise during their employment with the NYCHHC.[68] The first problem with this proposed amendment is that it would unconstitutionally deny the injured party his or her due process right to a trial by jury.[69] The statute forces injured parties to bring their actions against state and city employed physicians into the Court of Claims, which does not offer jury trials. The second more subtle problem is that patients of state and city run hospitals and clinics are usually of middle or lower income. As these patients do not have the resources to go to private physicians or hospitals of their choosing, they lose their constitutional right to a jury trial if they are injured by a physician at a state- or city-run medical facility.

B. CPLR 3101(d): Medical Expert Disclosure

The Reform Act of 1985 fostered CPLR 3101(d), with the purpose of facilitating settlement by broadening disclosure and speeding up litigation.[70] The courts struggled with the medical expert exception in subsection (ii) of the statute, which allows parties to exclude the identity of their medical experts, but requires the disclosure of their qualifications and summaries of their opinions, and the facts and data upon which they will testify.[71] In *Jasopersaud v. Rho*,[72] the court grappled with the idea of whether the proponent had a substantive right to withhold the identity of the expert. While discussing this issue, the court developed a 'balancing test' between broad disclosure and the risk that disclosed information would lead to the expert's identity.[73] In 2002, the Second Department stated that it was futile to try to conceal the identity of a medical expert due to the wealth of resources, especially the internet, which can identify the expert through the information disclosed.[74] Nonetheless, the court ruled that the proponent could seek a protective order under CPLR 3103(a) to prevent disclosure of the expert's qualifications which would lead to the disclosure of their identity.[75] Other than the exception being weakened by modern technology, the probability that the expert will be effectively pressured not to testify if the identity is disclosed is offset by the relaxation of the locality standard of care since the Reform Act of 1985.[76]

In the bill submitted by Assemblymember Robin Schimminger, the provisions pertaining to medical malpractice actions in CPLR 3101(d) would be amended. The amended provisions discard the medical expert exception in subsection (i) that protects the identity of the medical expert, and require, under subsection (ii), that the parties conduct oral depositions of medical experts at the expense of the requesting party.[77]

In practical terms, the medical expert exception no longer served its purpose, since it is now very difficult to conceal the identity of the expert while disclosing the expert's qualifications and other information. However, abandoning this exception means that the plaintiff no longer has the statutory or substantive right to seek a protective order under CPLR 3103(a). The exception still did serve a purpose in preserving the plaintiff's right to seek such a protective order.

The purpose of the proposed broader disclosure is to take CPLR 3101(d) a step further than the Reform Act of 1985 and try to achieve its goal of expediting litigation and facilitating settlement negotiations. Once again, this amendment places a harsh burden on the plaintiff. In practice, an oral deposition of an expert is very costly because experts are paid for their time. In addition, during discovery and pre-trial preparation, parties will identify numerous experts to finalize and strengthen their theory of the case before finally settling on one or more experts for trial. During discovery, a plaintiff will not know which of the defendant's experts will testify at trial and therefore is forced to choose which experts to depose. Depositions are very costly to a plaintiff and to the attorneys working on a contingency fee basis; they may hesitate to depose numerous experts. If the plaintiff chooses to depose only some of the defendant's experts, then the defendant can opt to bring one of the non-deposed experts to testify at trial.[78]

The amended provision also is counterproductive to the grand scheme of the bill, which is to lower costs to malpractice insurers and physicians. Litigation will also be expensive for the defendants if they choose to depose their co-defendant's experts and/or the plaintiff's experts. That very well may be the point of the amended statute — to get both sides to avoid high litigation costs by resolving the matter early on in the litigation process. At the same time, the provision acts as an inhibitor for the plaintiff to reach a jury trial because the plaintiff or the attorney cannot afford the high litigation costs associated with deposing experts.

C. CPLR 1601: Joint and Several Liability

One of the compromises in the Reform Act of 1985 is Article 16 of the CPLR, the joint and several liability provisions. Specifically, CPLR § 1601 affects the liability of defendants for non-economic damages, in that each defendant is liable for the percentage of non-economic damages in relation to their share of culpability. For economic damages, the plaintiff can recover 100% of the economic damages from any defendant found liable.[79] In addition, if a defendant's culpability exceeds 50%, then the plaintiff can recover 100% of the non-economic damages from that defendant.[80] For economic damages, the plaintiff usually seeks the deepest pocket, such as a hospital rather than a physician. Article 16 modified the common law rule of joint and several liability, based on the premise that the full compensation of a relatively innocent victim is more important than a balancing of fault.[81]

Schimminger's proposed bill amends CPLR § 1601 by removing the clause referring to a defendant who is more than 50% culpable who then

could be held responsible for 100% of all non-economic damages.[82] The bill also states that a defendant is liable to the plaintiff for non-economic *and* economic damages not exceeding that defendant's share of liability.[83] Defendants would only be at risk for paying that portion of the economic damages commensurate with their percentage of fault. Under the bill, the defendant's share of the culpability dictates the percentage of both economic and non-economic damages that that defendant is liable to the plaintiff.

This amendment to CPLR §1601 undermines the common law purpose of joint and several liability, which is to compensate plaintiffs fully and allow them to recover from the deep pocket (i.e., the hospital instead of the physician) in actions for medical malpractice. Under the current statute, in an action where the plaintiff sued and received a favorable judgment against a hospital and physician, the plaintiff would usually try to recover the economic damages from the deeper pocket, the hospital. If the plaintiff tries to recover all the economic damages from the physician, the plaintiff runs the risk that the physician would not have sufficient insurance coverage or enough assets to fully compensate the plaintiff. By recovering all economic damages from the hospital, the plaintiff has a better chance of full compensation. The burden is on the 'deep pocket' to indemnify itself against the physician.

The amendment of CPLR §1601 flips the burden and forces the plaintiff to deal with recovering economic damages from all the defendants. Thus, the plaintiff might not receive full compensation because a defendant may not have sufficient coverage or assets to cover its percentage of damages. In essence, the amendment protects the hospitals over the injured party.

D. Article 50-C: Limitation on Non-Economic Damages

Putting a cap on non-economic damages is very controversial in medical malpractice tort reform actions. The majority of states that enacted some form of malpractice reform include statutes capping non-economic damage awards. The theory behind such a cap is that reducing the amount of judgments in medical malpractice claims will reduce malpractice premiums for physicians.[84]

Schimminger's proposed bill includes the enactment of a new article to the CPLR, Article 50-C, which places a cap of $250,000 on non-economic damages, regardless of how many defendants are in the action.[85] Caps on damages do not reduce malpractice insurance premiums, and only hurt the severely injured plaintiffs. Other states that have imposed caps on non-economic damages did not experience a correlation between reduced judgments and reduced premiums. In 2002, Nevada passed caps on damages and within days, its two largest insurance companies announced that they had no intention of lowering their rates.[86] When Mississippi considered damages caps in the summer of 2002, physicians were told by their insurers that they would face a 45% increase in premium rates regardless of whether the state implemented damage caps.[87] The Nations' largest medical malpractice insurer, GE Medical Protective, tried to raise premiums by 19%, claiming that non-economic damage caps are nominal and will only create loss savings of one percent. This occurred six months after Texas passed its caps on non-economic damages.[88] Lastly, the 2003 Farmers Insurance Group demonstrated that caps do not result in affordable insurance for physicians — the Group pulled out of five states, including California, which has had caps and tort reform for decades.[89]

Insurance companies respond to the state of the economy and the cyclical effects of the industry's investment market.[90] A study explicitly concluded that between 1991 and 2002, the states with caps on non-economic damages saw median physician premiums rise 48%, while in states without caps, physicians' median premiums rose only 36%.[91] Experiences in other states and studies done on the connection between premium rates and damages caps demonstrate that there is in fact no correlation. Some would argue that it would make more sense for the statutes imposing caps on damages to include a provision that reduces premiums as well — an option that New York has not considered. Tort reform supporters point to the fact that in California, where there are caps on non-economic damages of $250,000 (not adjusted for inflation), malpractice insurance premiums stabilized and declined.[92] However, the decline in malpractice insurance premiums was not due to the damages caps but, rather, because California passed Proposition 103 in 1988, which required insurers to open their books to justify their rate increases.[93]

The real downside to imposing damage caps, especially on non-economic awards, is that the greatest negative effects from such caps are those plaintiffs who suffer severe injuries without substantial economic loss.[94] In essence, plaintiffs would be facing "double-jeopardy," first hurt by the health care provider, and then penalized by the law. In addition, damage caps nullify claims for decrease in quality of life. Disfigurement, deafness, blindness, and other injuries may have minimal economic damages, but have large non-economic damages because of the person's reduced quality and enjoyment of life.[95]

Women are especially adversely affected by non-economic damage caps. Women who bring gynecological malpractice suits can lose their awards because their

"Caps on damages do not reduce malpractice insurance premiums, and only hurt the severely injured plaintiffs."

injuries, which include impaired fertility, impaired sexual functioning, miscarriage and scarring, do not carry large economic losses, even though they account for serious emotional suffering, lost sense of self, and reduced quality and enjoyment of life.[96] These women would be deprived of their legal rights to bring such lawsuits because the role of the jury is abrogated by the damage caps in actions for gynecological malpractice. Thus, the injured women are not fully compensated for their injuries. Instead, Californian women are subject to an arbitrary flat cap on damages that is not adjusted for inflation. If the cap were adjusted for inflation, the cap level would have been set at $779,000 in 1999.[97]

Non-economic damage caps do not affect insurance premium rates or healthcare costs in general, because premiums account for less than two percent of total health costs.[98] In the end, the caps deprive plaintiffs of their legal rights to having a jury determine the full extent of their damages, while plaintiffs lawyers operating on contingent fees likely will decide not to pursue non-economic damage-oriented claims.

E. Medical Malpractice Insurance Reform

When the New York State Insurance Department announced that it approved an increase of 14% in medical malpractice insurance rates, the Department cited the misappropriation of funds as one of the chief causes of this "crisis."[99] Specifically, the State previously appropriated $691 million of the medical malpractice insurance reserve funds from the Medical Malpractice Insurance Association (MMIA) to meet other budgetary needs.[100] The MMIA fund was created to provide insurance for those physicians who could not get regular commercial coverage because of their high risk status. The Insurance Department admits that if "MMIA's reserves [had] been preserved and allowed to grow by collecting interest over the years . . . medical malpractice insurers would be in a much stronger financial position today."[101] The Medical Malpractice Insurance Plan (MMIP) replaced the MMIA but, according to the Insurance Department, it has a deficit of $525 million, which by law must be shouldered by the malpractice insurers in the State.[102]

In January 2007, State Senator Liz Krueger proposed a bill to amend § 6524(11) of the Education Law to require that every practicing physician in the State of New York procure a policy of at least one million U.S. dollars.[103] In that same month, another bill was proposed which would establish a separate state fund to compensate neurologically impaired infants as a result of the acts or omissions of obstetricians-gynecologists (OB/GYN) and midwives.[104] Two months later, another insurance bill was proposed which would provide excess insurance to physicians who are unable to obtain commercial insurance because they are considered "high-risk."[105] The fourth proposed insurance bill of 2007 dealt with requiring the medical liability insurance association to replace the insurance pool which the State drained of all of its funds.[106]

The MMIP has a deficit of $525 million because it subsidized high-risk physicians who could not obtain commercial insurance. Seven percent of physicians are responsible for two-thirds of all medical malpractice payouts.[107] This small number of physicians is responsible for draining the fund, thus forcing the insurers to cover the losses. These physicians, who are so high-risk they cannot even obtain commercial insurance, are still allowed to continue their practice without disciplinary actions and are guaranteed by the State to receive insurance.

> In essence, plaintiffs would be facing "double-jeopardy," first hurt by the health care provider, and then penalized by the law. In addition, damage caps nullify claims for decrease in quality of life.

Bills S0973 and S7038 both require practicing medical professionals to obtain insurance of one million U.S. dollars. However, in order to qualify for excess insurance of one million U.S. dollars from the medical liability insurance fund, a physician must have $1.3 million in insurance coverage.[108] Instead of requiring these physicians to obtain the extra $300,000, the bill proposes further subsidies for the physicians by providing them with the $300,000 from a state-operated hospital fund that is under the control of the Superintendent of the Insurance Department.[109] On top of providing subsidized insurance to high-risk physicians through the medical liability insurance plan, the State further subsidizes all physicians from a hospital fund in order to qualify for excess insurance. Bill S7038 does not differentiate between good and bad doctors; nor does it differentiate between specialties. Instead the proposed bill provides a subsidy across the board to all physicians.

Instead of disciplining high-risk physicians, the State is guaranteeing insurance for these physicians under the Medical Liability Insurance Association. A study shows that, if New York stopped physicians who committed three malpractice acts or more from harming more patients, malpractice cases would decline by one-third.[110] Instead, the State is subsidizing insurance for physicians like Dr. Finkelstein,[111] while ethical

physicians, who are the overwhelming majority, bear the burden of paying higher premiums.

The other shortcoming of the rise in medical malpractice insurance premiums is that insurance rates are not based on experience. Premium rates are not adjusted individually to reflect the physician's performance history, such as with auto insurance. On the contrary, malpractice premiums are the same across the board based on the specialty rather than the performance of individual physicians. Thus, the large percentage of medical errors caused by that seven percent of New York physicians negatively affects all physicians' access to affordable insurance, rather than just themselves.

The neurologically impaired infant fund also is not necessary based on statistics available on OB/GYB malpractice actions. The purpose of the fund is to protect OB/GYN physicians by capping their liability, based on the presumption that these specialists will leave and are leaving the State due to high health insurance costs.[112] In fact, New York ranks third in the nation with 39 OB/GYNs per thousand, while California — the national 'model' for reform — ranks, 17th.[113] Additionally, Florida and Virginia both attempted to implement the same program; however, it failed in both states. No other state has implemented such a program.[114] One reason for its failure is that the program is funded by fixed assessments from doctors and hospitals, so the administrators have a strong resolve for solvency of these funds versus making compensation available.[115]

There is no evidence that these types of lawsuit are so rampant that they should be removed from the courthouse and subject to the whims of a state fund. In reality, neurologically impaired infants are part of a group that does not comprise a major part of medical malpractice costs.[116] Instead, under such a fund, plaintiffs would be barred from receiving redress from the courts, thus encroaching on their constitutional rights. The proposed bill also bars the plaintiff from seeking non-economic damages on behalf of the infant who will undoubtedly suffer pain and suffering, mental anguish, and reduced quality of life.[117] The only group that has an option to enter or leave the fund is the OB/GYN, not the infant. In short, the fund's main purpose is to isolate and protect OB/GYNs from paying out malpractice awards[118] to the detriment of the legal rights of injured infants and their families. The injured infant endures a 'double-jeopardy' through the health care system, both injured from medical errors and deprived of their legal rights.

These funds and insurance pools are initially what drove New York State and the insurance companies into this "crisis." Controls need to be imposed in order to prevent another misappropriation of funds, such as what happened with the $691 million that was in the insurance pool. Administrators for the subsidized insurance coverage should conduct physician screening to weed out those physicians who pose not only a risk to the funds in the pool, but also a risk to patients.[119]

Due to the absence of experience rating — adjusting rates based on how safe or not safe individuals conducts themselves — in medical malpractice insurance, medical professionals cannot control their premiums by improving their quality of care.[120] Thus, there is no incentive to avoid liability. The main dilemma, and error, is that good physicians suffer just because they are in a certain specialty.

F. Malpractice Prevention and Medical Peer Review

Attacking the root of medical malpractice, such as physician errors, neglect and carelessness through oversight and prevention programs could curtail rising medical malpractice costs and payouts. For instance, anesthesiologists had the highest premium rates as compared to most other specialists in the 1980s, until anesthesiologists began implementing safer practices.[121]

Similar safety initiatives have occurred as a response to mounting litigation in a particular specialty or area of medicine. In Connecticut, an investigative journalist used records from a pending malpractice lawsuit to uncover an epidemic of hospital-borne infections.[122] It was not until the lawsuit commenced and bad publicity ensued that the hospital adopted safety measures which reduced infection rates from 22% to nearly zero.[123] The Harvard Medical Practice Study shows that litigation drives safety as the experience of being sued makes physicians twice as likely to take the time to explain risks and communicate with patients.[124]

In New York, a major problem is oversight and discipline by the OPMC. According to the National Practitioner Data Bank (NPDB), only 28% of the physicians who made ten or more payouts were disciplined by the OPMC.[125] Instances such as Dr. Finkelstein's case are commonplace. In a sense, it is a breakdown of the health system in New York, because hospitals fail to investigate their physicians, and the OPMC fails to investigate individuals who have a number of payouts or who are known to be high risks.

In January 2007, a bill was proposed to amend Public Health Law § 230(12-a) by requiring the commissioner

to inform the OPMC immediately of a physician who is the subject of a medical malpractice lawsuit.[126] In February 2007, a bill was submitted in the Assembly to amend Public Health Law § 230 (9-b) by providing that the OPMC conduct a thorough investigation into the conduct of a physician when the office accrues three reports relating to separate incidents within a five-year period, or five reports within any two-year period for more severe penalties.[127]

The goal and purpose of these amended statutes is to compel the OPMC to regulate the conduct of medical professionals within the State of New York to curtail rising medical malpractice costs and prevent further harm to patients. As of now, litigation is the catalyst for such safety measures. When errors occur on a frequent basis, then lawsuits will mount and place costs upon providers until a balance is met and it becomes less costly for the provider to implement measures to improve quality.[128] The tort system is the only means of gaining insight into serious misconduct that endangers patients, especially since the New York Patient Occurrence Reporting and Tracking System (NYPORTS) denies access to injured patients who wish to see data and peer reviewed records.[129]

These proposed laws existed in the guidelines for the OPMC; however, they did not live up to their standard of review and oversight.[130] The agency failed to investigate doctors with payments for malpractice that would usually trigger an investigation.[131] In addition, there was a chronic recurrence of inexcusable errors, including surgery on the wrong limb and leaving foreign bodies in the patients. These acts amounted to at least 550 deaths per year in New York.[132] The fact that these inexcusable errors occur on such a frequent basis is an indication of poor patient safety and OPMC laxity in its oversight of negligent and unethical doctors.

Public Citizen reported on the recommendation that the State's licensing board investigate those physicians who are unable to obtain commercial insurance coverage to see if they are suited to continue practicing medicine.[133] Elimination of such 'bad' doctors will protect the safety of patients and will remove their adverse affects on insurance funds due to multiple malpractice payouts.

Reducing medical malpractice litigation against healthcare providers starts with the conduct of the doctors and the safety measures they implement to ensure the well-being of their patients.

III. Diagnosing the "Crisis" in New York

There are several misconceived notions and allegations made by groups such as MSSNY pertaining to the cause of the current "crisis" situation in New York. The primary cause of this insurance problem is a failure by the State to manage properly the funds in the insurance pool for high-risk physicians, and a failure of the OPMC to monitor and oversee their professionals properly. The State also failed to regulate medical malpractice insurance rates properly.[134] From 1991-2007, the rates increased at a stagnant average of 3.5% annually, with virtually no increase in insurance rates until 2003. The average rate hike in the United States in that same time period was nearly double at 6.5%.[135] Thus, with premiums lower than the national average and declining revenues, the only way for the insurance companies to rebound was to hike rates dramatically. However, the Insurance Department would not grant a 30% raise request in 2007 and instead raised premiums by 14%.[136]

Nearly 100,000 people die in the United States each year from medical mistakes, which exceeds the number of individuals who die in automobile or workplace accidents.[137] Emphasizing the poor regulation of physicians by the OPMC, it is important to note that approximately 6,189 doctors made two or more malpractice claim payouts. Of that group, only 8.5% received some disciplinary action, and only 11% of the 3,057 doctors that made three or more payments were disciplined.[138] Under the OPMC regulations and the proposed bills, reports of three separate payments automatically trigger an immediate investigation by the OPMC as to that physician's conduct.

MSSNY claims that, as a result of the hostile litigation climate of New York and the recent increase in premium rates, there are shortages in several medical specialties.[139] In contrast, New York's physician pool actually is flourishing. The physician population has increased by 20.5% from 1995–2007, an increase of 15.8% in the number of physicians per 100,000 residents.[140] If physicians are fleeing New York for friendlier environments (i.e., states that have less medical malpractice litigation) then why does New York boast a greater amount of practicing physicians and specialists per capita and nearly double the residents and fellows on duty than both California and Texas, which are considered tort reform states?[141]

MSSNY, the New York Chapter of the American College of Surgeons, and New York State Society of Orthopaedic Surgeons contend that, during "crisis" periods, physicians flee those areas, and most specialties restrict their scope. As to the first contention, a report by the Government Accountability Office (GAO), clearly states that physicians did not flee perceived medical malpractice "crisis" states, contrary to the contentions of the AMA.[142] Another study also clearly contradicts the medical societies' contention that specialists limit the scope of their practices during "crisis."[143] Connecticut has the highest percentage of orthopedic surgeons even though general surgeons pay thousands of dollars more in premiums than general surgeons in New York.[144]

The Orthopaedic Society asserts in its submissions to the Task Force that there is a scarcity of specialists, as evidenced by certain counties having two or fewer orthopedic surgeons.[145] However, the counties that the Orthopaedic Society referred to are rural counties and are in regions with the lowest premiums, thus contradicting its argument. The surgeons are actually leaving cheaper premium regions to work in New York City or Connecticut where the premiums are much more expensive.[146] This demonstrates that premiums have little to no effect on where a physician practices. In addition, there has not been an increase in medical malpractice claims. According to the Insurance Information Institute, one in eight patients who suffer an injury from an adverse event will file a malpractice lawsuit and one out of 15 will receive compensation.[147] The amount of malpractice payouts has remained steady from 1991 to 2006, with a slight decline in the average between 2002–06.[148] Further, the number of payments made by physicians has also steadily declined in recent years.[149] Furthermore, the number of Request for Judicial Intervention in medical malpractice actions has stayed around 4,300 per year.[150]

Medical malpractice premiums only account for two percent of healthcare costs.[151] Lawsuits are one of the smallest factors driving up health costs, at less than one percent of total healthcare spending.[152] Malpractice cases could be cut by one-third if the OPMC disciplined doctors who committed three or more malpractice payments.[153] Lastly, limiting medical malpractice

liability will undermine any incentives for safety because there will be one less check on the conduct of physicians in the treatment of patients. This will make it more difficult for those patients with legitimate but difficult claims to find legal representation, especially with reforms driving up litigation costs.[154]

IV. Conclusion

There is a crisis in the State of New York, but it has little if anything to do with litigation of malpractice claims. The crisis is the unsafe environment that patients in New York deal with when undergoing treatment — whether it is within a physician's office or in a hospital. As long as unethical doctors like Dr. Harvey Finkelstein are allowed to continue their practice and receive subsidized malpractice insurance, patients will be at a great risk of injury. The unchecked and unmonitored subsidizing of high-risk physicians guarantees the continuation of inexcusable medical errors. Good doctors should not be penalized simply because they practice a particular specialty. Neither they nor their insurer should be forced to subsidize physicians who are not able to obtain commercial insurance.

Tort reform is not the solution — all it will do is subject the malpractice victims to further hardships and deprive them of their legal rights to due process and a trial by jury. Funds like the Neurologically Impaired Infant Fund forces this remedy upon plaintiffs and encroaches upon their constitutional right to a jury trial. Caps on non-economic damages only subject the severely injured plaintiff to the further harm of "double-jeopardy." The caps do not correlate with a reduction in premium rates; however, they do reduce the claims brought by women, children and the elderly. If the bill for the subsidized insurance for high-risk physicians is allowed to pass, then the bill should be named "Harvey's Law," because it will only benefit doctors like Dr. Harvey Finkelstein, and subject the public to further harm and injury.

1 American Medical Association (AMA), *Principles of Medical Ethics*, Adopted by the AMA's House of Delegates on June 17, 2001, *available at* http://www.ama-assn.org/ama/pub/category/2512.html.
2 New York State Insurance Department, *Rate Increase Staves off Looming Insurance Industry Crisis as New Task Force Confronts Medical Malpractice Reform*, Press Release- July 2, 2007, *available at* http://www.ins.state.ny.us/press/2007/p0707021.htm; Medical Society of the State of New York (MSSNY), *NYS Medical Society Says Rate Increase Bodes Ill for New York Patients*, Press Release- July 2, 2007, Lake Success, New York.
3 *See*, NYS Insurance Department, Press Release July 2, 2007 (reasoning that the raise in premium rates was deter the financial deterioration of medical malpractice insurance companies).
4 *Id.*
5 New York Civil Practice Law and Rules (N.Y. C.P.L.R.) Section 3012-a(1) (Consol. 2008).
6 N.Y. C.P.L.R. § 3012-a(3)(e) (Consol. 2008).
7 *Berger v. Becker*, 272 A.D.2d. 565 (2nd Dept. 2000).
8 155 N.Y. 201 (1898).
9 *Pike*, 155 N.Y. at 209.
10 *Boland v. Montefiore Medical Center*, et al., 2005 NY Slip Op 50289U *6 (1st Dept. 2005) (holding that "unless the alleged malpractice falls within the competence of the jury to evaluate," the plaintiff is required to present expert testimony to support its claims and establish a prima facie case); *see also Hoagland v. Ira Kamp*, et al., 155 A.D.2d 148, 150 (allowing an expert to testify as to the minimum standard of care required of all dentists in the State of New York, even though the expert could not testify as to the locality standard of care where the defendant practiced).
11 *Torns v. Samaritan Hospital*, 305 A.D.2d 965, 966 (3rd Dept. 2003).
12 N.Y. C.P.L.R. § 3101(d)(i) (Consol. 2008); *see also* N.Y. C.P.L.R. § 3101 (d)(ii) (Consol. 2008) (oral depositions of medical experts are optional).
13 *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923); *see People v. Wesley*, 83 N.Y.2d 417, 422 (1994).
14 *Wesley*, 83 N.Y.2d at 423 (ruling that general acceptance does not have to be unanimous acceptance).
15 *Id.* at 436; *compare with Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (relaxing the standard for a *Frye* hearing by weighing the evidence, and considering margin of error and peer reviews along with general acceptance).
16 Jeffrey M. Kimmel, *'Frye's' Applicability to Medical Malpractice Cases*, New York Law Journal, June 13, 2007; *citing* Marsh v. Smyth, 12 A.D.3d 307, 311-312 (1st Dept. 2004) (holding that expert testimony which opines the causation of the injury to be the defendant's conduct is not novel as per the *Frye* test, but rather is exactly what is the "primary point of contention in a personal injury action.").
17 N.Y. C.P.L.R. § 3101(d)(ii) (Consol. 2008) (all parties to the action must consent to oral depositions of medical experts in order for such disclosure to take place during discovery).
18 N.Y. C.P.L.R. § 1600 (Consol. 2008).
19 *See*, *Torns*, 305 A.D.2d at 966-67 (held a hospital vicariously liable for conduct of an independent contractor because plaintiff could reasonably believe that the physician was provided by that hospital and acting on its behalf).
20 N.Y. C.P.L.R. § 1602 (Consol. 2008).
21 *Id.*
22 *Id.* (allowing the plaintiff to not consider the liability of a non-party if they show even after due diligence they were unable to obtain jurisdiction over that person).
23 Betsy A. Rosen, *The 1985 Medical Malpractice Reform Act: The New York State Legislature Responds to the Medical Malpractice Crisis with a Prescription for Comprehensive Reform*, 52 Brook. L. Rev. 135, 139 (1986).
24 *Id.* at 145.
25 *Id.* at 161 (discussing how some courts found panels to be unconstitutional, unworkable, and inequitable to litigants).
26 Gagliardi, *Report of the Ad Hoc Committee on Medical Malpractice Panels to the Chief Administrative Judge of the State of New York on the Operation of Medical Malpractice Panels*, 159-64 (1980) (concluding that panels do not facilitate settlements and in many instances actually reinforce a party's resolve to go to trial).
27 Rosen, *supra* note 23, at 135.
28 NY Public Health Law § 2803(2)(a)(v).
29 N.Y. C.P.L.R. § 3101(d)(i) (Consol. 2008).
30 Rosen, *supra* note 23, at 158.
31 *Gabrelian v. Gabrelian*, 108 A.D.2d 445, 455, 458 (2nd Dept. 1985) (Justice Lazer reversed the imposition of such sanctions on the basis that they were beyond the 'inherent powers' of the court, and stated that "an action or motion which may appear frivolous . . . may in fact be the beginning of a new development in the law.").
32 NY Jud. Law § 474-a (McKinney Supp. 1986).
33 Rosen, *supra* note 23, at 164-65; *see also* CPLR § 4545(a).
34 C.P.L.R. § 4111(d) (Consol. 2008) (juries shall award the full amount of future damages without reductions).
35 Rosen, *supra* note 23, at 170-711.
36 *Id.*
37 A. 3139, 2007 Assemb., 230th Sess. (N.Y. 2007) (proposed by Assemblymember Robin Schimminger) (amending C.P.L.R. §§ 3012-a, 1600, 1601, 3101(d)(i), 3101(d)(ii), and adding Article 50-C to the C.P.L.R.).
38 N.Y. C.P.L.R. § 214-a (Consol. 2008) (in the case of continuous treatment for the same illness, the statute runs from the last treatment for that illness).
39 *Id.*
40 Tom Baker, *The Medical Malpractice Myth*. 92, 157 (University of Chicago Press. 2005) (discussing how physicians should be open with their patients and disclose to them when a medical error takes place).
41 *Id.* at 157.
42 Kathleen Lucadamo. *State's slow bust pricks needle suits*, N.Y. Daily News. November 21, 2007.

43 *Id.* (Instead of notifying all of his patients immediately, Dr. Finkelstein decided to hire a lawyer in order to negotiate with the Department of Health. He has not been disciplined, but OPMC states that he has been "re-educated.").
44 91 N.Y.2d 291, 693 N.E.2d 196, 670 N.Y.S.2d 169 (N.Y. 1998).
45 *Id*. at 296 (citing that the 'continuous treatment doctrine' does not toll the Statute of Limitations unless the action is filed within the limitations period after the last treatment where there is continuous treatment for the same illness or condition which gave rise to the cause of action); *citing Borgia v. City of New York*, 12 N.Y.2d 151, 155 (1962) (stating that the rationale behind the continuous treatment doctrine is that it would be absurd to require an individual to interrupt corrective treatment to commence a lawsuit and thus undermine the confidence and trust in the treating physician).
46 *Young*, 91 N.Y.2d at 296 (stating that a general physician-patient relationship for routine and periodic examinations will not satisfy as continuous course of treatment, which is what occurred between April and November 1990).
47 *Id*. at 296-97 (citing the rule that a course of treatment does not necessarily end on the last date of treatment if the patient and physician affirmatively contemplate further treatment for the condition through regularly scheduled appointments).
48 A. 6416, 2007 Assemb., 230th Sess. (N.Y. 2007) (proposed by Assemblyman Grannis Weinstein).
49 *Id.*
50 N.Y. C.P.L.R. § 3012-a (Consol. 2008).
51 Laws 1986, Chapter 266, § 1 (the legislative intent behind certificates of merit is to "improve the quality of medical malpractice adjudications and deter the commencement of frivolous suits.").
52 *Bowles v. State*, 208 A.D.2d 440 (1st Dept. 1994) (ruling that the proper sanction was not dismissal, but to grant the plaintiff an extension of 30 days to comply with the statute).
53 N.Y. C.P.L.R. § 3012-a(a)(3) (Consol. 2008) (defendant may move for disclosure when notified that three physicians refused to certify).
54 A. 3139, *supra* note 37, at page 1, lns. 14-17.
55 *Id.* at page 2 (failure to comply with the filing of the certificate and affidavit will result in dismissal of the complaint).
56 Baker, *supra* note 40, at 157.
57 *Id.* at 91-92 (the large number of suits that are closed without payments are not "frivolous claims," but rather is the plaintiff realizing that one of the doctors did not contribute to the injury so they therefore dismiss that claim).
58 Court of Claims Act § 8 (plaintiff must file a Notice of Claim one year after commencement of the action).
59 *Id.*
60 For purposes of this article, it is important to note the hierarchy of the New York State Courts. In New York State, the trial courts for each county are called Supreme Courts. Appeals from the Supreme Courts are heard in the Appellate Divisions which is divided into four Departments. Each of the four Departments has jurisdiction over several New York counties. For example, the First Department has jurisdiction over the lower courts in New York and Bronx Counties. The First and Second Departments have jurisdiction over appeals originating in the New York City and Long Island areas, while the Third and Fourth Departments have jurisdiction over appeals from Upstate New York. The top appellate court in the State is the Court of Appeals. *Available at* http://www.courts.state.ny.us/courts/structure.shtml.
61 *Id.*; *see* Public Officers Law § 17.
62 *Morell v. Balasubramanian*, 70 N.Y.2d 297, 301 (1987) (allowing an action against State-contracted physicians to be brought into Supreme Court).
63 *Id*.
64 *Id.* at 302 (rejecting the narrow interpretation because it would deprive an injured party of an action since only the State can be brought into the Court of Claims).
65 *Id.*
66 Court of Claims Act §8; N.Y. C.P.L.R. 1601 (Consol. 2008).
67 *Id.* (a non-party's culpability will not be factored in with the defendants' culpability if the plaintiff can show that through due diligence they were unable to obtain jurisdiction over that non-party tortfeasor); *see Rezucha v. Garlock Mechanical Packing Co.*, 159 Misc.2d 855 (1993) (permitting defendants to prove State's share of culpability in order to reduce their own liability towards the plaintiff).
68 A. 491, 2007 Assemb., 230th Sess., at 2 (N.Y. 2007) (proposed by Assemblyperson Seminerio).
69 *Matter of Flannery v. State of New York*, 91 Misc.2d 797. (N.Y. Ct.Cl. 1977).
70 Rosen, *supra* note 23, at 135.
71 Mark D. Shifton, *Identity Crisis: The Obsolescence of Jasopersaud v. Rho and the Medical Malpractice Expert Exception*, 30 Fordham Urb. L.J. 2061 (2003).
72 572 N.Y.S.2d 700 (2nd Dept. 1991).
73 *Id*. at 701.
74 *Thomas v. Alleyne*, 752 N.Y.S.2d 362, 368 (2nd Dept. 2002).
75 *Id.* at 371 (granting a protective order if the proponent can show that disclosing the expert's qualifications and other information, would reasonably lead to disclosure of the expert's identity and there would be a reasonable probability that the expert would suffer abuse, harassment, expense or embarrassment).
76 Shifton, *supra* note 71, at 2078 (experts no longer have to be from the exact locality as the defendant physician, but rather they must be knowledgeable of the standard of care for their specialty and for State requirements); *see Hoagland*, 155 A.D.2d at 150.
77 A. 3139, *supra* note 37, at 4-5.
78 *Id.* (The amended provision does not require that every retained expert must be deposed. It only requires that the party produce the expert when they receive of notice for deposition of an specific expert).
79 N.Y. C.P.L.R. § 1601 (Consol. 2008).
80 *Id.*
81 N.Y. C.P.L.R. § 1601, C1601:5 (McKinney 2008) (if a plaintiff is slightly comparatively negligent, the court usually will err on the side of the plaintiff, as per the common law purpose of the statute, and remove the plaintiff culpability from the equation so the plaintiff can recover 100 percent of the damages from the defendants).
82 A. 3139, *supra* note 37, at 3.
83 *Id.* at 3, lns. 22-24.
84 A. 3139, *supra* note 37 *available at* http://assembly.state.ny.us/leg/?bn=A03139 (capping non-economic damages at $250,000).
85 A. 3139, *supra* note 37, at 3-4 (also allowing contributory negligence and the collateral source rule to be used against the recover of damages).
86 Joelle Babula, *Medical Liability Company Requests Premium Increase*, Las Vegas Review-Journal, February 11, 2003; Babula, *State Insurance Program Holds Off on Lowering Rates*, Las Vegas Review-Journal, August 14, 2002.
87 *Mississippi Tort Reform Effort Falls Short*, Commercial Appeal, February 18, 2003.
88 *Nation's Largest Medical Malpractice Insurer Declares Caps on Damages Don't Work, Raises Docs' Premiums*, The Foundation for Taxpayers & Consumer Rights, (2004), *available at* http://www.consumerwatchdog.org/insurance/pr/pr004698.php3.
89 Peter Neurath, *Hospitals Lose Provider of Malpractice Coverage*, Puget Sound Business Journal, December 26, 2003.
90 *Medical Malpractice Insurance: Stable Losses/Unstable Rates 2004*, 2004 Americans for Insurance Reform; *see also* The Association of the Bar of the City of New York, *Report Opposing H.R. 534/S.354 — Medical Malpractice Legislation*, New York, June, 2005.
91 Weiss Ratings, *Medical Malpractice Caps Fail to Prevent Premium Increases*, *available at* http://weissratings.com/News/Ins_General/20030602pc.htm.
92 The Assoc. of the Bar of NYC, *supra* note 90, at 4.
93 Harvey Rosenfield, *California's MICRA: Profile of a Failed Experiment in Tort Law Restrictions*, June 1993 (in fact, 12 years after the enactment of the caps the physician premiums nearly tripled before Proposition 103).
94 David M. Studdert, Y. Tony Yang & Michelle M. Mello, *Are Damage Caps Regressive? A Study of Malpractice Jury Verdicts in California*, The Harvard School of Public Health, *Health Affairs*, July/August 2004, Vol. 23, Issue 4, page 54 (discussing how gravely injured plaintiffs are poorly compensated as a result of the reductions imposed by damage caps in California); *see also* Pace, Nicholas M., Daniela Golinelli & Laura Zakaras, *Capping Non-Economic Awards in Medical Malpractice Trials, California Jury Verdicts Under MICRA*, Prepared for by the Rand Institute for Civil Justice, July 2004.

95 *Id.* (suggesting that the cap should be on a sliding scale in proportion with the severity of the injury rather than a flat cap).
96 Lucinda M. Finley, *The Hidden Victims of Tort Reform: Women, Children and the Elderly*, paper delivered to Thrower Symposium, Emory Law School, February 19, 2004 (concluding that the greatest loss will be the loss of deterrence, dependency on societal funds, and lost opportunity to bring these problems to the public notice and regulatory attention).
97 Assoc. Bar of NYC, *supra* note 90, at 1.
98 David Morris, *Malpractice Suits Aren't What Needs Fixing Here*, Minneapolis Star Tribune, *available at* http://www.ilsr.org/columns/2005/011005.html (limiting liability, according to the Congressional Budget Office (CBO), will undermine incentives for safety and make it difficult for those with legitimate claims).
99 NYS Insurance Department, *supra* note 2.
100 *Id.* (the funds were used by the state to fix other budget deficits).
101 *Id.*
102 *Id.* (the debt shouldered by the carriers is one of the reasons for the approval of a 14% increase in rates).
103 S. 973, 2007 Sen., 230th Sess., at 1 (N.Y. 2007) (proposed by Senator Kruger).
104 S. 157, 2007 Sen., 230th Sess., at 1 (N.Y. 2007) (proposed by Senator Golden).
105 S. 7038, 2007 Sen., 231st Sess., at 1 (N.Y. 2008) (proposed by Senator Flanagan). (the bill passed the Senate on April 15, 2008 and is now up for vote in the Assembly).
106 A. 6471, 2007 Assemb., 230th Sess. (N.Y. 2007) (proposed by Assemblyperson Carrozza).
107 *Consumer Advocate Testifies CA Limits for Malpractice Victims Failed; Malpractice Insurers Paid Out Less than 50% of Premiums to Victims*, The Foundation for Taxpayers & Consumer Rights, (2002), *available at* http://www.consumerwatchdog.org/healthcare/pr/pr002549.php3.
108 S. 7038, *supra* Note 105.
109 *Id.* at 2.
110 *New York's Dangerous and Undisciplined Doctors*, Public Citizen, March 2003.
111 Lucadamo, *supra* note 42 (Dr. Finkelstein was not disciplined after potentially infecting 628 patients with HIV and Hepatitis because he reused syringes).
112 *A Self-Inflicted "Crisis": New York's Medical Malpractice Insurance Troubles Caused by Flawed State Rate Setting and Raid on Rainy Day Fund*, Public Citizen, November 2007. Pages 11-13.
113 New York State Conference of Blue Cross and Blue Shield Plans, "The Facts About Physician Supply," *available at* www.nysblues.org.
114 Public Citizen, *supra* note 110, at 11-13 (both Florida and Virginia implemented these programs because there was a threat of withdrawal of liability coverage for physicians who delivered babies, which is not the case in New York).
115 *Id.*
116 *Id.* at 11 (these injuries rank 5th out of ten categories of injuries, right below minor permanent injury).
117 S. 157, *supra* note 104, at 3 (the fund also limits what future damages the plaintiff can claim and collect from the fund).
118 *Id.* (the physician is only liable for $250,000 of the award, and anything in excess is covered by the fund).
119 Public Citizen, *supra* note 110.
120 Mark Geitsfeld, *Malpractice Insurance and (Il)legitimate Interests of the Medical Profession in Tort Reform*, 54 DePaul Law Review 439.
121 Dr. Ellison Pierce, Jr., *ASA Monitoring Guidelines: Their Origin and Development*, 66:9 ASA Newsletter, September, 2002 (presently, death rates from anesthesia related injuries 1 out of 250,000, compared to 1 out of 5,000 in the 1980's).
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123 *Id.*
124 Hyman & Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution*, March 28, 2004, page 21, *available* from the Social Science Research Network *at* http://ssrn.com/abstract=526762.
125 Public Citizen, *supra* note 110 (only 7% of doctors account for 68% of all malpractice payments).
126 S. 1011, 2007 Sen. 230th Sess. (N.Y. 2007) (proposed by Senator Kruger).
127 A. 5995-B, 2007 Assemb, 230th Sess, (N.Y. 2007) (proposed by Assemblyperson Brennan). (this bill also requires insurance companies to investigate and report malpractice actions against their insured).
128 Hyman & Silver, *supra* note 124, at 28 (as quality rises and errors subside, consumers will litigate less).
129 Joseph P. Awad, "NYSTLA Submission for Topic #4," *available at* http://www.nystla.com.
130 Public Citizen, *State Government Responsible for Medical Malpractice Troubles in New York, New Report Shows*, November 29, 2007, *available at* http://www.citizen.org/pressroom/release.cfm?ID=2553 (citing the New York Comptroller's reprimand of the OPMC for failing to live up to its basic requirements).
131 *Id.*
132 *Id.* (negligent oversight of bad doctors allowed these errors to occur).
133 *Self-Inflicted "Crisis," supra* note 112, at 37 (even though only 1 percent of doctors cannot obtain commercial insurance, it is this group of doctors that caused the insurance pool to go $500 million into the red).
134 Joan Claybrook, *New York Should Look at Itself and its Doctors to Address Medical Malpractice Woes*, Public Citizen, November 29, 2007, *available at* http://www.citizen.org/pressroom/release.cfm?ID=2554.
135 *Self-Inflicted "Crisis," supra* note 112, at 14; NYS Insurance Dept., *supra* note 2 (discussing how as a result of artificially low rates, the insurance companies face a difficult road to regain profits).
136 NYS Insurance Dept., *supra* note 2.
137 Baker, *supra* note 40, at 1-14 (citing a report by the Institute of Medicine of the National Academy of Science).
138 *Self-Inflicted "Crisis," supra* note 112, at 24.
139 Jessica Best, "Med Mal Rates to Increase 14 Percent, Spitzer Creates task Force," *Insurance-Advocate*, July 3, 2007.
140 *Self-Inflicted "Crisis," supra* note 112, at 28 (steady and consistent increase in physician population yearly).
141 *Id.* at 32; *First Do No Harm: A Consumer Response to the Medical Lobby's Campaign to Limit the Legal Rights of Injured Patients*, page 9.
142 United States Government Accountability Office (formerly the General Accounting Office), *Medical Malpractice: Implications of Rising Premiums on Access to Health Care*, August 2003.
143 Michelle M. Mello, *Change in Physician Supply and Scope of Practice During a Malpractice Crisis: Evidence from Pennsylvania*, Health Affairs, April 24, 2007.
144 Joseph Awad, Letter to Eric R. Dinallo, Superintendent of the New York State Department of Insurance, and Richard F. Daines, M.D. Commissioner of the New York State Department of Health, October 15, 2007, *available at* http://www.nystla.com (Connecticut premiums for general surgeons range from $65,000 to $118,000, while premiums for New York General surgeons ranges from $18,000 to $85, 000).
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146 Awad, *supra* note 144, at 2.
147 Insurance Informtion Institute, *Medical Malpractice: Recent Developments*, February 2008, *available at* http://www.iii.org/media/hottopics/insurance/medicalmal/.
148 *Self-Inflicted "Crisis," supra* note 112, at 8.
149 *Id.*
150 First Do No Harm, *supra* note 141, at 6.
151 Assoc. of the Bar of NYC, *supra* note 90, at 6.
152 *Id.* at 8; *see also* Congressional Budget Office Report, 1992.
153 Public Citizen, *supra* note 110.
154 Morris, *supra* note 98.

Metropolitan Life Insurance Co. v. Glenn and the Employee Retirement Income Security Act of 1974

*Thomas B. Sparkman**

I. Introduction

On June 19, 2008, the U.S. Supreme Court issued its opinion in the case of *Metropolitan Life Insurance Co. et al. v. Glenn* (*MetLife*), affirming that the petitioner, Metropolitan Life Insurance Company (MetLife)[1] had abused its discretion in denying the respondent, Wanda Glenn, long-term disability benefits.[2] The ruling affirms the holding of the the Sixth Circuit U.S. Court of Appeals, which found that MetLife "acted under a conflict of interest" and failed to provide a fair and balanced administrative process when it determined whether to approve Glenn's long-term disability benefits.[3] Although the type of insurance benefit at issue in the *MetLife* case was long-term disability insurance, the Supreme Court's decision has broader implications for all employee benefit programs that the Employee Retirement Income Security Act of 1974 (ERISA) covers.

Broadly, ERISA sets standards for private sector "employee welfare benefit plans" and "employee pension benefit plans."[4] "Employee welfare benefit plans" include insurance plans such as the long-term disability benefit at issue here and also health insurance plans provided by private employers.[5] *MetLife* respondent, Glenn, sought judicial review of MetLife's denial of her long-term benefits as allowed under §1132 of ERISA.[6] This civil remedy is available to any participant or beneficiary of an ERISA-covered benefit plan.[7] Applying *Firestone v. Bruch*, the Court treated the benefit plan administrator as a trustee of a common-law trust[8] so that a conflict of interest within that administrator "must be weighed as a factor in determining whether there is an abuse of discretion."[9] Under this standard, the Court found that the Circuit Court properly found, weighed, and ruled that MetLife improperly acted upon its conflict of interest as a plan administrator and payor.[10] The Court's ruling affirmed the decision against MetLife.[11]

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Six justices in *MetLife* agreed to rule against the petitioner insurance company, but only five justices agreed to the majority opinion in whole.[12] Concurring only in part, Justices Roberts and Kennedy disagreed as to how much an insurer's conflict of interest should be weighed in an action arising under ERISA,[13] and how that conflict of interest weight should be applied to the present case.[14]

At first blush, some reviewers have suggested that the Supreme Court has "put the thumb on the scale in the employees' favor."[15] This paper summarizes and examines the Court's holding in *MetLife* and its application of *Firestone*, and examines if and to what extent this decision will shift policy under ERISA.

II. *MetLife v. Glenn*

The following section describes the facts behind *MetLife v. Glenn* and discusses the sequential court holdings up to and including the recent Supreme Court decision.

A. Facts

In 2000, the respondent in *MetLife*, Wanda Glenn, was an employee of Sears, Roebuck & Company when she was diagnosed with a disabling heart malady which rendered her unable to continue working.[16] As the long-term disability insurance administrator and insurance payor for Sears, MetLife initially approved Glenn for 24 months of disability benefits.[17] MetLife further referred Glenn to a law firm so that she could apply for long-term disability benefits through the Federal Social Security program.[18] Glenn was subsequently determined to qualify for the benefit under Social Security in 2002, retroactive to 2000.[19] MetLife demanded and received over $13,000 out of the retroactive Social Security payments from Glenn,[20] with the remainder of the retroactive payments going to the law firm that helped petition for the Social Security disability determination.[21]

To continue receiving disability benefits from MetLife beyond 24 months, MetLife required Glenn to be evaluated by a much stricter standard.[22] In denying extended benefits, MetLife appeared to have relied on a single evaluation from Glenn's physician, Dr. Patel, where he indicated that Glenn "was able to work in

"ERISA sets standards for private sector "employee welfare benefit plans" and "employee pension benefit plans."

a sedentary physical exertion level occupation."[23] MetLife appeared to give no weight to other, more recent, more detailed and more declarative evaluations by Dr. Patel, namely that Glenn was unable to "handle any kind of stress well at her work."[24] Glenn subsequently filed appeals with MetLife to reconsider the determination.[25] MetLife eventually referred the case to an external medical evaluation consultant, Dr. Pujara.[26] Upon later review, MetLife was found to have only forwarded Dr. Patel's negative evaluations to Dr. Pujara, while excluding Dr. Patel's other evaluations, which argued for Glenn's continued disability status.[27] Although Dr. Pujara's report on Glenn's status was arguably ambiguous, MetLife used the negative findings to deny once again Glenn's further disability coverage.[28] Glenn finally sued MetLife under the civil action provisions of ERISA.[29] The District Court granted MetLife's cross-motion for summary judgment based on the administrative record and Glenn subsequently appealed.[30]

B. The Sixth Circuit

On appeal, the U.S. Sixth Circuit Court of Appeals reviewed the lower court's decision de novo, applying the "'arbitrary and capricious' standard [as did the lower court], because the plan at issue granted the plan administrator discretionary authority to interpret terms of the plan and to determine benefits."[31] The Court of Appeals agreed with the District Court that MetLife had an inherent conflict of interest in being authorized both to "decide whether an employee is eligible for benefits and to pay those benefits," and that this conflict was a relevant factor to be weighed in "determining whether abuse of discretion had taken place."[32] Nonetheless, the Court of Appeals found that the District Court had not appropriately given consideration to this inherent conflict of interest.[33] Ultimately, the Sixth Circuit Court of Appeals reversed the District Court's decision, finding that "MetLife acted under a conflict of interest,"[34] and that MetLife failed to consider and reconcile fully the Social Security Administration's determination and other physician's evaluations, which found Glenn to be permanently disabled contrary to MetLife's own final determination.[35]

C. Certiorari

The U.S. Supreme Court granted certiorari to MetLife's request that the Court determine "whether a plan administrator that both evaluates and pays claims operates under a conflict of interest in making discretionary benefit determinations."[36] Previously, *Firestone* only indicated that an employer, and not an insurance plan administrator, who evaluates and pays claims, operates under an inherent conflict of interest.[37] Further, the Supreme Court accepted the suggestion to determine "how any such conflict should be taken into account on judicial review of a discretionary benefit determination."[38]

D. Holding

In his majority opinion, Justice Breyer first affirmed the Sixth Circuit's use of *Firestone* to apply trust law to the case at bar. This approach used a deferential standard of review where the plan administrator has "discretionary authority to determine eligibility for benefits."[39] Moving to the question of whether a conflict of interest exists for a plan administrator, as the Court found for an employer in *Firestone*, MetLife attempted to make an argument that an employer has a much more implicit conflict.[40] MetLife further argued that finding such a conflict for plan administrators would run contrary to both "ERISA's efforts to avoid complex review proceedings . . . [and] with Congress's efforts not to deter employers from setting up benefit plans."[41]

Breyer conceded that a plan administrator, unlike an employer, is incentivized through the marketplace to provide accurate and less biased claims processing by the mere fact that a processer, with a reputation for inaccurate or biased claims, will lose business.[42] Breyer argued that, although the market decreases the risk of inaccuracy and bias, the market does not fully eliminate that risk.[43] First, according to Breyer, "the employer's own conflict" may lead to its choice of the thrifty insurance plan over an accurate one.[44] Further, Breyer found that "ERISA imposes higher-than-marketplace quality standards on insurers" which mandates a duty to plan beneficiaries and "full and fair review of claim denials."[45]

Moving to the matter of how to apply this conflict of interest in matters of benefit determination, the majority took a less structured approach. Breyer stated that new "special burden-of-proof rules . . . [and] special procedural or evidentiary rules" are unnecessary.[46] Rather, the majority held that the *Firestone* model is a multi-factor weight test, whereby the courts will "take account of several different considerations of which conflict of interest is one."[47] Explaining further:

> In such instances, any one factor will act as a tiebreaker when the other factors are closely balanced, the degree of closeness necessary depending upon the tiebreaking factor's inherent or case-specific importance. The conflict of interest at issue here, for example, should prove more important (perhaps of great importance) where circumstances suggest a higher likelihood

> "The Court of Appeals agreed… that MetLife had an inherent conflict of interest."

> that it affected the benefits decisions, including, but not limited to, cases where an insurance company administrator has a history of biased claims administration.[48]

Applying this model to the lower circuit's decision, the Supreme Court found that "the Court of Appeals gave the conflict weight to some degree,"[49] but that other factors were given heavier weight to tip the scale in favor of the respondent, Glenn. These factors included the un-reconciled discrepancies between MetLife's own benefit determination and the Social Security Administration's determination, the failure to give all of Dr. Patel's evaluations to the independent reviewer, Dr. Pujara, and the failure to factor properly all of Dr. Patel's and Dr. Pujara's evaluations into MetLife's final determination.[50]

Closing the majority's affirmation against MetLife, Breyer used the case of *Universal Camera Corp. v. NLRB*[51] to support the majority's decision and to avoid dictating an exacting formula with which to factor in a conflict of interest: "the want of certainty in judicial standards partly reflects the intractability of any formula to furnish definiteness of content for all the impalpable factors involved in judicial review."[52]

E. Concurrences in Part

Concurring Justices Roberts and Kennedy, however, split from the five justice majority on the majority's method of factoring in an insurer's conflict of interest and the application to the case at bar. Although Chief Justice Roberts agreed with the majority's finding that an insurer, like an employer, who administers and funds a plan, has a conflict of interest,[53] he expressed the opinion that the majority went too far with a "kitchen-sink approach."[54] Rather, Roberts would prefer that consideration of a conflict of interest in judicial review were limited to those cases in which the evidence potentially implied "that the benefits denial was motivated or affected by the administrator's conflict."[55] As a matter of policy, Roberts argued, "certainty and predictability" are critical guarantees to employers providing benefits pursuant to ERISA.[56] Despite this disagreement in judicial model construction, Roberts ultimately agreed with the resulting judgment against MetLife, finding that the inconsistencies in MetLife's determinations provided adequate deciding weight "wholly apart from MetLife's conflict of interest."[57]

Conversely, Justice Kennedy agreed with the framework constructed by the majority, but disagreed with the ultimate affirmation of the Sixth Circuit Court of Appeals judgment against MetLife.[58] According to Kennedy, the majority's model provided protection for "the interests of plan beneficiaries without undermining the ability of insurance companies to act . . . as plan administrators and [payors]."[59] The protection for insurance companies, Kennedy elucidated, arose from the majority's "recognition that a structural conflict should prove less important" where there is adequate evidence that the insurer has insulated the benefit determinations from this conflict.[60] By simply affirming the Sixth Circuit decision, Kennedy asserted that MetLife was deprived of its fair day in court with the newly minted standard of review.[61] According to Kennedy, the case should be remanded, allowing MetLife to provide evidence that Glenn's benefit denial was adequately insulated from MetLife's conflict of interest. This decision then would allow for a rebalancing of the multi-factor test to determine if the other discrepancies were egregious enough to condemn MetLife without the conflict of interest.[62]

F. The Dissent

Justice Scalia's dissenting opinion, joined by Justice Thomas, combined the spirits of the disagreements voiced by Justices Roberts and Kennedy. Scalia wrote that, although he agreed that MetLife had a conflict of interest vis-à-vis its dual role as benefits determiner and payor,[63] if a court were to apply the majority's multi-factor test, the factors would "all be chucked into a brown paper bag and shaken up to determine the answer."[64] Like Chief Justice Roberts, Scalia would only allow inclusion of a conflict of interest as a deciding factor if and when evidence suggests that "the conflict actually and improperly motivates the decision."[65] Scalia based his perspective on a constructionist adoption of the Second Restatement of Trusts, whereby a court would substitute a de novo judgment where a plan administrator "had no discretion [or] had discretion and abused it."[66] Similar to Kennedy, Scalia would remand the case at bar for review of Glenn's benefit denial. Unlike Kennedy, Scalia would completely exclude reassessment or consideration of any such conflict of interest held by MetLife.[67]

> "…the majority went too far with a "kitchen-sink approach."

G. Summary of *MetLife*

Although the nine justices disagreed on the circumstances in which a conflict of interest should be factored into the judicial review of an employee benefits determination, they all agreed that a conflict of interest is present in some form for those third-party insurers that both determine a participant's eligibility for a benefit and directly pay for that benefit.[68] This homogeny should provide ERISA payors cautionary notice that any inappropriate application of their inherent conflict of interest will be viewed with serious aversion by the courts. The result, in itself, achieves the majority's goal of affirming a "higher-than-marketplace quality standard" on those insurers that provide ERISA benefits.[69]

III. *Firestone v. Bruch*

Given the weight of precedent accorded to the 1989 *Firestone* decision in *MetLife*, this article briefly turns to review *Firestone* and its application to ERISA.

A. Facts

In 1980, the petitioner employer, Firestone and Rubber Co. (Firestone), provided to its employees a number of ERISA-governed employee pension and welfare benefit plans, which Firestone self-administered and paid.[70] That same year, Firestone sold a number of its plants, which employed over 500 workers, to another corporation.[71] After the sale, Firestone essentially separated itself as an employer from the workers in the plants that had been sold. As a result, a number of the workers filed for severance benefits under the termination pay plan — one of the ERISA-governed benefit plans.[72] Several other respondents petitioned Firestone for disclosure of benefit provisions as allowed by ERISA.[73] Firestone first denied the workers' request for severance under the termination pay plan arguing that the plan's trigger for severance benefits of a "reduction in work force" was not met by the sale of the plants.[74] In addition, Firestone denied the request for disclosure citing that the employees "were no longer participants" and therefore not entitled to disclosure under ERISA.[75] The employees subsequently filed a civil action as allowed under §1132(a)(1) of ERISA.[76]

B. Lower Court Decisions

Similar to the procedural history of *MetLife*, the District Court granted significant deference to the determinations by Firestone and found in their favor.[77] First, the District Court found that Firestone's "decision not to pay severance benefits to respondents under the termination pay plan was not arbitrary or capricious."[78] Second, the District Court determined that the respondents' requests for disclosure were not made while they were actual participants of the benefit plans but, rather, after they no longer participated.[79]

On appeal, the Third Circuit was less willing to grant such great deference to Firestone's determinations, overturning the District Court's holding for the petitioner on these two counts.[80]

> The Court of Appeals held that where an employer is itself the fiduciary and administrator of an unfunded plan, its decision to deny benefits should be subject to *de novo* judicial review. It reasoned that in such situations deference is unwarranted given the lack of assurance of impartiality on the part of the employer.[81]

The U.S. Supreme Court granted certiorari to untangle discrepancies in the standard of review for actions brought under ERISA.

C. Holding in *Firestone*

Justice O'Connor, speaking for the Court, rejected Firestone's multiple arguments that an arbitrary and capricious standard of review would be appropriate for civil actions brought under ERISA. Firestone argued that, since Congress intended to "incorporate much of [Labor Management Relations Act (LMRA)] law into ERISA . . . the LMRA arbitrary and capricious standard should [also] apply to ERISA actions."[82] Nonetheless, the Court found that the arbitrary and capricious standard, which is accorded actions under LMRA, does not automatically translate to ERISA actions. This is largely because ERISA, unlike LMRA, "explicitly authorizes suits against . . . plan administrators [as a] remedy."[83]

O'Connor subsequently moved to affirm the application of trust law principles to ERISA, applying the precedent set in *Central States, Southeast and Southwest Areas Pension Fund v. Central Transport* (*Central States*).[84] Applying these trust law principles, the Court set forward that ERISA plan administrators, like trustees, will be subject to "a deferential standard of review . . . when . . . exercise[ing] discretionary powers."[85] Further, courts will apply the de novo standard of review in those cases involving the interpretation of a plan's terms.[86]

As later seen in *MetLife*, *Firestone* also raises the policy concern that these heightened standards of review "would contravene the spirit of ERISA because it would impose much higher administrative and litigation costs and . . . discourage [the creation of] benefit plans."[87] Nonetheless, the the narrower standard of de novo is unlikely to create new and litigation under ERISA.[88]

> "…ERISA plan administrators, like trustees, will be subject to "a deferential standard of review."

D. Summary of *MetLife* and *Firestone*

The holdings in *MetLife* and *Firestone* are largely consistent with one another. Courts have indicated that a plan administrator executes a fiduciary act in making a benefit determination analogous with fiduciary acts by trustees in the common law.[89] In its establishment of de novo and a deferential standard of review,[90] the Supreme Court further sets the tone that the judiciary will not automatically show discretion to employers and insurers that administer and fund employee benefit plans.

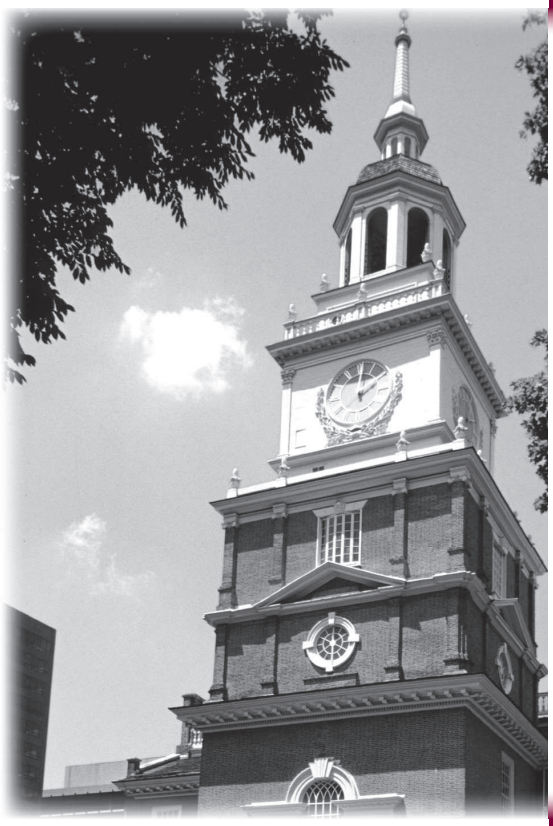
IV. ERISA in the Broader Context

MetLife and *Firestone* both involve employee benefit plan-types which fall under the scope of ERISA. ERISA, however, has even broader applicability and has come under increased scrutiny as public dissatisfaction with health insurance in the United States has grown. This section will discuss the origins of ERISA and its present-day scrutiny.

A. Original Concerns and Design

Congress passed ERISA out of a concern over the adequate funding and preservation of employer-sponsored benefits for employees, which had been growing over the previous twenty years.[91] This concern developed after the epic collapses of some benefit plans, such as the collapse of automobile manufacturer Studebaker in 1963. During a period of financial duress, Studebaker management and the United Auto Workers Union (UAW) thinned out the funding timeline of the pension plan while maintaining wages.[92] The deal only delayed the company's inevitable collapse by a couple of years.[93] Employees of the company, including those who had forty years or more of tenure, lost approximately $15 million in pension benefits.[94]

With public pressure pushing for government protections from such catastrophes, Congress finally moved to pass ERISA. Like most bills that pass Congress, however, ERISA was not without its compromises. Although the legislation provides certain protections and guarantees to workers as beneficiaries of employer-sponsored benefit programs, the law also gave employers protections of their own.[95] Employers who provided ERISA benefit programs were guaranteed federal protection from varied and overly burdensome state laws from the fifty states. Thus, employers were given "the ability to provide a uniform set of benefits to employees across state lines."[96] This federal preemption from state law focused on protecting multi-state employers from state legislators more easily influenced by state lobbyists, and more willing to make "off-budget regulatory transfers"



leading to an increased cost of health care insurance nationally.[97]

B. Developing Concerns in Health Care

Although the intent behind ERISA was noble enough, frustration with the federal preemption of state health insurance reform has grown over the past fifteen-to-twenty years. In the early to mid-1990s, state governors were mounting their own federal policy push along side President Bill Clinton's 1993 national health care reform proposal. State governors became involved mostly out of concern that Clinton's proposal would fail.[98] Even then, governors were frustrated by ERISA and other federal laws which prohibited states from mandating any level of health benefits from ERISA-covered employers while requiring an increase in payments to hospitals and nursing homes serving low-income populations.[99] Mid-to-large sized employers, however, remained loathe to forgo their federally protected ability to provide uniform benefits across all 50 states.[100]

The state clamor for reform has grown to a fever-pitch over the past few years. Maryland was the first state to act, passing the Fair Share Health Care Fund Act (Maryland Health Care Act) in January 2006.[101] The Maryland Health Care Act sought to make Wal-Mart a "poster-child" for the problems with ERISA protections.[102] States complained that, although Wal-Mart provided a health package that was protected from state interference, the health package remained out of

"The state clamor for reform has grown to a fever-pitch over the past few years."

reach for a significant plurality of Wal-Mart's lowest paid workers, leaving state budgets and state-funded health care programs (e.g., Medicaid) to cover the gaps in coverage.[103] In fact, Wal-Mart would have been the only employer affected by the Maryland law,[104] which would have required the company to contribute "8 percent to 11 percent of their payroll to health insurance or contribute a fee to a state fund."[105] The Federal District Court intervened and found that ERISA preempted the Maryland law, thus making it invalid.[106] Despite the contravening federal ruling, Maryland's legislative efforts and those of other states embody the notion that, over time, ERISA has given greater leverage to "large employers at the expense of individuals and small businesses, who lacked capital to self-insure or cover their own health care costs."[107]

Even with the threat of ERISA preemption litigation, another state, Massachusetts, has begun implementing a comprehensive health care reform package that was signed into law in April 2006.[108] The Massachusetts law creates a mandate that individuals purchase health care insurance, while assessing per-worker tax on employers with ten or more employees who do not already provide insurance to their employees.[109] The plan also proposes to extend subsidies to low-income families and expand Medicaid coverage in the state.[110] Although Maryland's attempt at reform was quickly struck down under ERISA, Massachusetts's reform proposal remained unchallenged.[111] Two key differences protecting Massachusetts from preemption challenges are that, first, the program only assesses those employers who do not already provide a health care benefit (i.e., an ERISA protected benefit).[112] Conversely, the Maryland plan unabashedly targeted Wal-Mart, a company already providing a health benefit, albeit meager.[113] Second, the mandates on employers are loosely defined as requiring "fair share contributions to health care" and "cafeteria plan[s] that permi[t] workers to purchase health care with pre-tax dollars.[114] These two differences represent key negotiations by Massachusetts legislators, who recognized the goals and preemption authority of ERISA and worked toward a solution that fills in the gaps left by ERISA.

V. Conclusion

A discussion tying together a seemingly narrow Supreme Court ruling on the standard for judicial review of an employee's denial of long-term disability benefits and sweeping state-led health care reform may be seen as loosely drawn together. Case studies — ranging from disability benefit challenges in *MetLife*, to pension benefit challenges in *Firestone*, to federal preemption of Maryland's reform, to whether compromises in Massachusetts will protect their attempt at universal health care coverage — all fall under the very large federal umbrella of ERISA.

In many ways, that the Massachusetts reform package began implementation in 2007 without a legal challenge under ERISA is impressive in and of itself. As shown historically by *Central States* and *Firestone*, large employers aggressively defend their autonomous discretion to create and maintain employee benefit programs that cross state lines. In fact, as recently as November 2007, large employers like AT&T and Xerox teamed together in a lobbying coalition, the National Coalition on Benefits, to preserve their nationwide autonomy.[115] With the formation of the coalition, a General Motors (GM) government affairs executive cited the motivation to join as a desire to keep benefits at "the same level" for all GM employees.[116]

The lack of challenge to Massachusetts's reform package and the Supreme Court's conflict of interest bar-setting in *MetLife* may be indicators of the shifting policy environment alluded to by American Enterprise Institute Fellow Scott Gottlieb, recognizing the oversized leverage enjoyed to date by large employers under ERISA.[117] Indeed, in his *MetLife* dissent, Justice Scalia expressed the view that the majority had gone too far in its wholesale declaration that *both* third-party insurers *and* employers operated under an inherent conflict of interest which *must* be weighed in review of benefit denials.[118] Properly interpreted, rather than simply affirming the Court of Appeals' ruling against MetLife, or even denying certiorari, the majority instead chose to make a seemingly small policy declaration that these plans and employers should be on notice of improper administration of their employee benefits. Further, given the Court's ease in applying these standards across different forms of ERISA-covered plans, all administrators of ERISA-covered plans, including health care management organizations and pharmacy benefit managers, should consider taking a cautionary approach rather than an overly cavalier attitude towards benefits' denial and cost control.

Taking a view across the spectrum of ERISA protections for employers *and* employees, there have been growing concerns over gaps and cracks in benefits coverage — from health care in Massachusetts to disability benefits provided to Sears employees like respondent Wanda Glenn. Thus far, analysts believe that *MetLife*'s holding will only "make a difference in close cases."[119] That said, large employers and their insurers should be watchful of large-scale legislative attempts to reform and even overhaul ERISA and health care at large.

1 MetLife is a long-term disability benefits administrator and insurer.
2 *Metro. Life Ins. Co. v. Glenn*, 128 S.Ct. 2343, 2352 (2008) [hereinafter *MetLife*].
3 *Glenn v. Metro. Life Ins. Co.*, 461 F.3d 660, 674 (6th Cir. 2006) [hereinafter *Glenn*].
4 *See* 29 U.S.C. §1002 (2006).
5 *See* U.S. Department of Labor (DOL), Health Plans — ERISA, http://www.dol.gov/dol/topic/health-plans/erisa.htm (last visited July 9, 2008).
6 *MetLife*, *supra* note 2 at 2347.
7 *See* 29 U.S.C. §1132(a)(1).
8 *MetLife*, *supra* note 2 at 2347.
9 *Id.* at 2348 (quoting *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101 (1989)) (internal quotes omitted).
10 *Id.* at 2352.
11 *Id.*
12 *Id.* at 2345.
13 *Id.* at 2352.
14 *MetLife*, *supra* note 2 at 2356.
15 Mary Williams Walsh, *In a Ruling on Benefits, Justices Aid the Worker*, N.Y. Times, June 20, 2008, at C3, *available at* http://www.nytimes.com/2008/06/20/business/20bizcourt.html.
16 *MetLife*, *supra* note 2 at 2346.
17 *Id.*
18 *Id.*
19 *Id.* at 2346-47.
20 *Glenn*, *supra* note 3, at 663.
21 *Metlife*, *supra* note 2, at 2347.
22 *Id.*
23 *Glenn*, *supra* note 3, at 664 (internal quotes omitted).
24 *Id.*
25 *Id.* at 670.
26 *Id.* at 665.
27 *Id.* at 670.

28 *Id.* at 665.
29 *Glenn*, *supra* note 3, at 665.
30 *Id.*
31 *Id.* at 665-66.
32 *Id.* at 666.
33 *Id.*
34 *Id.* at 674.
35 *Glenn*, *supra* note 3, at 674; *see also MetLife*, *supra* note 2, at 2347.
36 *MetLife*, *supra* note 2, at 2347.
37 *See id.* at 2348.
38 *Id.* at 2347 (quoting Brief for United States as *Amicus Curiae* on Pet. For Cert. 22) (internal quotes omitted).
39 *Id.* at 2347-48.
40 *Id.* at 2348-49.
41 *Id.* at 2349.
42 *MetLife*, *supra* note 2, at 2349.
43 *Id.* at 2349-50.
44 *Id.*
45 *Id.* at 2350 (analyzing 29 U.S.C. §1104(a)(1) (2006) and quoting *Firestone*, *supra* note 9, at 113) (internal quotes omitted).
46 *Id.* at 2351.
47 *Id.*
48 *MetLife*, *supra* note 2, at 2351.
49 *Id.*
50 *Id.* at 2352.
51 340 U.S. 474 (1951).
52 *Metlife, supra* note 2, at 2352 (quoting *Univ.l Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951)) (internal quotes omitted).
53 *Id.*
54 *Id.* at 2354.
55 *Id.* at 2353.
56 *Id.* at 2354.
57 *Id.* at 2355.
58 *Metlife, supra* note 2, at 2355-56.
59 *Id.* at 2356.
60 *Id.*
61 *Id.* at 2356.
62 *Id.*
63 *Id.* at 2356-57.
64 *See Metlife, supra* note 2, at 2358.
65 *Id.* at 2357 (emphasis omitted).
66 *Id.* at 2359.
67 *Id.* at 2361.
68 *See id.* at 2348 (finding that MetLife has a conflict of interest); *id.* at 2352 (Roberts, J. concurring) (finding dual role creates conflict of interest); *id.* at 2355-56 (Kennedy, J. concurring) (agreeing with majority's framework for establishing and reviewing an insurer's conflict of interest); *id.* at 2356-57 (Scalia, J. dissenting) (agreeing that MetLife has a conflict of interest through its dual roles). *But cf. id.* at 2357 (Scalia, J. dissenting) (disagreeing with the majority's assertion "that *an employer* who administers its own ERISA-governed plan 'clear[ly]' has a conflict of interest").
69 *Id.* at 2350.
70 *Firestone*, *supra* note 9, at 105.
71 *Id.*
72 *Id.*
73 *Id.* at 106.
74 *Id.*
75 *Id.*
76 *Firestone*, *supra* note 9, at 106.
77 *Id.* at 106-7
78 *Id.*
79 *Id.* at 107.
80 *Id.*
81 *Id.* at 107-8.
82 *Firestone*, *supra* note 9, at 109.
83 *Id.* at 110.
84 *Id.* at 111. *See also Cent. States, Se., & Sw. Areas Pension Fund v. Cent. Transp.*, 472 U.S. 559, 570 (1985) ("Congress invoked the common law of trusts"); *id.* at 570 n.10 (cites ERISA statute and Congressional legislation which used explicit trust language).
85 *Firestone*, *supra* note 9, at 111.
86 *Id.* at 112.
87 *Id.* at 114.
88 *Id.* at 115.
89 *MetLife*, *supra* note 2, at 2347; *Firestone*, *supra* note 9, at 110.
90 *MetLife*, *supra* note 2, at 2348.
91 Roger Lowenstein, *The End of Pensions*, N.Y.Times, Oct. 30, 2005, at Magazine, *available at* http://www.nytimes.com/2005/10/30/magazine/30pensions.
92 *Id.*
93 *Id.*
94 *Id.*
95 Margaret Crane, *Redress for Broken Nest Eggs*, N.Y.Times, Nov. 3, 1996, §3, at 10, *available at* http://query.nytimes.com/gst/fullpage.html?res=9B00E7DE1F39F930A35752C1A960958260&sec=&spon=.
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98 Robert Pear, *Governors Ask for Power Over Self-Insurance Plans*, N.Y.Times, Jan. 30, 1994, § 1, at 20, *available at* http://query.nytimes.com/gst/fullpage.html?res=9800E6D81439F933A05752C0A962958260&sec=&spon=&pagewanted=all.
99 *Id.*
100 *Id.*
101 Hakim, *supra* note 96.
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Medical Tourism: A Rapidly Growing Industry

According to the Deloitte Center for Health Solutions (Deloitte), the practice of traveling abroad for medical treatment is expected to expand substantially in the coming years. Deloitte recently published its 2008 report, *Medical Tourism: Consumers in Search of Value*, detailing the rapid growth of domestic and international medical tourism. The report estimates that 750,000 Americans traveled abroad for medical care in 2007 and that this number will increase to six million by 2010. Market drivers for medical tourism included: cost savings, comparable quality of care, shorter waiting periods, and quicker access to care.

Uninsured and under-insured American consumers find that traveling abroad for medical services is less expensive than paying high deductibles, co-payments, or out-of-pocket costs in the United States. The cost of medical care at facilities in India, Thailand, and Singapore can be as little as ten percent of the cost of equivalent care in the United States. Furthermore, because the price of care is often so low, many Americans can afford to pay for airfare, stay at a luxury resort, and cover all of their health care costs.

In the past, concerns over quality of care kept Americans from seeking medical treatment abroad; however, now that organizations like Joint Commission International accredit foreign medical facilities, American health care consumers feel more comfortable with the safety and quality of health care available abroad.

The Health Effects of Stress Increase as a Result of the Economic Crisis

The United States' economic downturn not only affects the Nation's finances, but also its health. The sub-prime mortgage crisis, the decline of Wall Street, and company downsizing have placed tremendous stress on American families. Not only does stress increase the immediate and long-term risk for cardiac events (e.g. heart attacks and strokes), it also causes people to engage in poor health behaviors, such as consumption of fatty and sugary foods. Acute stress is also one of the most detrimental triggers of relapse for those persons who are recovering from drug or alcohol addiction.

In October 2008, the American Psychological Association released a survey on the factors that most contribute to Americans' stress levels. Eighty percent of Americans reported that the economy is a significant cause of stress, an increase of 15% since April 2008. Overall, the most commonly reported stresses were the economy, job stability, housing costs, and health problems affecting the family. These results were a shift from the previous years' most commonly reported concerns about personal finances, work, and child rearing. In the past 12 months, physical and emotional symptoms of stress (e.g. fatigue, irritability, insomnia, feelings of depression and sadness, headaches, and muscle tension) have increased across persons of all genders, age groups, races, and ethnicities.

Continued economic stress will lead to increased health care needs, unfortunately, when the same economic stress will potentially decrease access to that care. Americans who have lost their jobs due to company lay-offs have lost health care coverage along with their employment. Many companies are also choosing to eliminate health care plans or increase deductibles and co-pays to offset mounting costs. Hospitals, like other industries, are struggling with variable-rate debts which had previously financed capital improvements and patient care. Furthermore, charitable donations to hospitals are expected to decrease as wealthy Americans experience a loss of prosperity.

To address these concerns, health practitioners and policy makers are strategizing new ways to assist Americans in the increasingly troublesome economic environment. Opportunities for stress mediation through exercise, meditation, drug and alcohol counseling, and social networking are more important now than ever as Americans look for constructive ways to cope with stress.

State Sunshine Laws Employ Broad Exceptions to Mandated Gift Disclosures for Pharmaceutical Companies

In an effort to market drugs, the pharmaceutical industry dedicates huge sums of money to form relationships with health care professionals who prescribe prescription medications. Public interest groups have raised concerns about the conflicts of interests that may arise due to these targeted marketing schemes. In reaction to these concerns, a few state legislatures have enacted "sunshine laws," requiring companies to disclose the amounts and types of payments specific companies provide physicians. Certain exceptions in these statutes prevent full disclosure of physician payments and gifts. For example, Vermont's law contains one of the most significant exceptions by allowing companies to withhold information about payments made to physicians that they deem "trade secrets."

Payment exchanges between companies and medical professionals are considered "trade secrets" because companies that possess the information have a competitive advantage over rival pharmaceutical companies. By mandating disclosure, the companies believe that their vast marketing expenditures and efforts will be lost and competitors will gain the intelligence of where and how companies are spending these dollars. As a result of this exception, pharmaceutical companies in Vermont refused to release 61% of physician payments. Since only five states and the District of Columbia have enacted laws that mandate disclosure of payments, each statute's construction serves as a valuable lesson for future disclosure legislation. Under the Vermont statute, it is difficult to know whether the withheld information is in fact a trade secret. With the public's health at stake, state and federal legislators must strike a difficult balance between protecting companies' economic interests and informing the public about the nexus between their physicians and the pharmaceutical industry.

Electronic Medical Records

Despite experts' warnings that bringing patient records into the computer age is critical to improving the standard of care, fewer than one in five doctors in the United States uses electronic medical records. Although the use of electronic medical records has been shown to improve the quality and cost of care, financial constraints prevent physicians from using these new technologies. In addition to cost constraints, the time commitment necessary to transfer data to an electronic system would require physicians to hire new staff or even could prevent them from seeing their patients. Furthermore, electronic systems available to health care providers are tailored for hospitals that serve a larger number of patients than the average medical practice. The government is taking steps to subsidize the cost for private practices with a $150 million Medicare project that will offer doctors incentives to make the change from paper to electronic records.

The presidential race brought the issue of electronic records to the attention of the general public. Both candidates discussed the need for investment in electronic health information technology systems. Senator John McCain's (R-AZ) plan recognized the need for the health care system to move to electronic systems as soon as possible and places importance on the need for the electronic records system to be interoperable across state lines. President-Elect, Barack Obama's plan will invest $10 billion a year, over the next five years, to transfer the health care system to a standards-based electronic health system including electronic medical records. Obama's plan will place emphasis on the protection of patient privacy.

Kristen C. Barry, Walawekon Blegay, Kathryn Coniglio, Adam S. Frankel, and Megan McCarthy contributed to this column.

Washington Update: News From Our Nation's Capital

Equal Coverage for Mental Health and Substance Use Disorders

For decades, insurance companies have denied coverage and payment for equal access to treatment for individuals with mental health or substance use disorders by charging higher co-pays and limiting coverage of treatment.

In October 2008, President George W. Bush signed the Emergency Economic Stabilization Act of 2008 (P.L. 110-374). P.L. 110-374 incorporated the Paul Wellstone (D-MN) and Pete Domenici (R-NM) Mental Health Parity and Addiction Equity Act of 2008, which prohibits inequality in insurance coverage. The House introduced the Mental Health Parity Act earlier this year. The Emergency Economic Stability Act previously failed because the House and the Senate disagreed about specific provisions. The incorporation of the Mental Health Parity Act facilitated the passing of the stabilization package and resulted in the enactment of monumental health insurance reform. The incorporation of the Paul Wellstone Mental Health Parity Act facilitated the passing of the stabilization package and resulted in the enactment of monumental health insurance reform.

P.L. 110-374 mandates improvements in health coverage in four specific areas. First, group health plan co-pays for mental health or substance use disorders may not exceed the plan's co-payments for medical or surgical procedures. Second, group health plans may not limit treatment for mental health or substance use disorder more than the restrictions of the plan's surgical and medical benefits. Third, group health plans that offer out-of-network coverage for medical and surgical procedures must allow out-of-network coverage for both mental health and substance use disorders. Finally, the Act provides transparency in the claims and denials process by requiring insurers to provide a written explanation for denial of coverage.

Employers and insurers will have a year to prepare for the legislative changes. Requirements under the Paul Wellstone and Pete Domenici Mental Health Parity Act will be effective on October 3, 2009.

House of Representatives Passes Legislation to Provide the Food and Drug Administration with Regulation Power of Tobacco Products

On July 30, 2008, the House of Representatives passed the Family Smoking Prevention and Tobacco Control Act (H.R. 1108) by a vote of 326 to 102. This legislation grants the Food and Drug Administration (FDA) regulatory power over tobacco products — including advertising authority and complete product regulation. H.R. 1108 would not allow the FDA to ban cigarettes or nicotine from tobacco products. Supporters are hopeful this regulation will curb smoking in the United States, especially among minors.

The White House issued a Statement of Administrative Policy veto threat of H.R. 1108. The Administration cites concerns about user fees placed upon cigarettes to generate more revenue to fund the FDA's new regulatory power, and refers to the fees as a new tax that would be paid disproportionately by low-income individuals as these individuals are the largest consumers of tobacco products. Further criticism stems from the fact that H.R. 1108 would outlaw the production of many types of flavored cigarettes and tobacco, excluding menthol. This provision, along with advertising provisions, would give Philip Morris USA, a supporter of H.R. 1108, an even greater share of the United States tobacco market. In 2000, the Supreme Court ruled against FDA regulatory power over tobacco. This ruling prompted the creation of H.R. 1108, to clarify powers granted to the FDA.

During the House floor debate, John Boehner (R-OH), House Minority Leader and a smoker, and John Dingell (D-MI), Chairman of the House Committee on Energy and Commerce, engaged

in a heated debate over the regulatory powers of H.R. 1108. Minority Leader Boehner stated, "Most people who smoke in America know that smoking is probably not good for their health. Do we need the federal government to tell us?" Chairman Dingell replied, "This legislation is on the floor because people are killing themselves by smoking these evil cigarettes. The . . . minority leader is going to be amongst the next to die. I am trying to save him . . . because he is committing suicide every time he puffs on one of those things."

Currently, H.R. 1108 is in the Senate Committee on Health, Education, Labor, and Pensions. The Senate companion legislation (S. 625), introduced by Senator Edward Kennedy (D-MA), has 59 co-sponsors. The Senate is scheduled to return for a "lame duck" session on November 17, 2008; however, it is unclear whether this legislation will be brought for a floor vote during this time. If H.R. 1108 does not come before the Senate before the end of the 110th Congress, it will need to be reintroduced in the 111th Congress, to be considered from "square one" of the legislative process.

Legislation Aims to Address Deficiency in Veterans Mental Health and Substance Use Care

On October 10, 2008, President George W. Bush signed the Veterans' Mental Health and Other Care Improvements Act of 2008 (P.L. 110-387) into law. First introduced in October 2007 by Senate Chairman of the Veterans' Affairs Committee Daniel K. Akaka (D-HI), P.L. 110-387 intends "to improve the treatment and services provided by the Department of Veterans Affairs to veterans with post-traumatic stress disorder and substance use disorders, and for other purposes."

P.L. 110-387 originated, in part, from the plight of the family of one Iraq war veteran, Justin Bailey. Bailey was among the first wave of Marines deployed to Iraq in 2003. Seeking treatment for Post Traumatic Stress Disorder (PTSD) and drug abuse, Bailey checked himself into the West Los Angeles Veterans Administration (VA) Hospital in November 2006. Bailey died under VA care on January 26, 2007 at the age of 27. The Bailey family has worked actively towards reform treatment for veterans' mental health. In August 2007, Tony Bailey (Justin Bailey's father) addressed the Senate Veterans' Affairs Committee pleading for evaluation of the current system and implementation of system-wide changes.

The Act sets a standard minimum level of care for substance abuse disorder by providing short- and long-term motivational counseling, detoxification services, relapse prevention, and drug treatment. As well, it improves treatment for veterans with multiple disorders, mandates staffing reviews of residential VA mental health facilities, creates a PTSD and substance use research program, and enables VA to provide mental health services to veterans' families. The broad reaching law provides improvements for veterans' emergency care, veterans' pain care, and rehabilitation for formerly incarcerated veterans, rural veterans, and low-income veterans.

The care mandate is accompanied by authority to construct new facilities, provide long-term caregiver assistance services, correct emergency care reimbursement procedures, and establish six VA Epilepsy Centers of Excellence for research, education, and clinical care.

Molly Elizabeth Conway, Kimberly Hodgman, and Aaron Jones Wong contributed to this column.

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