



Health Law Institute Newsletter

Monitoring the pulse of health law

Volume 1, Number 1

September/October 2004

PATIENTS CALL FOR MORE HEALTH CARE ACCESS AND INFORMATION: THE SUNSHINE STATE ANSWERS

Millions of American healthcare consumers are now facing increasing health insurance premiums and decreasing employer based coverage. Providers and employers are asking patients to be savvy consumers with their health care decisions. Patients are being asked to investigate the range of health services offered, their costs, and coverage levels offered by their health care insurance plans and providers. How are states charged with protecting the health and safety of their citizens helping?

On June 14, 2004, Florida Governor Jeb Bush signed House Bill 1629 into law. This Act is a legislative effort to provide Floridians with health care cost and quality information so they can make better informed health care decisions. This legislation creates the 2004 Affordable Health Care for Floridians Act. The Act is based in large part on recommendations by the Governor's Task Force on Access to Affordable Health Care and the House of Representatives Select Committee on Affordable Health Care for Floridians. The Act provides for

several health care consumer measures for Florida citizens: improves access to quality health care, provides affordable health care, and directs the Florida Agency for Health Care Administration (AHCA) to implement new initiatives and expand current programs that will improve Florida's health care system.

The Act's measures include among the following:

- **Transparency in Health Care Service Pricing:** Health care facilities are required to provide a website link on the AHCA website which allows consumers to obtain hospital and ambulatory surgery and related charges for both inpatient and outpatient procedures.

- continued on page 2

News of Interest: *GAO Report: Medicare: CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals*

The Government Accountability Office (GAO) recently issued a report finding that JCAHO's pre-2004 hospital accreditation process did not identify most of the hospitals found by state survey agencies to have deficiencies in Medicare requirements. In a sample of 500 JCAHO accredited hospitals from 2000-2002, state survey agencies identified 157 hospitals (31%) as having "serious deficiencies" with Medicare requirements. Of those hospitals, JCAHO did not identify 123 hospitals (78%), as having deficiencies in Medicare requirements, approximately 69% of the total number of deficiencies in Medicare Requirements found by state agencies. However, the most alarming statistic is that the number of deficiencies found by the validation survey only represents about 2% of the 11,000 Medicare requirements surveyed by state agencies during this period. Examples of the deficiencies JCAHO failed to identify include inade-

quacies in nursing care and the hospital's physical environment.

JCAHO responded with concerns over the methodology used by GAO in its report, stating it was "incomplete and did not comprehensively assess the performance of JCAHO's hospital accreditation program." JCAHO further argued that the report did not consider the potential of JCAHO's new hospital accreditation process to improve the detection of deficiencies in Medicare requirements because the new process was just implemented in January 2004.

- continued on page 5

Inside this issue:

Health Care Access	1
GAO Report	1
Domestic Violence Victims	2
Case Notes	3
Pharmaceutical Settlements	3
Tort Reform	5
Stem Cell Debate	5
Drug Importation	6
Healthcare Disparities	6
Recent Publications	7

Fall Lecture Series

Welcome Reception

Health Care As A Right

Presenter: Jesse Jackson, Congressman

September 22, 2004

HIPAA: An Overview

Presenter: Ericka Adler, Partner, Comisnsky, Rubenstein, Hechman & Delott, LLP

October 4, 2004

Maternal/Fetal Conflict: Miller v. HCA, Inc.

Presenter: John Paris, Professor, Boston College

November 2004

Boutique Hospitals

Presenter: James Unland, CEO, Health Capital Group

- **Emergency Room (ER) Diversion Programs:** In an effort to encourage cost reduction in emergency care services hospitals may now develop ER diversion programs such as a fast track clinic for minor injuries and illnesses to an emergency hotline which will assist patients in determining whether the ER is the best place to obtain care. The Act makes it a joint responsibility for health care providers and insurers to inform patients of these low cost treatment options to urgent care.
- **Health Care Provider Performance Information:** Allows health care consumers to compare health care facilities. Hospitals and ambulatory care facilities are required to submit inpatient and outpatient data to the AHCA including the number of patients treated in the ER by performance measures such as: level of acuity, infection rates, and complication rates. The data compiled will be risk adjusted by AHCA.
- **Electronic Health Records:** AHCA is required to create and implement a strategy for the adoption and use of electronic health records.
- **Quality Improvement and Reduction of Medical Errors:** The Florida Patient Safety Corporation is created as a non-regulatory

educational organization which will assist health care providers to improve the quality and safety of health care services provided to patients.

- **Alternative Small Employer Health Insurance Market:** The Florida Health Insurance Plan is created to provide health insurance coverage for high-risk individuals who cannot get individual health insurance due to health reasons or high cost of coverage. High-risk pools also offer the consumer price protection and choice of high-quality health plans.
 - **Small Employer Access Program:** Creates purchasing pools by regions for small employers with 2-25 employees who had no health insurance coverage for the last 6 months, nursing home employees, as well as for any municipality, county, school district, or hospital located in a rural community.
 - **Health Savings Accounts (HSAs):** HSAs allow individuals and employers to contribute money to a savings account for their health care needs on a preferred tax basis. The Act requires small group coverage carriers to offer high-deductible plans which meet the federal HSA standards effective January 1, 2004.
- "This Act will improve patient safety and provide con-

sumers with information they have never had access to before....[it demonstrates] a commitment to improving health outcomes and making access to health care a priority for this state", said Alan Levine, AHCA Secretary.

For more information visit www.leg.state.fl.us (HB 1629) and www.saveforyourhealth.com (HSAs)

- By Carlota Toledo,
Assistant Director,
Health Law Institute

"This Act will improve patient safety and provide consumers with information they have never had access to before"

<p>2004-05</p> <p>Symposia</p> <p>at</p> <p>DePaul University</p> <p>College of Law</p> <p>Friday, March 4,</p> <p>and</p> <p>Saturday, March 5,</p> <p>2005</p>	<p>DePaul Law Review:</p> <p><i>Precious Commodities: The Supply and Demand of Body Parts</i></p> <p>DePaul Health Law Journal:</p> <p><i>Disentangling Fact From Fiction: The Realities of Unequal Health Treatment</i></p>
--	--

News of Interest: *Asylum for Domestic Violence Victims*

In Guatemala, Rodi Alvarado was severely beaten by her husband, Francisco Osorio, a former Guatemalan soldier, for over a decade. On five separate occasions, Alvarado sought help from the Guatemalan police. However, neither the police nor the courts would intervene because it was a domestic matter. As a result, Alvarado fled to the United States in 1995 seeking a better life. In 1996, an immigration judge in the United States granted Alvarado asylum. Nevertheless, three years later, the Board of Immigration Appeals reversed the decision because Alvarado did not fit into one of the five categories of persecution for which asylum is granted: race, religion, ethnicity, political associations,

or membership in a particular social group. The then-Attorney General Janet Reno voided the Board's ruling and ordered them to issue a new decision based on proposed Justice Department regulations. These regulations were to declare domestic violence as grounds for asylum but were never finalized due to the change in administration. Yet, the new Attorney General, John Ashcroft, decided to reexamine Alvarado's case in 2003. Currently, her case remains under consideration.

- continued on page 7

Case Note: *Aetna Health Inc. v. Davila*, 124 S. Ct. 2488 (2004)

Respondents, a plan participant, and a beneficiary in ERISA-regulated employee benefit plans, brought separate Texas state-court suits alleging that petitioners, their respective HMOs, had refused to cover certain medical services in violation of an HMO's duty "to exercise ordinary care when making health care treatment decisions", and that those refusals "proximately caused" respondents' injuries under the Texas Health Care Liability Act (THCLA). Petitioners removed the cases to Federal District Courts, arguing that respondents' causes of action fit within the scope of, and were therefore completely pre-empted by, ERISA § 502(a). The District Courts agreed and dismissed the complaints with prejudice after respondents refused to amend the complaints to bring explicit ERISA claims. The Fifth Circuit reversed, determining that respondents' claims did not fall under the scope of ERISA § 502(a)(2) because petitioners were being sued for mixed eligibility and treatment decisions that were not fiduciary in nature.

The United States Supreme Court granted certiorari and concluded that the legislation enacted ERISA to provide a uniform regulatory system in employee benefit systems and to protect those employees in such systems. The Court found that the respondents were complaining about denials of coverage, a "pure eligibility decision," and an HMO's denial of coverage is not a medical determination that would allow a malpractice claim, but that it was an administrative decision. Respondents sued only to rectify a wrongful denial of benefits promised under ERISA-regulated plans and do not attempt to remedy any violation of a legal duty independent of ERISA. Therefore, Respondents' state causes of action fell within the scope of ERISA § 502(a)(1)(B).

- Anne Brown and Dayna Vidas

Case Note: *Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004)

The Supreme Court of Minnesota held that physicians owe a duty to biological parents to test for and diagnose a genetic disorder if it is reasonably foreseeable that the parents would be injured by a lack of diagnosis.

The plaintiff alleged that the defendant physicians failed to test for and diagnose a genetic disorder in her three year old daughter, causing the plaintiff to conceive another child with the same genetic disorder. The prevailing standard of care in the medical community showed that if a patient exhibited symptoms of the disorder, combined with the family history, the physician should 1) order the tests for Fragile X, and 2) confirm that the testing has indeed occurred. Each one of the defendants was on notice that the plaintiff's daughter showed symptoms of Fragile

X and that there was a family history of mental retardation. Therefore, the physicians owed a duty to the daughter and her parents for genetic testing and diagnosis, as well as the resulting medical advice. Yet, not one of these doctors ordered the testing to diagnose Fragile X.

The court concluded that the harm to the family was foreseeable when the family relied on the physician to communicate the diagnosis of a genetic disorder, especially when the family was advised by the physicians of the need for such genetic testing.

- April Vesely

News of Interest: *Pharmaceutical Settlements*

In the past two months, the federal government announced major settlements involving some of the largest pharmaceutical companies and their subsidiaries. On July 30, the United States and Philadelphia Attorney's Offices released a press report disclosing that both the Schering Sales Corporation and the Schering-Plough Corporation agreed to a global resolution in which they would pay \$345 million in fines to settle criminal and civil charges in connection with the widely used allergy drug Claritin.

Schering Sales plead guilty to criminal charges and agreed to pay a \$52.2 million fine for violating the federal Anti-Kickback Act. The Information filed on July 30 charged that in the late 1990s a major health maintenance organization ("HMO") contacted Schering Sales and demanded a reduction in price for Claritin, which cost the HMO millions of dollars more to purchase Claritin for their beneficiaries compared with other allergy medications. Had Schering Sales agreed to lower the price of Claritin they would have been required to similarly lower the price charged to the Medicaid programs. In response to Schering Sales denial, the HMO responded by

removing Claritin from its formulary (a list of prescription drugs that an HMO will cover for its beneficiaries); rather than lose one of their best customers, Schering Sales paid the HMO a kickback in the amount of \$1.8 million in order to keep Claritin on their formulary at the elevated price. Further, Schering Sales offered to provide the HMO with a "value added" package totaling \$10 million, which included in part, Schering Sales to annually pay the HMO 2% of the gross sales of all Schering drugs.

- continued on page 7

Case Note: *Garhart v. Columbia/Healthone*, 95 P.3d 571 (Colo. 2004)

The Supreme Court of Colorado held that capping damages in medical malpractice cases is constitutional. A mother and her child questioned the constitutionality after both suffered permanent injuries, resulting from the hospital's negligence during the childbirth.

Colorado's Health Care Availability Act ("HCAA") places a cap of \$1,000,000 on damages, yet no more than \$250,000 of that award shall be attributable to noneconomic losses. The court denied each of the plaintiff's challenges to the constitutionality of this statute. First, the court held HCAA does not infringe on the plaintiffs' right to receive a jury award because there is no constitutionally provided right to a jury trial in civil cases. Second, HCAA does not interfere with the trial court's remittitur

power seeing that a jury is still able to determine if the award is excessive. Third, because the statute is substantive and not an attempt to regulate the operation of the courts, there is no constitutional challenge regarding the issue that "HCAA damages caps forces a court to enter a judgment based not on a jury's verdict, but on a statute." Finally, the plaintiffs were treated exactly like any other negligence victim whose cause of action accrued on September 4, 1996, thus resulting in no disparate treatment and no denial of equal protection.

- April Vesely

Case Note: *Joshi v. St. Luke's Episcopal-Presbyterian Hosp.*, No. ED 83566, 2004 WL 1554486

This case is premised on suspension of the plaintiff's medical staff privileges based on the Hospital's internal peer review procedure under the Health Care Quality Improvement Act. The trial court granted the Hospital's summary judgment motion and Joshi appealed. Joshi claimed the Act is unconstitutional since it deprives physicians of a jury trial and that the evidence the court relied on was inadmissible. However, he did not raise either issue in the trial court. His remaining claims dealt with whether the defendants were entitled to immunity under the Act.

Joshi argued that the defendants did not meet their requirements under the Act because Joshi's supervisor, the Chief of the Anesthesiology Department, acted alone without peer review and the Hospital failed to make reasonable efforts to find the facts of the matter. However, the record showed the supervisor reviewed cases submitted to the peer review committee, worked with the Head Nurse who received numerous complaints about Joshi, reviewed complaints from two other doctors, and consulted with another doctor to get an independent evaluation. Based on this, Joshi's privileges were temporarily suspended pending a full hearing. The appellate court agreed with

the trial court and ruled that the defendants' efforts constituted a proper professional review and that the defendant was more than reasonable in its efforts.

Joshi also argued that he was deprived the full hearing and was not provided reasonable notice for a hearing. However, the notice was not relevant since the defendants' determined that Joshi posed an immediate threat to patient care. Furthermore, although the full hearing had been scheduled, it was canceled by Joshi. The court held it is disingenuous for the plaintiff to cancel the hearing and then argue that he was denied that right. Joshi further contended that the actions of the Hospital were taken in bad faith based on his efforts to unionize anesthesiologists. This point was irrelevant since the defendant had a reasonable belief that the suspension of Joshi would further the quality of health care.

- David Brueggen

Case Note: *Knowles v. Superior Court*, 13 Cal. Rptr. 3d 700 (Cal. Ct. App. 2004).

The decedent's wife, daughter and two sons filed a wrongful death suit, alleging negligence by Knowles in performing a renal stenting. One son is mentally disabled and therefore is unaware his father has died. He is not seeking economic damages, but instead damages for loss of companionship. Knowles responded to the wife, daughter and competent son by moving for summary judgment based the statute of limitations of one year after the plaintiff discovers or through the use of diligence should have discovered the injury. Knowles responded to the mentally disabled son's allegations by moving for summary judgment on the ground that the damages could not be established as a matter of law due to his incompetence. The trial court denied both of Knowles motions.

The appellate court reversed the holding with regard to the statute of limitations. It stated that the mere suspicion of

negligence suffices to trigger the limitation period and moreover that the precise manner or identity of the wrongdoer need not be known. In the present case, the three plaintiffs admit to suspecting negligence shortly after the death, but filed two years after the death. However, the appellate court affirmed the denial of Knowles's motion for summary judgment as to the mentally disabled son. The court stated that in the past it has expressly rejected the argument that mental retardation necessarily renders a person less able to suffer loss of companionship. Furthermore, Knowles did not produce any evidence regarding the extent of the plaintiff's incompetence and why he was unable to suffer the loss. Therefore, Knowles failed to meet his burden of production to make a prima facie showing that no issue of material fact existed.

- David Brueggen

LEGISLATIVE UPDATE: TORT REFORM

The issue of tort reform has been getting a lot of attention this election, especially since Democratic presidential candidate John Kerry chose trial lawyer John Edwards as his running mate. Healthcare costs are rising, and the Bush administration supports a plan to cap medical malpractice awards for non-economic damages at \$250,000 as a way to reduce costs. Opponents of this plan argue that caps penalize patients who have been injured by medical negligence, and that judges and juries ought to retain the right to determine award amounts. It is unclear whether caps actually lead to lower health care costs. Currently, twenty-three states have capped non-economic damage awards, and the caps range from \$250,000 to \$750,000.

It is instructive to consider one of the oldest state tort reform plans in order to ascertain the effect of caps. California enacted the Medical Injury Compensation Reform Act (MICRA) in 1975, and it contains a provision limiting non-economic damage awards to no more than \$250,000. Additionally, MICRA has served as a model both to Congress and to other state governments wishing to enact tort reforms. Under MICRA, California juries are not instructed about the cap, so they award whatever damages they deem fair, and then the judge adjusts the award to comply with MICRA.

The MICRA caps appear to have reduced award amounts resulting from malpractice litigation in California. This appears to achieve the goal of reducing costs to physicians and insurance companies. However, studies have found that the way the caps are applied penalizes some plaintiffs more than others. It has been found that the more severely injured the plaintiff, the more likely that his or her non-economic award amounts will be reduced, with the median reduction totaling more than \$1 million. Furthermore, plaintiffs who lost the greatest percentage of their total awards due to the cap had injuries that tended to cause the greatest loss to their quality of life. Cases where plaintiffs were killed were subject to caps 58% of the time, injury awards were capped 41% of the time, and cases with plaintiffs less than one year of age were capped 71% of the time. MICRA caps have been successful in eliminating "horizontal" inequity- meaning that individuals with similar injuries now receive similar levels of compensation. However, this disparity was eliminated in part because most plaintiffs received the maximum award allowed under the cap. In addition to capping non-economic damages, MICRA also limits the amount that plaintiff attorney may charge. While this may allow plaintiffs to keep more of their award money, it may also dissuade attorneys from taking less lucrative cases on a contingent fee basis, thereby limiting the number of injured individuals who will have access to the legal system.

- Leah Eisenberg

LEGISLATIVE UPDATE: STEM CELL DEBATE

Although it is relatively rare for a scientific research method to become political, the issue of stem cell research is simmering on the front burner of America's political stove. The issue was introduced to the American public by the Clinton administration's plan for generous stem cell research funding guidelines. Subsequently, the Bush administration scaled back President Clinton's planned appropriation and, in 2001, President Bush limited the federal government's funding to approximately 20 stem cell lines created prior to August 2001. In June of this year, President Bush renewed his commitment to stem cell restrictions despite former first lady Nancy Reagan's pleas to loosen those restrictions in an effort to expedite potential cures to diseases such as Alzheimer's, which had recently claimed her husband's life. In response to questions from the press regarding his rationale for the restrictions President Bush explained, "Life is a creation of God, not a commodity to be exploited by man." President Bush's opponent in his run for reelection, Senator John Kerry, has promised that if elected president he will remove the restrictions on federal funding of stem cell research. His promise initiated a rare endorsement of 48 Nobel laureates who, according to Nobel laureate Burton Richter, "tend not to use their names for anything outside of science," but felt compelled to endorse Senator Kerry as a statement of their fervent disapproval of the Bush administration's present course.

Unfortunately, the disagreements over stem cell research restrictions as seen in the 2004 campaigns are also evident in stem cell legislation across the country. For instance, the laws in California and New Jersey support embryonic stem cell research, even if the source is a cloned embryo. However, Arkansas, Iowa, Michigan, and North Dakota specifically prohibit research on cloned embryos. South Dakota prohibits embryonic research regardless of the source. On the other hand, some of the states that forbid stem cell research make exceptions for fetuses aborted to preserve the mother's health, so long as the mother consents to the use of her fetus for that purpose.

In addition to presidential candidates and lawmakers, American scientists and ethicists are debating the funding sources of stem cell research. Many scientists are frustrated by the current federal funding restrictions on stem cell research. One scientist analogized, "... you cannot do science with one hand tied behind your back." Moreover, a recent opinion written in *The New England Journal of Medicine* complained of the many missed opportunities, both current and future, as a result of the restrictions. While some Americans may disagree with or criticize the *Journal's* article as alarmist, consider the fact that South Korean scientists created the first human embryo for therapeutic research in February of this year and British regulators announced last month that they issued their country's first license to clone human embryos from which stem cells may be harvested.

- Stacie Phillips

GAO Report: Medicare, *continued from page 1*

CMS has limited oversight authority over JCAHO's accreditation program because the program's unique legal status prevents CMS from taking actions that it has the authority to take with other health care accreditation programs. To strengthen the ability of CMS to identify and report to Congress on JCAHO's ability to ensure compliance with Medicare requirements, the GAO recommends that Congress consider granting CMS the same oversight authority over JCAHO's accreditation program as it has for other health care accreditation programs. The GAO also recommends that the Administrator of CMS modify the methods used to evaluate JCAHO's performance

Medicare: CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals, GAO-04-850 (July 2004), available at <http://www.gao.gov/new.items/d04850.pdf>

- Anne Brown

Although Federal law prohibits drug importation from other countries, an estimated 1 million Americans filled their prescriptions at Canadian pharmacies last year, at prices as much as 40 percent less than what is available in the U.S. These savings have spurred efforts by cities and states to implement government-sponsored websites encouraging consumers to purchase their drugs from foreign countries. The Food and Drug Administration (FDA) has responded to these state and municipal efforts by warning that their actions are not only illegal but pose a significant safety risk to U.S. citizens because the FDA cannot guarantee the safety of foreign drugs. The following is a brief summary of three states' attempts to implement drug importation programs.

California: The California legislature is considering four bills, each of which would allow certain sectors of the population to purchase drugs from Canada, saving the state as much as \$30 million dollars. On September 2, 2004, all four bills passed the Assembly and Senate and were forwarded to Governor Schwarzenegger for his signature. Those in support of setting up an importation program argue that steering state residents to Canadian pharmacies would not violate federal law because under California law the state has a right to certify mail-order pharmacies through the Board of Pharmacy. In addition, supporters point to an 11-member California delegation that visited Canadian pharmacies in July to determine whether residents could safely purchase prescription drugs from Canada. Based on the results of the three day visit, members of the delegation said that they support a state-sponsored website. Despite broad public and legislative support however, Governor Arnold Schwarzenegger recently sent a letter to state lawmakers stating he would veto any

importation bill unless the bills are revised to include a program to provide discounts for uninsured low-income state residents.

Vermont: In November 2003, Vermont requested the federal Food and Drug Administration (FDA) to approve a pilot program whereby the state would contract with Canadian pharmacies to distribute prescription drugs through a mail order program. Vermont's pilot program was designed to initially allow importation for current and retired state employees and their dependents with the goal of expanding coverage to additional Vermonters. Jason Gibbs, a spokesman for Governor Douglas, estimates the program would save Vermont nearly 900k in its first year alone. Following an FDA letter denying the request because of safety concerns, Vermont will become the first state to challenge the authority of the FDA in federal court.

Illinois: Despite earlier pledges to refrain from implementing any drug importation programs without federal approval, Governor Blagojevich announced last month that Illinois will aid residents in obtaining prescription drugs from pre-screened pharmacies in Canada, England, and Ireland. The plan would allow residents to purchase about 100 products the state has determined can safely be transported from outside the USA. While generally thought to be a gross overstatement, the state said the program has the potential of saving the state 91 million, while saving consumers 25-50% off their prescription costs. This is the first program to use pharmacies outside of North America, a move made necessary by the efforts of drug companies to cut supplies to Canadian pharmacies supplying drugs to U.S. residents.

- Akhil Goel

News of Interest: *Healthcare Disparities: Civil Rights Revisited*

In 1985, a report by the U.S. Department of Health and Human Services' (DHHS) Task Force on Minority Health identified 42% of deaths among blacks, 25% of deaths among American Indians, and 25% of deaths among the Texas-Hispanic population, as excess deaths (a concept that compares actual deaths within a particular minority group with predicted deaths assuming a universal white mortality rate). Although 20 years passed since the Civil Rights Acts' promise of equality, the higher prevalence of disease, injury, and public health problems amongst these populations were seen as expected products of a history of oppression that time would cure. However, a recent report by the Institute of Medicine (IOM), *Unequal Treatment*, suggests otherwise. Despite steady improvements in the overall health of the U.S. population, the report documents deep and pervasive disparities in the health and health care received by racial and ethnic minority populations. Studies included in the IOM report indicate that racial and ethnic minorities experience disparate treatment and have higher rates of morbidity across many different disease areas, such as cardiovascular disease, cerebrovascular disease, HIV/AIDS, cancer, infant mortality, substance abuse, hypertension, diabetes, tuberculosis, and mental illness. Many of these differences remain even after controlling for socioeconomic position and access-related factors. Compared to their white counterparts, racial and ethnic minorities in the United States are less likely to receive appropriate preventative care, organ and tissue transplants, and aggressive treatment for end-stage renal disease. In fact, the disparity in average life expectancy between African Americans and whites has increased since 1960; a trend that suggests that the healthcare gap is not simply static, but may be increasing.

But we would be wrong to point the finger at medicine and declare it a racist institution; the health care disparity may be a function of differences in: cultural attitudes toward health; treat-

ment preferences following informed consent; education; literacy or ability to understand treatment options; lifestyle choices; social and environmental risk factors; pharmacogenomic response to drug therapy; and pathophysiology or susceptibility to certain diseases. Likewise, many aspects of the healthcare system exert effects on patient care that disproportionately affect minorities. High minority enrollment in Medicaid and "lower end" affordable-but-limited health plans has translated to fragmented care and unavailable preventive services. Additionally, inadequate translation services, geographic unavailability of healthcare institutions, provider discretion in appropriate treatment options, and time pressures experienced by health professional also factor into the disparities equation. Still, perhaps the greatest contributor to the healthcare gap is a collective memory of the Tuskegee experiments and the history of segregated and inferior care. This has led to a general distrust and disuse of the healthcare system by minorities.

Effective policy relies not only on evidence of healthcare disparities, but promising results from quality improvement initiatives. While the unpredictable interplay of healthcare factors makes the health disparities issue difficult, we should not use this as an excuse to abandon the pledge of healthcare equality. To ignore the system's profound disparate impact on racial and ethnic minorities is to trivialize their civil rights struggle. In the face of a rapidly growing minority population, we cannot afford to wait any longer.

- Sid Khanijou

Domestic Violence Victims, *continued from page 2*

Several organizations and individuals support granting asylum to Alvarado and other women in similar cases. For example, the Department of Homeland Security has submitted a legal brief to Ashcroft in support of asylum for Alvarado and is proposing rules that would permit asylum for women fleeing severe domestic violence in countries where officials refuse to come to their aid. Those opposed to the Homeland Security's position argue that granting asylum to victims of domestic violence would open a floodgate of women seeking asylum. However, Homeland Security stated in its brief that the policy would only affect a small number of domestic violence victims. Also, immigration attorneys argue that similar floodgate fears did not become a reality in Canada, which is one of the countries already granting asylum to victims like Alvarado. Other countries include Britain, Australia and New Zealand.

Alvarado and the world await Ashcroft's decision. If Ashcroft grants Alvarado asylum and the proposed rules go into effect, the United States would join forces with Canada, Britain, Australia, and New Zealand to lead the world in offering asylum to domestic violence victims. In addition, immigration judges would gain much-needed guidance in deciding these cases in the future. On the other hand, if Ashcroft does not grant Alvarado asylum and the proposed rules do not go into effect, Alvarado and other women will continue to suffer at the hands of their husbands.

- Katy Sikich

Pharmaceutical Settlements, *continued from page 3*

In addition to the criminal charges, Schering-Plough agreed to pay a total of \$292,969,482 to settle its False Claims Act liabilities. The civil claims arose from alleged violations of the Medicaid Rebate Statute and the Public Health Service ("PHS") drug pricing program, under which Schering-Plough was required to provide drugs to Medicaid at the best price it charged its commercial customers and to provide a discounted price on drugs to PHS entities such as community health centers, respectively. The civil violations arose from similar circumstances to the criminal charges, where Schering-Plough used various incentives including providing deep discounts on other Schering products and payment of interest free loans to prevent two of their largest managed care customers from removing Claritin from their formularies.

In addition to the settlements paid by Schering Sales and Schering-Plough, two of largest generic drug manufactures recently

agreed to pay the Federal Trade Commission ("FTC") \$6.25 million in order to settle antitrust charges that their non-competition agreement drove up the prices for wholesale suppliers of an over-the-counter ("OTC") store-brand children's liquid ibuprofen. According to the FTC complaint, Alpharma, Inc. and Perrigo Company mutually agreed to limit competition for an OTC ibuprofen of which they are the only two manufacturers. Specifically, Perrigo allegedly paid Alpharma an up-front payment as well as royalties in order to secure the exclusive right to sell the drug for a period of seven years, thereby effectively eliminating their only other competing supplier of the medication. As a result of the agreement, the FTC alleges that Perrigo was able to raise the price of the ibuprofen for those customers who had previously successfully negotiated lower prices when both companies were competing suppliers. The FTC will use the \$6.25 million to compensate customers harmed by the conduct of both companies.

- Patrick McHale

RECENT PUBLICATIONS

- Michele Goodwin, *Altruism's Limits: Law, Capacity & Organ Commodification*, 56 RUTGERS L. REV. 305 (2004)
- Michele Goodwin, *Race as Proxy: An Introduction*, 53 DEPAUL L. REV. 931 (2004)
- Michelle Oberman, *Dying Children and Medical Research: Access to Clinical Trials as Benefit and Burden*, 29 AM. J.L. & MED. 301 (2003)
- Michelle Oberman, "Lady Madonna, Children at Your Feet:" *Tragedies at the Intersection of Motherhood, Mental Illness and the Law*, 10 WM. & MARY J. WOMEN & L. 33 (2003)
- Mark C. Weber, *Litigation Under the Individuals with Disabilities Education Act After Buckhannon Board and Care Home v. West Virginia Department of Health and Human Resources*, 65 OHIO ST. L.J. 357 (2004)
- Kathleen Boozang, *Reconciling Health Care Needs and Religious Practices*, 5 GOV'T L. & POL'Y J. 23 (2003)
- Carl H. Coleman, *Rationalizing Risk Assessment in Human Subject Research*, 46 ARIZ. L. REV. 1 (2004)
- LAWRENCE O. GOSTIN, *THE AIDS PANDEMIC: COMPLACENCY, INJUSTICE, AND UNFULFILLED EXPECTATIONS* (University of North Carolina Press, 2004) (Foreword by the Hon. Michael Kirby, Supreme Court Justice of Australia)
- Lawrence O. Gostin & Lance Gable, *The Human Rights of Persons with Mental Disabilities: A Global Perspective on the Application of Human Rights Principles to Mental Health*, 63 MD. L. REV. 20 (2004)
- Lawrence O. Gostin, *International Infectious Disease Law: Revision of the World Health Organization's International Health Regulations*, 291 JAMA 2623 (2004)
- Lawrence O. Gostin, Jo Ivey Boufford, Rose Marie Martinez, *The Future of the Public's Health: Vision, Values, and Strategies*, 23 HEALTH AFFAIRS 96 (2004)
- Lawrence O. Gostin, *International Human Rights Law and Mental Disability*, 34 HASTINGS CENTER REPORT 11 (2004)
- Lisa C. Ikemoto, *Racial Disparities in Health Care and Cultural Competency*, 48 ST. LOUIS U. L.J. 75 (2003)
- Timothy S. Jost, *Pharmaceutical Research and Manufacturers of American v. Walsh: The States may Proceed Cautiously with Expanding Access to Drugs*, 4 YALE J. HEALTH POL'Y, L. & ETHICS 69 (2004)
- Kevin Outterson, *Free Trade Against Free Riders?*, 9 PHARMA PRICING & REIMBURSEMENT (2004)
- Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 HEALTH MATRIX 155 (2004)
- Rand E. Rosenblatt, *Health Care Entitlements and the Policy Gorilla*, 29 J. HEALTH POLITICS, POL'Y & LAW 529 (2004)

*Monitoring the pulse of health law***Newsletter and sources available on the web!**www.law.depaul.edu/health**CONTRIBUTORS**

Anne Brown	Stacie Phillips
David Brueggen	Katy Sikich
Leah Eisenberg	Carlota Toledo
Akhil Goel	April Vesely
Sid Khanijou	Dayna Vidas
Patrick McHale	

EDITORS

Melissa Junge, Editor-In-Chief
Pamela Koszut, Business Editor

NOTES FROM THE DIRECTOR

Welcome to our new publication. This newsletter celebrates the significant interdisciplinary achievements in the fields of medicine, bioethics, psychiatry, and the law over the past twenty years. To expand the dialogue between these fields and promote interdisciplinary collaboration that enriches the law school experience, the Health Law Institute and the Center for the Study of Race & Bioethics are publishing a bi-monthly newsletter edited by senior Fellows in the Health Law Institute. Each edition will provide you with recent health oriented case notes, legislative updates, information about forthcoming publications, and conferences.

The newsletter contains essential information for all health law students, scholars, physicians, practitioners, judges and community advocates. As part of our vision, we aim to enlighten our readership and bridge the gap in scholarship, information and attention on issues ranging from biotechnology to health care disparities.

We invite you to submit your own projects or publications to our editorial committee. The Health Law Institute Newsletter compliments our existing publications, including the Journal of Health Care Law.

- Michele Goodwin

LETTER FROM THE EDITOR**Welcome!**

The DePaul Health Law Institute is proud and excited to issue its first bimonthly newsletter. In each publication, we will strive to address a broad scope of health law issues that directly or indirectly impact health and the law. Additionally, we recognize that decisions and changes are made on state, federal and international levels; therefore, our publication will transcend accordingly. The past year or two demonstrated great change in the field of health law. Substantial legislative debate within areas such as stem cell research, damage caps, and health care reform are in the forefront of this election year. The intersection between public health, medicine and the law has reached unprecedented levels. There is much to discuss in each issue, including case notes, legislative changes, research and news. The Health Law Institute will highlight the recent and compelling developments in health law. We are monitoring the pulse of health law!

- Melissa Junge