



Seton Hall University School of Law
Health Law Forum

Health Law Outlook





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Donor Leave Acts

Protecting Employees Who Choose to Give the Gift of Life

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New Jersey should adopt state legislation requiring private and public employers to provide a paid leave of absence during testing for, surgery of, and recovery from organ donation. Currently, only inadequate programs are in place: New Jersey has a Donated Leave program, which allows employees to donate up to ten sick or vacation days to co-workers affected by health issues, those caring for sick family members, or a co-worker who requires absence from work due to the donation of an organ.¹ However, New Jersey has

no explicit legislation requiring public or private employers to give organ or bone marrow donor employees a compensated or uncompensated leave of absence.

Congress has responded to the need for donor leave acts. In 1999, Congress passed legislation which allows all federal employees to take up to thirty days a year of paid leave for donating organs or seven days of paid leave when donating bone marrow.² It further encourages that employers of donor employees liberally extend the time of paid leave.³ Leave for bone marrow and organ donation is considered a separate category of leave that is in addition to annual and sick leave.⁴ In 2007, some members of Congress also attempted to amend the Family and Medical Leave Act of 1993 with the Living Donor Job Security Act, which would



entitle employees to unpaid leave if they provide living organ donations. This unpaid leave would include time for testing, physical and psychological evaluations, pre-transplant and postoperative services, travel, and appropriate recovery time.⁵ Unfortunately, possibly due to lack of realization of its imperativeness and lack of support among congressmen, this bill has never been passed.

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Overcrowded U.S. Prisons and Mentally Ill Offenders

Moving to a Model of Rehabilitation

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In a decision handed down on May 23, 2011, the United States Supreme Court affirmed the inmate population cap of California prisons at 137.5% of its design capacity, which was previously imposed by a three-judge district court.¹ Capping the inmate population at 137.5% was an effort to provide relief to California’s overcrowded prisons, which were testified to be populated at 200% of their design capacity.² The court determined that the degree of overcrowding in California’s prisons was the cause of a systemic failure to deliver adequate physical and mental health care to inmates in violation of

inmates’ constitutional rights.³ The decision addresses the growing problem of prison overcrowding in California, as well as across the nation, and the impact overcrowding has on the provision and delivery of effective mental health treatment in a timely fashion. It also underscores the need to set limits on the harmful environmental conditions within the criminal justice system. Addressing the issue of prison overcrowding is critical to ensure that the combination of sentencing policies and fiscal constraints do not create inhumane conditions within correctional settings that ultimately compromise the mental health of incarcerated persons, and their ability to eventually reenter the community, in ways that protect the interests of society.

In the majority opinion, the Supreme Court documented examples of how prison overcrowding has strained exist-

ing resources to the disadvantage of inmates with mental illnesses. A few examples include: a wait time of up to 12 months to receive mental health treatment; an increased rate of suicide, of which an estimated 72.1% were deemed reasonably foreseeable and preventable had appropriate mental health treatment been available; and the placement of inmates with mental illnesses in “telephone-booth sized cages” for extended periods of times due to the lack of treatment beds.⁴ In one case, an inmate, found catatonic and unresponsive, had been forced to stand in his excrement for 24 hours because there was “no place to put him”.⁵ (See Picture C, on page 8, included in the majority opinion).

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A Prescription for Change

Holding Brand Manufacturers Liable for Deficient Warnings on Generic Drugs

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Imagine that seventy percent of Americans who take prescription medications were denied the right to sue the drug manufacturer for failing to adequately warn of harmful side effects simply because they took the generic rather than the brand medication.¹ On its face, this may be the reading from the recent Supreme Court case *PLIVA, Inc. v. Mensing*,² which held that state tort liability claims against generic drug manufacturers on failure-to-warn claims were preempted by federal law.³ However, the Supreme Court left unresolved the issue of whether a brand manufacturer can be held liable for the injuries caused by another company's generic equivalent. Thus, while one door has effectively been shut against plaintiffs harmed by prescription medications, another has been potentially opened. "Faced with the alternative of providing plaintiffs no avenue of relief, courts may hold innovators liable for all pharmaceutical injuries,"⁴ even if the plaintiff was harmed by the generic company's medication.

This article will first address the decision in *PLIVA* and then examine several other court decisions regarding liability of brand name and generic drug manufacturers. The article concludes that plaintiffs should not be left without a remedy when harmed by a generic manufacturer's medication based on principles of tort law and public policy. In light of *PLIVA* and to better protect the consumer, brand

name drug manufacturers should be held accountable when they negligently cause harm to plaintiffs taking the generic equivalent of their product.⁵ While this article recognizes that there may be certain shortcomings inherent in holding brand manufactures liable, it concludes that brand manufacturers should not escape liability merely because the plaintiff used the generic rather than the brand medication.

"... THE SUPREME COURT LEFT UNRESOLVED THE ISSUE OF WHETHER A BRAND MANUFACTURER CAN BE HELD LIABLE FOR THE INJURIES CAUSED BY ANOTHER COMPANY'S GENERIC EQUIVALENT."

PLIVA, Inc. v. Mensing. Generic Manufacturers are not Liable

There are two recognized forms of preemption under the Supremacy Clause.⁶ The first type, express preemption, occurs when Congress enacts legislation that specifically reserves the area of law in question for federal regulation.⁷ The second type, implied preemption, takes place under two circumstances.⁸ It can either occur through field preemption, which arises when Congress legislates so comprehensively in a certain area of law that there is no room for state regulation,⁹ or it can arise through conflict preemption, which occurs when a state's regulation conflicts with a federal law in such a way that it is impossible to comply with both.¹⁰

Just a few years before *PLIVA*, the Supreme Court in 2009 held that state failure-to-warn claims against brand manufacturers were not preempted

when the plaintiff was injured by the brand medication.¹¹ But, this holding did not prevent generic manufacturers from claiming preemption. The Food and Drug Administration (FDA) regulates the approval of both brand and generic pharmaceuticals, but does so under separate statutory and regulatory provisions.¹² The Hatch-Waxman Act enables generic drug manufacturers to submit a smaller collection of clinical data prior to receiving the FDA's approval to market a new generic medication.¹³ In return, the FDA requires the generic manufacturers to duplicate the labeling of the branded drug.¹⁴ In effect, the generic manufacturers forfeit all control over the safety and efficacy warnings of the generic drug and rely solely on the information disseminated by the brand manufacturers.¹⁵ With this backdrop, the Supreme Court then addressed the issue of preemption against generic manufacturers in *PLIVA*.

The plaintiffs in *PLIVA* alleged that they developed tardive dyskinesia, a severe neurological disorder, from their long-term use of metoclopramide, a generic drug commonly used to treat digestive tract problems.¹⁶ Additionally, the plaintiffs claimed that the generic manufacturer failed to adequately warn of the long-term usage risks of metoclopramide, in violation of state tort law.¹⁷ But, federal law requires a generic manufacturer to ensure that its warning labeling is exactly the same as that of the brand.¹⁸ Accordingly, the issue at trial was whether, and to what extent, generic manufacturers could unilaterally change their warning labels in the absence of the brand

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Penalties for Federal Health Privacy Violations

Are they Sufficiently Enforced?

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On February 11, 2011, the U.S. Department of Health and Human Services' (HHS) Office of Civil Rights (OCR) imposed a \$4.3 million dollar civil money penalty on Cignet Health of Prince George's County, MD, for violations of the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).¹ This penalty was the first civil money penalty imposed by HSS for a Privacy Rule violation.² In announcing the penalty, OCR Director Georgina Verdugo vowed that, "The U.S. Department of Health and Human Services will continue to investigate and take action against those organizations

that knowingly disregard their obligations under these rules."³

True to its word, HHS reached a settlement with the University of California at Los Angeles Health Systems this past summer for potential violations of the Privacy Rule when "A rouge employee reportedly peeped into confidential medical files of 32 celebrities, politicians and other high-profile patients... as well as 29 noncelebrities, in 2006 and 2007."⁴ Under the terms of the settlement, UCLA Health System agreed to pay \$865,000 and has committed to a corrective action plan.⁵

HHS has demonstrated a recent willingness to investigate and take action against Privacy Rule violators, but its enforcement activities invite the ques-

tion: has the level of action taken been enough? Or, does HHS need to be even more proactive and take more widespread action against potential Privacy Rule violators? This article begins by outlining the penalties available to HHS for Privacy Rule violations under HIPAA. It then considers statutorily created alternative options to penalties available to HHS and analyzes their effectiveness (or lack thereof). It concludes by suggesting that HHS' action thus far against Privacy Rule violators has been insufficient. Public policy dictates that greater penalties and more extensive imposition of those penalties are necessary.⁶

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Punishment, Prevention, Protection and the Challenge of Diagnosing Mental Disorders

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In the context of the criminal legal system, the government is empowered to intervene in the lives of its citizens by punishing past acts, preventing future harm, or protecting those deemed unable to protect themselves. A critical step in these interventions is determining the mental status of the individual being assessed. When that individual's mental capacity is called into question, either by the state or the individual himself, the presence, absence, or treatability of a mental disorder is central to the court's decision-making. The centrality of mental disorder diagnosis raises many issues, especially whether the diagnoses themselves may be trust-

ed. The current state of diagnostic precision and consistency in the mental health profession is an issue that relates directly to the interventions carried out by the legal system and profoundly impacts all involved, from judges and psychiatrists down to the criminal defendant.

A diagnosis of mental disorder is relevant in all three models of intervention: in the punishment model, one's culpability may be lessened (or eliminated) if a mental disorder is identified; in the prevention model, one's propensity toward harmful behavior is often judged by assessing the presence or absence of a mental disorder; in the protection model, one's ability to function in wider society may be compro-

mised by a mental disorder.¹ The diagnosis of a mental disorder could completely alter the course of a criminal defendant's life, leading either to incarceration, commitment, or acquittal. The centrality of mental disorder diagnosis, and the difficulty in obtaining an unassailable diagnosis, is illustrated in the trial of John Hinckley.² Tried in 1982 for the attempted assassination of Ronald Reagan, Hinckley pled not guilty by reason of insanity, claiming that he wanted to shoot the President in order to win the love of Jodie Foster.³

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‘Donor Leave Acts,’ Continued

Following Congress’ example, state governments have enacted legislation regarding organ and bone marrow donor leave. Twenty-nine states have enacted laws against this form of employer retaliation against employees who take leave for organ and bone marrow donation.⁶ For example, as of January 1, 2011, California requires employers, who have 15 or more employees, to provide at least 30 days of paid leave for employees making organ donations and up to five days of paid leave for employees making bone marrow donations.⁷ All 29 states require that public employers give donor employees paid leave of absence; however not all require that private employers do so. Only

Arkansas, Connecticut, Illinois, Louisiana, Maine, Minnesota, Nebraska and Oregon require or incentivize leave of absence for private sector employees.⁸ If leave is granted, the period of leave is usually 30 days for organ donors and five to seven days for bone marrow donors.⁹

When a state will not require an employer to pay its donor employees, it may create incentives so that employers choose to pay an employee’s leave of absence. For example, under Arkansas Act No. 2235, private employers are required to provide, at a minimum, unpaid leave of absence; however, the act also provides an income tax credit for employers electing to pay the wages of the employee on organ or bone marrow donation leave.¹⁰ Idaho, Louisiana and Utah

have followed this example. Similarly, South Carolina has a provision which **requires employer’s authorization for a donor employee’s requested leave.**¹¹ Indiana and Louisiana prohibit employers from retaliating against employees from taking donor leave.¹²

Other states have created individual incentives for organ donation. While many national organizations, such as the National Transplant Assistance Fund and the National Living Donor Assistance Center, provide monetary assistance to donors, states such as Mississippi, New Mexico, and Virginia have legislation in place which allows living organ donors to deduct as much as \$10,000 on their

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Medical Legal Partnerships

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Dr. Barry Zuckerman, Chief of Pediatrics at Boston Medical Center, was frustrated about sending sick children home to substandard apartments only to see them return again after having not responded to medical treatments. He recognized that many of these problems were caused by social determinants of health, and a lawyer could help patients navigate the complex legal systems that hold solutions. Dr.



Zuckerman decided that a doctor and a lawyer working together gave the patients the best chance to stay healthy, and so the first Medical Legal Partnership (MLP) was born. This MLP was developed in Boston in 1993 in collaboration with the Boston Medical Center for Pediatrics.¹

MLPs are a healthcare and legal services delivery model that aims to improve the health and well being of vulnerable individuals, children and families by integrating legal assistance into the medical setting. MLPs address social determinants of health and seek to eliminate barriers to healthcare in order to help vulnerable populations meet their basic needs and stay healthy.² Basic needs include, income supports for families, utility shut-off protection during cold winter months, and mold removal from the homes of asthmatic children.³

In 2007, the American Bar Associa-

tion (ABA) passed a resolution that created the MLP Support Project (the Project).⁴ Following the ABA’s adoption of the project, the American Medical Association (AMA) adopted a similar model.⁵ Both programs encourage working closely with hospitals and health officials and they honor those individuals that participate in the movement.⁶ The resolution passed by the ABA is modeled after other initiatives already in place to promote service to vulnerable populations which include: public health law generally, long term care for HIV/AIDS patients and breast cancer patients.⁷ Within the next few years, the formation of these types of partnerships may become critical in the success of solving the problems of struggling families and individuals. Indeed,

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‘Overcrowded U.S. Prisons and Mentally Ill Offenders,’ Continued

The consequences of prison overcrowding are not simply soaring costs, unsanitary living conditions, increased violence, and increased recidivism.⁶ These inhumane conditions instigate mental illness in those who are predisposed to or have minor symptoms of mental illnesses.⁷ The former warden of San Quentin State Prison and Acting Secretary of the California Department of Corrections and Rehabilitation testified that the current prison conditions in California, “make people worse, and...we are not meeting public safety by the way we treat people.”⁸ As

such, the conditions resulting from prison overcrowding have serious and aggravating contra-indications; they produce more mental illness and criminal behavior, which impose future costs on society.

More than 1 in every 100 adults in the U.S. is incarcerated.⁹ Among those incarcerated, persons with severe and persistent mental illnesses are disproportionately represented.¹⁰ It is estimated that 44.8 to 66.2% of those incarcerated in state prisons, federal prisons, and local jails have a mental health problem, defined as receiving a clinical

diagnosis or treatment by a mental health professional.¹¹ Additionally, approximately 14 - 16% of individuals in the criminal justice system have a severe mental illness (schizophrenia spectrum disorders, bipolar spectrum disorders, and major depressive disorders).^{12,13} Inmates with mental illnesses, like their counterparts in the community, have special treatment needs and often challenging behaviors that can be difficult to manage.¹⁴

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‘Penalties for Federal Health Privacy Violations,’ Continued

I. Overview of Violations that Can Result in a Penalty

The HIPAA Privacy Rule applies to all covered entities, which include health plans, health care clearinghouses, and health care providers who transmit protected health information electronically in connection with a standard transaction.⁷ Once an entity is designated a covered entity, and thus subject to the Privacy Rule, that entity must follow strict guidelines for uses and disclosures of protected health information. Generally, a covered entity is permitted to use protected health information in the following circumstances: (1) when giving it to the individual (i.e., a patient); (2) for treatment, payment, and health care operations; (3) when the individual patient is given the opportunity to accept or reject the use/disclosure; (4) with an individual’s authorization.⁸ Outside the scope of these parameters, use and disclosure of personal health information is unauthorized. That is, if any covered entity, or individual agent of a covered entity, uses or discloses protected health

information for any other reason than as provided (i.e., for unauthorized research or to “snoop” on a celebrity patient), HHS may impose penalties.

II. The HIPAA Penalty Framework

The HIPAA penalty framework divides penalties into two levels: (1) the general penalty and (2) the specific penalty. Failure to comply with HIPAA regulations can result in civil monetary penalties under the general penalty and, more harshly, both financial and criminal penalties under the specific penalty.⁹

A. *The General Penalty*

The HIPAA General Penalty distinguishes between a violator’s mental state in determining the penalty severity. These mental states include, in progressive order of severity: (1) the violator did not know (and by exercising reasonable diligence would not have known) of the violation; (2) the violation was due to reasonable cause; (3) the violation was due to willful neglect; (4) the violation was due to willful ne-

glect violation and was not corrected.¹⁰ The civil penalty amounts begin at \$100 at the first mental state and increases to \$1.5 million.¹¹ Although HHS has wide discretion in imposing the general penalty for Privacy Rule violations, “A violation of a provision...due to willful neglect is a violation for which the Secretary [of HHS] is required to impose a penalty.”¹²

B. *The Specific Penalty*

The HIPAA Specific Penalty likewise distinguishes between a violator’s mental state in determining the penalty severity. Any person who knowingly violates HIPAA by “obtain[ing] individually identifiable health information relating to an individual” or by “disclos[ing] individually identifiable health information to another person shall be punished.”¹³ A knowing violation of HIPAA can result in a

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‘Overcrowded U.S. Prisons and Mentally Ill Offenders,’ Continued

Psychotic symptoms can include bizarre behavior, delusions, hallucinations, problems with consciousness, faulty memory, impulsive actions, and uncontrollable mood swings.¹⁵ Incarcerated individuals with mental illness are also much more likely to have substance abuse problems when compared to those incarcerated without mental illness.¹⁶

Despite this, inmates with mental illnesses are often housed with the general population, and the symptoms of their illnesses are not taken into account in terms of expectations of behavior or compliance.¹⁷ Indeed, the “acting out” behaviors of untreated mental illness are often assumed to be volitional or manipulative.¹⁸ Not surprisingly, inmates with mental illnesses are more likely than the general inmate population to serve out their maximum sentence, be denied parole, and be placed in administrative segregation.¹⁹ It also costs significantly more to incarcerate inmates with mental illness than inmates without

mental illness.²⁰

While there is no consensus on whether prison is the right place for people with mental illnesses who commit crimes, it is clear that they will be a significant minority within prison populations across the country for the foreseeable future.²¹ During incarceration, inmates with mental illnesses are entitled to basic sustenance by the state, including adequate mental health treatment, the deprivation of which results in a violation of the 8th Amendment and cruel and unusual punishment, remediable by the court.²² Mental health treatment becomes compromised when prison resources are more strained by overcrowding. While California’s prison system is an extreme example, it represents conditions which are pervasive in other states. In 2005, the populations at state prisons were on average at 114% their facilities’ design capacity, with Alabama ranking highest at 179%.²³

The United States incarcerates more people per capita than any other country in the world and the rate of incarceration in the US has been increasing at annual rates between 8 to 12% since the 1970’s, outpacing the rate of growth of the population.²⁴ The U.S. appetite for incarceration has increased in large measure as a consequence of tougher sentencing laws resulting in lower thresholds to become incarcerated, or re-incarcerated once on probation or parole.²⁵ Examples of this trend in policy include laws such as California’s “three strikes” measure, mandatory minimum sentences, abolishment of discretionary release by the parole boards, and requiring probation and parole officers to report any violation of an offender’s conditional release.²⁶

With the expanding girth of state correctional systems, fiscal expend-

itures to fund these institutions have grown, absorbing substantial portions of state budgets. There is evidence, however, that crime and sentencing policies have exceeded the ability of fiscally-strapped states. Indeed, states like California have grown their correctional systems past the point of their affordability. And the consequence is overcrowding and underservicing, which has an immediate and devastating impact on the most vulnerable population within state prisons: inmates with mental illnesses. The Supreme Court’s opinion affirms that a limit must be placed on the extent to which fiscal constraints can be borne by inmates with mental illnesses who are guaranteed by law to receive adequate and timely mental health treatment while incarcerated. This provides credence to the continued evaluation of the U.S. correctional system with the aim of developing informed practices that facilitate offender rehabilitation, in part by pruning practices that further exacerbate crime and criminal behavior, so that the interests of incarcerated individuals and society are best protected. ☼



‘Penalties for Federal Health Privacy Violations,’ Continued

financial penalty of up to \$50,000 and a prison sentence of up to one year; a knowing violation under false pretenses can result in a financial penalty of up to \$100,000 and a prison sentence of up to five years; a knowing violation with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, person gain, or malicious harm can result in a financial penalty of up to \$250,000

and a prison sentence of up to 10 years.¹⁴ As is evident from the potential severity of the financial penalty, coupled with the possibility of prison time, the specific penalty is much harsher than the general penalty.

C. Limitations to HIPAA General Penalty

If HHS determines that imposing the general penalty is not a proper remedy for a particular violation, it may opt to employ one of the several limitations

built into the general penalty as a remedial measure. First, if HHS imposes the specific penalty, it may not also impose the general penalty.¹⁵ Second, if a violation is cured within 30 days of the date the person knew, or by exercising reasonable diligence should have

(‘Penalties for Federal Health Privacy Violations,’ Continued on page 11)

‘Donor Leave Acts,’ Continued

state income taxes for travel, lodging and lost wages related to the donation.¹³ While this is a great benefit to many donors and a great incentive to potential donors, leave of absence from employment will be necessary to undergo either procedure, and the disincentive of employer retaliation may be too great for many people. Without legislation providing otherwise, it is extremely difficult to protect employees from employer retaliation for when they take time to participate in and recover from organ donation. Since a specific cause of action is unavailable for organ donors in New Jersey, organ donors may look to recover damages based on unlawful discharge, such as discrimination based on disability. If an employee attempts to sue under New Jersey’s disability law, they must attempt to hurdle what New Jersey has qualified as a disability: a plaintiff suffers from a disability which is caused by illness and which includes any degree of amputation.¹⁴ Under this reading of New Jersey’s disability law, a court may find that the term “disability” limits itself to individuals who received a necessary amputation due a precondition or illness. Therefore, an organ donor employee at-

tempting to sue under a claim of disability would fail; thus, it is clear that there needs to be more specific legislation addressing the needs of organ donors.

Living organ and bone marrow donors are quite the opposite; they are typically healthy individuals who voluntarily have surgery for the benefit of another, not as a result of a condition or illness. Thus, without a specific provision indicating that donors specifically have a cause of action against an employer for discriminatory discharge, the donor will be unable to prove discrimination. Even if she can prove unlawful discharge based on her organ donation, there is no act prohibiting this form of employer retaliation against an organ donor employee.

New Jersey will see many economic and social benefits if it adopts a donor leave provision. First, the provision would encourage and enable many living organ donors by providing reassurance and job security. Currently, 25% of potential living organ donors do not donate because of concerns about potential unreimbursed expenses related to organ donation, salary reductions or potential loss of employment.¹⁵ Legislation would prevent employees from being fired due

to an extended leave of absence for recovery from donation.¹⁶ Thus, employees would not have to fear retaliation and would be more inclined to donate.

Encouraging organ donation also is cost-effective for society as a whole. There are approximately 83,000 people on the waiting list for organ and tissue transplants, and the list is growing due to a chronic shortage of organs.¹⁷ Last year, only 16,500 people actually received an organ.¹⁸ Encouraging living donors would provide a greater supply of organs for transplantation, which in turn would decrease time spent on dialysis and improve patient and organ survival rates.¹⁹ There would also be an overall savings in health-care expenditures for kidney disease services and services for other life-threatening illnesses.

(‘Donor Leave Acts,’ Continued on page 11)

‘A Prescription for Change,’ Continued

manufacturer making the label changes first.¹⁹ The Court ultimately held that conflict preemption precluded failure-to-warn lawsuits against generic manufacturers, even though their labeling was approved by the FDA.²⁰

Writing for the majority, Justice Thomas held that federal law preempts state law since the FDA has interpreted its regulations “to require that the warning labels of a brand-name drug and its generic copy [to] always be the same – thus, generic drug manufacturers have an ongoing federal duty of ‘sameness’”²¹ to the brand manufacturer’s label. As such, the Court rejected the plaintiffs’ contentions that the generic manufacturers could have unilaterally strengthened their warnings under the FDA’s changes-being-effected (CBE) process²² or by sending “Dear Doctor” letters²³ to physicians. The Court deferred to the FDA’s interpretation that the CBE process and “Dear Doctor” letters qualify as “labeling” and that generic manufacturers cannot alter their drug labeling without action first by the brand manufacturer.²⁴ The FDA’s views are “controlling unless plainly erroneous or inconsistent with the regulation[s]” or [if] there is any other reason to doubt that they reflect the FDA’s fair and considered judgment.”²⁵ Accordingly, the Court found conflict preemption because it was impossible for generic drug manufacturers to comply with both

state and federal requirements because “if the [generic manufacturers] had independently changed their labels to satisfy their state-law duty, they would have violated federal law.”²⁶

Foster v. American Home Products Corp.: Brand Manufacturers are not Liable

Prior to the decision in *PLIVA*, the vast majority of courts which had examined brand liability for plaintiffs injured by a generic manufacturer’s drug aligned themselves with the holding in *Foster v. American Home Products Corp.*²⁷ Applying Maryland state law, the *Foster* court affirmed the district court’s ruling, which held that the brand manufacturer of promethazine (Phenergan®) owed no duty to warn the recipients of the generic medication of the dangers associated with the drug.²⁸ Essentially, the court declared that product liability claims for pharmaceuticals can only be brought against the manufacturer of the product that actually caused the injury to the plaintiff.²⁹

The Fosters brought suit against the brand manufacturer because their daughter died from taking the generic version of Phenergan®.³⁰ The appellate court refused to recognize a cause of action against a manufacturer for injuries arising from another manufacturer’s product.³¹ The court explained that brand manufacturers have no duty to patients who receive generic medications because those patients have no right to rely on the labeling of the brand name medication.³² In addition, the court noted that even though the Fosters could not hold the brand manufacturer liable, they still had a remedy against the generic manufacturers.³³ Thus, following the holding in *Foster*, the only manufacturer that can be liable for the plaintiff’s injuries was the manufacturer who produced the ingested

drug, even though both the brand and generic labels must be exactly the same.³⁴

However, *Foster* was decided in 1994, seventeen years prior to the *PLIVA* decision.³⁵ Accordingly, the proposed remedy of holding generic manufacturers liable articulated in *Foster* is no longer a viable solution. The decision in *PLIVA* has definitively established that generic manufacturers cannot be held liable under failure-to-warn claims because federal law preempts state tort law.³⁶

Limitations of Foster

The *Foster* court erred in determining that it was not foreseeable for a brand manufacturer to owe a duty of care to the user of a generic medication.³⁷ The analysis in the *Foster* decision inappropriately focused on the foreseeability of the brand manufacturer owing a duty to the plaintiff taking the generic drug.³⁸ Instead, “[f]or a duty to arise, the question is not whether the defendant foresaw owing a particular duty to a plaintiff, but rather whether the defendant’s conduct create[d] a foreseeable risk to a foreseeable plaintiff.”³⁹ The court in *Foster* ignored this by simply stating that it was not foreseeable that a brand manufacturer would owe a duty to the user of generic medication.⁴⁰ The court quickly concluded that there is no duty of the brand manufacturer because the injured plaintiff did not take the brand manufacturer’s medication.⁴¹ The court never addressed the question of whether the brand manufacturer’s labeling requirement created a foreseeable risk to the patient taking the generic medication.⁴²

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Continued on Page 12)*



‘Donor Leave Acts,’ Continued

New Jersey is currently considering an act that would provide a tax deduction of up to \$10,000 for unreimbursed travel expenses, lodging expenses and wages lost while recovering from organ donation.²⁰ However, even if this act is passed, it is not enough; New Jersey state legislation is necessary to require private and public employers to provide a paid leave of absence during testing for, donations of, and recovery

from organ donation. Public policy practically necessitates the enactment of a donor leave act in New Jersey: legislation would increase donation rates and increase the number of organs available; it would improve patient survival rates; and there would be a saving of health-care expenditures both on an individual and on society as a whole. Thus, New Jersey should enact donor leave acts for public and private employees. ☀

“PUBLIC POLICY PRACTICALLY NECESSITATES THE ENACTMENT OF A DONOR LEAVE ACT IN NEW JERSEY...”

‘Penalties for Federal Health Privacy Violations,’ Continued

known, that the failure to comply occurred, no penalty can be imposed nor can any damage be collected.¹⁶ Third, HHS may, at its discretion, extend the 30-day cure period.¹⁷ Fourth, HHS may provide violators with technical assistance to help them come into compliance.¹⁸ Fifth, for any penalty that is not due to willful neglect, HHS may waive the general penalty “to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.”¹⁹

III. HHS Seems to Prefer the General Penalty Limitations to Imposing a Penalty

HIPAA complaints²⁰ are divided into three categories: (1) those that are resolved after intake and review (no investigation); (2) cases investigated and resolved with no finding of a violation; (3) cases investigated and resolved with corrective action obtained from the covered entity.²¹ Under the third category, where corrective action is obtained from a violating entity, HHS’ OCR has not necessarily imposed a penalty (or agreed to a settlement). OCR often allows violating entities to “come into compliance” or take “corrective action,” consequently fore-

going the imposition of any civil monetary penalty or criminal liability.²²

In cases where OCR has permitted a violating covered entity to come into compliance, it is effectively exercising the General Penalty Limitations. For example, HHS may grant a violating entity an extension to the 30-day cure period so that the entity can ensure compliance with the violated regulation(s).²³ Often, “providers who are found to have violated the requirements of HIPAA are asked to sign a Corrective Action Plan, obligating themselves to reporting and monitoring responsibilities that more resemble a Corporate Integrity Agreement (CIA) than a simple settlement agreement.”²⁴ Corrective Action Plans, like statutory limitations to penalty, help bring violators into compliance, but do not actually impose a penalty. In fact, since the Privacy Rule’s inception in 2003, HHS has only collected money (either through a civil monetary penalty or via settlement) from seven violators.²⁵

IV. A Private Right of Action: Without It, Redress of Past Harms Is Unlikely

Because HIPAA does not provide a private right of action, aggrieved individuals, whose health privacy has been vio-

lated, cannot pursue a lawsuit against the violating party.²⁶ Essentially, patients substantially affected by medical privacy “leaks” are without individual rights. The only action they can take is to file a complaint with HHS²⁷ and hope that HHS will then decide to act on the complaint pursuant to its enforcement powers. However, under this best-case scenario, any penalty imposed against the violating party will go to the government, not the aggrieved individual.²⁸

Alternative theories of obtaining individual redress for HIPAA violations have been explored.²⁹ Despite these theories, the only solution that will appropriately enable the victims of medical privacy violations to seek redress against the responsible party is a congressional rewriting of the HIPAA statute to provide for a private right of action. Such a rewriting of HIPAA would permit those who have already been

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In addition, the *Foster* court was mistaken in its unstated assumption that prescription medications were similar to all other manufactured products.⁴³ For most consumer goods, the customer has a choice between which manufacturers they wish to purchase, but with prescription drugs there often is no choice.⁴⁴ The decision is regularly dictated by the prescribing physician, pharmacist, insurance company, or by some other external factor that the patient cannot control.⁴⁵ Because of this lack of control, it is even more important for medication labeling to be uniform. Otherwise, this may lead prescribers and patients to believe that there are differences between the same medications produced by different manufacturers, when there is in fact no difference. The *Foster* reasoning is also based on the misguided belief that generic manufacturers may alter a label’s warnings without FDA approval⁴⁶ and practically ignored the continuing duty of the brand manufacturer to maintain the accuracy of its labeling.⁴⁷

Therefore, in light of these shortcomings coupled with *PLIVA*, courts should no longer follow the precedent established in *Foster*. *PLIVA* held that generic manufacturers cannot be liable for labeling defects because only the brand manufacturer can change the labeling to reflect new warnings.⁴⁸ *Foster* held that brand manufacturers cannot be liable when a generic drug harms a patient because the patient took the generic manufacturer’s drug and had no right to rely on the representations of the brand product.⁴⁹ Read together, these two cases would leave a patient harmed by a generic medication without a remedy because neither manufacturer could be held accountable. Now that the decision in *PLIVA* definitively estab-

lishes that generic manufacturers must rely on the brand manufacturers labeling, it shifts responsibility back to the brand manufacturers to ensure that their labeling adequately reflects new warnings.⁵⁰ Thus, in order to provide a potential avenue of relief for injured plaintiffs, courts must accept the application of the innovator liability theory as set forth in *Conte v. Wyeth*.⁵¹

Conte v. Wyeth: Innovator Theory Holds Brand Manufacturers are Liable

Now that *PLIVA* has effectively ruled out generic manufacturer liability,⁵² plaintiffs are left with the difficult task of seeking relief for their injuries. The injuries suffered by the plaintiffs would not have occurred but for the failure of the brand manufacturer to adequately warn about the dangers of their medication. As a result, brand manufacturers must be held accountable. They are the only entity which can update their warning labels to which the generic manufacturers must conform.⁵³ However, this stands as an enormous hurdle for plaintiffs because in twenty-two states that have addressed the issue, only one decision out of fifty-two⁵⁴ has found that brand name drug manufacturers are potentially liable for the inadequate warnings of its drug when the plaintiff was harmed by a generic equivalent.⁵⁵ Nevertheless, in light of the Court’s decision in *PLIVA*, two conclusions necessarily follow. The first is that “Congress intended the name brand drug manufacturer to bear the *sole* burden of coping with incipient risks...and [second], that Congress intended either that the name brand manufacturer be liable for *all* failure-to-warn claims – even those arising out of the use of generic substitutes – or, that the injured plaintiff be left with no remedy.”⁵⁶ It would be unjust to allow plaintiffs

harmed by pharmaceuticals to be left without a remedy against the manufacturer responsible for the injury. Thus, Congressional intent strengthens the validity of the *Conte* decision and further supports the application of the innovator liability theory.

The decision in *Conte* represents a novel approach for plaintiffs seeking relief from their injuries, especially now in the wake of *PLIVA*. In the decision, Justice Siggins invokes the theory of innovator liability, which established that brand name manufacturers owe a duty to convey accurate prescribing information about a medication’s risk and benefits to patients who consume a generic version of the drug.⁵⁷ In *Conte*, the plaintiff developed tardive dyskinesia after her long-term use of the generic drug metoclopramide to treat her acid reflux.⁵⁸ Invoking the theory of innovator liability, the court found that the brand manufacturer owed a duty to Conte because it was foreseeable that generic manufacturers would copy the brand drug’s labeling and that pharmacists would fill the prescription for the generic equivalent.⁵⁹

Furthermore, the court emphasized its decision was “rooted in common sense” by recognizing that the brand manufacturer should not escape liability just because Conte happened to receive the generic drug.⁶⁰ The court acknowledged that its decision was contrary to the majority of courts which have been presented with the issue.⁶¹ However, the court stressed that its holding was based in large part on the foreseeability that patients taking a generic drug could be injured as a result of their reliance on the brand manufacturer’s product label-

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‘Penalties for Federal Health Privacy Violations,’ Continued

the victims of medical privacy “leaks” to seek remedy for the wrong they suffered. However, while congressional rewriting is possible, it is highly unlikely given the overwhelmingly burdensome litigation and increased health care costs that would likely ensue.³⁰ Whereas the HIPAA statute is unable, as currently construed, to redress past health privacy violations, HHS can, and thus should, focus on preventing future harms.

V. Where Should HHS Go From Here?

In 2011, thus far, HHS has vastly increased its enforcement of HIPAA Privacy Rule violations. HHS has imposed its first-ever civil monetary penalty, and, moreover, has settled with two additional violators.³¹ Some have argued that this increased enforcement of penalties has sent a message to current (and potential) violators.³² But it is not enough. Public policy dictates that HHS’ OCR not only require violators to “come into compliance” whether through corrective action plans or by other means, but also impose a penalty against violators. This does not mean that HHS should not help violators on the road to compliance. That is, HHS must require compliance, providing violators with assistance when feasible, in order to protect private health information in the future. The imposition of civil monetary penalties, and criminal penalties in extreme cases, will conceivably help to deter future violations. While the imposition of these penalties will not remedy past violations, because of HIPAA’s exclusion of an individual cause of action,³³ previously compromised individuals can take some solace in knowing that HHS is actively working to prevent future harms. A mere promise to aggrieved individuals that improper use or disclosure of personal health information will not again occur, or

even the implementation of new, stricter workforce training and accountability standards, will not help to redress harms already done.

HHS must also be more willing to impose the specific penalty on violators and thereby seek enhanced penalties. In 2010 the first ever prison sentence was imposed on a HIPAA violator for unauthorized access of patient medical records.³⁴ While jail time, and application of the specific penalty in general, should remain reserved for the most egregious violations of the HIPAA Privacy Rule, HHS should more frequently seek incarceration as a penalty when patient health information is improperly accessed, used or disclosed. That is, incarceration should be a penalty reserved for instances when a covered entity, or its agent, knowingly violates an individual’s protected health information. The possibility of jail time could serve as a powerful warning and deterrent to those who consider illegally accessing patient medical information. While the recently imposed penalties have encouraged some to argue that increased HIPAA enforcement will become the norm,³⁵ HHS has not yet done enough. The massive HIPAA Privacy Rule was enacted to help protect individual personal health information. HHS must ensure that those protections are safeguarded.

VI. Regardless of Enforcement Levels, Workforce Training and Accountability Are Key

While aggressive enforcement of the HIPAA Privacy Rule is necessary, including the increased imposition of penalties on violators, covered entities can nonetheless contemporaneously mitigate their chances of being penalized and protect individual health information. The easiest way to do this is through strict workforce training and workforce

accountability.³⁶ Only if covered entities implement required administrative requirements, namely workforce training and sanctions, can they hope to prevent their employee’s improper access, use and disclosure of personal health information. Essentially, covered entities must strive to make all employees attentive to HIPAA Privacy Rule regulations and, moreover, must be willing to enforce internal sanctions against violators of those regulations.³⁷ Proper workforce training and a strict demand of accountability will likely decrease the potential of Privacy Rule violations, while, at the same time, personal health information will be protected.

Altogether, the proscribed penalties for HIPAA violations, the lack of an individual right of action, and HHS’ haphazard imposition of penalties against violators have resulted in a chaotic system that neither redresses previous harms nor adequately protects against future harms. To “fix the system,” so to speak, HHS must aggressively enforce penalties against HIPAA Privacy Rule violators. Such enforcement is the only means to systematically deter future health privacy violations. Because no private right of action currently exists, and such a right is unlikely to be written into the statute, direct recourse for already aggrieved individuals is unlikely. However, if HHS takes HIPAA Privacy Rule enforcement seriously and covered entities work earnestly to implement strict workforce training and accountability, previously aggrieved individuals can, at the very least, have some relief from knowing that future violations are less likely to occur. ✕

‘Punishment, Prevention, Protection and the Challenge of Diagnosing Mental Disorders,’ Continued

The court’s evaluation of Hinckley’s mental state quickly devolved into a “war of the experts.”⁴ The defense’s psychiatrist diagnosed Hinckley with various mental disorders directly impacting volition, and therefore his culpability, while the prosecution’s expert concluded that Hinckley was not suffering from a disorder serious enough to impair his decision-making capacity.⁵ Both psychiatrists shared similar medical training, yet they arrived at contradictory diagnostic conclusions.

A potential explanation for this outcome is discussed by Harvard Medical School professor Marcia Angell in an article primarily focused on the interplay between the clinical diagnosis of mental disorder and the development of drugs for the treatment of those disorders.⁶ According to Angell, before the advent of psychoactive drugs, the psychiatric profession subscribed to the Freudian approach to mental disorders.⁷ Nearly all known mental disorders were treated with a strict regimen of “talk therapy,” a treatment arising out of the Freudian concept that the root of the disorder was within the patient’s mind.⁸

By the 1950’s, the use of Thorazine and other tranquilizers became commonplace in the treatment of both serious depression and schizophrenia.⁹ These drugs, originally used for the treatment of epilepsy, infections, and other non-mental disorder conditions, became popular after it was noticed that one of their secondary effects was a significant decrease in symptoms related to depression and schizophrenia.¹⁰ Researchers and clinicians then postulated that, because these drugs affected the brain’s serotonin reuptake mecha-

nism, depression must be related to serotonin levels.¹¹ Later drugs like Prozac, known generally as Selective Serotonin Reuptake Inhibitors (SSRIs), were developed to specifically target the nervous system’s levels of serotonin, in the belief that the cause of depression was a serotonin imbalance.¹² Both the American Psychiatric Association and the major pharmaceutical companies ultimately concluded that, because SSRIs specifically targeted the brain’s serotonin reuptake process, depression must be the result of too little serotonin.¹³ Since serotonin reuptake inhibitors were shown to have the secondary effect of reducing symptoms of depression, Angell argues that drug companies and clinical psychiatrists effectively reverse-engineered a drug for depression (the pharmacological treatment for schizophrenia had a very similar genesis).¹⁴ In essence, concluding that depression and schizophrenia are the result of imbalances in serotonin is analogous to claiming that the sensation of physical pain is the result of too little aspirin or acetaminophen in the nervous system.¹⁵

According to Angell, there have been no subsequent studies supporting the thesis that depression and schizophrenia are solely the result of either too little serotonin or too much dopamine, yet this idea has become the prevailing scientific explanation for both disorders.¹⁶ The American Psychiatric Association (APA) and the Diagnostic and Statistical Manual (DSM) both refer to depression and schizophrenia as disorders caused by a chemical imbalance, despite recent studies showing that treatment with SSRIs actually causes imbalances in patients that had no chemical imbalance before the treat-

IN ESSENCE, CONCLUDING THAT DEPRESSION AND SCHIZOPHRENIA ARE THE RESULT OF IMBALANCES IN SEROTONIN IS ANALOGOUS TO CLAIMING THAT THE SENSATION OF PHYSICAL PAIN IS THE RESULT OF TOO LITTLE ASPIRIN OR ACETAMINOPHEN IN THE NERVOUS SYSTEM.”

ment.¹⁷ Dr. Angell’s description of the development of pharmaceutical treatments for depression and schizophrenia illustrates the difficulties facing the mental health profession as the diagnostic process is developed and refined. These developmental difficulties, specifically those effecting diagnosis of mental disorder, have serious implications for criminal defendants whose level of culpability may be determined by such a diagnosis.

A “battle of the experts,” in which two equally trained and qualified clinicians reach contradictory conclusions, seems unavoidable when the development of diagnoses and treatments for major mental disorders is founded on a reverse-engineering process unsupported by empirical studies. At least in the context of diagnosing depression and schizophrenia, clinicians are forced to rely on a process that does not seem to rise to the level of proof required by the criminal justice system.

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‘Medical Legal Partnerships,’ Continued

given the success in both patient outcomes and the ability to save institutions money on emergency costs, it seems very likely that MLPs will become an indispensable tool to fight against social determinants of health.

MLPs are important because traditional health and legal services treat individuals in isolation from each other, resulting in a system where people can fall through the cracks. The MLP model bridges this divide by focusing on giving individual patients the comprehensive care that they need.⁸ There is fluidity to the organization of these various models. MLPs vary in size and scope, but are comprised of at least one legal institution and one healthcare institution in the community.⁹ Successful MLPs establish and maintain active engagement of key leaders at every level, from front lines to administration, in both the healthcare and legal partner institutions. Legal staff are present at the healthcare institution on a regular basis.¹⁰ Working together, healthcare and legal teams devise strategies for efficient referrals, joint data collection and monitoring, and fundraising to ensure high quality patient-centered care in the medical home.¹¹

The current national model, as laid out by the National Center for Medical Legal Partnerships, focuses on three core components: (1) direct service for patients and families, (2) training for healthcare staff, and (3) joint medical-

legal systems and policy change and advocacy.¹² Direct service in the healthcare setting focuses on legal professionals becoming members of the healthcare team to assist patients with legal issues, such as unhealthy housing conditions. This ensures timely access to assistance. Training and practice transformation allows the MLPs to reorient health and legal services to include early detection and preventive care through training and education of all health care staff, including: medical students, residents, nurses, social workers and practicing physicians. It also allows the MLP teams to improve institutional practices and to address legal needs, such as establishing a hospital policy regarding low-income utility protections. Finally, policy change and advocacy involves the use of MLP teams to leverage health and legal expertise to improve local, state and federal laws and regulations that impact the health of vulnerable populations. The goal is to find a system wide solution to improve health.

The major source of startup funding for most MLPs is private non-governmental grant money from the National MLP Organization (the National Organization). New MLPs can gain access to this money through the **National Organization’s website**, which includes documents for creating a budget and applying for grants. The National Organization usually distributes startup funds to MLPs that are trying something novel or performing research on the benefits of MLPs.¹³ Governmental grants are becoming more rare as the idea of MLPs is becoming better known and more widespread. A report published by the National Organization showed that MLPs receive less than 4% of their funding through governmental resources, with the majority of funding

for continuing the work of the MLP coming from private donations.¹⁴ With these startup funds, MLPs are able to start building a model that connects with all the needs of their patients.

Patients report that after their encounter with a MLP they feel more empowered, their stress level is reduced, and they experience an improvement in their general health. There is a relationship between **patients’ stress levels and being under the care of a MLP**; Patients reported that the decrease in concern over dealing with legal issues related to their illness allowed them to give more attention to their treatments and increased their quality of life.¹⁵

A pilot study done in 2010 found that patients also reported a general improvement in their health after taking advantage of MLPs.¹⁶ This pilot study suggests that the addition of a legal aid attorney to the medical team can increase access to legal and social services and decrease barriers to health care.¹⁷ Of particular promise were increased awareness and use of free legal services, increased access to food and income supports, decreased barriers to health care and reported improvement in child health and well-being. The study also noted a decreased frequency of hospitalizations but did not draw conclusions, as the study did not focus on information on indications for hospitalization.¹⁸ Overall the study demonstrated high participant satisfaction with integration of legal services in the clinical setting.¹⁹ Health care facilities also reported high level of satisfaction

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‘Punishment, Prevention, Protection and the Challenge of Diagnosing Mental Disorders,’ Continued

This imprecision constitutes a significant threat to the legitimacy of the court’s system of confinement, commitment, or punishment.¹⁸ If a defendant’s mental status—which directly relates to her culpability—may only be determined by the flawed processes outlined above, the court’s decision becomes vulnerable to challenges on fairness and equal treatment under the law.¹⁹ Psychiatry, like any science, constantly undergoes change and modification, but the implications that arise from this evolution have repercussions for individuals facing a potential loss of freedom now.

David Eagleman discusses these challenges in his article on new developments in brain imaging and its impact on criminal sentencing.²⁰ Eagleman focuses on the improvements made in identifying parts of the brain that influence and determine behavior and personality, and argues that these imaging technologies will eventually allow judges and juries to assess an individual’s culpability, volition, and even propensity for recidivism.²¹ He argues that courts will no longer be forced to rely on statistical predictions or the

opinion of a mental health expert.²² The imaging technology would render an empirical judgment on the defendant’s culpability, effectively removing the court’s burden of determining the defendant’s mental status. This new level of objectivity would dramatically reduce the fairness concerns raised by expert testimony and more traditional clinical diagnosis.²³ Though this argument raises difficult questions about free will and determinism, it does address the central issue now facing both the courts and the mental health profession: how best to make a meaningful diagnosis of mental disorders affecting an individual’s ability to interact with and participate in society.

The technology discussed by Professor Eagleman is still in the developmental stages, and would likely take a substantial amount of time for the criminal court system—as well as the American people—to accept and assimilate its implications, especially those concerning free will. Acceptance of the new technology would be predicated upon an absence of concern over imprecision and possible misdiagnosis, which so hampers clinical practitioners

now. Other legal scholars have offered alternatives to the “battle of the experts” approach, most notably Professor Stephen Morse’s argument that juries alone should measure and judge a defendant’s “craziness” (Morse’s term for socially unacceptable behavior) in relation to the general population.²⁴ For Morse, only juries are capable of determining how far outside the realm of acceptable or normal conduct a defendant has gone.²⁵ In deciding whether the defendant’s actions were “crazy,” the jury determines the defendant’s mental status.²⁶ Yet this approach carries the same risks of unfairness and lack of legitimacy that the “battle of the experts” model does. It is neither objective nor empirical. It would seem that until the advent of brain imaging technology that explicitly measures culpability and volition, we are left with a fairly imprecise, and potentially unfair, method of dealing with mental disorders. ☼

‘A Prescription for Change,’ Continued

ing.⁶² The fact “that Wyeth did not manufacture or sell the metoclopramide Conte ingested [did] not relieve Wyeth from its general duty to use due care in disseminating product information”⁶³ to patients who could foreseeably be harmed by their reliance on the brand manufacturer’s information. In light of industry practice, where the brand manufacturer provides all the labeling information, and in the

aftermath of the *PLIVA* decision, the holding in *Conte* could seemingly apply to all failure-to-warn cases in which the plaintiff took the generic version of a drug.⁶⁴ Therefore, the *Conte* decision may ultimately turn out to be much more influential as plaintiffs seek to invoke the theory of innovator liability as a way of holding the brand manufacturers liable.

Critics of the *Conte* Decision are Mistaken

Critics of the *Conte* decision fail to properly understand the critical distinction the court made between product liability and strict liability.⁶⁵

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with the integration of health and legal service.

Preliminary evidence shows that MLPs help reduce barriers to care in the medical home and help institutions that serve indigent populations. With a MLP, these institutions, obtain more reimbursement for the care they provide while helping people meet their legal needs.²⁰ Receiving this reimbursement makes the creation of MLPs financially attractive to health care facilities and could help to lower operating costs.

Another benefit that is evident to health care facilities is the utilization of health care recovery dollars. Health care recovery dollars are funds reimbursed to hospitals as a result of a successful appeal of improperly denied Medicaid or Social Security Disability application.²¹ Normally, when a hospital has treated an uninsured individual whose application for public health insurance has been denied, the hospital will remain unpaid for those services provided.²²

Yet if a legal service organization can help that individual successfully appeal his or her Medicaid denial, the hospital can then re-bill Medicaid for the services rendered since the initial date of application (and oftentimes before) and be reimbursed for the healthcare provided to that now-insured patient.²³ In this way, the legal services provided have a direct financial impact on the hospital; legal aid organizations become moneymaking partners with their medical counterparts. While the **advocates’ goal is to benefit the client**, his or her advocacy work directly **enriches the medical center “on the back end.”**²⁴ Health care recovery dollars projects capitalize on that back end benefit to create a business partnership with the hospital.²⁵

Within this program model, hospitals identify which of their patients have applied for and been denied Medicaid or other public health insurance and benefits programs. They use various referral systems to direct those patients to the legal organization, which has an office or set office hours within the hospital. The legal services organization processes high numbers of appeals cases, **carefully tracking which clients’ appeals have been granted and the amount of medical debt that each client is considered to owe to the hospital.**²⁶ As part of any **medical debt case, the advocate’s job is to contact the hospital billing department, alert them that the client is now insured, and demand that the billing department stop billing the client and instead re-bill Medicaid.**²⁷

It is important to note that the model could work backwards as well: medical-legal partnership programs that focus on other areas of law could begin to

part of representing the client; it’s necessary to get the bills re-sent to Medicaid. All that is different in this model is that one is claiming credit for the money coming in, and having the hospital track the benefits that an individual has been getting for them all along.

What started as a small idea between one doctor and one lawyer in 1993 has turned into a movement that cannot be ignored. The benefits for patients and healthcare providers alike are immense. Given the current changes in our health care system and a desire to drive down costs, this is a viable option to address the problems of excess spending within the system. MLPs require further monetary and ABA support because they truly are able to generate better patient outcomes and lower costs to hospitals, presenting to viable solution to the current state of health care within the United States. ✨

“PRELIMINARY EVIDENCE SHOWS THAT MLPs HELP REDUCE BARRIERS TO CARE IN THE MEDICAL HOME AND HELP INSTITUTIONS THAT SERVE INDIGENT POPULATIONS.”

incorporate a large number of Medicaid and Supplemental Security Income appeals cases into their repertoire, track the benefit to their partner medical institutions, and then use that financial data to argue for a shift in the character of their relationship with their partner medical institution. For a program that already exists, there is little need to change forms, etc., because telling the hospital that the client is now insured is

‘A Prescription for Change,’ Continued

Product liability claims require proof of negligence while strict liability claims do not require such evidence.⁶⁶ Strict liability applies only to the manufacturer and to the sellers that place the allegedly defective product on the market,⁶⁷ but the decision in *Conte* does not challenge this proposition in any way.⁶⁸ The court expressly stated that strict liability cannot apply to a brand manufacturer when the plaintiff took the generic form of the drug produced by a different manufacturer.⁶⁹ Justice Siggins articulated that “[n]egligence and strict products liability are separate and distinct bases for liability that do not automatically collapse into each other”⁷⁰ merely because the plaintiff was able to assert both claims.⁷¹ When a plaintiff’s claim of strict liability fails, it does not preclude the plaintiff from asserting other forms of liability. Rather, the principles of tort liability apply which provide that defendants who caused foreseeable harm can be held liable for their negligence.⁷² Consequently, even though a brand manufacturer cannot be held strictly liable for the harm to patients who took its generic equivalent, the manufacturer can potentially be liable if it was negligent in failing to adequately warn the patient through its labeling.⁷³ The brand manu-

facturer is not being blamed for producing the generic drug; rather, the manufacturer is being held liable because it was negligent in failing to adequately warn the patient through its labeling.⁷⁴

Moreover, the critics of *Conte* have incorrectly insisted on the unfairness of the decision since brand manufacturers have no control over the drugs produced by the generic companies.⁷⁵ While this is true of the actual product, it is not true about the product labeling.⁷⁶ All of a drug’s information is derived from the brand manufacturer and they are the only manufacturer that can update or change a medication’s labeling.⁷⁷ Brand manufacturers can readily foresee that generic companies will imitate their drugs, and through the FDA, the brand manufacturers can force the generic companies to conform to the brand’s labeling requirements.⁷⁸ In fact, this is the cornerstone of federal law which requires generic manufacturers to ensure that their labeling exactly match the brand drug’s labeling.⁷⁹

The Supreme Court in *PLIVA* specifically held that generic manufacturers cannot unilaterally change their labeling and must always conform to the brand’s labeling.⁸⁰ Thus, the only avenue for a generic manufacturer to change their labeling to reflect new warnings is to have the brand manufacturer first change its labeling. The brand manufacturers have complete control over the labeling requirements because they dictate the information that can be on the generic label. For example, if a “plaintiff took a generic drug, the brand-name manufacturer will not be subject to strict liability; it will be liable only if it failed to use reasonable care in...crafting the drug’s warnings, instructions, or promotional statements.”⁸¹ Therefore, holding the brand manufacturer liable for negli-

gence when its actions were a significant cause of a plaintiff’s injury is fair. The harm suffered by the plaintiff would have been the same regardless if they received the brand or generic medication. It would be unjust to punish the patient simply for receiving the generic, rather than the brand version of the drug. Rather, the injustice of allowing brand manufacturers to claim immunity from the injuries caused by generic drugs is remarkably severe in the sense that it would mean no drug manufacturer would be legally responsible.⁸²

Limitations and Defenses to *Conte*

Nevertheless, the decision in *Conte* is not without its limitations. First, *Conte* was decided on summary judgment and not at trial. Accordingly, the court stated that policy implications, such as the “burdens, societal consequences, cost, and insurance implications” were not fully explored.⁸³ Hence, the broader consequences of duty could not be considered and it was left up to the jury to ultimately determine Wyeth’s liability.⁸⁴

In addition, brand manufacturers may attempt to avoid liability by assigning the rights of the medication to the generic competitor once the brand patent expires.⁸⁵ In theory, the brand manufacturer would be assigning away its liability and responsibility to continually update the drug labeling.⁸⁶ The responsibility to update the labeling would then fall squarely on the shoulders of the generic manufacturer.⁸⁷ However, this tactic will prove difficult

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“AN EXPANSION OF CONTE COULD HAVE THE NEGATIVE EFFECT OF DETERRING THE BRAND MANUFACTURERS FROM DEVELOPING NEW DRUGS, AS WELL AS REDUCING THE INCENTIVE OF GENERIC MANUFACTURERS TO ENSURE THE CONTINUED SAFETY OF THEIR OWN DRUGS.”

‘A Prescription for Change,’ Continued

in practice because it is very unlikely that the FDA would permit such assignments.⁸⁸ Also, the assignment of liability may limit the prospective labeling issues for the brand manufacturer, but it would not necessarily protect the brand manufacturer from negligence claims arising prior to any assignment.⁸⁹ Such an argument would be contrary to law and against the public policy of promoting safe and effective medications.⁹⁰ The generic manufacturer would also insist on an indemnification clause since all of the data regarding the drug was collected by the brand manufacturer.⁹¹ After the *PLIVA* decision, FDA regulations clearly set forth that a generic manufacturer cannot unilaterally change its drug labeling; the change must first be done by the brand manufacturer.⁹² This in effect frustrates the reasoning behind the brand manufacturer assigning away the rights to their drug.

Lastly, to protect itself from liability, the brand manufacturer may consider voluntarily withdrawing their drug from the market at the end of the exclusivity period.⁹³ The reasoning behind this tactic is that the generic manufacturers would then have no labeling to copy and no information to rely upon and thus could not market the drug.⁹⁴ However, the Hatch-Waxman Act anticipated this and provided an exception which would allow generic manufacturers to continue to market the generic version as long as the original drug was not withdrawn for safety and efficacy reasons.⁹⁵ Thus, the withdrawal of the **brand manufacturer’s medication** does not necessarily prevent generic manufacturers from continuing to market their generic equivalent.⁹⁶

Conclusion

As the number of available generic medications on the market continues to

rise,⁹⁷ the Court’s decision in *PLIVA* will have broad ramifications for brand manufacturers and the public. While the decision in *Conte* represents one critical approach to assigning liability to brand manufacturers, it must be noted that imposing liability on drug manufacturers deserves a cautious and thorough analysis by the courts.⁹⁸ An expansion of *Conte* could have the negative effect of deterring the brand manufacturers from developing new drugs, as well as reducing the incentive of generic manufacturers to ensure the continued safety of their own drugs.⁹⁹

Brand manufacturers develop enormously valuable products that benefit modern medicine, and tort law must not go too far towards discouraging the innovation of new drugs.¹⁰⁰ If every individual harmed by a generic medication was allowed to bring suit against the brand manufacturer, it would be disastrous for the drug industry. This risks driving brand manufacturers from the market and the search for safer and more effective pharmaceuticals would be hindered. On the other hand, pharmaceutical companies have been held responsible for serious drug disasters in the past, such as with Diethylstilbestrol (DES) and thalidomide, and tort liability is one safeguard to protect against the reoccurrence of such events.¹⁰¹

While twenty-two states have already addressed the question of brand liability and sided with the *Foster* court, the majority of the states have yet to determine the issue.¹⁰² Especially after *PLIVA*, state courts now faced with the matter may increasingly turn to the reasoning in *Conte* and the theory of **innovator liability**. To date, the FDA’s regulatory oversight has proven ineffective in preventing dangerous drugs from coming to market and tort law provides

vital incentives for drug manufacturers to act with the appropriate care.¹⁰³ Striking the right balance between encouraging drug manufacturers to continue to produce innovative products and yet also ensure that their products are accompanied by adequate warnings is a difficult task the courts must strive to meet.¹⁰⁴ ✧

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- 81 Rostron, *supra* note 4, at 1176-77.
- 82 *Id.* at 1177 (both the brand name and generic manufacturers will insist that they can have no liability. The brand name manufacturer will say the plaintiff did not take its product and the generic drug maker will assert the holding in *PLIVA* stating they could not unilaterally alter their warning label. Accordingly, both drug companies will argue they should escape liability in those circumstances, even if both were negligent and their wrongdoing caused harm to the plaintiff).
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Penalties for Federal Health Privacy Violations: Are they Sufficiently Enforced?

1 News Release, *HHS Imposes a \$4.3 Million Civil Penalty for Violations of the HIPAA Privacy Rule*, U.S. Department of Health and Human Services, Feb. 22, 2011, [available at http://www.hhs.gov/news/press/2011pres/02/20110222a.html](http://www.hhs.gov/news/press/2011pres/02/20110222a.html); The HIPAA Privacy Rule – located at 45 CFR Part 160 and Subparts A and E of Part 164 – “establishes national standards to protect individuals’ medical records and other personal health information...The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.” *The Privacy Rule*, U.S. Department of Health and Human Services, [available at http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html](http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html).

2 *Id.*; While HHS had brought violations against other entities in the past, including Providence Health and Services, CVS Pharmacy, and the Rite Aid Corporation, these violations were all settled before a civil money penalty was issued. *See* James B. Wieland and Joshua J. Freemire, *Corrective Action Plans Can Mean Significant Compliance Monitoring Requirements*, HEALTH LAW ALERT, July 19, 2011, [available at http://www.ober.com/publications/1454-corrective-action-plans-can-mean-significant-compliance-monitoring-requirements](http://www.ober.com/publications/1454-corrective-action-plans-can-mean-significant-compliance-monitoring-requirements).

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5 News Release, *University of California Settles HIPAA Privacy and Security Case Involving UCLA Health Systems Facilities*, U.S. Department of Health and Human Services, July 7, 2011, [available at http://www.hhs.gov/news/press/2011pres/07/20110707a.html](http://www.hhs.gov/news/press/2011pres/07/20110707a.html); Corrective Action Plans (“CAPs”) “require specific corrective action obligations to prevent another violation, with appropriate tailoring to address the gaps in the entity’s policies and procedures that led to the violation at issue...The entity must also present an implementation report to HHS within a specified number of days after the entity’s policies and procedures are approved...The entity, finally, submits an Annual or Periodic Report to HHS each year the CAP is in force. This Report, among other entity-specific requirements, includes disclosing training schedules and materials; confirmation that the entity has certifications from all members of the workforce that went through training; summaries of any violations; and certification that a designated entity representa-

tive reviewed the Report and confirms the information is accurate and truthful;” Anna Timmerman, *HIPAA Settlements Between Healthcare Providers and the Government*, BECKER’S ASCREVIEW, June 23, 2009, [available at http://www.beckersasc.com/news-analysis/hipaa-settlements-between-healthcare-providers-and-the-government.html](http://www.beckersasc.com/news-analysis/hipaa-settlements-between-healthcare-providers-and-the-government.html); for an example of a Corrective Action Plan. *See* Exhibit 2 of the Rite Aid Resolution Agreement, [available at http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/riteaidres.pdf](http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/riteaidres.pdf).

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8 45 C.F.R. § 164.502 (2006); Use and disclosure of protected health information is also permitted, and sometimes required, under some more specialized circumstances. For example, as required for public health purposes or under a limited data set. *See* 45 C.F.R. § 164.514(e).

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20 HIPAA does not provide for individual causes of action. *See e.g., Acara v. Banks*, 470 F.3d 569 (5th Cir. CA, 2006) (upholding a district court decision that HIPAA does not afford a private right of action). However, HHS does accept Privacy Rule violation complaints from anyone. *See* Health Information Privacy Complaint Form, [available at http://www.hhs.gov/ocr/privacy/hipaa/complaints/hipcomplaintform.pdf](http://www.hhs.gov/ocr/privacy/hipaa/complaints/hipcomplaintform.pdf). Some have argued against this existing framework and instead for an individual cause of action. A private right of action would provide individualized rights of action for aggrieved patients. *See, e.g.,* Joshua D.W. Collins, *Toothless HIPAA: Searching for a Private Right of Action to Remedy Privacy Rule Violations*, 60 VAND. L. REV. 199 (2007).

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- 24 James B. Wieland and Joshua J. Freemire, *Corrective Action Plans Can Mean Significant Compliance Monitoring Requirements*, HEALTH LAW ALERT, July 19, 2011, *available at* <http://www.ober.com/publications/1454-corrective-action-plans-can-mean-significant-compliance-monitoring-requirements>.
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- 26 See *supra*, note 20; “Although the [HIPAA] statute allows the HHS Secretary to impose civil and criminal sanctions on those who blatantly ignore the Privacy Rule regulations, this type of enforcement only deters future violations – it does nothing to compensate those patients who have suffered real and direct harm as a result of such unauthorized disclosures.” Joshua D.W. Collins, *Toothless HIPAA: Searching for a Private Right of Action to Remedy Privacy Rule Violations*, 60 VAND. L. REV. 199, 232 (2007).
- 27 See 45 C.F.R. § 160.306 (2006); Health Information Privacy Complaint Form, *available at* <http://www.hhs.gov/ocr/privacy/hipaa/complaints/hipcomplaintform.pdf>.
- 28 “Regardless of any enforcement action taken by HHS, the victim will not be compensated for the harm caused by this breach of [his or her] privacy...Unless patients harmed by the improper disclosure of their private medical records are able to bring actions against the responsible parties, HIPAA’s Privacy Rule will remain woefully under-enforced, and Congress’ goal of protecting medical privacy will remain frustratingly out of reach.” Joshua D.W. Collins, *Toothless HIPAA: Searching for a Private Right of Action to Remedy Privacy Rule Violations*, 60 VAND. L. REV. 199, 202-03 (2007).
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- 36 HIPAA requires covered entities to implement certain policies and procedures, or administrative requirements, regarding personal health information that are designed to aid in Privacy Rule compliance. These administrative requirements include, but are not limited to, documenting a privacy official, documenting workforce training, documenting workforce sanctions, documenting mitigation of violations, and documenting compliance policies and procedures. 45 C.F.R. § 164.530 (2006).
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Student Contributors



Lauren Glozzy is a second-year student at Seton Hall University School of Law. She graduated from Villanova University in 2009 with a major in English and a minor in Business. After graduating from college, Lauren worked for a health care company which peaked her interest in health law. She is also interested in taxation and after law school; Lauren plans to work within a government regulatory agency or hospital.



Jessica Huening is a research associate at the Center for Behavioral Health Services and Criminal Justice Research (CBHS&CJR). There she is involved with several projects and works that seek to improve the availability and effectiveness of services for individuals with mental illnesses who are involved with the criminal justice system. Prior to her work at CBHS&CJR she worked as an IRB analyst at the Mount Sinai School of Medicine and as a research coordinator at the Nathan Kline Institute for Psychiatric Research. Her research interests include: the social systems of, and services provided for, vulnerable and high-risk populations involved with the criminal justice system; policy initiatives that affect individuals with mental illness and high-risk populations involved with the criminal justice system; healthcare law and ethics; and the regulations and policies concerning the use of human subjects in research.



Jonathan Keller is a second-year student at Seton Hall University School of Law. He graduated with a doctorate degree in pharmacy (Pharm. D.) from Rutgers University, Ernest Mario School of Pharmacy. He was a summer associate at the law firm Wilentz, Goldman & Spitzer in Woodbridge New Jersey, where he worked in the mass tort/toxic tort division. While there, Jonathan worked on a variety of health care issues, ranging from Medicare/Medicaid fraud to class action law suits involving pharmaceuticals. He is currently a practicing pharmacist at a retail pharmacy and looks forward to entering the field of health law.

Student Contributors (Continued)



Anthony W. Liberatore is a second-year student at Seton Hall University School of Law pursuing the Health Law Concentration. He graduated from Loyola University Maryland (formerly known as Loyola College in Maryland) in 2007 with a major in Sociology and a minor in Political Science. His health care experience includes an internship at the Baltimore City Health Department, volunteer experience in a community hospital emergency room, and research on the medical treatment of seriously ill and injured undocumented workers in the United States.



Ben Smith is a second-year student at Seton Hall University School of Law. He graduated from the University of Georgia with a B.A. in English and Philosophy. After graduation, he became certified and worked as an EMT/Paramedic in the Emergency Room at Kennestone Hospital in Atlanta, GA. During his time at Kennestone Hospital, Ben served on the Shared Governance and Error Prevention Boards, which involved working with the general counsel for the Hospital. These interactions led to his interest in the interplay between health law and healthcare delivery.



Sarah Turk is a second-year law student at Seton Hall University School of Law. She graduated from Fordham University with a B.A. in History and Theology. Her interest in health law comes from being an EMT for the past 4 years. At Seton Hall, she has done research for Professor John Jacobi on issues relating to the implementation of the Patient Protection Affordable Care Act and hopes to continue focusing her interests on health law.



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