



Seton Hall University School of Law
Health Law Forum

Health Law Outlook



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Neuroimaging and the Law

Powerful Legal Applications and Important Considerations

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Cutting-edge neuroscience is advancing at an incredible rate. Technologies like functional magnetic resonance imaging (fMRI) are becoming more sophisticated and precise. The maturation of these technologies has recently provided researchers a glimpse of the ways in which our brains process information, emotions, and moral judgments. The findings of this research will pose vexing questions for the practice of law in the future.

How Does Functional Brain Scanning Work?

fMRI scanning works by utilizing magnets to detect changes in the levels of oxygenated blood in the brain.

Active neurons utilize oxygen and, therefore, require a greater amount of hemoglobin-rich blood to provide them with the oxygen required to function. Computers can interpret the difference between the way that deoxygenated hemoglobin and oxygenated hemoglobin respond to the magnets. This difference is referred to as

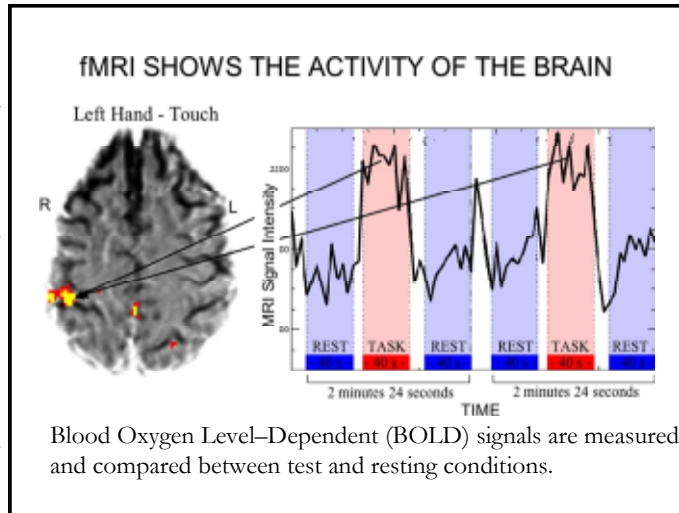
the Blood Oxygenation Level Dependent (BOLD) effect. The underlying assumption is that an increase in the BOLD signal indicates an increase in blood flow and is believed to indicate neural activity.¹ fMRI scans can be administered while the person being scanned performs various tasks such as answering a question, observing a

picture, or hearing a sound. Scans occurring during these activities reveal which parts of the brain are activated during the specific tasks.

Setting the Scene—Theories of Punishment

To understand the impact that neuroscience research will have on our criminal justice system, we must first describe the two broad

(*Neuroimaging,* Continued on page 10)



Three Essential Steps for Healthcare Reform

The Obama Administration's Healthcare Agenda

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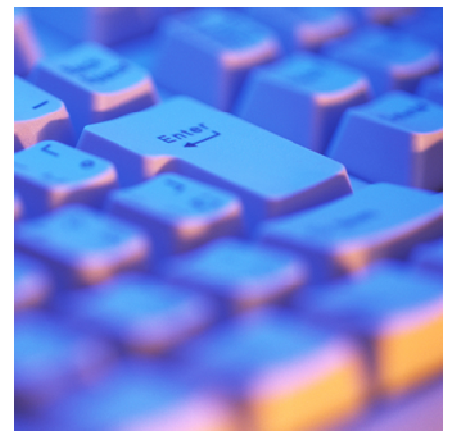
As a part of the 2008 election campaign, President Obama and Vice President Biden published their "plan to lower healthcare costs and ensure affordable, accessible health coverage for all."¹ Despite reports in Obama's first few weeks in office that his promised reforms would be delayed,² he took the first steps toward reaching his health goals when he signed the American Recovery and Reinvestment Act of 2009, appropriating approximately \$140 billion to healthcare spending.³ On February 26, 2009,⁴ Obama announced the establishment of "a reserve fund of more than \$630 billion over 10 years to finance fundamental reform of our healthcare system that will bring down costs and expand coverage."⁵ The

plan calls for lowered drug costs through a new regulatory pathway to approve generic biologics.⁶ With the economy at a standstill and potential opposition from American health-related companies, Obama's team must focus on the essential components of the nine-page agenda—those steps that will result in the greatest public health improvements with the least cost and political resistance.

First: Electronic Health Records

The first essential step is already at the forefront of Obama's agenda: electronic health information technology systems. The stimulus bill set aside \$19 billion for electronic health records,⁷ much more than the \$10 billion proposed during the campaign.⁸ Electronic health records impact the entire healthcare system, including the coordination of care and reduction of costly medical errors. Electronic processing of insurance claims is projected to cut

processing costs in half.⁹ It may also lead to an eighteen percent reduction in duplicative physician ordered tests resulting from the inability to quickly locate or transmit printed test results.¹⁰ In addition to increased efficiency, electronic records increase safety. The Veteran's Administration had an 86.2% improvement in the



(*Healthcare Reform,* Continued on page 9)

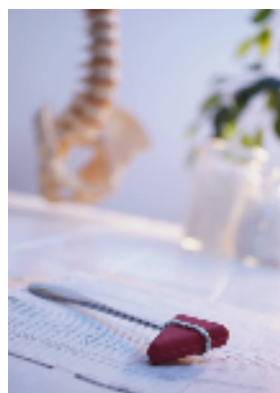
To Disclose, or Not to Disclose

Off-Label Use of Surgically Implanted Devices

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In *Blazoski v. Cook*, a sixty-seven year old man with chronic back disease sued his orthopedic surgeon for medical malpractice.¹ The surgeon had recommended a procedure to stabilize the vertebrae in Mr. Blazoski's back using a screw and rod assembly, assuring Mr. Blazoski that he would "feel like a new man" after the surgery. The procedure involved boring into the pedicle bones of several vertebrae to implant the rod and using screws to secure the rod into place. The screws the surgeon intended to permanently implant in Mr. Blazoski's back were not approved by the FDA for use in the lumbar region of the spine, and their use for that purpose is considered off-label. (The term "off-label" refers to the use of any drug or medical device for a different purpose than the one for which the FDA approved it.)² The surgeon had no legal duty to tell Mr. Blazoski this fact.³



In New Jersey, physicians are not required to disclose FDA off-label status of a medical therapy when obtaining a patient's informed consent.⁴ This is

true whether the therapy is drug treatment or implantation of a medical device. Thus, if a medical device falls apart in one's body, causing pain and the need for further surgeries, as happened to Mr. Blazoski and thousands of other patients implanted with AcroMed or Sofamore Danek orthopedic screws,⁵ malpractice is one option as a remedy. Another option is a products liability suit against the manufacturer. However, the physician's

failure to disclose off-label status of the device will not support a claim of failure to obtain informed consent. The Law Division held that Mr. Blazoski had no cause of action against his doctor. The Appellate Division affirmed this point, and the New Jersey Supreme Court denied certiorari.⁶

"[T]HE PHYSICIAN'S FAILURE TO DISCLOSE OFF-LABEL STATUS OF THE DEVICE WILL NOT SUPPORT A CLAIM OF FAILURE TO OBTAIN INFORMED CONSENT."

The reasons commonly given for this peculiar lacuna in informed consent law are varied, but primarily center on the following points touched on in an article in the *Food and Drug Law Journal* by James Beck and Elizabeth Azaria⁷:

- (1) The misconception rationale: People would not understand the FDA approval process and would think "not yet approved" meant disapproved. Such information "would only confuse patients."⁸
- (2) The government interference rationale: The government does not interfere with the practice of medicine and hence permits off-label innovation.⁹ This point is explicitly stated in the Food and Drug Act¹⁰ and is restated in every case challenging physician non-disclosure of FDA status, including *Blazoski*.¹¹
- (3) The confused jury rationale: In a products liability or malpractice case, the jury would be confused about inherent dangers of a medical device if informed consent law required physician disclosure of FDA off-label status. Requiring that this information be disclosed would tend to impugn the safety of the product or the judgment of the doctor who chooses to use it or both.¹²

Yet for each of these rationales there is a countervailing argument addressing how to satisfy the concerns at issue without sacrificing the patient's right to true, informed consent:

- (1) The misconception rationale: If people do not understand the FDA approval process, that is the result of the FDA failing to effectively communicate with the public. Patients in the twenty-first century are different from those fifty years ago; they are more active in choosing their medical therapies. Patients are generally inquisitive, literate, and *guardedly*, rather than automatically, deferential to the doctor's advice. Yet they are completely in the dark about the physician's prerogative to choose not to disclose FDA status of a medical device, or where to find FDA-related information that is available to assist them (for example, the general public is unlikely to know that recalls and safety alerts are available on the FDA website or that they may report device and drug safety concerns directly to the FDA through its Medwatch program). Information is all that is needed to correct this problem.
- (2) The government interference rationale: The law can support medical advances, doctors' privilege to offer innovative treatments, and people's right to try unapproved remedies while still requiring full and detailed informed consent. Researchers working with vulnerable subjects are sometimes required to read the informed consent form aloud before subjects sign it; not only do subjects hear the entire text aloud, they are permitted a question-and-answer period in which additional information can be supplied, as needed. In this way, the research subject's legal right to give informed consent is safeguarded. A patient seeking care and treatment for a painful or debilitating condition may be even more vulnerable than a research subject. The

(*Off-Label Use*, Continued on page 12)

The Genetic Information Nondiscrimination Act

A Synopsis and Potential Implications

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Last May, President Bush signed the Genetic Information Nondiscrimination Act of 2008 (GINA). The Act, which is aimed at health insurance providers and employers, bars discrimination based on results of genetic testing.¹ GINA is set to go into effect in May 2009 for health insurance companies and November 2009 for employers. The Act forbids these entities from requiring or demanding genetic testing. The force behind GINA was a desire to coalesce the inconsistent policies of various states and to extend the protection afforded by federal anti-discrimination laws enacted prior to GINA.

History of Anti-discrimination Acts

The movement against discrimination in the workplace began with the Civil Rights Act of 1964. Under Title VII of the Act, an employer cannot discriminate against a potential or current employee based on his "race, color, religion, sex, or national origin."² The Act also created the Equal Employment Opportunity Commission (EEOC), which was charged with ensuring compliance with the Act. The Americans with Disabilities Act of 1990 (ADA)³ furthered protection against discrimination by prohibiting it against individuals who have disabilities.

Though neither of these two acts explicitly discusses genetic discrimination, it can be argued that under these acts genetic discrimination founded upon racially or ethnically linked disorders or upon disability-related genes could be considered

unlawful.⁴ However, only a few disorders have been linked to race or ethnicity, and neither of the two acts protect against unexpressed genes (those encoded genetic characteristics that are not manifested). These issues led to the creation of basic genetic information regulation in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and now more comprehensive regulation in GINA. HIPAA, the first federal law to discuss genetic discrimination, prohibits health insurance companies from denying coverage to individuals in group plans because of their genetic information.⁵ It also states that unexpressed genes cannot be considered pre-existing conditions. Though these regulations were a step toward furthering anti-discrimination, they were not comprehensive enough because they did not forbid health insurers from collecting genetic information, charging

(*'GINA,' Continued on page 8*)

Mental Health Parity Re-visited

Two Steps Closer to True Parity

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Mental health advocates are overjoyed with the recent passage of two laws.

On October 3, 2008, President Bush signed into law H.R. 6983, the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).¹ Four months later, on February 4, President Obama signed into law H.R. 2, the Children's Health Insurance Program Reauthorization Act (CHIPRA).² Although both laws drew some criticism, they are a big step in the right direction toward eliminating the gap in access to treatment for adults and children with mental disorders as opposed to other medical conditions.³ The MHPAEA closes many of the gaping

holes that existed in previous mental health legislation by mandating mental health parity: the requirement that group health plans provide mental health services with the same benefits and restrictions that are provided for other health services.⁴ CHIPRA similarly mandates mental health parity for state children's health insurance programs.

These laws clearly show that the United States has come a long way in its treatment of citizens with mental illness. In the early 1990s, approximately twenty percent of the adult population was affected with a mental disorder.⁵ There were no federal mental health parity laws and only five states had laws mandating mental health parity.⁶ In the absence of parity laws, health plans that offered coverage for

mental illnesses often placed significant restrictions on mental health benefits that were not placed on other medical conditions.⁷

Prior Federal Legislative Efforts

The Mental Health Parity Act of 1996 (MHPA)⁸ was the first federal response to mental health parity and was enacted specifically to address the practice of employment-based group health plans discriminating in coverage benefits against those with mental illnesses.⁹ It amended the Employee Retirement Income Security Act (ERISA),¹⁰ which regulates employee benefit plans, including employer-provided health insurance plans. Specifically, the MHPA prohibited employer-provided group health plans that offered mental health coverage from placing annual or lifetime dollar limits on mental health benefits that were less favorable

(*'Mental Health Parity,' Continued on page 15*)

"[T]HE UNITED STATES HAS COME A LONG WAY IN ITS TREATMENT OF CITIZENS WITH MENTAL ILLNESS."

Access v. Excess

A Struggle with Schedule II Narcotics

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On February 9, 2009, the Food and Drug Administration (FDA) announced that many commonly-prescribed narcotics will be subject to limitations on both method and frequency of prescription.¹ The form letter announcing the matter stated that “certain opioid products, including [those narcotics produced by the letter’s recipients] will be required to have Risk Evaluation and Mitigation Strategies (REMS), to ensure that the benefits of the drugs continue to outweigh the risks” According to the FDA, a company’s REMS must “include elements to assure safe use to ensure that prescribers, dispensers, and patients are aware of and understand the risks and appropriate use of these products.” “Risks” of opioid drugs include use of certain opioid products in non-opioid-tolerant individuals, abuse, and overdose, both accidental and intentional.

The decision to require REMS stems from rising rates of death and injury occurring from “inappropriate use” of Schedule II opioids. Under the 2007 Food and Drug Administration Amendments Act (FDAAA), the FDA is permitted to ask any drug company to submit a REMS “to ensure that the benefits of a drug outweigh the risks of the drug.”² Yet it is not drug companies alone that are affected by the FDA’s decision to apply REMS to these narcotics. Doctors and patients alike will soon be impacted by the REMS of popular narcotics.

The effects of regulations on narcotics cannot be ignored, because narcotics usage is so widespread. In 2007, about 2.7 million adult American patients were written 21 million prescriptions from amongst the twenty-four different drugs now requiring REMS.³ These include both the generic and name brand formulations of fentanyl, hydromorphone,

methadone, morphine, oxycodone, and oxymorphone. All of the drugs affected by the new FDA policy are for extended-release pain management; instant release prescriptions are not affected.⁴

“IN 2007, ABOUT 2.7 MILLION ADULT AMERICAN PATIENTS WERE WRITTEN 21 MILLION PRESCRIPTIONS FROM AMONGST THE TWENTY-FOUR DIFFERENT DRUGS NOW REQUIRING REMS.”

Dr. John J. Jenkins of the FDA expressed his concern in a February 9, 2009, news conference about reports of sharp deviations from the medical standard of appropriate prescription of extended release opioids.⁵ These time release opioids are typically prescribed after building resistance to instant release medications or to meet long-term chronic pain management needs. In contrast to the circumstances under which one should prescribe extended release narcotics (cancer, persisting pain, serious infection, etc.), short-term narcotics should be prescribed for temporary pain associated with ailments such as broken bones or tonsillectomies.⁶ And even if a medical condition warrants the use of extended release narcotics, not every patient is a good candidate for a prescription; a requisite ability to handle potentially addictive side effects should exist. These and other factors have led to increased rates of “misuse and abuse and accidental overdose . . . over the past decade.”⁷

Throughout the years, the FDA has tried to prevent these harmful effects in various ways, such as by “providing additional warnings in product labeling, implementing risk management plans, conducting inter-agency collaborations, and issuing direct communications to both prescribers and patients.” However, these methods did not prove to be as powerful as hoped, leading the FDA to resort to requiring REMS from enumerated time-release narcotics.

While it is unknown what specific REMS each drug company will create, one can consider the possibilities by looking at the REMS Code, 21 U.S.C. § 355-1.⁸ As part of the FDAAA, the REMS Code guides the FDA to promulgate regulations restricting the prescribing and dispensing of certain drugs. The Code seeks not to “be unduly burdensome on patient access,” considering in particular “patients with serious . . . diseases or conditions” and “patients who have difficulty accessing health care.” In light of this, the drafting of each REMS “shall . . . seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use . . . may be standardized.” The REMS Code provides for six methods by which one can “mitigate a specific risk,” and the FDA can use one or a combination of these strategies. These six proposals represent the ways a drug company can satisfy the statute.

Proposal One: Special Certification of Health Care Providers

The first proposal would require that “all health care providers who prescribe the drug . . . have particular training or experience, or [be] specially certified . . . in a widely available training



or certification method.” Training would be available in a variety of settings, including through “an on-line course or via mail.” Providing a widely available course would achieve many goals. The training could conveniently reach any interested physician, including those working in more remote areas, while simultaneously meeting one of the goals of the Code—preventing burdens on those in sparsely

(‘Narcotics REMS,’ Continued on page 13)

Keeping the Right Focus

Why HHS-OIG Should Continue to Focus Investigations on Pharmaceutical and Medical Device Manufacturers Over Physicians

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The Department of Health and Human Services through the Office of Inspector General (HHS-OIG) reclaims billions of dollars annually to the federal government through anti-fraud enforcement.¹ The Anti-Kickback Statute has become a main enforcement mechanism for HHS-OIG against pharmaceutical and medical device companies, but recent scrutiny on physicians may change the focus of future enforcement actions.

History

The first version of the Anti-Kickback Statute (AKS) was enacted in 1972 as part of the Social Security Act Amendments.² The 1972 version allowed the government to charge persons accused of receiving a “kickback” or “bribe” with a misdemeanor punishable by up to one year imprisonment and/or a \$10,000 fine per violation. The statute



allowed the government to begin prosecuting persons and entities for what had previously been merely unethical behavior. However, Congress was seemingly unsatisfied with the ability of the government to control fraud and abuse and enacted a 1977 revision in the Medicare and Medicaid Antifraud and Abuse Amendments to give the government greater breadth and power in enforcing the AKS. Violations under the new version of the AKS were then punishable as a felony by up to five years imprisonment and/or a \$25,000 fine per violation. Nevertheless, this revision came with a limiting principle—the revision transformed the AKS into an intent-based statute requiring the government to show a person knowingly and willfully violated the AKS.

While initial enforcement of the AKS focused on physicians, more recently HHS-OIG has focused its enforcement actions on pharmaceutical and medical device companies.³ In the last century, HHS-OIG has sought innovative approaches to enforce the AKS while continuing several prosecutions of pharmaceutical and medical device companies.⁴ Among these new approaches are Corporate Integrity Agreements (CIA), which contractually bind companies with the government to avoid continuing unlawful or harmful practices, and Deferred Prosecution Agreements (DPA), which allow the government to reserve the ability to prosecute if a company fails to perform as per the DPA and also permit monetary settlements. While these innovative approaches may deter large companies from violating the AKS, their deterrent value regarding individual physicians has yet to be proven.

A 2007 New England Journal of Medicine article stated that nearly ninety-five percent of physicians receive some kind of incentive from a pharmaceutical company.⁵ The study included a broad range of items received, including free food or drink at the physician’s workplace, drug samples, honoraria for speaking engagements, sporting events tickets, and free travel accommodations. Despite the broad range of incentives included in the study, some commentators have been quick to suggest a correlation between incentives created by pharmaceutical companies for physicians who prescribe their drugs and the loss of the physician’s independent judgment. Gregory E. Demske, Assistant Inspector General for Legal Affairs of HHS-OIG, stated that “[a]lthough most physicians believe that free lunches, subsidized trips, or gifts have no effect on their medical judgment, the research has shown that these types of perquisites can affect, often unconsciously, how humans act.”⁶ Even the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed), groups designed to advocate for the pharmaceutical and medical device industries, have revamped their rules to almost obliterate physician incentives, perhaps to preempt future investigations.⁷

“[N]EARLY NINETY-FIVE PERCENT OF PHYSICIANS RECEIVE SOME KIND OF INCENTIVE FROM A PHARMACEUTICAL COMPANY.”

Despite these efforts to avoid future investigations, qui tam suits brought by individuals on behalf of the government continue to be filed while the degree of HHS-OIG scrutiny on physician-industry relationships remains an unresolved issue.⁸ To further complicate matters, HHS-OIG has a tremendous backlog of cases to investigate.⁹ The question remains whether the government should accept, investigate, and litigate these qui tam actions against individual physicians and give preference

(HHS-OIG Investigations, Continued on page 16)



'GINA,' Continued

higher rates for coverage based on genetic information, or even requiring genetic testing. Thus, in 2000 President Clinton signed an Executive Order to protect federal employees from discrimination based on genetic information for hiring or promotion.⁶ Eight years later, GINA extended this protection to the rest of the public.



Legal, Social, and Ethical Implications of GINA

1. Legal Implications

Despite the vast litigation involving the Civil Rights Act, no case has yet reached the courts under the genetic discriminations laws. One case involving a worker fired because she required expensive medication for a mildly symptomatic genetic condition was reportedly settled by the EEOC.⁷ There is a high possibility that more suits may arise with the passing of an expansive bill like GINA.

2. Social Implications

There will also surely be several social implications of the enforcement of GINA. Theoretically, it should promote the adoption of genetic testing in society, which thus far has proven to be a difficult task. One reason for this slow diffusion of genetic testing is simply that its nature as a preventive technology (a technology intended to evade unwanted conse-

quences) causes it to have a lower adoption rate.⁸ A second and more probable reason is fear on the part of the individual that negative genetic information may result in the individual losing her job or health insurance.⁹ Regardless of the reasons why people choose not to be tested, GINA should promote genetic testing.

Alternatively, some argue that the ability to freely obtain genetic information without the restriction of possible negative consequences may lead to potential misuse of insurance. For example, individuals who find out that they are at risk for a certain disorder may request other preventive services that are unnecessary and expensive, knowing that the law insulates them from the prospect of losing their insurance. This is a concept known as "moral hazard." The aggregate effect of such a practice could lead to higher costs for coverage or less availability of care.

3. Ethical Implications

GINA's enforcement will have many ethical implications. First, it will affect the patient-physician relationship. Without patients worrying that test results could negatively impact their health coverage or employment status and in turn objecting to testing, physicians will be better able to test for potential disorders in their patients. Because of this, physicians will be able to apply more preventive measures and hence more comprehensive care. GINA's enforcement will also provide patients with more autonomy in their decisions to pursue genetic testing. This may create a more deliberative relationship between the patient and physician, where both can openly discuss and perhaps carry out wishes that could have otherwise been stifled by the fear of negative consequences.¹⁰

Confidentiality and privacy are constant issues in genetic medicine and will also be impacted by GINA, but not in the way that one may think. Though it would appear logical that protection from discrimination would promote privacy for

the individual and aid in confidentiality of his test results, GINA is not this comprehensive. It does not shield against genetic discrimination when individuals apply for other types of insurance.¹¹ Hence those seeking life insurance, long-term insurance, or even disability insurance are not protected from the sharing of, and potential discrimination due to, their genetic information.

A second and more imminent concern related to privacy is the possible mishandling of genetic information. With an expected influx of genetic testing demands, there is potential that genetic information may be mismanaged.¹² Genetic testing labs may be under-staffed and pressured by the increase in demand. In such cases, they may compromise the security of information for efficiency. Other healthcare workers may be ill-informed about handling genetic information and may ignorantly mishandle the information.

"AS TECHNOLOGY ADVANCES, IT IS IMPERATIVE THAT LEGISLATION BE ENACTED TO HALT ITS NEGATIVE USE AND PREVENT ITS FUTURE ABUSE."

Conclusion

GINA is a much-needed addition to the family of anti-discrimination laws. As technology advances, it is imperative that legislation be enacted to halt its negative use and prevent its future abuse. In this way, GINA also protects against some of the misuses of genetic information. The Act hopefully will also provide the impetus needed for higher adoption rates of genetic testing. Despite the benefits, GINA may still need improvement to combat the potential mishandling of private genetic information. Though necessary amendments will surely come with time, GINA is a good start to preventing discrimination based on genetic information. ☼

'Healthcare Reform,' Continued

reported drug error rate after implementing electronic records.¹¹ Thus, electronic health records are a relatively small investment that will result in massive savings.

Second: Comparative-effectiveness Research

A second essential step toward lowering healthcare costs is the introduction of comparative-effectiveness research to prioritize health spending. "The Institute of Medicine estimates that only 4% of treatments and tests are backed up by strong scientific evidence; more than half have very weak evidence or none."¹² With \$1.1 billion for comparative-effectiveness research in the American Recovery and Reinvestment Act and authorization for a "Federal Coordinating Council for Comparative Effectiveness Research"¹³ ("the federal council"), the Obama administration is carrying out its campaign initiative to establish "an independent institute to guide reviews and research on comparative effectiveness."¹⁴

On March 19, 2009, the Department of Health and Human Services announced the fifteen members of the newly created federal council.¹⁵ Republicans have criticized the federal council, claiming it "will become a 'government rationing board' that will make life-and-death decisions about which treatments doctors will be able to use."¹⁶ However, comparative research has been conducted by the federal government for over twenty years. In 1985, the Republican-controlled Congress created the Agency for Health Care Policy and Research, precursor of the Agency for Healthcare Research and Quality (AHRQ). The AHRQ's mission—to "identify the most effective ways to organize, manage, finance, and deliver high-quality care, reduce medical errors, and improve patient safety"¹⁷—is aligned with the new federal council's mandate. In addition, two bills were introduced in the past two years, both establishing a center for Comparative Effectiveness

Research within the AHQR.¹⁸ The federal council naturally proceeds from ongoing, bipartisan efforts to spend federal healthcare money more efficiently.



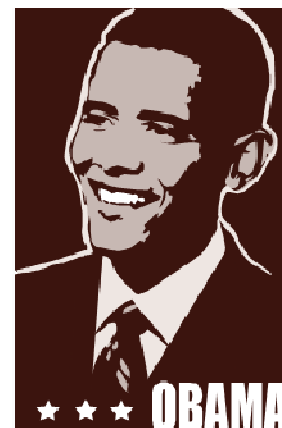
Third: Alignment of Incentives

The third essential step is to "align incentives for excellence."¹⁹ Present reimbursement schemes focus on acute care, which rewards over-treatment and undermines preventative care. Counter-intuitively, more treatment often leads to poorer health, which leads to further spending. The result is that patients receive sixty percent more care in the highest-spending regions of the nation; however, increased spending did not correlate to improved quality of care, but rather to a decreased rate of survival.²⁰ Several attempts to realign reimbursement schemes have led to alternative problems.

There are negative repercussions to enforcement of care guidelines as performance measures. For instance, Medicare's Pay-for-Performance (P4P) has been criticized for pressuring physicians to supply specific treatments before the diagnosis is firm, regardless of concurrent medical conditions. Currently, "forty-eight percent of Medicare beneficiaries over 65 have at least three chronic conditions. Twenty-one percent have five or more."²¹ Administration of specified

treatment plans when the patient has multiple conditions raises the specter of over-treatment and mistreatment; the variety of concomitant conditions requires physician autonomy to develop a specialized treatment plan. Incentives should not be aligned with patient outcomes, either. States' enforcement of mandatory surgical report cards, a system that links physician compensation to patient outcomes, leads to "cherry-picking" of patients with the healthiest outlook.²² Patients with poorer outlooks are relegated to less-experienced physicians, if they receive any care at all. Comparative-effectiveness research should guide payors to properly reimburse physicians for informed decision-making and effective care, not serve as a deterrent to physicians taking on patients with poor prognoses.

The Obama plan for healthcare reform is a robust vision, seeking to improve the entire system for the benefit of all portions of the population. It is unrealistic, however, to attempt such dramatic change at once. Obama has begun the essential first steps with the passage of the American Recovery and Reinvestment Act and expanded healthcare funding in the proposed budget. Each of the essential three steps proposed builds on the prior. Electronic health records will reduce waste and increase safety. They will also provide the basis for the comparative-effectiveness research to determine which treatments and tests are best. Once physicians have the tools to make informed decisions, payors should incentivize the most effective treatments and overall patient health. These three steps will provide the budgetary efficiency to enable further healthcare reforms.



'Neuroimaging,' Continued

schemes of justifying punishment: the retributivist theory and the consequentialist theory. The retributive theory justifies punishment by arguing that those who commit crimes deserve to be punished. The retributive model looks back at the crime committed and weighs the moral blameworthiness of the criminal behavior when deciding on the level of punishment. In contradistinction, a consequentialist justifies punishment by looking to the future benefits that punishment affords to society. Typically, the consequentialist justifies punishment by pointing to the power of punishment to deter others in society from committing crime, deter the same individual from committing future crimes, reduce risk to other members of society by incarcerating the individual, and reform and rehabilitate the criminal.² These theories rely on the basic assumption of a criminal as voluntarily choosing what behavior to engage in, assuming that the individual is free from duress.³

Reconsidering Our Reasons for Punishment

Recent neuroimaging studies have identified a network of brain regions involved in moral processing that may alter our notions of free will and moral blameworthiness.⁴ For example, researchers at the University of Southern California found that specific areas of the brain's cortex were activated when subjects performed tasks involving moral conundrums.⁵ Other neuroimaging studies have found that patients with lesions in the prefrontal cortex (the portion of the brain behind the forehead) show impaired moral judgment for emotional dilemmas.⁶

In addition to moral judgments, neural corollaries of other aspects of human cognition have been found that may likewise affect our theories of punishment, most notably that of intent. For example, researchers have found that certain parts of the motor cortex and prefrontal cortex are involved when attending to intentional activities.⁷ In the

future, it is conceivable that defendants will voluntarily undergo brain scanning in order to determine if the areas of the brain that are necessary for intentional decision-making are functioning at the level expected from a healthy individual. If a defendant's scan turns out to be "abnormal," how should this affect the punishment and sentencing of the individual?

These research findings pose a difficult question for the retributivist—namely, whether society is justified in punishing the behavior



of an individual when the functional part of their brain

governing intent is shown to function abnormally. If

the neural machinery of moral judgments and intent is compromised due to a brain injury or defect, larger questions of that individual's blameworthiness arise. If neuroscience undercuts the ability to assign blameworthiness to certain individual actions, the retributivist theory of punishment is greatly attenuated.

These studies also raise difficult questions for consequentialist theories of punishment. If the neural architecture and function of some individuals make them predisposed to violent or aggressive behavior, the deterrent effects of punishment championed by the consequentialist may be illusory.⁸ Research over the last decade has begun to show that there may be scientific means by which to gauge violent tendencies. One study of forty-one persons charged with murder or manslaughter found a statistically significant lack of prefrontal cortex activity.⁹ Another study compared forty aggressive psychiatric patients with forty non-

aggressive patients. Aggressive psychiatric patients demonstrated a statistically significant decrease in prefrontal cortex activity and an increased activity in other parts of the brain.¹⁰ Using PET scanning (another evolving imaging technique), neuroscientists have also found decreased rates of blood flow to the frontal lobes of violent individuals and convicted criminals.¹¹ Other studies of patients with lesions support the notion that the prefrontal cortex plays an important role in a person's social behavior.¹² As neuroimaging becomes more precise and more common, it is likely that courts will consider evidence of structural or functional brain abnormalities when performing adjudicative functions. Should a judge, when sentencing criminals, admit neuroimaging evidence that suggests that the defendant may have a neurobiological propensity to commit violent crimes?

The Polygraph's Bigger Brother

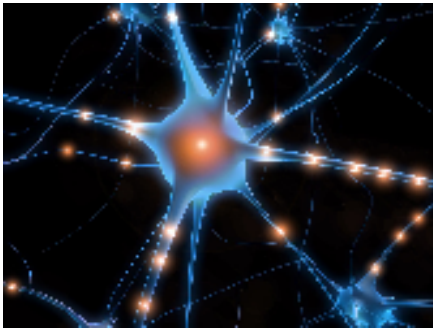
A multitude of recent studies have demonstrated an ability to identify certain regions of the brain associated with active deception. Whereas the studies regarding a neurological tendency toward violence apply primarily to uncovering abnormal brain function, fMRI lie detection attempts to uncover information about what an individual knows by seeking to identify specific brain patterns that are believed to be active at greater levels when an individual engages in conscious deception. The accuracy of predicting deception currently varies; however, some studies claim to have reached ninety percent accuracy. Interestingly, two companies, No Lie MRI Inc. and Cephos Corp., have begun to commercialize the technology, allowing citizens to get scanned in an attempt to prove their innocence.¹³

(Neuroimaging,' Continued on page 11)

‘Neuroimaging,’ Continued

Fundamental Evidentiary Problems of fMRI

Any legal practitioner or juror using fMRI scans to draw conclusions about the psychological or cognitive state of a defendant must rely on a chain of assumptions and inferences. Before describing the assumptions and inferences that must be present when considering fMRI scans, it would be helpful to illustrate this chain of assumptions and inferences with an analogy.



Imagine a worldwide tsunami warning system. The instruments (called seismographs) measure vibrations within the earth. The designers of the system must specify a threshold level of vibration that will register on the map as a warning—artificially represented by a color. This threshold is critical: set the threshold too low and the warning will activate too frequently; set it too high and it may miss important vibrations. But it is important to understand that the threshold is in a sense arbitrary. It is certainly not a natural phenomenon. After a threshold is set and the map is created, an individual (e.g., the President of Indonesia) must then make an initial inference, namely, that the increased vibrations reliably indicates an increase in activity of the earth’s plates, rather than some other phenomena such as a methane gas eruption. With that inference made, the individual must now make a second inference, namely, that an increase in activity of the earth’s plates corresponds to an increased likelihood of a tsunami. Since these inferences occur after looking at the map, the inferences drawn must rely

to some extent on the initial threshold vibration level, since that determines what initially appears on the map.

Likewise, for regions of the brain to show up as “active” on the fMRI radiological images (i.e., as colors), the investigator must specify a threshold level of fMRI data that qualifies as the BOLD threshold. In our tsunami analogy, this would be the threshold level of vibration that is required for the vibration data to show up on the map as a warning area. The lower the vibration level required for warnings, the more warnings will register on the map. Likewise, with fMRI scanning, the lower the threshold, the more regions appear as “active” colored regions on the scan. In this sense, a juror looking at fMRI evidence is very much like the individual looking at the map in that she depends (whether consciously or not) on the threshold BOLD determination when drawing subsequent inferences about the defendant’s cognitive capacities. (See Figure 1 below.)

Evidentiary Issues of fMRI

Insofar as the legal profession is concerned, a vexing question arises: what threshold level of activity do we believe is appropriate, and additionally, who determines the threshold level? Is it the medical community, the judge, the lawyer, or the state? This determination is critical given that one threshold level will produce an fMRI image that shows activation (i.e., a colored region of the scan) whereas a different threshold may not. Another difficulty with fMRI data is the inherent difficulty in drawing inferences

based on the activity of any one brain region. Current research suggests that many different regions may be involved in any specific cognitive function, thus undermining the inferential ability of fMRI data from one, single area of the brain.¹⁵

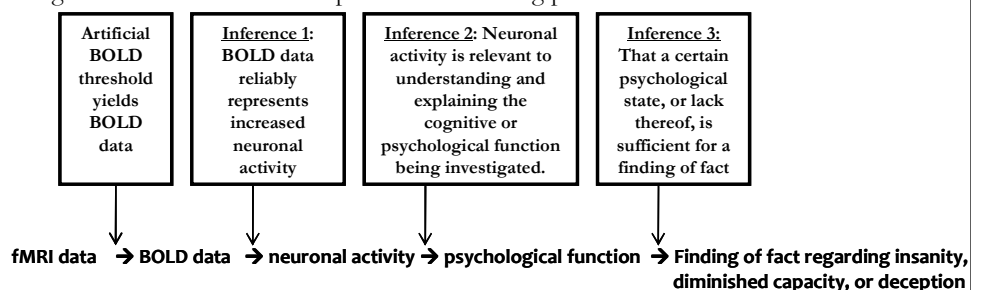
The shortcomings describe above impede fMRI’s ability to be admitted as evidence at trial. Specifically, the *Daubert* test formulated by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals* is the primary obstacle to fMRI acceptance.¹⁶ The test is used by judges to decide on whether to admit scientific evidence. One of the factors of the *Daubert* test concerns the existence of standards controlling the scientific test under consideration. Since there is no community-wide standard as to the ways in which BOLD data is constructed, the ability for fMRI evidence to pass this aspect of the *Daubert* test remains a significant impediment to its admissibility.

Constitutional Implications of fMRI Evidence

Neuroimaging, whether anatomical or functional in nature, also raises serious concerns about the right to privacy as well as a defendant’s Fourth and Fifth Amendment rights against unreasonable searches and seizures and self-incrimination. Can fMRI studies that show possible deception be admitted without the consent of the defendant? Professor and attorney John New points out that an initial question is whether

(*Neuroimaging,’ Continued on page 12*)

Figure 1. We therefore end up with the following process:



‘Neuroimaging,’ Continued

results of brain activity measurement should be considered by the legal system to be physical evidence or actual testimony by the individual.¹⁷ Treating fMRI data as physical evidence, as is the custom for DNA or fingerprints, is an attractive approach given that fMRI data is a physical measurement of a concrete, tangible phenomenon. However, if classified as physical evidence, the recording of brain activity by way of neuroimaging could be compelled in criminal cases and used against the accused by the prosecution. On the other hand, if neuroimaging evidence is considered testimony, then the argument could be made that any inclusion would violate the defendant’s right against self-incrimination.

Regardless, the legal community will have to determine which strategy best serves to promote justice.

Conclusion

Though fMRI tests have not yet been admitted as evidence in U.S. court cases, courts have admitted related functional scanning technologies such as PET scans as evidence of abnormal brain function.¹⁸ With respect to fMRI evidence, courts have been justifiably reluctant to embrace a technology that is still relatively nascent. Nevertheless, the ability to observe brain function in real-time has enabled scientists to conclude that—at the very least—certain brain regions are necessary for

specific cognitive and behavioral functions. The upshot of this technology to the legal system is its potential to uncover the neural machinery required for mens rea and other questions of psychology and cognition that have perpetually concerned our criminal justice system. Though fMRI evidence may not be dispositive, it has the potential to refine our legal system’s conception of punishment, while at the same time providing another tool by which to evaluate an individual’s basic capacity to make moral judgments and executive decisions. In short, it may help to explain the requisite psychological function for criminality. ☀

‘Off-Label Use,’ Continued...

clinical setting of physician and patient interaction does not negate the patient’s vulnerability and the need for a carefully regulated informed consent process.

- (3) The confused jury rationale: Rules on disclosure to patients need not create additional jury confusion. Juries in consent and malpractice cases such as *Blazowski* already must grasp instructions beyond the ordinary citizen’s understanding of the boundaries between physician prerogative and FDA regulations. With or without disclosure requirements, a jury must be apprised of these matters. Further, potential jury confusion is not a justifiable reason to limit patient rights.

New Jersey updated its caselaw definition of informed consent two decades ago in *Largely v. Rothman*,¹³ adopting the prudent patient standard of what a reasonable patient needs to know.¹⁴ The attorney who argued *Largely*, Richard B. Ansell, thinks the outcome in *Blazowski* does not honor the patient protections advanced in *Largely*.¹⁵ Off-label status of a medical device is information that a

reasonable patient would likely deem material in making the choice whether or not to proceed with surgery, where the surgery involves permanent implantation. The advance made for patient rights in *Largely* is lost by permitting surgeons to conceal the off-label status of medical devices.

“OFF-LABEL STATUS OF A MEDICAL DEVICE IS INFORMATION THAT A REASONABLE PATIENT WOULD LIKELY DEEM MATERIAL IN MAKING THE CHOICE WHETHER OR NOT TO PROCEED WITH SURGERY”

Arguments in *Blazowski*, as well as from other litigation against the orthopedic screw manufacturers,¹⁶ did not make the distinction between off-label use of devices and off-label use of drugs. Likewise, the New Jersey regulations make no such explicit distinction: several sections address issues of off-label drug use, while none address off-label use of medical devices.¹⁷ Nevertheless, the argument can be made that off-label use of an implantable medical device is markedly different from off-label use of drugs. In many

cases, if a patient has an adverse reaction to a drug, that patient can discontinue the therapy. If a patient has an adverse reaction to an implanted medical device, the patient cannot simply discontinue use of the device. In addition, most patients



have had ample experience taking medicine and may even have some experience with adverse reactions to a drug. In this regard, the patient may feel more confident in reporting to the doctor that something is wrong. In turn, the doctor, aware that stopping administration of a drug will be a relatively simple matter, has little

(‘Off-Label Use,’ Continued on page 13)

'Off-Label Use,' Continued

reason to resist the patient's request to discontinue that drug.

In contrast, this is not so with surgically implantable devices. The patient may have little experience with post-operative symptoms in general and, even more likely, with the signs of a poor outcome after surgical implantation of a device. More importantly, the physician has a strong disincentive to make a prompt assessment that his recom-



mended therapy was a failure. The cost of surgical removal or "explanation" may not be recoverable from the patient or patient's insurance, and may in fact have to be absorbed by the surgeon. The patient may defer to a hesitant surgeon, despite pain and discomfort. For these reasons as well as others, patients should be told the quasi-tested nature of the treatment, along with other risks disclosed about the surgery.

Beck and Azaria argue that "[t]he patient's interest in medical information is not served by a minicourse in medicine. Even less do patients need a course in the federal regulation of medical devices and drugs—particularly one that inaccurately suggests that accepted off-label therapies are investigational or experimental."¹⁸ This is not necessarily so. The patient may not understand the FDA status right away, but patients of the twenty-first century are likely to make it their business to find out what off-label status means before undergoing therapeutic yet elective surgery to have a device permanently im-

"[P]ATIENTS OF THE TWENTY-FIRST CENTURY ARE LIKELY TO MAKE IT THEIR BUSINESS TO FIND OUT WHAT OFF-LABEL STATUS MEANS BEFORE UNDERGOING THERAPEUTIC YET ELECTIVE SURGERY"

planted in their bodies. Many will choose to go ahead with the surgery. Those patients who would rather wait for more clinical results or try another therapeutic approach deserve the right to choose their own therapy in light of current data. Research should be conducted regarding the best techniques for physicians, nurses, or guided-learning software to help patients comprehend FDA-status information without misconception and confusion. As patients navigate their way in the information age, the court system should ensure that the patient's right to make an informed choice is still honored. ☼

'Narcotics REMS,' Continued

populated areas—since certified doctors would not be limited to metropolitan areas. The flexibility of the program would allow for busy doctors to complete certification on their own time as well. A REMS using this element would likely be feasible for both physicians and their patients.

Proposal Two: Special Certification of Pharmacies and Drug Dispensers

The second proposal would offer the same readily available certification to any interested "pharmacies, practitioners, or health care settings that dispense the drug." This would probably be most effective in conjunction with certification of physicians, leading to a double-check on patients by those who prescribe and fill the narcotics. The convenience for all

pharmacists translates to greater patient access. Even if drug dispensers alone were certified, physicians would likely be more careful in prescribing a narcotic to an unqualified patient if they were aware that pharmacists would be specially certified to question their judgment.

Proposal Three: Limitations on Narcotic-Prescribing Localities

Proposal three begins the more extreme solutions. It describes a plan requiring that "the drug be dispensed to patients only in certain health care settings, such as hospitals." Enacting this idea would likely be controversial for many reasons. First, informed citizens experiencing extreme pain in non-emergent situations may be likely to bypass their primary care physician or specialist in private practice to go to a hospi-

tal in order to acquire the best pain relief prescription. This would burden already over-crowded emergency rooms and take business away from private doctors. Further, it would compromise access to care for patients unable to get to these specialty sites. It would also unfairly sanction well-qualified physicians not employed in a hospital, including those who have only prescribed narcotics in the past in the most prudent fashion.

Proposal Four: Stricter Screening of Patients

The next proposal would limit the drug's issuance "to patients with evidence or other documentation of safe-use conditions, such as laboratory test results." While in theory this idea would eliminate

(Narcotics REMS,' Continued on page 14)

'Narcotics REMS,' Continued

risks of adverse chemical reactions, it would not solve all of the problems that plague the narcotics industry. One's vulnerability to long-term addiction cannot be deciphered from mere chemical tests alone, because a "patient's medical history and whether an individual has had addictive disorders in the past" are relevant as well.⁹ Concerns about stereotyping and discrimination would likely emerge if physicians implemented screening arbitrarily. Also, the purpose of such powerful drugs is to eliminate strong pain; a patient in an emergent situation in need of these pain relievers will be forced to wait until test results come back for relief. This may not be consistent with the goal of not being "unduly burdensome" on the patient as the Code requires.¹⁰ Yet since the goal of extended-release narcotics is long-term pain management, it might be appropriate to treat patients with immediate pain relief solutions until test results dictate the appropriateness of a patient to receive a drug.

Proposal Five: Stricter Patient Monitoring

The fifth proposal would require patients who are prescribed the drug to "be subject to certain monitoring." This idea seems feasible as each physician would be responsible for every prescription that she wrote. It would lead physicians not to overuse their prescription power, because they would be responsible for observing the patients' long-term reactions. If a drug dependency occurs, the doctor will be able to intervene before it turns into a full-blown addiction. This may also lead patients to think twice about using their pain medication recklessly, since they would be evaluated. Even a minor deviation of patient use due to monitoring negligence is grounds for physician liability. This proposal could also be subject to criticism that it is "unduly burdensome" to patients and therefore inconsistent with the Code.

Proposal Six: Enrollment in a Federal Registry

The last proposal also deals with accountability, as patients on the drug would be automatically added to a registry. The acne drug Accutane, dangerous to fertile women because of the risk of birth defects, has a REMS using this element.¹¹ It "requires doctors, pharmacists and patients to register and meet certain requirements in order to get a new prescription each month." Similar to physician monitoring, the idea that somebody is "keeping tabs" might encourage doctors and patients alike to refrain from the drug's inappropriate use. It would also stop patients with addictions from seeking multiple prescriptions of narcotics from a bevy of sources, since there would be a paper trail of their usage. Some may argue this violates privacy rights, but those patients really in need of the pain relief may not be as concerned about their privacy.

Proposed REMS Elements

- 1. Special Certification of Health Care Providers**
- 2. Special Certification of Pharmacists/Distributors**
- 3. Limitations on Specific Prescribing Localities**
- 4. Stricter Screening of Patients**
- 5. Stricter Patient Monitoring**
- 6. Enrollment in a Federal Registry**

Recommendations

The ideal REMS would incorporate five of the six proposals. It would include Proposals One and Two, certification of physicians and pharmacists, as this would serve as a "double check" by two medical professionals before narcotics reach the patient. Also, as some doctors and pharmacists are years out of school, it may serve as a refresher course on the criteria for prescribing and dispensing extended-release narcotics. These flow nicely into Proposal Five, strict patient monitoring, because after



being certified in this specialty, physicians will be able to keep a keener eye on their patients who are prescribed such drugs. Extended release narcotics prescriptions should also be subject to Proposal Four, administering chemical tests to patients, as the test would provide a physiological clue as to a patient's ability to take such a drug that mental screening alone could not provide. Proposal Six, maintaining a federal registry, would be ideal to prevent doctor shopping; in the end it enhances both patient and physician safety. However, Proposal Three should not be incorporated, as it is unwise to classify a physician's capability of prescribing a substance based solely on where he or she provides health services. Instead, prescription rights of extended release narcotics should be based on the individual health care professional's record of making sound prescription choices.

While it is still unclear what combination of proposals will be used for extended release narcotics, the final REMS will be "posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk."¹² The REMS developed for time-release narcotics will hopefully reconcile the broad range of views on how to achieve the ultimate goal of "balance between appropriate access and risk mitigation."¹³ ☼

‘Mental Health Parity,’ Continued

than those on medical and surgical benefits.¹¹

The MHPA, however, had several limitations. First, it did not define the term “mental health benefit” or “mental illness,” leaving the definition up to the terms of the health plan, thus permitting a plan to exclude any mental illness it chose by narrowly crafting its definition.¹² Second, it permitted two exemptions, one for small employers (those group health plans with fewer than fifty-one workers) and one for any health plan that would experience an increase in cost of one percent or more if the MHPA were to apply.¹³ Third, nothing in the MHPA mandated that health plans provide mental health benefits, and therefore, it only applied to plans that voluntarily offered such benefits. Fourth, because it only created parity in maximum annual and lifetime dollar limits, it did not affect the “terms and conditions (including cost sharing, limits on numbers of visits or days of coverage, and requirements relating to medical necessity) relating to the amount, duration, or scope of mental health benefits.” Finally, the MHPA did not apply to public health plans or insurance companies. Therefore, the MHPA had a far weaker effect than advocates hoped for.

“[T]HE [MENTAL HEALTH PARITY ACT] HAD A FAR WEAKER EFFECT THAN ADVOCATES HOPED FOR [AND] RESULTED IN A LARGE NUMBER OF HEALTH PLANS DENYING OR LIMITING TREATMENT FOR MENTAL ILLNESSES THROUGH MANAGED CARE PRACTICES . . .”

The numerous gaps left by the MHPA resulted in a large number of health plans denying or limiting treatment for mental illnesses through managed care practices, limiting the impact the law could have upon achieving mental health parity.¹⁴ Several states enacted much more protective laws mandating mental health parity and defining specific

mental illnesses that group health plans must cover.¹⁵ However, the mandates do not apply to all group health plans that



operate within these states. ERISA explicitly preempts state regulation relating to employee benefit plans, although it carves out an exception for state regulation of the business of “insurance.”¹⁶ Therefore, states can regulate fully insured group health plans, because in these types of plans, employers provide benefits by purchasing coverage from third party insurers such as Aetna or Cigna. These plans are therefore considered to be the business of insurance and are not preempted by ERISA.¹⁷ However, states cannot regulate self-insured health plans because these types of plans, where employers pay for coverage directly and insurance companies only administer the plans, are considered to be employee benefit plans.¹⁸ States therefore are unable to fill in all the gaps left by the MHPA through legislation.

Because the MHPA affected only health plans obtained through employment, there were also gaps in mental health coverage in public insurance plans administered by the government. One such program was the State Children’s Health Insurance Program (SCHIP) of 1997.¹⁹ Designed originally to help fund state insurance programs to provide health benefits for uninsured, low-income children and their families who did not qualify for Medicaid, SCHIP provided funding

for states to provide coverage for treatment of physical and mental illnesses. Because SCHIP funded state public health plans rather than employer group health plans, the limited form of parity required by the MHPA did not apply. SCHIP left each state free to develop its own regulations and procedure for administering the program. Mental and physical health coverage varied among the state programs, and because many of the states that chose to offer mental health coverage to children and their families did not have parity laws, restrictions on treatment were similar to those of group health plans.²⁰ CHIPRA reauthorized SCHIP for an additional four years, modifying the previous version significantly by including among other changes parity in mental health for children and their families covered by SCHIP in all fifty states.

Current Parity Legislation

Both CHIPRA and the MHPAEA go a long way to correct the limitations of the previous laws. In addition to other important provisions, CHIPRA’s mental health parity section will generally require states to provide the same financial stipulations, treatment limits, and cost-sharing arrangements for mental illnesses as for other physical illnesses. While many states voluntarily provide for mental health treatment, CHIPRA does not mandate that states provide coverage for mental illnesses, and states thus will be able to determine what, if any, mental illnesses they will provide coverage for. Although CHIPRA succeeds in strengthening mental health parity, it still will allow far too many people to be denied treatment for their mental illnesses.

The MHPAEA does the same—it requires the same financial stipulations, treatment limits, and cost-sharing arrangements for mental illnesses while also providing for parity in substance abuse treatment. It also creates more transparency for consumers by requiring health plans to provide their standards for medical neces-

(‘Mental Health Parity,’ Continued on page 16)

‘Mental Health Parity,’ Continued

sity determinations and any reasons for the denial of mental health and substance abuse benefits upon request.²¹ However, the MHPAEA does not affect the ability of a plan to make treatment decisions based upon “medical necessity” or engage in other common managed care practices. The MHPAEA also does not mandate minimum mental health benefits and continues to leave the definition of mental illness to the states or health plans.

The MHPAEA leaves in place the two exemptions of the prior Act of 1996, exposing a large number of people to continued restrictive terms and conditions set by health plans that are eligible for the exemptions. The MHPAEA also, like the prior Act, does not limit the ability of a health plan to impose cost-saving practices, such as providing only for treatment that the plan determines to be

medically necessary. Congress simply could not find a solution to effectively address these limitations and the very real concerns of employers and insurers with respect to mental health coverage.

Is There a Solution?

CHIPRA and the MHPAEA have certainly made great progress towards extending mental health parity. The laws provide a great deal more protection for mental illnesses and generally will ensure that the same terms and conditions for individuals with other physical illnesses also apply to those with mental illnesses. They will limit the ability of group health plans to charge higher premiums or co-payments or to impose visit limitations on mental health treatments unless the same are imposed upon other health conditions. However, significant limitations still re-

main, and the laws as they stand permit plans to continue to allow the denial of treatment by choosing not to offer any mental health coverage, restricting the types of mental illnesses covered (unless prohibited by state laws), or denying coverage through “medical necessity” determinations. While mandating employers provide mental health coverage will not solve the problem, perhaps a uniform standard of “medical necessity” determinations with regard to mental health treatment is needed. In addition, states are certainly capable of enacting legislation that defines mental illness as encompassing all DSM-IV mental disorders. Until these limitations are resolved, true parity for mental health is unlikely to be achieved. ☼

‘HHS-OIG Investigations,’ Continued

to cases involving individual practitioners over pharmaceutical and medical device companies.

Who Should HHS Investigate?

The recent guilty plea of four Miami physicians and medical assistants for submitting \$10 million in false claims demonstrates the potential for physicians to abuse and defraud the government.¹⁰ The real question is whether the financial incentives for physicians to engage in fraud or abuse actually compromise patient care. Any physician will tell you that he makes each decision based upon the patient’s best interest. However, recent scrutiny on physician practices has caused the public to question physician decisions. Should the growing public distrust cause HHS-OIG to change its strategy and start targeting these physicians?

In a perfect world, all possible violations would be investigated as they were

discovered. In this perfect world, HHS-OIG would have the staff and resources to investigate every qui tam action to the fullest and complete all its investigations before handing them over to the Department of Justice for either further enforcement action or a recommendation that no action be taken. However, our world and our economy are far from perfect.

President Obama has made health care reform a priority in his administration.¹¹ The cost of reform is tremendous—especially given the current state of our economy, the increase in debt due to the recently passed stimulus package, and President Obama’s commitment to reduce the federal deficit to under \$600 billion. Part of the President’s plan to fund healthcare reform is through increased enforcement of the False Claims Act, the AKS, and other federal statutes. However, with a small staff of attorneys working on an ever-growing stack of complaints, strategy is key. In order to maximize return on expenditures, HHS-OIG should continue to focus on qui tam com-

plaints against large companies rather than those against individual physicians, practice groups, or ambulatory surgery centers.



The greatest benefit to focusing on corporations rather than individuals is that if a pharmaceutical or medical device manufacturer is found to have violated the AKS, it is extremely likely that physicians are involved anyway. It is much easier to obtain a list of these physicians from the company’s files and enforce the AKS against all parties than it is to find the violative physicians first and use such documents to enforce the AKS against the manufacturer.

(HHS-OIG Investigations, Continued on page 17)

‘HHS-OIG Investigations,’ Continued

Interactions between manufacturers and physicians are not always as simple as free samples and lunches. This is especially true in the medical device industry, where physicians may contribute intellectual property to the manufacturer as independent contractors. This kind of relationship mirrors a much more ethical and mutually beneficial relationship that may not offer any threat of abuse. These cases are complicated, and HHS-OIG will save tremendous time and energy by going straight to the manufacturer to determine whether or not a project involving physicians is likely to compromise their integrity in making decisions regarding the care of their patients. This avoids duplication of efforts by multiple agents and offices regarding the same project or company and may result in a database of practices and projects the office approves for future reference.

If one of the government’s goals is to pay for healthcare reform, it also makes more sense to go after parties with a greater ability to pay. By focusing on manufacturers, HHS-OIG has not only settled cases for very significant amounts, but it has also retained the right to prosecute if the company fails to change its violative behavior through the DPA.¹² Undoubtedly, physicians also have an ability to pay large fines, but DPAs and similar compromises other than settlements have not been offered to physicians in the past. If a physician is adjudicated and found liable for some wrongdoing, even if the physician is able to pay the AKS fines, she may then be excluded by Medicare and/or Medicaid. Without payments by these programs, physicians realistically lose everything, which is a major motivating factor in a physician’s decision to settle.

Yet money should not be the government’s only goal—recidivism should also be a major concern. Enforcement is only an effective means of combating recidivism if the violator has an opportunity to correct his past unlawful behavior, and as a result regain his good standing with the government. If a physician

is excluded from Medicare/Medicaid, the physician will most likely lose the ability to practice medicine unless the exclusion is for a limited time. Without the ability to practice medicine by re-entering the Medicare program, the physician is unable to change future behavior, as there is no ability to perform the same behavior. In one view, this satisfies the recidivist focused solely on future bad deeds. Another more practical view, however, is that this cheats the theory of recidivism by eliminating the opportunity to prove whether enforcement actually changes behavior. Instead, the government should focus on changing physician behavior through the headlines by prosecuting large companies with many relationships with patients. While prosecuting physicians will certainly catch the attention of a few doctors, such cases rarely receive the same press as multi-million dollar DPAs.

“NO MATTER HOW MANY STUDIES SHOW THAT PHYSICIANS AND MANUFACTURERS HAVE RELATIONSHIPS AND THAT ITEMS OF VALUE PASS BETWEEN THE TWO, THE EXISTENCE OF THESE RELATIONSHIPS IS NOT NEARLY ENOUGH TO PROVE THE KNOWING AND WILLFUL STANDARDS REQUIRED BY THE AKS.”

Finally, and probably most importantly, HHS-OIG has to remember the AKS is an intent-based statute. No matter how many studies show that physicians and manufacturers have relationships and that items of value pass between the two, the existence of these relationships is not nearly enough to prove the knowing and willful standards required by the AKS. If HHS-OIG can prove a company intended to create a relationship with physicians to pass remunerations, it can prosecute the manufacturer for each and every instance the company created such a relationship.

However, proving a company intended to create a violative relationship with a physician does not prove the *physician* intended

for the relationship to be remunerative.¹³ To some degree, the problem is not that physicians are greedy, but rather that they are usually quite wealthy. Their time is valuable, and what may seem improper to pay the average worker may be vastly below what a physician would expect to compensate him for his time. It is possible, then, that expensive dinners with representatives and \$2,500 per diem rates for work on a pharmaceutical company’s project are ethical and should not be cause for enforcement actions.¹⁴ While case law varies over exactly what evidence the government must present to satisfy the AKS’s intent requirement, at a minimum, the physician has to know that what he is doing is wrong.¹⁵

Companies have corporate compliance officers and have a duty to conduct their business in accordance with the law. AdvaMed and PhRMA create guidelines for manufacturers, not physicians. A physician’s ethical focus is on treating patients, not the ethics of dining or entering contracts, and he may not be aware of potential AKS violations. Finally, proving intent can be quite difficult, especially where it is unclear whether or not the party had reason to know that what he did was wrong. Generally, the more difficult to prove, the more expensive to prove. With finite resources, HHS-OIG should focus on picking winners, not digging for the truth through lengthy and expensive discovery.

The future of the healthcare industry is never clear and changes are inevitable, but some things remain the same. HHS-OIG has acquired great success through DPAs and other actions against manufacturers, which has proven to be a highly efficient model for creating capital while reducing recidivism. Though obvious violators should always be prosecuted, it makes little sense to stray from the HHS-OIG’s current focus to enforcements against physicians without a great likelihood of success from the start. ☼

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On an abstract level, apart from how the technology is applied across studies, a threshold determination is required. Additionally, I believe that it is crucial to include the final inference regarding the finding of fact that is the ultimate step for anyone considering fMRI data in the legal context.

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(Continued on page 19)

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(Continued on page 20)

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[Note: In some instances, multiple citations to the same source have been omitted or combined for space-saving purposes.]

Student Contributors



Cathy Casriel is a social worker with a specialization in public health research. She directed a CDC-funded AIDS prevention program aimed at young heroin users; the program is cited in CDC's Compendium of HIV Prevention Interventions with Evidence of Effectiveness. She has authored or co-authored articles on cocaine, drug addiction, AIDS prevention, and psychotherapy. While raising a family in the Maplewood/South Orange area, she also worked as a freelance writer, editor, and photographer for educational books and other publications. Her three fabulous children make her proud every day of her life. She earned her M.S.J. from Seton Hall in 2008.



Jordan Cohen's interest in health law-related issues arose after implementing an electronic medical record system for his father's neurology practice. Jordan continued to explore these interests, culminating in an undergraduate thesis at Cornell University which focused on the privacy issues surrounding electronic medical records. Recently, Jordan has become interested in the impact that cutting-edge neuroscience will have on the legal system. This summer he will serve as a research assistant under Professor Frank Pasquale.



Brad Davidsen will graduate this May with a concentration in Health Law. Brad has been intimately involved with the Health Law Forum since starting law school and was a co-creator of the Health Law Outlook Newsletter last year. After serving as a Research Assistant to Dean Boozang and Cindy Wilson, he worked for the firm of Stern & Kilcullen specializing in health law. When he graduates, he hopes to work in the area of public health with either a governmental agency or a non-governmental organization.



Katherine Freed graduated with a B.E. in Biomedical Engineering and B.A. in History from Stevens Institute of Technology. She is named as principle inventor on a patent application in the field of medical imaging. The summer before beginning law school, she volunteered with the Irish government's Health Services Executive, Ireland's healthcare system. Katherine will work this summer for Fitzpatrick, Cella, Harper & Scinto.



Nicole Hamberger graduated from Gettysburg College in 2008 with an English major and a Writing minor. She interned for one summer at Wolf Block in Roseland, NJ, and for two summers at Gold Albanese & Barletti in Morristown, NJ, where she assisted in medical malpractice and personal injury cases. In summer 2009 she will complete a legal externship at St. Michael's Medical Center in Newark, NJ.



Krystyna Nowik's interest in health law lies primarily in the social and public policy sector, especially with respect to issues affecting hospitals and access to care. Before coming to Seton Hall, Krystyna completed her Masters of Science in Social Work, including an internship with Project COPE, a federal HIV/substance abuse prevention initiative. She is currently serving as a legal extern to General Counsel at St. Peter's University Hospital.



Maansi Raswant is a first-year student at Seton Hall University, School of Law. She graduated from the Interdisciplinary Studies program at University of Maryland, Baltimore County, in May 2007 with a degree in Healthcare Ethics and Public Policy. As an undergraduate, she completed a capstone project on resource allocation in pandemic influenza. Prior to entering law school, she worked as a research assistant at The Hilltop Institute, a research organization for governmental and non-profit health services. At Seton Hall, Maansi plans to continue this interest in health and policy by pursuing a Health Law concentration.

Health Law Forum News

Naureen Jaffery ☀ naureen.jaffery@gmail.com

Working as General Counsel in a Hospital

Newark, NJ—February 23, 2009

Revising a restructuring proposal, answering questions regarding volunteer massage therapists, meeting to revisit a Microsoft licensing issue, along with responding to emails, attending numerous daily meetings, and making many phone calls—this describes a typical day in the life of a General Counsel in a hospital. Francine Katz, who serves as General Counsel at St. Peter's University Hospital, shared her professional experiences with the students of Seton Hall Law. She provided a list of her regularly scheduled meetings in order for students to get a feel for her professional life. She supplemented this long list with her personal feelings towards her work. Ms. Katz shared that making decisions directly impacting someone else's life is what inspires her and makes her love her job. Whether it is a physician or a patient, she appreciates the opportunity to make a significant change in someone's life. ☀



Francine Katz (center) with Christina Hage, former St. Peter's extern (right), and Krystyna Nowik, current extern (left).

Health Law Discussion with SHU Professors

Newark, NJ—March 19, 2009

This event, a round table discussion involving current health law issues, turned out to be a very successful one. Approximately twenty students were in attendance to hear Dean Boozang, Professor Jacobi, and Professor Coleman discuss a variety of health law topics. The faculty introduced themselves and provided some information into their areas of specialty and then proceeded into an open discussion. Among the topics discussed were issues concerning flu vaccination, community health, and obesity epidemic law and public policy. Dean Boozang advised students to obtain a “well-rounded legal education,” as many other areas of law are interrelated with health. Professor Jacobi ended the discussion with some words of wisdom: “Good lawyers know and recognize other good lawyers. It is a meritocratic system.” ☀



From left to right: Professor Jacobi, Dean Boozang, and Professor Coleman with HLF President, Christina Hage.

Blood Drive

Newark, NJ—April 14, 2009



Teamwork pays off. It certainly did on Tuesday, April 14th. Members of the Health Law Forum, along with the Environmental Law Society, Women's Law Forum, and Public Interest Network helped put together a successful event for a noble cause. The drive recruited fifty-one successful donors, including many walk-in donors who inquired at the check-in table set up outside of the Student Lounge. The medical staff of the Red Cross was friendly and professional, and grateful to Seton Hall Law students for their support. The Red Cross will return again next year in the fall for the semi-annual SHU Law Blood Drive. ☀

Health Law Forum News

About the Health Law Forum

The Health Law Forum is a student organization at Seton Hall Law School for those interested in health law.

The Health Law Forum hosts speakers, panel discussions, community service projects, and networking events throughout each academic year.

The Health Law Outlook (HLO), a subsidiary of the Health Law Forum for students interested in health policy, hosts monthly round-table discussions about current topics in the healthcare field. Each semester, HLO presents healthcare issues using debate, brain-storming, presentation, and Socratic method formats. Many of the articles included in newsletters are the product of these meetings and discussion.

This semester's HLO and HLF meetings and events included

- A discussion of the effects of physician-industry relationships on physician prescribing patterns
- A speaker discussing the roles of in-house general counsel and outside counsel for a hospital
- An analysis of healthcare and insurance options for those without employer-provided benefits and who cannot afford individual coverage
- A faculty panel discussion of current healthcare topics and healthcare opportunities in the legal profession
- An ABA Health Law Section teleconference discussing career options for attorneys in the healthcare field
- Fundraising for Public Interest Fellowships to sponsor students for unpaid summer internships at non-profit organizations
- Fall and Spring Blood Drives producing over 130 donations this year.

HLF 2008-2009 Executive Board:

Christina Hage (3L), President

Matt Colford (2L), Vice President

Pat Reilly (3L), Treasurer

Nicole Ho (2L), Secretary

Brad Davidsen (3L), Co-VP, HLO

Sarah Geers (2L), Co-VP, HLO

Julie Gendel (3L), HLO Newsletter Editor

Kaitlin Semler (2L), SBA Rep

Laurie Kelly (1L), SBA Rep

Naureen Jaffery (1L), HLO Journalist

Faculty Advisor:

Professor Carl Coleman



HLF Treasurer Pat Reilly (center) and HLO Co-VP Brad Davidsen (right) work with HLO Newsletter Editor Julie Gendel (left) during "Readings Day," the date each semester when the HLF Executive Board meets to discuss and edit newsletter submission for each issue.

Contact us at SHU.Outlook@gmail.com

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Health Law Outlook

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