Surgeon Questions Study With "Off-Label" Uses of Medtronic Spinal Product

Dr. Charles Rosen, president of the Association for Medical Ethics and professor of orthopedic surgery at the University of California-Irvine, questioned a 2002 study at Walter Reed Army Medical Center that used Medtronic spine products on soldiers in ways not approved by federal regulators. Rosen expressed concern about the study in a Sept. 29 letter to Army Surgeon General Eric Schoomaker.

In the letter, Rosen questioned if patients knew the products were not approved by the Food and Drug Administration for use in their surgeries and if an independent Institutional Review Board oversaw and approved the "experiments on the men and women of the armed forces." (Janet Moore, *StarTribune.com*, Nov. 29, 2009).

Vatican Alerts Doctors to Anti-Life Mindset

Cardinal Tarcisio Bertone, Pope Bendedict XVI's secretary of state, cited an urgent need to educate society about the culture of life at a meeting of Italian physicians at the National Council of Catholic Medical Associations at the Vatican last November.

The cardinal reminded physicians that the activity of the Catholic doctor is revealed useful not only for the purpose of physical health, but also, in a certain sense, for the moral and spiritual health of the patient. (Antonio Gaspari, ZENIT, Nov. 2, 2009).

Weighing Medical Costs of End-of-Life Care

Based on annual data compiled by Dartmouth College, the Ronald Reagan UCLA Medical Center consistently ranks near the top of medical centers that spend the most on end-of-life care but do not have better results than hospitals which spend much less. The medical center has become a target for critics of wasted funds for needless test and futile procedures.

Dr. J. Thomas Rosenthal, chief medical officer of the UCLA Health System, and his colleagues worry that unless the distinction can be clearly drawn between excellence and excess in medical care, efforts to cut wasteful spending could be blunt rationing. "There's a real risk of doing harm here – real harm," he said.

Research recently published by UCLA and five other big California medical centers found that for heart failure patients, the hospitals that spend the most seem to save the most lives. Dartmouth researchers maintain that decades of research shows that higher spending does not necessarily buy better patient outcomes. (Reed Abelson, *New York Times,* Dec. 23, 2009).

Who Gets Expensive Cancer Drugs? A Tale of Two Nations

Research by the Johns Hopkins Berman Institute for Bioethics into comparisons of access to 11 expensive cancer drugs in the United Kingdom and the U.S. found both countries' systems far from perfect.

Seven of the medications studied are free to all British patients, who pay no out-of-pocket costs. The other four are not covered in the National Health Service because policy-makers determined that costs were not worth the limited benefits provided. U.K. patients who want the drugs have to pay for them on their own.

In the U.S. by comparison, most patients who have health insurance have some coverage for all 11 drugs. However, there is great variation in out of pocket costs based on insurance. Expenses for people on Medicare can range from $1,200 to $24,000. For those with limited or no insurance, costs can exceed $100,000 annually in some cases.

"Policy makers and our society now need to do the hard work of developing a reasoned, evidence-based system of using health care resources wisely, and the first step is to engage in an honest and transparent conversation about the values that should guide those decisions, a conversation that is informed by facts, not politics," said study lead author, Ruth R. (*ScienceDaily*, Dec. 14, 2009).

Bending the Rules of Clinical Trials

Ninety percent of 700 clinicians surveyed who are involved in clinical trials consider it acceptable to ignore certain entry criteria if they believe their patient could benefit from the trial, according to a report in the bioethics journal, *IRB: Ethics and Human Research.* Nearly 60 percent of those surveyed believed researchers should deviate from study rules if research could improve a patient's care.

"There's a pervasive idea among clinicians and patients that a new drug or device is going to make things better," said Dr. Charles W. Lidz, research professor of psychiatry at University of Massachusetts Medical School in Worcester and lead author of the study. Statistically, however, while many experimental treatments are as good as standard therapy, few actually end up being superior, and some are worse.

Dr. Lidz believes it is important for patients to participate in clinical trials if their current treatment isn't working. Clinical trials are central to determining if a new treatment works. Patients need to realize they are doing this for a larger cause, not necessarily their own interest. (Pauline W. Chen, MD, *New York Times,* Oct. 29, 2009).

Faith-Based Objections to Vaccines May Threaten Common Good

In light of concerns for a potential swine flu pandemic, some bioethicists say members of religious groups who choose to forgo vaccinations put their neighbors' health at risk and threaten the common good."Viruses and other contagious diseases don't care about our personal beliefs," said Nancy Berlinger, deputy director of the Hastings Center, a New York-based bioethics research institute.

Berlinger cited a 1944 U.S. Supreme Court decision that said "the right to practice religion freely does not include the liberty to expose the community or the child to communicable disease or the latter to ill health or death." Another ethical concern when a population refuses to be vaccinated is that public health resources have to be diverted to that population if an outbreak strikes.

"We're all members of the public, no matter what our personal beliefs are," Berlinger said, "and there's a point at which those beliefs start affecting someone else." (Tim Townsend, *beliefnet.news*, Dec. 8, 2009).

Students from the Center for Health Law Studies at Saint Louis University School of Law contributed the following items to this column. Amy N. Sanders, JD, assistant director, Center for Health Law Studies, supervised the contributions of health law students Gregory Barr (JD anticipated '11) and Meghan McNally (JD anticipated '10).

Fraud and Abuse: Allegran Files Latest Motion in Case Challenging Ban on Off Label Promotion

On October 1, 2009, Allegran, maker of Botox, filed a lawsuit against the government "seeking a declaration that FDA regulations that prohibit companies from engaging in truthful, non-misleading, accurate, and balanced speech about off-label uses of their product are unconstitutional." Allegran's concern stems from the plethora of non-label uses of their product Botox. The government responded by filing a motion to dismiss arguing that the claim is not ripe for review as the FDA has never brought claims against Allegran based on off-label promotions before and a motion for summary judgment stating that the FDA's drug approval system is consistent with the U. S. Constitution. Additionally, the FDA stated, "that it intended to rigorously pursue off-label promotion activities." On January 15, 2010, Allegran

filed a response to the government's summary judgment motion. In the complaint, Allegran argued, "that it cannot disseminate any information about off-label uses without fear of prosecution until it knows how the government differentiates between promotional and non-promotional speech."(BNA *Health Care Daily Report*, January 21, 2010).

Johnson & Johnson Accused of Drug Anti-Kickback Scheme

According to a complaint filed by the United States Attorney in Boston, "Johnson and Johnson paid kickbacks to the nation's largest nursing home pharmacy to increase the number of elderly patients taking several of its medications" when it paid Omnicare "tens of millions of dollars to buy and recommend Risperidoal, prescription pain relievers Duragesic and Ultram, and the antibiotic Levaquin." (American Health Lawyers*, Health and Life Sciences Daily, January 19, 2010).*

Deals to Restrain Generic Drugs Face a Ban

A group of House lawmakers and the head of the Federal Trade Commission plan to ask Congress to "block business deals in which the makers of name-brand drugs directly or indirectly pay generic makers to delay competition from cheaper drug alternative." The group wants Congress to include this in health care legislation. The current House bill includes the prohibition, while the current Senate bill does not. The group claims that Americans could save several billion dollars a year when purchasing prescription drugs and that, "deals between brand names makers and generic makers have delayed the introduction of a range of generics." (Natasha Singer, *The New York Times*, January 13, 2010).

Health Care Fraud Becomes the Newest Multi-Billion Dollar Industry

In recent months, health care fraud has become the nation's newest multibillion-dollar industry with scammers making an estimated $100 billion per year as the result of fraud schemes. Health care identity theft topped the list of crimes. According to Louis Saccoccio, executive director of the National Health Care Anti-Fraud Association (NHCAA), this most commonly occurs when someone with legitimate access, such as a hospital administrator or a doctor's assistant, sells patient information to organized criminal groups. Increasingly, criminal groups are hacking into digital medical records so they can steal money from the $450 billion, 44 million-beneficiary Medicare system -- making the government, by far, the "single biggest victim" of health care fraud, according to Rob Montemorra, chief of the FBI's Health Care Fraud Unit. One key reason Medicare information is a virtual "goldmine" for fraudsters, according to Montemorra, is the system's "pay and chase" system. Under the law, Medicare must send out payments within a very short time period.

Using stolen information and Social Security numbers, those engaging in fraud falsely bill Medicare and private insurers for drugs, equipment or treatment that were never prescribed. (*CNN* January 13, 2010 http://money.cnn.com/2010/01/13/news/economy/health_care_fraud/)

MS Pills Show Promise and Risk, Studies Say

Tests of the first two oral drugs for multiple sclerosis show that both reduce the frequency of relapses and may slow progression of the disease, but have side effects that could pose tough decisions for patients. About 2.5 million people worldwide have MS, a neurological disease that can cause muscle tremors, paralysis and problems with speech, memory and concentration. The studies involve the most common form of the disease, in which people are well for a while and then suffer periodic relapses. Current treatments can reduce the duration and severity of symptoms but require daily injections or infusions. The new studies tested two types of pills. Cladribine, made by Merck Serono and used to treat a rare blood cancer, could be taken by those with MS eight to 10 days a year. The other drug, Fingolimod, is being developed by Novartis for daily use in MS. The research found that patients on the pills were about half as likely to suffer relapses of symptoms as those who took placebos or a commonly prescribed shot for MS. But they also found both drugs significantly lowered immune defenses—in one study, two people died of unchecked herpes infections. The side effects detailed in the new studies are giving some physicians pause. Physicians are mindful of what happened with Tysabri, an MS drug that was approved in November 2004 and pulled from the market the next year after cases of a rare but lethal brain inflammation in some patients. It was reintroduced in 2006, but doctors are still monitoring for side effects. (Mike Stobbe, AP Medical Writer, Jan. 20, 2010 http://news.yahoo.com/s/ap/20100120/ap_on_ne_me/us_med_multiple_sclerosis)

CDC: 1 in 5 Teens Has Cholesterol Problem

One in five teens in the U.S. and more than 40% of obese teens have abnormal cholesterol, according to a new report from the Centers for Disease Control and Prevention (CDC). The findings suggest that the American Academy of Pediatrics' (AAP) 2008 guidelines—which recommend more aggressive cholesterol testing and intervention in kids, particularly the overweight and obese—make sense, the authors conclude. Overall, one-third of adolescents in the new CDC survey were overweight or obese; 22% of the overweight teens and 43% of the obese teens had at least one blood-fat abnormality (as did 14% of teens who weren't overweight). Findings were published in the *Morbidity and Mortality Weekly Report*. "It used to be that family history drove who should be screened. Now the recommendations say to include

weight as a criterion," says Joyce M. Lee, MD, assistant professor of pediatric endocrinology at the University of Michigan. "With obesity being such a problem in [American] children, conditions that we thought were exclusively adult conditions do seem to be prevalent in a small amount of children." (*CNN* January 22, 2010 http://www.cnn.com/2010/HEALTH/01/22/teens.cholesterol/)