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Biosimilars Will Change Market

The manufacturers of tumor necrosis factor–alpha inhibitors could lose billions of dollars in revenue with the introduction of biosimilars in the United States and Europe, according to the research firm Decision Resources. By 2018, biosimilars of TNF-alpha drugs could cut $9.6 billion from brand sales in the United States, France, Germany, Italy, Spain, and the United Kingdom. But the development could also be a boon for payers in those countries, which could save $4 billion during that period. Decision Resources said it expects the movement to TNF-alpha biosimilars to be driven largely by payers, not physicians. "For the second year in a row, surveyed U.S. payers rank TNF-alpha inhibitors as their top priority" for reducing biologics spending, MaryEllen Klusacek, Ph.D., an analyst at the research firm, said in a statement. "Based on this finding, we anticipate that payer pressure on physicians to prescribe biosimilar TNF-alpha inhibitors will be high."

Arthritis Kit Seller Busted for Fraud

The owner of a Houston-based durable medical equipment company has pleaded guilty to selling medically unnecessary orthotic devices as parts of "arthritis kits" to Medicare beneficiaries. The kits included braces for both sides of the body and related accessories, such as heating pads. Noel Wayne Jhagroo, owner of Trucare Medical Equipment Services, is alleged to have billed Medicare about $4,000 per kit, according to U.S. Health and Human Services Inspector General Daniel R. Levinson. The case was investigated by the FBI and Inspector General Levinson's office as part of a larger HHS effort to crack down on Medicare fraud.

Pipeline Is Full of Treatments

Pharmaceutical and biotechnology companies have nearly 1,000 medications and vaccines in the pipeline to treat diseases that disproportionately affect women, according to a report released by the Pharmaceutical Research and Manufacturers of America. The 969 medicines are either in clinical trials or under review by the Food and Drug Administration. They include medications for breast and cervical cancers, arthritis and musculoskeletal disorders, diabetes, autoimmune diseases, eye conditions, gastrointestinal problems, kidney and urologic diseases, respiratory diseases, neurologic conditions, psychiatric disorders, sepsis, obstetric and gynecologic diseases, and more, according to the trade group. For example, there are 114 medicines under development for autoimmune diseases, which affect women at a rate three times that for men.

Electronic Tools Effective: AHRQ

Consumer health informatics (electronic tools and applications designed to provide tailored health advice to patients) could save money by eliminating the need for some health education activities now performed by clinicians, said a report from the Agency for Healthcare Research and Quality. The agency reviewed more than 100 studies of consumers' getting health information via the Web, computer programs, and other electronic avenues such as texting and chat groups. The analysis found that the most effective health informatics applications tailor messages using a patient's own health information and give feedback about that person's progress as the intervention progresses. The AHRQ report also found that feedback from a clinician doesn't seem to be any more effective than that provided by computer. The key is timeliness, not the human touch, the study concluded.

Provider Fraud Most Common

By far, most health care fraud (80%) involves providers' systematically overcharging public or private insurers, according to a report from researchers at George Washington University, Washington, and the National Academy for State Health Policy. The study found that these schemes disproportionately target demographic groups who are likely to be enrolled in Medicare and Medicaid. However, the study found that fraud information on the public programs is frequently confused with payment-error data. The authors recommended stronger laws governing insurance marketing, enrollment, claims payments, and antifraud procedures.

DEA Effort Delays Pain Relief

Heightened efforts by the Drug Enforcement Administration to prevent the theft of prescription narcotics are denying pain relief to many nursing home, hospice, and other long-term care patients, said two senators in a letter to Attorney General Eric Holder. Sen. Herb Kohl (D-Wis.), chairman of the Senate Special Committee on Aging, and Sen. Sheldon Whitehouse (D-R.I.) called on Attorney General Holder to issue new directives to the DEA. To deter theft and diversion of prescription drugs, the agency recently stepped up the enforcement of laws that require pharmacies to obtain hard copies of prescriptions with signatures from physicians—instead of routine medication orders—for controlled substances that are prescribed in residential care settings. This has disrupted "well-established medication coordination protocols" and has led to delays in providing those medications to sick patients, the two lawmakers said.

—Mary Ellen Schneider

Failure to Follow Safety Standards Needs Penalties

BY SUSAN BIRK

ROSEMONT, ILL. — Despite major patient safety strides during the past decade, health care providers need to create more accountability for medical errors and patient safety lapses in order to continue improving, according to Dr. Robert M. Wachter, professor of medicine at the University of California, San Francisco.

At the Joint Commission national conference on quality and patient safety, Dr. Wachter offered his perspectives on the status of patient safety in health care 10 years after the publication of the first Institute of Medicine report, "To Err Is Human: Building a Safer Health System." He and Dr. Peter J. Pronovost of Johns Hopkins University, Baltimore, published an editorial on the topic shortly after the conference (N. Engl. J. Med. 2009;361:1401-6).

Balancing a culture of "no blame" with a culture of accountability remains a key challenge for providers. Although it's true that "most errors are committed by caring, competent people trying hard to get it right ... the system produces low-quality, unsafe, unreliable care partly because there's been no business case to do otherwise," he said.

" 'No blame' is the right response for innocent slips and mistakes, which turn out to be most errors. But there need to be clear demarcations of blameworthy acts—not just gross incompetence, not just disruptive behavior, but also failure to follow reasonable safety standards," said Dr. Wachter, who edits two online publications for the Agency for Healthcare Research and Quality: WebM&M (www.webmm.ahrq.gov) and Patient Safety Network (www.psnet.ahrq.gov).

Dr. Wachter cited the fact that average hand washing compliance rates continue to hover at only about 50% as an example of the need for more accountability. "I don't believe that is fully a systems problem," he said. Part of the problem is that "there have been no penalties for transgressions."

Although accountability is essential, "my guess is it will go too far," Dr. Wachter added. "We've created an environment where people don't want to have to talk about errors. We're probably going to have to go too far and then come up with a sweet spot."

Dr. Wachter also commented on other aspects of patient safety:

► **Regulation.** Health care organizations need regulators to set standards, but the challenge is ensuring that these standards truly help organizations improve safety. Until the Joint Commission developed standards for reading back instructions, "virtually none of us thought of doing that on our own," he said.

At the same time, "it is extraordinarily difficult to have a set of rules and standards that apply equally in nuanced areas to organizations that are incredibly different in the way they do business, their financial resources, and their capacity," he added.

For that reason, regulation is useful to get people moving, "but it tends to run out of gas over time," Dr. Wachter said. To illustrate, he cited the Joint Commission's recent decision to remove adherence to medication reconciliation standards as a requirement for accreditation because organizations struggled to develop appropriate processes.

However, having an "outside organization creating rules and standards we must abide by was extraordinarily important in the first 5 years" after the IOM report, he said. Despite some glitches, "the Joint Commission has improved its processes tremendously" and recently made an important step in the right direction with the creation of the Center for Transforming Healthcare.

► **Reporting.** "The admonition to report everything is silly," Dr. Wachter said. "Our mistake here was to not be thoughtful about what we are going to do with all of these reports" before requiring them.

However, providers have learned from this experience and begun to think more critically about what should be reported and how the data should be used, he said.

State reporting requirements on the 27 "never events" put forth by the National Quality Forum have led to more focused patient safety efforts. "Until the state reporting system, our process [at UCSF] for doing root cause analysis was pretty haphazard," he noted. Now the institution holds a weekly 2-hour root cause analysis meeting attended by the same group of leaders.

► **Information technology.** Health care providers have developed a more robust, less naive understanding of the role of health care information technology in patient safety and now realize that it is not a panacea. Improvement efforts are not nearly as effective "if we just do the computer piece but don't educate people," Dr. Wachter said.

Still, "even though we've got plenty of room to go, I think we should all be proud" of what has been accomplished in the past 10 years, he said. ■

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