FDA Seeks Proposals to Improve Drug Safety

BY ALICIA AULT
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WASHINGTON — Acknowledging that its drug safety system is inadequate, several Food and Drug Administration officials told an Institute of Medicine panel examining the issue that the agency is ready for recommendations on how to better protect the public's health.

The IOM committee, convened at FDA's request, has been charged with examining every aspect of the agency's drug safety program, including whether it needs new powers to mandate postmarketing safety studies by pharmaceutical companies. At its first meeting in June, the panel heard from representatives of the FDA, the pharmaceutical industry, and consumers.

Janet Woodcock, M.D., acting deputy commissioner for FDA operations, said the agency had come a long way but could improve on predicting, preventing, monitoring, and mitigating adverse drug events. Changes in the past decade have made it more difficult to ensure safety, she added.

The United States is now often the first avenue for sales, and drug marketing campaigns aimed at physicians and consumers have led to a much quicker uptake of new drugs, bringing safety issues to a head even faster. Recalls are happening faster after a drug comes to market, but there has been no big increase in the number of withdrawals, Dr. Woodcock said.

The FDA is hamstrung by international agreements on how much premarket safety data can be requested, and the agency can't force drug makers to conduct postmarketing safety studies, she said.

MedWatch, FDA's postmarketing surveillance system is full of gaps, Dr. Woodcock added. Pharmaceutical makers must report adverse events to MedWatch, but reports from physicians, pharmacists, and other health care providers, and patients are voluntary. MedWatch receives 400,000 reports a year, but the FDA acknowledges it captures only a fraction of the events.

Alan Goldhammer, Ph.D., associate vice president of regulatory affairs at the Pharmaceutical Research and Manufacturers of America, said, "simply increasing the number of spontaneous reports is not the answer" because it might just "increase the noise" instead of providing real signals.

"We know more about safety profiles of drugs approved today than those approved 20 years ago," Dr. Goldhammer said, adding that "FDA's current legal authorities over drug safety are robust and do not need to be changed."

Bill Vaughan, a senior policy analyst with Consumers Union, vehemently disagreed, saying that the Washington-based nonprofit believes that "legislative action is essential to address the substantial problems in drug safety and oversight that have been highlighted over the last year."

Mr. Vaughan urged the IOM panel to make interim recommendations to Congress as early as this summer, rather than waiting until its final report, which is due next year.

Steven Galson, M.D., the acting director for FDA's Center for Drug Evaluation and Research touted the FDA's new Drug Safety Oversight Board, saying it would help provide "independent" oversight. The board's first meeting was in late June.

Sen. Chuck Grassley (R-Iowa), chairman of the Senate Finance Committee, said he was skeptical of the board's capabilities, noting in a letter to FDA acting commissioner Lester Crawford, D.V.M., that it does not seem independent enough.

The next meetings of the IOM panel are scheduled for July 20 and Oct. 25. ■

Drug Adverse Event Surveillance System Delivers Mixed Results

A new national active surveillance system designed to detect adverse drug events is good at picking up true cases, but not particularly sensitive—especially in detecting hypoglycemia caused by diabetes medications and bleeding associated with anticoagulants, the Centers for Disease Control and Prevention reported.

In 2003, the CDC worked with the Consumer Product Safety Commission and the Food and Drug Administration to develop the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project.

Adverse drug events (ADEs) are often more difficult to identify than other injuries, so the CDC conducted an independent chart review in a sample of six NEISS-CADES hospitals (0.2%-1.7% of emergency department visits).

Of 4,561 charts reviewed, 68 ADE cases were identified. Of the 29 ADE cases that had been reported to NEISS-CADES prior to the chart review, 25 were among the 68 cases detected by the reviewers. The remaining four were false positives in which an injury attributed to a drug in the chief complaint section of the chart was not confirmed elsewhere in the chart (MMWR 2005;54:380-3).

The estimated sensitivity of the NEISS-CADES for ascertaining ADEs was 0.33, while the estimated positive predictive value of a reported ADE was 0.92. The relatively low sensitivity was attributed to the difficulty in detecting hypoglycemia associated with diabetes agents (just 3 of 16 were detected), and of bleeding associated with anticoagulants such as warfarin and heparin (1 of 9 were detected). When those two types of cases were excluded, sensitivity of the NEISS-CADES increased to 0.45. That figure compares favorably with the FDA's Adverse Event Reporting System, a passive surveillance system.

—Miriam E. Tucker

POLICY & PRACTICE

Dozing Doctors

Residents and medical students are still suffering from fatigue, despite the shorter work hours established in 2003 by the Accreditation Council for Graduate Medical Education. In a survey of 1,126 medical students and 1,010 residents, the American Medical Association found that 44% of residents and 39% of medical students said they've experienced sleep deprivation about once a week or more often during their most recently completed rotation. The ACGME work limit is currently 80 hours per week, but 11%-12% of the respondents said their workweek exceeded those hours on their most recent rotation. Nearly half of the respondents thought that sleep deprivation or fatigue may have had a negative impact on the quality of patient care they delivered.

More Options Versus Saving Costs

Elderly patients aren't willing to sacrifice physician/hospital choice to save on out-of-pocket medical costs, the Center for Studying Health System Change reported. In a 2003 survey of 36,000 adults, including 6,700 aged 65 years and older, only 45% of the seniors were willing to trade broad provider choice to save money, compared with 70% of people aged 18-34 years. "The findings suggest that Medicare managed-care plans will face a tough sell in convincing seniors to switch from fee-for-service Medicare where they have unfettered choice of doctors and hospitals to private plans that limit provider choice but offer cost savings," said HSC president Paul B. Ginsburg, Ph.D. Given these concerns, it's clear that Medicare Advantage Plans will need to offer broad provider networks to attract more seniors.

Weight Loss Surgery Coverage

The American Society for Bariatric Surgery (ASBS) is asking Medicare to provide coverage for bariatric surgery. Medicare currently covers gastric bypass surgery if it is medically appropriate and if the surgery is used to correct an illness that caused the obesity or was aggravated by it. ASBS is asking Medicare to expand its coverage to include laparoscopic procedures and to make coverage more uniform around the country, since Medicare coverage decisions for weight-loss surgery are generally decided from region to region. "The current coverage policy has become outdated as new surgical procedures have become available and as evidence mounts as to their safety and effectiveness," ASBS President Harvey Sugerman, M.D., said in a statement.

Medicare Drug Benefit Explained

The Centers for Medicare and Medicaid Services is requiring all health plans serving Medicare patients to include all drugs in six categories on their formularies starting in 2006, when the Part D drug benefit begins. The agency noted that in earlier guidance on the Medicare drug plan, it stated that "a majority" of drugs in these categories—antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and HIV/AIDS drugs—would have to be on plan formularies and that beneficiaries should have uninterrupted access to all drugs in those classes. But in training sessions and in answering user calls, "CMS has consistently explained that this meant that access to 'all or substantially all' drugs in these specific categories needed to be addressed by plan formularies," the agency said. "This is because the factors described in our formulary guidance indicated that interruption of therapy in these categories could cause significant negative outcomes to beneficiaries in a short timeframe."

Underinsured Statistics

A little insurance isn't necessarily better than none, according to a study from the Commonwealth Fund. Drawing from a survey of 3,293 adults, the study found that 16 million adults were underinsured in 2003, meaning their insurance did not adequately protect them against catastrophic health care expenses. Underinsured adults are almost as likely as the uninsured to go without needed medical care and to incur medical debt. For example, more than half of the underinsured (54%) went without needed care during the year, failed to fill a prescription, or failed to visit a physician for a medical problem. "An increase in the numbers of underinsured could undermine effective care, health, and financial security—making it harder to distinguish the uninsured from the insured," according to the report. The study appeared as a Web-exclusive article in Health Affairs, June 14, 2005.

The OxyContin Wars

The federal Drug Enforcement Administration's efforts to stop illegal use of the prescription painkiller OxyContin have "cast a chill over the doctor-patient candor necessary for successful treatment," Ronald T. Libby, Ph.D., a political science professor at the University of North Florida in Jacksonville, wrote in a policy analysis for the Cato Institute, a libertarian think tank. The DEA's campaign includes elevating OxyContin to the status of other schedule II substances and using "aggressive undercover investigation, asset forfeiture, and informers," he notes. "By demonizing physicians as drug dealers and exaggerating the health risks of pain management, the federal government has made physicians scapegoats for the failed drug war," Dr. Libby wrote. When asked for comment, a DEA spokeswoman referred to a recent statement by DEA Administrator Karen Tandy. "We employ a balanced approach that recognizes both the unquestioned need for responsible pain medication, and the possibility … of criminal drug trafficking," Ms. Tandy said, noting that physicians "are an extremely small part of the problem."

—Jennifer Silverman