FDA Not Yet Ready to Get Behind the Counter

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WASHINGTON — The Food and Drug Administration has no immediate plans to seek establishment of a new, behind-the-counter class of drugs, agency officials said at the conclusion of a day-long meeting on the topic in November.

FDA Deputy Commissioner for Policy Dr. Randall Lutter told reporters that he realized that by holding the meeting the agency had likely raised expectations that it would take action. But, he said, the FDA was merely soliciting views and comments on which, if any, pharmaceuticals might be moved to a special status by which they could be dispensed directly by a pharmacist after counseling, but without a physician's prescription.

The agency accepted comments until Nov. 28, and would decide afterward "whether additional action is appropriate," said Dr. Lutter. He added that the FDA had no specific timetable in mind.

This is the fourth time the FDA has broached the idea of following the lead of several other nations, including Canada and the United Kingdom, by creating a third class of drugs.

At the public meeting, Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, contended that the agency's latest foray had been "precipitated by drug companies who make statins and want to switch them to [over-the-counter]."

Merck & Co. has sought permission to sell lovastatin (Mevacor) over the counter in the United States. An FDA panel was due to review that request on Dec. 13.

Dr. Lutter said, however, that agency officials convened the meeting "on our own initiative," and not at the behest of any drug maker. The agency decided to take another look at BTC (behind the counter) drugs because consumers increasingly are involved in their own health care and frequently use the Internet not just to access information, but also to buy products without a physician's advice or counsel, Dr. Lutter said.

A BTC class of drugs might be one way both to empower consumers and to ensure that they get safe and effective medications, he said.

Not surprisingly, pharmacists who spoke at the meeting were in favor of creating a new BTC class, while physicians were opposed. There was a mixed response from consumer advocates.

Joseph Cranston, Ph.D., a pharmacist and director of science, research, and technology for the American Medical Association, said that the AMA opposes creation of a BTC class. The FDA does not have the statutory authority to create such a class, he said, adding, "thus, it is perplexing that this meeting is even being held today."

Dr. Cranston said that the AMA was concerned that insurers might require use of BTC medications before covering prescription medications, and that it wasn't clear if moving drugs behind the counter would increase or decrease access or costs.

Also, pharmacists do not have the training to make the same types of patient management decisions as physicians, he said.

The National Community Pharmacists Association said that BTC drugs could reduce consumer health care costs, increase patient convenience, and perhaps add yet another avenue to track postmarket drug safety. An early November survey of its membership found that 97% of members were in favor of the new BTC class, according to Stephen L. Giroux, who serves as NCPA president.

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DR. WOLFE

Dr. Giroux also cited polling data that showed that patients would support a BTC category.

Michael Moné, director of regulatory compliance for Medicine Shoppe International and a member of the American Pharmacists Association (APhA) board of trustees, said that having a BTC class of drugs would benefit consumers and public health. "With increased access to medications, combined with a pharmacist intervention, a patient is less likely to go untreated or incorrectly treated, and therefore is less likely to deal with more advanced symptoms or the adverse effects of inappropriate usage," he said.

All pharmacy groups that presented at the meeting said that if BTC were to become a reality, standard protocols for dispensing and counseling should be established, and that pharmacists should be reimbursed for their services.

Some consumer advocacy groups expressed concern that insurers not only would not reimburse pharmacists, but that they would also drop coverage altogether of products that were moved behind the counter. Laurie Tansman of Mount Sinai Medical Center, New York, said that diabetes patients who could get oral agents BTC might forego hard lifestyle changes and perhaps skip needed physician visits.

The Consumer Healthcare Products Association, whose members make OTC products, argued against creation of a new class, saying that consumers were well served by the current two-class system. OTC switches have mostly been a success, said David C. Spangler, CHPA senior vice president for policy and international affairs.

George Quesnelle, president of GlaxoSmithKline Consumer Healthcare, echoed the CHPA position. GSK makes and markets Nicorette. Mr. Quesnelle said significantly more people have quit smoking since nicotine replacement products were moved OTC. ■

POLICY & PRACTICE

FDA Warning on Effexor

The Food and Drug Administration has warned Wyeth Pharmaceuticals that a journal ad for Effexor XR (venlafaxine) was misleading because it overstated the drug's efficacy, made unsubstantiated superiority claims, and minimized its risks. Effexor XR is approved for major depressive disorder. The ad suggested that patients who did not respond to other antidepressants could be successfully treated with Effexor XR; that superiority has not been demonstrated through substantial evidence or clinical experience, said the FDA. Wyeth also said that Effexor was used in 20 million patients; that is misleading because it is not an accurate tally of unique users, said the agency. "Falsely inflating the number of people treated with Effexor XR may mislead consumers and healthcare providers into inferring greater efficacy and safety than would be warranted by the actual numbers," wrote the FDA.

Psych Disorders = More Drug Use

Men who have a psychiatric diagnosis tend to have higher rates of daily substance abuse, compared with peers who do not have a co-occurring diagnosis, according to a survey of men admitted to hospitals in 2005. The DASIS (Drug and Alcohol Services Information System) Report compiled data from 544,800 male hospital admissions in 26 states in 2005. Of those, 86,500 (16%) were for admission with co-occurring substance use and psychiatric disorders. Daily use of alcohol, cocaine, marijuana, and stimulants, were higher for those with a codiagnosis. These men also were more likely to report abuse of multiple substances, and to have started using alcohol or drugs before age 13 years. The DASIS Report is produced by the Substance Abuse and Mental Health Services Administration, and its most recent report was issued in mid-December. Copies can be found at www.oas.samhsa.gov.

Access Reduced by Cost

Forty million Americans can't get access to needed health care, and 20% said the main reason was because they could not afford the services, according to a report issued in December by the Centers for Disease Control and Prevention. "Health, United States, 2007" is a compilation of pertinent data gathered by the CDC's National Center for Health Statistics. According to the report, in 2005, 1 in 10 people between the ages of 18 and 64 years reported that they had not been able to get prescription drugs in the past year because of the cost. Another 10% said they had delayed necessary medical care because of cost issues. The report also found that 30% of 18- to 24-year-olds were uninsured, and another 30% of that age group did not have a usual source of medical care. Ten percent of 45- to 64-year-olds did not have a usual source of care. The report highlighted some other age-specific data as well. For instance, about 70% of men and more than 80% of women over age 75 either had hypertension or were taking antihypertensives in 2001-2004, compared with about 35% of adults aged 45-54. And about 20% of 16- to 17-year-olds, and more than 40% of 18- to 25-year-olds reported binge alcohol use in 2005; 20% of the latter age group reported illicit drug use in the previous month.

FDA Can't Fulfill Mission

Three members of the FDA Science Board issued a damning report on the state of the agency, saying that "the agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." The authors wrote that the FDA has become weak and unable to fulfill its mission because of the increasing number of demands and an inability to respond because of a lack of resources. "FDA's inability to keep up with scientific advances means that American lives are at risk," wrote the panelists, adding that the agency can't fulfill its mission "without substantial and sustained additional appropriations." The report was written by Gail Cassell, Ph.D., vice president of scientific affairs at Eli Lilly & Co.; Dr. Allen D. Roses, Jefferson-Pilot Corp. Professor of Neurobiology and Genetics at Duke University; and Dr. Barbara J. McNeil, head of the health care policy department at Harvard Medical School, Boston. Members of the Coalition for a Stronger FDA and the FDA Alliance urged Congress to heed the report's warnings. "FDA can't improve its science, prepare for the future, or protect American consumers without significant additional resources," said coalition member Don Kennedy, Ph.D., a former FDA commissioner and editor in chief of the journal Science, in a statement.

Agency's Approval Plan Flawed

FDA is considering new guidance that would allow drug companies to use journal articles to promote "potentially dangerous uses" of drugs and medical devices without prior FDA review and approval, according to a top lawmaker. Rep. Henry Waxman (D-Calif.), who chairs the House Committee on Oversight and Government Reform, urged the FDA in a Nov. 30 letter to reconsider its draft guidance, which the congressman said was close to being finalized. "The draft guidance that I have obtained would, in effect, allow drug and device companies to short-circuit FDA review and approval by sponsoring drug trials that are carefully constructed to deliver positive results and then using the results to influence prescribing patterns," Rep. Waxman said. "This undercuts the prohibition on marketing of unapproved uses of drugs and devices." He asked the FDA to provide detailed information on the development of the new policy and how it would address his concerns.

—Alicia Ault