Study shows women and blacks are less likely to get heart devices. Although clinical trials have shown that implantable cardioverter defibrillators can save people at risk for sudden cardiac death, women are still less likely to receive the devices than men, and black patients overall are less likely to receive them than white patients, two studies have reported. One study reported that among eligible patients, 32.3 out of 1,000 men received a defibrillator within one year of diagnosis, while only 8.6 out of 1,000 women did. The other study found that about 44 percent of eligible white men got a device, compared with only 30 percent of white women. Among eligible black patients, only about 33.5 percent of men and 28 percent of women got one. The new studies are among the first to show underuse and disparities in the use of implantable defibrillators. (USAToday.com, Oct. 3, 2007)

Expanded testing for Down syndrome raises concerns. Under a new recommendation from the American College of Obstetricians and Gynecologists, doctors have begun to offer a new, safer Down syndrome screening procedure to all pregnant women, regardless of age. About 90 percent of pregnant women who are given a Down syndrome diagnosis have chosen to have an abortion. A dwindling Down syndrome population, which now stands at about 350,000, could mean less institutional support and reduced funds for medical research. It could also mean a lonelier world for those who remain. A growing group of parents of Down syndrome children are pressing obstetricians to refer couples to them who have been given a prenatal diagnosis of Down syndrome. They see themselves as society's first line of defense against a use of genetic technology that can border on eugenics. Many see expanded testing as a step toward a society where children like theirs would be unwelcome. (*The New York Times*, May 9, 2007)

Death reveals risks in clinical research. Jolee Mohr, a participant in a gene therapy experiment whose chief goal was to test the safety of a novel arthritis treatment that had virtually no chance of helping her, died from massive bleeding and organ failure July 24. A close look at the events leading to Mohr's death reveals failures in the safety net that is supposed to protect people from the risks of medical experimentation. Breaches of clinical research standards and a federal oversight system that allowed key decisions to be made behind closed doors may have helped draw Mohr into an experiment that was not what she thought it was. "It was presented to her like this is going to make her knee better," said husband Robb. A two-sentence paragraph halfway through a 15-page consent document that Mohr signed warns of the possibility of "unknown side effects," including, "in rare circumstances, death." Further in, after long descriptions of how the product may help, a single sentence states: "We do not expect you to receive any direct medical benefits from participation in this study." (WashingtonPost.com, Aug. 6, 2007)

Patients do not have right to use unapproved drugs. A federal appeals court ruled that patients with terminal illnesses do not have a constitutional right to use medicines that have not yet won regulatory approval. The 8-to-2 decision by the Court of Appeals for the District of Columbia Circuit came in a closely watched and emotional case that pitted desperate patients willing to try unproven, even risky, therapies against those arguing that drugs should be proved safe and effective before they are made available. It was argued that forcing patients to wait years for a drug to go through the process of clinical trials deprived dying patients of their right to self-defense. Judge Thomas B. Griffith, writing for the majority, said a right to experimental drugs was not deeply rooted in the nation's history and tradition. He said the right of self-defense "cannot justify creating a constitutional right to assume any level of risk without regard to the scientific and medical judgment expressed through the clinical testing process." (*The New York Times*, Aug. 8, 2007)

Catholic group campaigns for study of adult stem cells. The Michigan Catholic Conference launched a major education campaign aimed at promoting support for research using adult stem cells and clarifying the church's opposition to embryonic stem cell research. The campaign "Finding Cures & Protecting Life," described as the largest in history for the conference, includes the distribution of a stem cell DVD and supporting materials to more than 500,000 Catholic households in Michigan and encourages 800 parishes around the state to focus on the issue. Paul Long, vice president for public policy at the conference, said Friday the campaign is intended to counter "the hype over embryonic stem cell research that has overshadowed the real hope" offered by adult stem cell research. (*Detroit Free Press*, Sept. 30, 2007)

Study Links Religion to Medical Treatments. A study by medical ethics experts suggests doctors and patients need to talk about religion. Researchers have examined responses from more than 1,100 doctors. The results show differences between religious doctors and those who are not religious. The co-author of the study, Dr. John Lantos with the Kansas City-based Center for Practical Bioethics, says the results are clear that referral patterns are shaped by the doctors' religious beliefs. He says the more religious doctors are likely to refer someone suffering from depression or deep grief to clergy counseling. He says less religious doctors are more likely to send those patients to psychiatrists or psychologists. Lantos says the study found only 10 percent of the doctors surveyed profess no religious affiliation. Forty percent were Protestant, 20 percent Catholic, 14 percent Jewish, with the other 11 percent being Mormon, Muslim, Buddhist or Hindu. (Missourinet.com, Sept. 24, 2007)

Religious physicians found not to disproportionately care for the poor. A recently published study examined whether physicians' self-reported religious characteristics and sense of calling in their work are associated with practice among the underserved. Researchers found that physicians who are more religious do not appear to disproportionately care for the underserved. Of the 2,000 physicians invited to participate, 63 percent responded. Twenty-six percent of respondents reported that their patient populations are considered underserved. Physicians who were more likely to report practice among the underserved included those who were highly spiritual and those who said the family in which they were raised emphasized service to the poor. Physicians who were more religious in general, as measured by intrinsic religiosity or frequency of attendance at religious services, were much more likely to conceive of the practice of medicine as a calling but not more likely to report practice among the underserved. (*Annals of Family Medicine*, vol. 5, 2007)

New limits debated for organ donation. A debate between surgeons and patient advocates reflects a tension between the need for organ donors and concerns that doctors may be lowering standards for living donors too far or failing to catch problems that could put the donor at unacceptable risk. Proposed new guidelines—from the United Network for Organ Sharing—include two contentious sets of voluntary guidelines. The first aims to ensure that potential donors are properly screened, both medically and psychologically; that afterward they are followed to ensure no problems develop; and that people who are at increased risk never make it to the operating room. The second lays out recommendations to ensure donors give their informed consent. "It's troubling," says David Cronin, a transplant surgeon at Yale University, where he says doctors have dropped their standards for donor blood pressure, weight and diabetes. He argues that even if donors fully consent to overly risky operations, doctors shouldn't do them. Still, Dr. Cronin doesn't believe UNOS should be setting guidelines for medical practice. "This is an external agency practicing medicine," he said. "You don't see my patient, and you don't see my donor, and you're going to tell me who I can and can't use?" (*Wall Street Journal*, Sept. 13, 2007)

Study shows disparities aren't usually due to bias. Two recently released studies added to the increasing weight of evidence suggesting that health care disparities are due mostly to where minorities receive treatment rather than to racism or cultural insensitivity. An *Archives of Internal Medicine* study examined how 123 teaching hospitals scored on Hospital Quality Alliance measures in caring for more than 320,000 patients. After adjusting for where minority patients were treated, the researchers found racial and ethnic disparities were vastly reduced or even eliminated. And a report released by the Commonwealth Fund, a health care policy nonprofit, surveyed nearly 3,000 patients and determined that those whose physicians provided a medical home received more equitable treatment. An editorial accompanying the *Archives* article said the study's findings "demonstrate that most disparities in the quality of hospital care depend on where you seek care, not on your race [or] ethnicity." (Amednews.com, Aug. 6, 2007)

Senate addresses rise in suicide rate in the elderly. Suicide rates among older adults are higher than those in any other age group in the nation, with individuals 85 years and over most at risk. Proposed Senate Bill (S. 1854) is designed to improve early intervention strategies to prevent suicide among the elderly. S. 1854 would establish an Interagency Mental Health Planning Council to coordinate the delivery of mental health services for the elderly,

and would empower the Secretary of Health and Human Services to award grants for the development of strategies addressing elder suicide. The bill would also end discriminatory Medicare co-payment rates for outpatient mental health services, emphasizing the need for parity in coverage for mental and physical conditions. (Stop Senior Suicide Act, S. 1854, 110th Congress, 2007)

States take action to eradicate HPV. The Human Papilloma Virus (HPV) infects tens of millions of Americans. In 2007, 24 states proposed legislation mandating the HPV vaccine for school age children. The HPV vaccine was approved by the FDA and recommended for use by the American Committee on Immunization Practices (ACIP) in 2006. Since 2006, 41 states and the District of Columbia have proposed legislation for HPV vaccine funding, distribution or education. Seventeen states have enacted such legislation. Despite states' rush to mandate use of the vaccine, many questions still remain, such as the ethical issues surrounding parental rights for exemption and the impact of the vaccine on children's sexual practices. (The National Conference of State Legislatures, August 2007)

Senate endorses mental health parity. The Mental Health Parity Act of 2007 was passed unanimously by the Senate in late September. The act requires certain health plans to provide equal coverage for both physical and mental disorders, and will preempt state laws related to mental health parity. If enacted, the federal legislation would require covered plans to provide benefits for mental health and substance abuse treatment equal to those available for medical and surgical services. (The National Conference of State Legislatures, January 2007; *The New York Times*, Sept. 19, 2007)

New Jersey physicians not required to characterize embryo as human being to obtain informed consent for abortion. On Sept. 12, 2007, the Supreme Court of New Jersey unanimously decided that a physician's duty to obtain informed consent, including information about the risks of an abortion procedure, does not include suggestions that the procedure results in the death of a living human being. The plaintiff was advised that carrying a pregnancy to term would endanger her life because of an underlying kidney disease. She subsequently underwent an abortion in her 7th week of pregnancy but later alleged her physician was negligent in not informing her that she would be "killing a human being." Because the consent process included material medical information such as gestational age and medical risks, the court dismissed the plaintiff's claims of negligence (based on lack of informed consent) and negligent infliction of emotional distress. (Acuna v. Turkish, 2007 N.J. LEXIS 1058, 2007 WL 2609054(N.J. 2007))

HIPAA does not prevent the release of psychotherapy notes in a life insurance dispute. On September 28, 2007, the U.S. District Court for the Middle District of Florida ruled that the Health Insurance Portability and Accountability Act (HIPAA) did not protect psychotherapist notes from discovery in a life insurance dispute. Although the court acknowledged the existence of comments in the final HIPAA regulations suggesting that the notes were private, the court held that this did not outweigh other regulatory language anticipating their production in specific circumstances. (*BNA Health Care Daily Report*, Oct. 3, 2007)

NIH unveils plan to foster research on human embryonic stem cell alternatives. The National Institutes of Health (NIH) released its plan to encourage research on embryonic stem cell alternatives. The plan, entitled "Expanding Approved Stem Cell Lines in Ethically Acceptable Ways," was created in response to President Bush's executive order 13435, which was intended to shift research endeavors away from embryonic stem cells. Research is currently eligible for federal funds only when performed on approved embryonic stem cell lines (embryos created prior to August 9, 2001). (*BNA Medical Research Law & Policy Report*, Oct. 3, 2007)

Grand jury refuses to indict doctor for Katrina hospital deaths. Dr. Anna Pou, who was accused of administering a "lethal cocktail" to four elderly patients at Memorial Medical Center during Hurricane Katrina, will not be charged with the deaths of those individuals. On July 24, 2007, a grand jury declined to indict Pou for either second degree murder or conspiracy to commit murder. Pou gave up her practice after her arrest, but continues to teach at LSU medical school in Baton Rouge, La. (CNN.com, July 24, 2007)

Virginia legislators push for easier involuntary commitments. In the wake

of the Virginia Tech tragedy, legislators in the state of Virginia have proposed a three-part plan to reform the state's mental health system. The most controversial part of the plan would allow a judge to involuntarily commit individuals believed to be a danger to themselves or others, even if not evident at the time of the hearing. Mental health advocates fear the proposal will infringe on the rights of the mentally ill, and may lead to a flooding of the mental health system without an appropriate increase in funding. (WashingtonPost.com, Sept. 7, 2007)

State to pay $925,000 to participants of stuttering study. An Iowa state court approved a settlement for $925,000 to the participants of a 1939 University of Iowa stuttering study. The former participants, children from a Davenport home for neglected youths, were part of a five-month study that used negative reinforcement to induce stuttering in otherwise unaffected children. The participants claimed that the study led to a loss of self-confidence and self-esteem, and sought recovery for intentional infliction of emotional distress, invasion of privacy and fraudulent misrepresentation. The settlement awards a total of $925,000 to three of the study's living participants and to the estates of three deceased participants. (*BNA Medical Research Law & Policy Report*, Sept. 5, 2007)

Congress, states address influence of drug and device companies in treatment decisions. New Jersey is the latest in a series of states to examine the impact of drug and device industry gifts on patient care. The Attorney General's Advisory Task Force on Physician Compensation is set to examine data collected by the State Board of Medical Examiners to assess the effects of such gifts on the physician-patient relationship. Congress has also taken note of the potential influence of drug and device companies on consumer purchasing, and may soon debate the appropriateness of direct-to-consumer advertising in proposed legislation from Rep. Rosa L. DeLauro (D-Conn.). (*BNA Medical Devices Law & Industry Report*, Sept. 26, 2007 and Oct. 10, 2007)

Federal officials begin to define bounds of emergency medical care under Medicaid. Federal officials recently informed New York State that emergency Medicaid funds can no longer be used to cover chemotherapy costs for illegal immigrants without other access to chemotherapy. Denise Smith, director of the Center for Medicaid and State Operations at the Centers for Medicare and Medicaid Services, cited a "longstanding interpretatio[n] by the agency . . . that emergency Medicaid benefits are to cover emergencies." However, "emergency" is not adequately defined and states are therefore forced to construe the term themselves, often resulting in inconsistent interpretation. (*The New York Times*, Sept. 22, 2007)

Emergency department overcrowding adversely impacts patients. According to a recent poll from the American College of Emergency Physicians (ACEP), more than 80 percent of physicians surveyed indicated that emergency department overcrowding had increased either slightly or significantly within the past year. A majority of physicians cited inadequate staffing or resources as the leading cause of concern. Also of concern were long wait times and "boarding" of patients in the ED. Dr. Linda Lawrence, President of ACEP, expressed concern about patient suffering. "We watch it each and every day as they've lost their privacy and dignity lying in our hallways." (*Modern Healthcare*, Oct. 10, 2007; NBC Nightly News, Oct. 9, 2007)

OIG offers positive opinions on charity care. Two recent opinions by the Department of Health and Human Services Office of the Inspector General (OIG) positively influence charity care. The first opinion, posted September 27, 2007, approved a proposal by a not-for-profit medical center to compensate for emergency department on-call coverage. Payments were aimed at covering the uncompensated care that physicians are expected to provide to the uninsured and underinsured, and was cited by the OIG as having an "obvious public benefit." The second opinion, posted October 3, 2007, allowed a charitable group's proposal to establish a foundation to provide grants to financially needy cancer patients, despite the fact that the foundation might generate payments violating anti-kickback prohibitions. (*BNA Health Care Fraud Report*, Oct. 10, 2007)

Students from the Center for Health Law Studies and Student Writers Association at Saint Louis University School of Law contributed to this installment of "Of Note." Center Assistant Director, Kelly Dineen supervised the contributions of health law students Heather McCollum, Kristen Reiss, Mark Tolman, Stephanie To and Geeta Wadhwa.