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IN THE VIOXX FALLOUT, THE FDA TAKES ACTION TO ENSURE THE CONTINUED SAFETY OF ALREADY APPROVED DRUGS

Doctors have written more than 100 million prescriptions of Vioxx since the Federal Drug Administration ("FDA") approved Vioxx in 1999. On September 30, 2004, the manufacturer of Vioxx, Merck & Co. voluntarily pulled Vioxx from the shelves due to a new study, which showed that patients who took Vioxx for 18 months had an increased risk for heart attack and stroke. In early 2001, a FDA advisory panel recommended the agency issue warnings about cardiovascular risk with Vioxx. The agency didn't take that step until April 2002.

By April 2002, a widely reported article in the Journal of the American Medical Association warned Vioxx and a rival drug, Pfizer's Celebrex, may increase the risk of heart attacks. "A (safety) study could have been completed in 2001," said Jerry Avorn, a Harvard Medical School professor and author of "Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs." "The FDA was being inappropriately passive."

Crystal Rice, a spokeswoman for the FDA, said the agency took the "appropriate" action once Merck shared its latest data.

With the recent Vioxx recall, many question whether the FDA is equipped to exercise good judgment in closely examining and warning about a drug's side effects as the drug reaches the pharmacy shelves. Specifically, members in the health care and legal communities feel that the FDA's processes are not adequate to firmly ensure that an approved drug is safe.

Some accuse the FDA of having an "internal conflict" in that the FDA has a section that approves a new drug while the drug safety office test the approval decision. Critics of this process state, "once the people in the reviewing decision approve a drug, there is a natural human tendency to not confront information that shows that decision might be faulty," said Dr. Wayne A. Ray, a Vanderbilt Professor of Preventive Medicine.

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News of Interest: *OIG Advisory Opinion No. 04-11: Obstetrical Malpractice Subsidies*

In an Advisory Opinion, the Office of Inspector General (OIG) for the Department of Health and Human Services recently expanded the use of obstetrical malpractice subsidies specifically to a proposed agreement. The advisory opinion was requested to avoid problems that obstetrical malpractice insurance subsidies can create under the anti-kickback statute, 42 U.S.C.S. 1320a-7b (b). To avoid these problems the Department promulgated safe harbor regulations. These safe harbor regulations protect payments made by a hospital or other entity, and is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner. To qualify for the safe harbor regulations seven standards must be satisfied: (1) the payment is made in accordance with a written agreement setting out the payment amount and terms; (2) the practitioner must certify that: for initial coverage period (not to exceed 1 yr) at least 75% of the obstetrical patients treated under the coverage will reside in a HPSA or MUA or be

part of a MUP, and for each additional coverage period (not to exceed 1 yr) at least 75% of the patients treated in the prior year met the HPSA, MUA or MUP requirements; (3) there is no requirement to refer or otherwise generate business for the entity providing the subsidy as a condition; (4) there is no restriction on the practitioner from establishing staff privileges at or referring patients to any other entity; (5) the amount of payment may not vary based on the volume of or value of any expected referrals; (6) the practitioner must treat obstetrical patients receiving Federal Health Care benefits or assistance in a nondiscriminatory manner; (7) the insurance is a bona fide malpractice insurance policy or program, and the premium is calculated based on a bona fide assessment of the liability risk covered under the insurance.

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DePaul Law Review Symposium

"Precious Commodities: The Supply and Demand of Body Parts"

March 4-5, 2005

Jenner & Block, LLP (Chicago, Illinois)

Overview of Issues:

- Whether the human body can ever be conceptualized as property, and if so under what circumstances?

- Who owns the body and can we trade it as we see fit, and whether these issues have different meanings based on race, socio-economic status, or gender?

This controversial and important topic will impact the future of medicine, biotechnology (stem cell research and cloning) and constitutional, property, tort, and contract law.

Critics have alleged that the FDA ignored risks associated with Vioxx, and then intimidated its own reviewers when they pointed to safety problems. It has been alleged that FDA epidemiologist David Graham was pressured by agency officials who wanted to prevent him from publishing a study that linked painkiller Vioxx to a high rate of heart problems, according to congressional investigators. Graham was subjected to "veiled threats and intimidation" about his efforts to release his findings, according to U.S. Sen. Charles Grassley.

The FDA is accused of "dropping the ball on Vioxx," and of having a "pattern of not being able to act quickly when products are already on the market," said Dr. Wayne A. Ray. On November 5, 2004, the FDA said that it would appoint a director of drug safety and "take other actions to assure the safety of medications it approves." Dr. Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research stated that criticisms of the FDA structure are so uncommon they "don't merit tweaking the agency's culture to ensure dissenting views are heard."

On the other hand, Dr. Eric Topol, a cardiologist who pointed to increased cardiovascular risks with Vioxx in 2001, said that at least three other FDA researchers complained about the risks of Vioxx and the agency minimized their concerns about the drug.

Dr. Galson said the FDA will name a director of the Office of Drug Safety to oversee the continued safety of drugs after approval. The FDA is also looking to the Institute of Medicine for assistance. The Institute of Medicine is an arm of, the National Academy of Science, an independent agency chartered by Congress to advise the government on scientific matters. The FDA is asking the Institute of Medicine to study whether improvements are needed in examining and warning about a drug's side effects as the drug becomes more widely used. Additionally, the study also will examine whether the FDA is too involved with the drug industry to regulate it effectively.

Consumer advocate Sidney Wolfe said he was cynical that Lester M. Crawford, acting FDA commissioner, would make

meaningful changes, such as granting more power for the drug safety office and making dissenting reviewers' comments more public. "This is an attempt to put up a cosmetic fix to a serious problem."

Lancet journal editor Richard Horton has also publicly criticized the FDA. Richard Horton wrote, "too often, the FDA saw and continues to see the pharmaceutical industry as its customer — a vital source of funding for its activities — and not as a sector of society in need of strong regulation."

Crystal Rice defended the agency's efforts to protect consumers once medicines are approved. "No drug is fully safe," Rice said. "Our job is to appropriately balance our decisions based on the risk benefit profile for a drug and the societal need and desire for new drugs and a range of options to treat diseases." The FDA, however, has an unlikely advocate. According to Steven Niessen, a cardiologist at the Cleveland Clinic who warned of Vioxx-related heart risks in a study published in 2002, the "FDA did the best it could." He added, "FDA has had a pattern of not being able to act quickly when products are already on the market."

Dr. Galson said that the FDA might require drug companies to perform definitive studies that address safety issues even after a drug reaches the market. "We will want more data on the long-term use for both drugs in the pipeline and those already approved."

Finally, the FDA stated that it is also considering whether it should require longer studies for COX-2 inhibitors, the class of drugs that Vioxx belongs to.

- By Shannon Verner

The FDA is accused of "dropping the ball on Vioxx," and of having a "pattern of not being able to act quickly when products are already on the market."

News of Interest: *Terri's Law and Physician Assisted Suicide*

Recently, two decisions were announced in cases concerning physician assisted suicide (PAS). Oregon's *Death With Dignity Act* (DWDA) survived another attack by the federal government and Florida's *Terri's Law* was found unconstitutional.

Implemented on October 27, 1997, Oregon's DWDA has been a primary legal target for those opposing assisted-suicide. It survived a state repeal effort by a 60-40% margin, as well as other attacks, primarily by the federal government. In November 2001, U.S. Attorney General John Ashcroft announced that the *Controlled Substances Act* (CSA) did prohibit the use of federally controlled drugs for PAS in Oregon because it is not a legitimate medical practice. This announcement reversed former Attorney General Janet Reno's June 1998 declaration that the DWDA fell beyond the scope of the Act. In 2002, a U.S. District judge ruled against Ashcroft, holding that it is up to individual states to determine "what constitutes a legitimate medical practice or purpose." Ashcroft appealed to the Ninth U.S. Circuit Court of Appeals. On May 26, 2004, in a 2-1 decision, the Ninth Circuit ruled that the U.S. Attorney General cannot penalize Oregon physicians who assist suicides by prescribing deadly doses of controlled substances. The majority held that Ashcroft's directive to punish physicians overstepped the bounds of the attorney general's office and violated the plain language of the CSA, which expressly limits federal authority under the act to drug abuse and prevention, not medical practices. In July 2004 Ashcroft requested a rehearing in the Ninth Circuit; his request was denied in August. On November 9, 2004, Ashcroft requested

the U.S. Supreme Court to give federal agents the authority to punish physicians who assist patients in suicide. The Court will likely decide whether to hear the case early in 2005.

In Florida, Terri's Law has been the subject of national debate since 2002. In February 1990, Terri Schiavo was permanently brain damaged. In January 2002, a Florida judge ruled that Michael Schiavo, Terri's husband, could order all food and fluids withheld from Terri starting March 12. Terri's parents, the Schindlers, appealed. Although in October 2001 the Second District Court of Appeals approved the Schindler's request to have Terri examined by independent physicians, by October 15, 2003 the Court allowed Michael to remove Terri's feeding tube. On October 21, 2003 the Florida legislature enacted an emergency measure, "Terri's law," allowing Florida Governor Jeb Bush to order Terri's feeding tube reinserted. Bush did, Michael appealed the court's decision. In May 2004 a Pinellas County Circuit Judge overturned the law, ruling that it was "an unconstitutional delegation of legislative power to the Governor" and "it unjustifiably authorized the Governor to summarily deprive Florida citizens of their constitutional right to privacy" to make their own medical decisions. Bush appealed the ruling to Florida's Second Circuit Court, which fast-tracked the case to the Florida Supreme Court. On September 23, 2004, the Florida Supreme Court unanimously declared Terri's Law unconstitutional because the legislature improperly set aside a judge's order to remove Terri's feeding tube.

- Amy Vanderbroucke

Case Note: *Klay v. Humana, Inc.*, 382 F.3d 1241 (11th Cir. 2004)

On September 1, the United States Court of Appeals for the Eleventh Circuit affirmed the District Court for the Southern District of Florida's grant of class certification to a group of "almost all doctors" ("Physicians") to bring federal RICO charges against "almost all major health maintenance organizations" (HMOs). The court did, however, urge the district court to reconsider the scope of the precise class and suggested dividing the class into two subclasses based on their reimbursement arrangements. The court also reversed the district courts' certification of the Physicians' various state law claims, finding them too broad for adjudication as a class action lawsuit.

In their complaint, the Physicians alleged that through various illegal practices including mail and wire fraud, extortion, and violation of the Travel Act (18 U.S.C. § 1952), the HMOs "systematically 'deny, delay and diminish the payments due to [them]'" for medically necessary services provided by them to patients covered under the various HMO policies. The Physicians' further alleged that "these practices are not occurring in isolation, but are instead the end-product of a decades-long nefarious conspiracy to undermine the American health care system."

Reviewing the district court's grant of class certification, the appellate court dismissed the HMOs' argument that the certi-

fication was inappropriate under Federal Rule of Civil Procedure 23 (a) and (b). In support of their holding, the court accepted the district court's finding that the Physicians complaint predominately contained common questions of fact and law. To that end, the court rejected the HMOs' argument that the Physicians' RICO claims were inappropriate because *each* individual plaintiff would have to specifically show that he relied on the misrepresentation and, as a result, the individualized claims of reliance would predominate over the common questions of fact and law.

The appellate court further dismissed the argument that class certification was inappropriate because individual determinations of damages would be necessary for each physician. Finally, the court rejected the HMOs' argument that a class action would be an inferior mode of adjudication since one jury would be able to dictate the fate of the managed health care industry. In response, the court listed the several reasons why adjudication by class action is superior, including: saving time and money; vindicating the rights of individuals who would be individually without recourse; and, concentrating and resolving counterclaims in the particular forum handling the case.

- Patrick McHale

Case Note: *In Re: Sealed Case* 2004 U.S. App. LEXIS 18340

The District of Columbia Appellate Court vacated a district court's order compelling the production of the mental retardation records of the appellant. The court concluded that records cannot be compelled without first determining if federal and state privileges apply.

The appellant was a committed ward of the District of Columbia Mental Retardation and Developmental Disabilities Administration (MRDDA). He was accused of sexually assaulting the plaintiffs who lived in the same group home. The district court ordered the complete files of the appellant to be produced. Objecting to the overbreadth of the court's order, the appellant contends that many of the documents are subject to the federal psychotherapist privilege and the state statutory medical records privileges.

The appellate court agreed. First, this court concluded that any materials covered by the federal psychotherapist privilege cannot be compelled by the plaintiffs "regardless of its assessment of the interests of justice." Second, with respect to the remaining records, the state privilege demands that the probative value of the records be weighed against the appellant's privacy interests before being produced. In this case "[t]he scope of this intrusion into the appellant's privacy is breathtaking." Furthermore, only until the federal and state privileges are properly applied will this court determine whether state or federal privilege law will apply to the remaining discovery order.

- April Vesely

News of Interest: *CMS and JCAHO Make It Easier For Consumers To Assess Hospital Quality*

The Centers for Medicare & Medicaid Services (CMS) and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) recently issued a technical manual that provides clear definitions for commonly used hospital quality measures. Beginning with 2005 discharges, hospitals will use these definitions when reporting for both the National Voluntary Hospital Reporting Initiative and for JCAHO accreditation. The revised quality measures will aid to eliminate the previous discrepancies between the two organizations' reporting methods.

The technical manual will make it easier for hospitals to report their quality of services, which will lead to improvements in

the quality of care delivered. Furthermore, the comprehensive set of reporting measures will make it easier for consumers and beneficiaries to make healthcare decisions. The technical manual can be found on the CMS website at <http://www.cms.hhs.gov/quality/hospital/>. Press Release, Centers for Medicare and Medicaid Services, CMS and JCAHO Make it Easier for Consumers to Assess Hospital Quality (Sept. 15, 2004) (available at <http://www.cms.hhs.gov/media/press/release.asp?Counter=1201>).

- Anne Brown

A special administrator of a child's estate brought a suit against the hospital and the treating physician alleging negligent treatment of the child. During discovery, the defendants claimed that certain documents were responsive to the plaintiff's request to produce, but were protected under the Illinois Medical Studies Act (735 ILCS 5/8-2101 *et. seq.*). The documents at issue were a "Patient Safety Digest Professional Peer Review Occurrence Summary" authored by the former Director of Risk Management, Lori Notowitz, and four memos from Notowitz to the Risk Management Committee summarizing her interviews with treating physicians. The trial court judge ruled that the documents were not protected and compelled production. The Appellate Court affirmed this order.

The Trial Court found that part of Notowitz's duties as director of Risk Management were to improve patient care and safety, but the court noted that she was also responsible for loss prevention and managing claims. Notowitz was a member of the Risk Management Committee, a peer review committee at the hospital. Notowitz stated in her affidavit that the purpose of the committee was "to review patient care incidents and related systems issues in an effort to improve safety, the quality of patient care, and to reduce morbidity and mortality." She was asked to initiate this investigation on behalf of the Risk Management Committee by its Chairman. The Trial Court points out

that her final report to the Committee states, "You have asked me to review the care of Ashley Webb to identify any issues of liability or potential patient safety." As a result, the Trial Court believed that the report was at least partially created to assess potential legal risks. Thus, the Trial Court concluded that since these documents were not generated specifically for the peer review process they are not protected by the privilege allowed by the Medical Studies Act.

After reviewing Notowitz's three affidavits, the Appellate Court noted the apparent inconsistencies between the stated purposes of the committee and of the report and who received the reports. The Court also relied on the hospital's lack of specificity as to when the peer review process began and ended. The Medical Studies Act does not protect information generated before the peer review process begins or after it ends. The Court cited Chicago Trust Co v. Cook Country Hospital 298 Ill.App. 3d 396 (1998) which held that a document created "in the ordinary course of the hospital's business or for the purpose of rendering legal opinions or to weigh potential liability risk or for later corrective action by the hospital staff is not privileged." The Appellate Court concluded that the trial court's decision was not against the weight of the evidence, and thus affirmed the trial court's order to produce the documents.

- Chris Anderson

News of Interest: *Don't Ask, Don't Tell: Patient's Immigrant Status and Federal Funding for Hospitals*

In August, the federal government offered a \$1 billion funding incentive in exchange for hospitals reporting the immigration status of its emergency room patients under Section 1011 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The proposed guidelines agreed with state official and hospital executive sentiments, that costs of medical care for undocumented immigrants belonged to the federal government and not the states. The states with the highest levels of medical care costs for undocumented immigrants include Texas, California, Arizona, New York, Illinois, and Florida. Federal health officials claim the data is needed to ensure that the federal monies are being used as Congress intended- to pay for the emergency health care services of undocumented immigrants. In early October, after hospitals and immigrant interest groups protested the proposed guidelines, the Centers for Medicaid and Medicare services backed off requiring hospitals to ask emergency room patients about their immigration status. Hospital and immigrant interest groups were concerned that this reporting requirement would lead undocumented workers to avoid seeking emergency care when needed which would lead to public health concerns. Undocumented immigrants may feel that any answers they provide might be used against them in deportation proceedings in the future. Administrators argued that in the long run complying with the reporting requirement may cost more than the federal funding the hospitals receive. The federal funds might only cover 10-15% of the costs of emergency care for undocumented immigrants.

Under EMTALA, a hospital is required to provide a medical exam and treatment to stabilize the medical condition of any patient that presents to their emergency room requesting care, regardless of their ability to pay for those services. Hospitals often absorb these costs as charity care for uninsured patients. Many hospital administrators and physicians asked their hospitals to turn down the federal funding as it directly conflicted with their duty to

provide medical care to anyone in need. Medical professionals and hospitals state their ultimate duty lies with the patient's health and not with the state. "We are caregivers, not cops," said David L. Allen, spokesperson for the American Hospital Association.

Hospital employees would certify forms that the immigration status information for each ER patient was "true and complete" to the best of their knowledge. Hospitals that knowingly submitted false information to DHS would be subject to civil penalties and hospital administrators would be liable to civil and criminal penalties. Among the proposed questions: Are you a U.S. citizen? Are you a lawful permanent resident, an alien with a valid current employment authorization card or other qualified alien? Are you in the U.S. on a nonimmigrant visa of the type issued to students, tourists, and business travelers? Are you a foreign citizen who has been admitted to the U.S. with a 72-hour border crossing card?

Attorneys have indicated that this reporting requirement is indicative of disparate treatment which would be in violation of the Civil Rights Act of 1964 which prohibits discrimination on the basis or race, color, or national origin by federally funded programs. In the end, Mark B. McClellan, administrator for the Centers for Medicare and Medicaid services, said the agency agreed with the public's advice to use "indirect, non-burdensome eligibility methods" that will not require hospitals to obtain "direct evidence" of a emergency room patient's immigration status to receive funding under this program. Hospital administrators, especially those located near any U.S. border, see the need to tally undocumented immigrants to verify the extent of the financial crisis faced by border hospitals in providing undocumented immigrants with medical care.

- Carlota Toledo, Asst. Director

LEGISLATIVE UPDATE: IL DRUG IMPORTATION

Illinois consumers and senior citizens demanded lower prescription drug costs. After a year of researching prescription drug safety in Canada, Ireland, and the United Kingdom, Governor Rod Blagojevich and the State of Illinois answered by launching the first state-sponsored prescription drug importation program in the U.S. The program claims it will save Illinois consumers 25-50% off retail prices on over 100 prescription drugs. Gov. Blagojevich said, "No one should have to choose between putting food on the table, paying the rent, or being able to afford the medicine they need."

On October 4, 2004, despite federal laws banning prescription drug importation, Illinois along with Wisconsin launched the program to help state residents purchase cheaper prescription drugs from Canada and Europe. The state of Missouri recently joined the program. The program titled "I-SaveRx" operates through a clearinghouse in Canada and works with over 45 foreign pharmacies and wholesalers in Canada, Ireland, and the United Kingdom all of which were approved by Illinois health inspectors and verified by Wisconsin. The prescription drugs listed on I-SaveRx include common brand-name prescription drugs used to treat long term medical conditions such as diabetes and high blood pressure. Generic drugs, narcotics, drugs susceptible to spoilage during shipping, or drugs needed for immediate treatment (e.g. antibiotics for an infection) are excluded from this program. Currently only refills of current prescriptions are accepted.

Possible concerns for consumers are the required 3-month refill order, strict out-of-pocket payment system (insurance cannot be billed), and the fact the names of the foreign pharmacies and wholesalers are not disclosed until the consumer receives their shipment. Interest groups such as the Illinois Pharmacists Association have raised concerns for patient safety and the fact that state governments are looking to foreign systems for help. The American Medical Association (AMA) is producing a report addressing whether drug importation can be done safely and how. Drug companies such as Pfizer, Inc. have reminded wholesalers in the United Kingdom that wholesalers cannot divert prescription drugs from their original intended market. However, many drug companies have yet to challenge the I-SaveRx program directly.

The U.S. Food and Drug Administration (FDA) has opposed drug importation claiming states cannot guarantee the safety of the prescription drugs sold by foreign pharmacies. However, the FDA has yet to stop states from setting up internet websites to help residents purchase prescription drugs from Canada. The FDA commissioner, William Hubbard, has issued a letter of complaint to Illinois and Wisconsin. Only Illinois, Wisconsin and Missouri residents are eligible for this program. For more information, visit www.i-saverx.net or call 1-866-I-SAVE33. To date, approximately 18,000 people have obtained the program enrollment form from this website or called the toll-free number.

- Carlota Toledo, Asst. Director

LEGISLATIVE UPDATE: HIPAA REPORT

On April 14, 2003, most entities were required to comply with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA provided individuals with new protections of their health information by implementing new requirements of health care providers, plans, and other entities to maintain patients' health information as confidential in light of new technology and an increased number of parties with access to such information. Upon HIPAA's first anniversary, the GAO reviewed the first-year experiences of health care providers, plans, and other entities that are required to comply with HIPAA as well as the patients who are meant to benefit from the law. As a result of the GAO's review, a report was issued containing its findings (GAO-04-965).

According to the entities interviewed by the GAO, HIPAA's implementation went more smoothly than expected. In fact, those entities stated that HIPAA's privacy procedures have become routine practice. On the other hand, the entities noted two requirements believed to be unnecessarily burdensome: the requirement to account for information disclosures and the requirement of business associate agreements. The entities complain that significant time and resources are crucial to implementing and maintaining a tracking system for disclosures not to mention the sheer volume of disclosures to be tracked. In addition, the entities question the tracking system's benefit to patients due to the lack of patient requests for this information. Similarly, the entities state that establishing business associate agreements has required significant resources of both time and money because of the lack of clarity surrounding HIPAA's definition of a business associate and the need for negotiation and customization of these agreements.

The GAO interviewed organizations that rely on patient information for monitoring, research, and advocacy. The organizations reported increased difficulty in obtaining patient health information because entities are reluctant to disclose even when permitted by law. Organizations have had to increase efforts to obtain data, which results in significant delays and less access to the information.

Lastly, the consumer groups interviewed by the GAO said that generally, patients either are not aware of or do not understand their privacy rights under HIPAA. As proof of this, the groups cite 5,648 complaints filed in the first year, of which two-thirds were beyond HIPAA's scope and half of those found to be within the scope contained no violation. However, despite the complaints and concerns of those interviewed, the GAO made only two recommendations. First, the Secretary of Health and Human Services ("HHS") should require that patients be informed of mandatory disclosures to public health authorities and exempt those disclosures from the accounting-for-disclosures requirement. Second, HHS should conduct a public awareness campaign to increase public knowledge of patients' rights under HIPAA.

- Stacie Phillips

Obstetrical Malpractice Subsidies: OIG Advisory Opinion No. 04-11, *continued from page 1*

In the advisory opinion all these standards were met except the requirement that the obstetricians practice in a "primary care" HPSA. The obstetricians to be covered in the proposed agreement practiced in HPSAs designated based on the shortage of health care services available to the local homeless, migrant agricultural worker, or low income population respectively. Failure to fit in a safe harbor requirement is not fatal, but requires a case by case evaluation. The OIG determined a deviation from a "primary care" HPSA to the other HPSAs would not result in any increased risk of fraud or abuse, and any increased risk would be mitigated by the proposed agreement's structure. The structure included three additional safeguards that the subsidies: (1) will be provided in response to escalation of premiums on a temporary basis for a fixed period; (2) will not create a windfall for the Obstetricians since the subsidy only covers part of the increased premium; (3) will cover the Obstetricians regardless of what facilities are used for service. Based on the reasoning supra, the OIG concluded that the proposed agreement could potentially generate prohibited remuneration under the anti-kickback statute, but that the OIG would not impose administrative sanctions under 42 U.S.C.S. 1320a-7(b)(7) or 42 U.S.C.S. 1320a-7a(a)(7) as those sections relate to the anti-kickback statute. The holding is only applicable to the specific proposed agreement as stated in the request and any similar agreements must be submitted to the OIG before similar treatment is afforded.

- David Brueggen

LEGISLATIVE UPDATE: NON-ECONOMIC DAMAGE CAPS

One of the main focuses for medical liability tort reform is on a non-economic damages cap. Non-economic damages include pain and suffering, disfigurement, and loss of consortium. The American Tort Reform Association believes that non-economic damages need to be limited to a specific sum because of the broad and unguided discretion that juries are given when awarding such damages. Additionally, the American Tort Reform Association believes that these damages are the "single greatest contributor to the inequalities and inefficiencies of the tort liability system." Eighteen states overall have modified the rules for awarding non-economic damages, while five more states, Alabama, Illinois, New Hampshire, Oregon, and Washington, have implemented reforms which were struck down by their state supreme courts as unconstitutional.

Alaska capped non-economic damages in 1997 to the greater of \$400,000 or the injured person's life expectancy years multiplied by \$8,000. If the person suffered "severe permanent physical impairment or severe disfigurement," then the cap is at \$1 million or injured person's life expectancy multiplied by \$25,000.

Colorado limited the amount of non-economic damages to \$300,000 in medical liability cases in 2003.

Florida capped the non-economic damages at \$750,000 per claimant against emergency room facilities and non-practitioners, with \$1.5 million aggregate for the claimant, and \$500,000 per claimant against practitioners, with \$1 million aggregate for claimants in 2003.

Hawaii limited the damages at \$375,000 for physical pain and suffering only in 1986.

Idaho limited the award of non-economic damages in personal injury cases to \$250,000 as of 2003.

Kansas has limited the non-economic damages award to \$250,000 since 1988.

Maryland limited the award of non-economic damages to \$500,000 and in wrongful death actions, capped the award at \$500,000 for one beneficiary and \$700,000 for two or more in 1986.

Michigan limited the award of non-economic damages in medical liability cases in 1993 to \$280,000 for ordinary occur-

rences and \$500,000 for incidents within certain exceptions.

Minnesota limited the non-economic damages for consortium, emotional distress, or embarrassment to \$400,000 in 1986.

Mississippi has limited non-economic damages in medical liability cases to \$500,000 in 2004.

Montana limited the recovery of non-economic damages in civil cases to \$1 million, with a hard cap of \$500,000 in medical liability cases in 2004.

Nevada has limited the non-economic damages in medical malpractice cases to \$350,000 since 2002, except when there is "gross malpractice."

North Dakota limited the award of non-economic damages in medical liability cases to \$500,000 in 1995.

Ohio limited the award of non-economic damages in medical malpractice cases in 2003 to \$350,000, with a provision to allow the cap to go up to \$1 million depending on the severity of the injury and number of plaintiffs.

Oklahoma capped non-economic damages at \$300,000 in 2004 for the medical liability cases as long as the defendant made an offer of judgment and the amount of the verdict is less than one-and-a-half times the amount of the final offer of judgment.

Texas limited non-economic damages in medical malpractice cases to \$250,000 against physicians and health care practitioners, \$250,000 per-facility and \$500,000 overall against health care facilities in 2003.

West Virginia limited non-economic damages in medical malpractice cases to \$250,000 to \$500,000 in 2003.

Wisconsin limited non-economic damages in medical malpractice liability cases to \$350,000 in 2003.

Five states have had reforms struck down as unconstitutional. These five states are Alabama, Illinois, New Hampshire, Oregon, and Washington.

- Dayna Vidas

RECENT PUBLICATIONS

Kathleen Boozang, *Mission, Margin & Trust in the Nonprofit Healthcare Enterprise*, 5 YALE J. HEALTH POL'Y, L. & ETHICS (forthcoming 2004).

Katherine J. Eder, *The Importance of Medical Testimony in Removal Hearings for Torture Victims*, 7 DEPAUL J. HEALTH CARE L.281 (2004).

Cynthia M. Ho, *Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patient-Based Discoveries*, 7 DEPAUL J. HEALTH CARE L. 185 (2004).

Timothy S. Jost, *SYMPOSIUM: The Future of Medicare, Post Great Society and Post Plus-Choice: Legal and Policy Issues: The 2002 Washington and Lee University Law Review Symposium Foreword*, 60 WASH. & LEE L. REV. 1087 (2003).

Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Pharmaceutical Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS (forthcoming 2004).

Louise G. Trubek & Maya Das, *Achieving Equality: Healthcare Governance in Transition*, 7 DEPAUL J. HEALTH CARE L. 245 (2004).

News of Interest: *New York Court Decision Limits Removal of Children from Abused Mothers*

The United States Court of Appeals for the Second Circuit is currently considering a federal class action suit brought on behalf of three battered mothers and their children against the New York City Administration for Children's Services ("ACS"). Under the ACS policy, the children were removed from their mothers because there was domestic violence in the home. The federal appeals court recently asked New York's state court to answer three questions regarding New York state law: whether a non-abusive parent is responsible for neglect when the parent is a victim of domestic violence and the child is exposed to that violence; whether a child's emotional injury, if any, resulting from witnessing domestic violence constitutes "danger" or "risk" to the child's "life or health" as defined under New York state law; and whether "removal is necessary" or "in the child's best interests" under New York state law when a child witnesses domestic violence against the non-abusive parent.

In response to the first question, the state court answered that a non-abusive parent is not presumptively responsible for neglect when the child has been exposed to domestic violence in the home. The court stated that more is required in order to find neglect under New York's state law. The court mentioned that the law requires proof of (1) "actual physical, emotional or mental impairment to the child"; (2) a "causal connection between the basis for the neglect petition and the circumstances that allegedly produce the child's impairment or imminent danger of impairment"; and (3) "the parent's failure to exercise a minimum degree of care." In other words, there is no presumption of neglect against the non-abusive parent merely because the child was exposed to domestic violence.

Similarly, the state court answered the second and third questions stating that exposing a child to domestic violence "is not presumptively ground for removal," and "removal may do more harm to the child than good." New York state law requires city officials to follow "a hierarchy of required review" before the child can be removed from the home. Earlier levels of review involve city officials seeking a family court judge's approval. Overall, the family court judge's determination of the best interests of the child is made by balancing the imminent risk to the child from being exposed to the domestic violence against the risk of harm removal from the home may cause the child. The family court judge must also "consider whether imminent risk to the child might be eliminated by" action other than removal of the child from the home, "such as issuing a temporary order of protection...." Later levels of review allow city officials to remove the child from the home only in "a rare circumstance in which the time would be so fleeting and the danger so great that emergency removal would be warranted." The New York state court's decision is one of the first to rule on this complicated and emotional issue. The decision is unique in that it requires city officials and family courts not only to consider harm the child faces from remaining in the home, but also the harm a child could suffer from being removed from the non-abusive parent. The United States Court of Appeals for the Second Circuit now has the answers to the questions it asked of the New York state court, and it is expected to decide this federal class action soon.

- Katy Sikich

News of Interest: *Race as Proxy: Healthcare Remedy or Defective Policy?*

While *Unequal Treatment*, a report by the Institute of Medicine (IOM), indicates that deep and pervasive disparities in the healthcare received by minorities exist, it leaves unresolved the more compelling question as to why these disparities exist. When the Civil Rights Act of 1964 was first enacted, any disparate treatment of minorities in such areas as employment, housing, and public accommodation was regarded as *de facto* discrimination for which the Supreme Court recognized a private right of action under Title VI of the Act. However, in the watershed case of *Alexander v. Sandoval*, the Supreme Court held that a private right of action to enforce disparate impact regulation was never promulgated under Title VI. Litigation as a recourse to *de facto* discrimination fell away leaving non-judicial approaches to accountability, healthcare policy and administrative enforcement of accreditation/licensure of providers, as the only remedies. Although minority health had been monitored by the DHHS since the mid-1980s, the movement did not gain national recognition until President Clinton passed Healthy People 2010; a national disparities initiative that sought to eliminate healthcare disparities by monitoring "individual behaviors and environmental factors" at the federal level. To collect the data required to enact effective quality improvement measures, Office of Management and Budget (OMB) revised and expanded Directive 15 to include six categories of racial classification. Many federal organizations including the FDA, NIH, CDC, DHHS, and Medicaid/Medicare have adopted this categorization to collect data required to measure healthcare disparities.

But is race an appropriate proxy to evaluate healthcare disparities? As a concept, race has come to take on a wide range of meanings mixing biological and environmental ingredients in varied proportions. It stands as a proxy for biological, cultural, socioeconomic, sociopolitical factors, as well as racism; what can research based on such a multifaceted and complex concept teach us about healthcare deficiencies? Even assuming time has eroded the value-laden meaning of color and that studies adequately control for socioeconomic position and access-related factors, biological and cultural factors remain. In the United States, it is self-evident that a substantial variation in health status among population subgroups exists. This variation has been used to justify movements ranging from eugenics to genomics, the current driving force behind the use of racial and ethnic categories in the surveillance of disease. But while many researchers are quick to view any observed biological differences as *prima facie* evidence of genetic variation, the fact that social processes exert substantial physiological effects indicates that the mere identification of different biological characteristics does not necessarily indicate genetic differences. Likewise, racial disparities in healthcare should not be presumptively ascribed to biological etiology "unless cultural and environmental factors can be ruled out." Although genomics and pharmacogenetic studies indicate statistically significant variations in the prevalence of drug-metabolizing enzymes and predisposition to certain diseases among certain subgroups, the effect of genetics alone on healthcare is likely *de minimis*. The healthcare gap is thus likely due to environment factors, manifestations of culture to which, perhaps, race serves as valid proxy. But even this concept can be unpacked into countless aspects including religious practices, language, folk medicine, diet, dress, lifestyle, norms, values, stoicism, and help-seeking behavior; all of which impact a subpopulation's perceptions of illness. The unintended result of categorizing people according to race is that it blinds us to the more relevant local and individual context. Moreover, to use race as a surrogate for healthcare disparities seems to suggest that genetic race (devoid of its tie to socioeconomic position or cultural elements) *normally* synergistically interacts with health-related behavior, such as compliance with medical treatment, to create a healthcare disparity; a conclusion that science cannot validate. Medicine instructs that mortality based on end-organ damage is a function of compliance with medical treatment to control blood pressure, not race or genetics. Minorities have fought discrimination for over 200 years; how receptive will they be to removing the vestiges of oppression through research that relies on stereotypes and subgroup generalizations?

- Sid Khanijou

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Monitoring the pulse of health law

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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

Call for Recent Publications. In each issue of the newsletter, the DePaul Health Law Institute is proud to list recent publications by our colleagues across the country. Please send your information to us if you would like to have a recent publication included in our upcoming issues.

Spotlight Opportunities. Additionally, each issue of the newsletter will have a spotlight article in which we hope to highlight current and work-in-progress research. If you are working on an article or topic area and would like to provide an abstract or an interview for our spotlight, please contact us.

I appreciate any feedback or questions you may have about our newsletter. The DePaul Health Law Institute and Newsletter staff are honored by your involvement in 'monitoring the pulse of health law.'

Please send submissions or comments to:
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- Melissa Junge