

## Of Note

### U.S. Orders Vast Review of Bioethics

President Obama ordered a vast review of standards for federally-backed research in Nov. 2010 to ensure ethical treatment of research participants. The action was in response to a revelation that American scientists intentionally infected people at a Guatemalan mental hospital with syphilis in the 1940s to test if penicillin, then relatively new, could prevent sexually transmitted infections. Obama and Secretary of State Hillary Rodham Clinton condemned the activity and apologized to Guatemala's President Alvaro Colum. Obama directed the Presidential Commission for the Study of Bioethical Issues to use its expertise across the fields of science, policy, ethics and religion to protect people who participate in medical research. **AP, Nov. 24, 2010**

### Turning Off Devices Near Life's End Stirs Ethical, Legal Debates

Many physicians believe that deactivating heart devices is a form of physician-aided death, according to a survey published in the Nov. 2010 *Mayo Clinic Proceedings*. That view contrasted starkly with recommendations of an expert panel of the Heart Rhythm Society, which represents more than 5,100 physicians specializing in cardiac pacing and cardiac electrophysiology. The organization said it is ethical and legal to honor a patient's request to turn off the pacing function

even when the patient is reliant on the pacemaker. An additional survey of legal professionals and patients found 12 percent of lawyers thought turning off a pacemaker amounted to physician-assisted suicide, compared with 24 percent of patients. **Kevin B. O'Reilly, *amednews.com, Nov. 24, 2010***

### Study Finds No Progress in Safety at Hospitals

A study of ten North Carolina hospitals from 2002-2007 found that patient harm was common and that many incidents stemmed from preventable problems involving drugs, procedures or hospital-acquired infections. "It is unlikely that other areas of the country fared better," said Dr. Christopher P. Landrigan, lead author of the study and assistant professor at Harvard Medical School.

Published in the *New England Journal of Medicine*, the study was one of the most rigorous efforts to collect data about patient safety since the 1999 landmark report by the Institute of Medicine showing that medical mistakes caused more than 98,000 deaths and more than one million injuries a year in the U.S. The report led to a nationwide movement to reduce medical errors.

North Carolina hospitals were the focus of Dr. Landrigan's study because hospitals there have been more focused on

improving patient safety than those in most other states. Many problems stemmed from the hospitals' failure to use measures that had been proved to avert mistakes and prevent infections from devices like urinary catheters, ventilators and lines inserted into veins or arteries. **Denise Grady, *New York Times*, Nov. 25, 2010.**

### **World Comparison Shows U.S. Health Care Lacking**

A study by the Commonwealth Fund published in the journal *Health Affairs* showed that while Americans pay far more per capita for health care, they are unhappier with the results and less healthy than people in other rich countries.

The study found that one-third of Americans went without medical care or skipped a prescription compared to only five percent in the Netherlands. Twenty percent of U.S. adults had problems paying medical bills compared with two percent in Britain and nine percent in France, the next costliest country. The report said that U.S. adults were the most likely to incur high medical expenses, even when insured, and to spend time on insurance paperwork and disputes or to have payments denied.

The Commonwealth Fund advocates for health reform. In 2010, President Obama's signature domestic policy effort went into effect with passage of the Affordable Care Act. Conservatives in Congress have promised to dismantle it. **Maggie Fox, *Reuters*, Nov. 18, 2010.**

### **Direct Conversion May Make Embryonic Stem Cell Research Obsolete**

The process of direct conversion involves changing one kind of specialized cell into another, offering the potential to be a viable alternative to controversial embryonic stem cell research. Unlike embryonic stem cells which produce immature cells, direct conversion produces mature cells with better prospects for patients and cures.

"I think everyone believes this is really the future of so-called stem cell biology," said researcher John Gearhart of the University of Pennsylvania. "Everyone's out there trying their different combinations (of chemical signals) to see if they can succeed."

Gearhart cautioned that direct conversion is new, unproven and needs considerable research to make it viable. "This stuff is all so new that we still have a lot of work to do," he said. **Steven Ertelt, *LifeNews.com*, Nov. 29, 2010.**

### **Conception Is a Rare Event, Fertility Study Shows**

Fewer than 8 percent of all attempts at making a baby in a lab dish succeed, according to a study by the Shady Grove Fertility Center in Maryland. Researchers reviewed all in vitro or IVF cycles at the center between 2004 and 2008. Out of 110,000 egg cells fertilized with sperm, only 31,437 resulted in viable embryos. Findings were presented at an American

Society for Reproductive Medicine meeting in Denver in Oct. 2010.

“It should surprise no one that the vast majority of sperm and eggs never get together to even begin the fertilization process,” said Dr. Robert Rebar, executive director of ASRM. “But, it is very important to understand that even once joined together for fertilization, an overwhelming majority of fertilized eggs do not become viable embryos, and only a small percentage thought to be viable produce a child. While this data come from the IVF lab, natural conception is also very inefficient,” he added. **Yahoo News, Reuters, Oct. 25, 2010**

*A health law student from the Center for Health Law Studies at Saint Louis University School of Law contributed the following items to this column. Amy N. Sanders, assistant director, Center for Health Law Studies, supervised the contributions of Chelsea Mortimer (JD anticipated '11).*

### **Consumers Concerned About Mergers in Health Care Driving-up Costs**

Some people are concerned that mergers and acquisitions of health care entities following passage of health reform law last year may lead to greater possibilities of increasing costs, reducing competition and creating incentives for doctors and hospitals to offer less care in order to maximize bonuses. Another concern is that accountable care organizations formed by mergers of large hospitals and care organizations will try to keep costs

down by picking healthier patients at the expense of sicker patients. One of the difficulties for regulatory agencies is to balance “potential benefits of clinical cooperation with the need to enforce fraud, abuse and antitrust laws”.

Proponents of the new organizations are asking the Federal Trade Commission to create exceptions to the antitrust laws, so as to facilitate the creation of more innovative programs without fear of antitrust prosecution. Opponents support integrated care, but believe it can happen without the harmful effects of monopolistic organizations. **Robert Pear, “Consumer Risks Feared as Health Law Spurs Mergers”, *New York Times*, Nov. 20, 2010**

### **Kos Pharmaceuticals Agrees To Pay Fine for Criminal and Civil Liabilities**

Kos Pharmaceuticals manufactures the drugs Advicor and Niaspan which the company offered doctors and other providers illegal incentives to prescribe, a violation of the Anti-Kickback Statute. According to the agreement, the company agreed to pay \$38 million in civil penalties under the False Claims Act. The firm also faces criminal charges in Louisiana for conspiracy to violate the Anti-Kickback Statute. From 2002-2006, two doctors wrote 4,130 prescriptions for Kos products that were funded in part by Medicare and Medicaid dollars. The company was granted a deferred prosecution due to its cooperation with an investigation into the wrongdoing. Lawsuits against the company were filed under the qui tam provisions of the False

Claims Act, allowing any recovery to be shared among the private citizens involved in the uncovering of fraud as well as the government. This action comes as a result of the 2009 initiative between the Attorney General and the Department of Health and Human Services to combat health care fraud. According to the article, the Justice Department has recovered \$5.8 billion since January 2009 under the False Claims Act initiatives. **Kos Pharmaceuticals to Pay More Than \$41 Million to Resolve Kickback and Off-Label Promotion Allegations, Department of Justice, Office of Public Affairs, Dec. 7, 2010**

### **Medicare Sees Arrival of First Wave of Baby Boomers**

The first wave of Baby Boomers turns 65 this year. As this group begins to utilize Medicare, experts predict it will demand and expect more than previous generations, straining the already burdened system. Compounding the problem is the shrinking number of geriatricians and primary care physicians, leading some to wonder who will care for new Medicare recipients. The American Geriatrics Society says there are now 7,029 board-certified geriatricians in the U.S., with a ratio of one for every 2,699 Americans 75 or older. By 2030, experts predict a drop to one geriatrician per 5,549 elderly. **Amanda Gardner, "Medicare Makes Way for Baby Boomers," *HealthDay*, Jan. 3, 2011**