

The use of Plan B has increased dramatically since the federal government approved the over-the-counter sale of the emergency contraceptive medication in August 2006. Sales, in fact, have doubled from about \$40 million a year to an expected \$80 million for 2007. Barr Pharmaceuticals, producer of the drug, has been advertising in women's magazines and has provided an online training program for more than 54,000 pharmacists. Some pharmacists refuse to provide the drug on moral grounds. Several states have passed laws that either require pharmacists to provide Plan B, or protect those who refuse. Nineteen other states are considering legislation. (*The Washington Post*, July 13, 2007)

Doctors can be deeply affected by medical mistakes according to a survey conducted by researchers at Washington University in St. Louis. The vast majority of the 3,171 physicians surveyed in St. Louis, Seattle and Canada said they had been involved in a minor or serious medical error, or a near miss. Sixty-one percent said they felt increased anxiety about the potential for future mistakes, 44 percent said they became less confident in their job abilities, 42 percent experienced sleep problems, and 42 percent had a decrease in job satisfaction. Most doctors said they would have liked counseling or other help after making mistakes, but that hospitals and other health care organizations didn't offer much assistance. Only 10 percent said hospitals offered them adequate resources for dealing with mistake-related stress. Survey results will appear in the August edition of *The Joint Commission Journal on Quality and Patient Safety*. (Associated Press, July 18, 2007)

A rule that dismisses a pharmacist's right of conscience was unanimously adopted in May by The Washington

State Pharmacy Board. The rule requires a pharmacy to fill a patient's lawful prescription, even if the pharmacist has a moral objection. It does allow for another pharmacist on staff to fill the prescription. The major debate is primarily over emergency contraception. Currently, nine states have pharmacists' conscience clauses, 17 states have proposed such legislation, and six states have proposals that would require the pharmacy to fill the prescription. (*National Catholic Register*, May 13-19, 2007)

Supreme Court upholds constitutionality of Partial Birth Abortion Act. On April 18, by a vote of 5-4, the U.S. Supreme Court upheld the Partial Birth Abortion Act, overturning the previous decisions of six federal courts which ruled that the act unconstitutionally restricted a woman's right to an abortion. (*Gonzales v. Carhart*, 127 S. Ct. 1610 (2007)). In the 1990s, Congress twice passed a partial-birth abortion ban, but these efforts ended with vetoes by President Bill Clinton. In 2003, Congress again passed such a ban and President Bush signed the bill. However, due to numerous court challenges, the law never went into effect. In the most recent rulings, Justice Anthony Kennedy, writing the majority opinion in the *Gonzales v. Carhart* and *Gonzales v. Planned Parenthood* cases, said the law's opponents "have not demonstrated that the act would be unconstitutional in a large fraction of relevant cases." (*Catholic News Service*, April 18, 2007)

HHS allocates \$430 million to improve hospital disaster preparedness. On June 29, HHS awarded \$430 million to states, territories and four major metropolitan areas "to improve the readiness of hospitals and other health-care facilities in their jurisdictions." These funds are to be used to better

respond to bioterrorism attacks, infectious diseases, and natural disasters by allowing for the implementation of interoperable communications, systems to track available hospital beds, advance registration of volunteer health professionals and planning for both fatality management and hospital evacuations. (*Modern Healthcare*, June 30, 2007)

FDA task force report urges increased oversight of human-tissue industry. An internal task-force report released June 12 recommends that the Food and Drug Administration require more extensive tracking of non-organ tissue such as tendons, bones and heart valves from the cadavers where they are retrieved to the patients where they are implanted. Although the agency's tissues chief, Dr. Celia Witten, pronounced the industry safe, critics like U.S. Senator Chuck Shumer (D-NY) emphasize that the industry still does not require certification and specific training of tissue-recovery operators. These critics believe that the task force's recommendations do not go far enough, as they do not bar funeral homes from recovering body parts and don't require background checks or certification or immediate inspection of new companies (Associated Press, June 13, 2007)

OHRP to consider incidental findings policy. The Department of Health and Human Services Office for Human Research Protections agenda includes a number of controversial items, Director Bernard A. Schwetz said June 7. One of these issues includes how to deal with incidental findings in human research studies. Although discussed for decades, renewed interest in this area has been driven partly by new technologies that make incidental findings more likely and give rise to more possibilities for secondary research on archived data sets. Incidental findings pose ethical

dilemmas on several important questions, suggesting the need for institutions to devise guidance to help find the answers and prevent internal policy inconsistencies, Schwetz said. "HHS regulations do not address incidental findings directly, so investigators need to be sensitive to the issues they raise," he said. "Very few institutions have policies to provide guidance on these issues. At this point, I think the institutions have to step forward to propose guidance." (*BNA Medical Research Law & Policy Report*, June 20, 2007)

Skin cells may be used as stem cells, researchers say. Researchers have come much closer to a major goal of regenerative medicine, the conversion of a patient's cells into specialized tissues that might replace those lost to disease. The advance is an easy-to-use technique for reprogramming a skin cell of a mouse back to the embryonic state. If the technique can be adapted to human cells, researchers could use a patient's skin cells to generate new heart, liver or kidney cells that might be transplantable and would not be rejected by

the patient's immune system. But scientists say they cannot predict when they can overcome the considerable problems in adapting the method to human cells. Previously, the only way to convert adult cells to embryonic form has been by nuclear transfer, the insertion of an adult cell's nucleus into an egg whose own nucleus has been removed. The egg somehow reprograms the nucleus back to an embryonic state. That procedure is known as therapeutic cloning when applied to people, but no one has yet succeeded in doing it. (*New York Times*, June 7, 2007)

Study shows that coverage for general medical care is better than coverage for substance abuse treatment. A recently released Health Affairs analysis of health benefits trends illustrates the incongruence between those benefits offered for general medical care and those offered for substance abuse treatment. While employer-sponsored coverage for substance abuse treatment continues to have annual limits and lifetime caps on treatment visits and inpatient days, and also requires higher cost sharing than

coverage for general medical care, such limitations do not apply to general medical care, where nearly all covered workers had unlimited medical-surgical hospital days and office visits. Additionally, many workers are exempt from state mental health "parity" laws aimed at bringing private-sector mental health benefits more in line with coverage for other types of disorders. As a result, as of 2003, only one-fifth of U.S. workers with employer-sponsored health insurance were covered by "strong" parity laws that mandated mental health benefits, prohibit limits on outpatient visits and inpatient days, and limit the extent to which enrollees can face higher cost sharing for mental health services. (Health Affairs Press Release, June 7, 2007)

Students from the Center for Health Law Studies and Student Writers Association at Saint Louis University's School of Law contributed to this installment of "Of Note." Center Assistant Director Kelly Dineen supervised the contributions of health law students Kristen Ratcliff, Amy E. Scherer and Nathan Sturycz.