

# FDA Seeks to Increase Fees for Drug Manufacturers

*The agency proposes to use most of the money to upgrade its postmarketing drug safety monitoring.*

BY ALICIA AULT

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The Food and Drug Administration has proposed greatly increasing the fees its drug division collects from pharmaceutical manufacturers, saying that current fees collected under the Prescription Drug User Fee Act have not kept pace with inflation or the agency's growing workload.

Most of the additional money would be used to upgrade the agency's postmarketing drug safety monitoring. The FDA also is proposing to create a separate program to collect fees from companies that want their direct-to-consumer television ads reviewed by the agency.

The FDA published its proposals in the Federal Register in January and collected comments on them at a public meeting this month. The final proposal will be sent to Congress later this year, said Jane Axelrad, associate director for policy at the Center for Drug Evaluation and Research (CDER), in a teleconference sponsored by the FDA.

Time is of the essence as PDUFA, first enacted in 1992 and reauthorized in 5-year increments, is due to expire Sept. 30.

Under PDUFA, the FDA charges pre-

scription drugmakers a set fee to review the safety and efficacy of products submitted under a new drug application. In return, the agency has to meet deadlines for review and approval.

The law has helped the FDA reduce review times and increase its postmarketing oversight, said Dr. Steven K. Galson, CDER director, during the teleconference.

Under the new proposal, FDA seeks to collect \$393 million annually, \$87 million more than it currently takes in each year. Drug user fees account for about half of CDER's budget, said Dr. Galson, adding that he could not say whether that would hold true going forward, since the agency has not yet received its appropriation for fiscal 2007 or a budget for fiscal 2008.

However, Ms. Axelrad said that drug user fees represent an increasing proportion of CDER's budget.

Public Citizen's Health Research Group criticized that trend, saying that the agency should not receive so much of its funding from the industry it regulates.

"The FDA's crucial drug regulatory functions are too important to be tainted and compromised by direct funding from the very companies whose drugs the agency reviews for safety," Dr. Sidney Wolfe, direc-

tor of the health group, said in a statement.

The biotechnology and pharmaceutical industries praised the FDA proposal.

"The PDUFA recommendations announced today are a win-win," said Jim Greenwood, president of the Biotechnology Industry Organization, in a statement. "If enacted, they will help enhance and improve drug safety while providing resources to continue to enable efficient and comprehensive review of new drugs."

The largest portion of the increase, \$29 million, would be devoted to postmarketing safety. With those funds, the agency said it could hire 82 new employees, and acquire the best tools and databases for improving the detection and analysis of safety signals. The agency also will institute new programs to reduce medication errors, in response to an Institute of Medicine report issued in September 2006 calling for drug safety improvements at the agency.

Some \$20 million would go to cover expenses incurred in the last few years to facilitate drug makers' requests for formal meetings about their products. Sheila Mullin, FDA assistant commissioner for planning, said that in fiscal 2005, the

agency held 1,800 formal meetings at manufacturers' request.

About \$4 million would be devoted to improving information technology for drug reviews, with the goal of moving to "an all-electronic environment," according to the FDA proposal.

"Reviewing data electronically helps to improve the efficiency of the drug approval process and expedites getting im-

portant new drugs to the patients who need them," said Billy Tauzin, president and CEO of the Pharmaceutical Research and Manufacturers of America, in a statement.

**FDA regulatory functions are too important to be compromised by direct funding from companies.**

DR. WOLFE

The agency is proposing to create a new user fee program solely to fund the review of direct-to-consumer television ads. Currently, companies can voluntarily submit their ads for review, but the FDA has not been able to keep up with the growing workload, said Dr. Galson.

The FDA anticipates charging \$6 million in the first year of the program, which would subsidize the hiring of 27 new employees. Another \$6 million would be collected for a reserve fund, to cope with unanticipated increases in volume of advertisements. ■



## Talk Dollars and Cents With Patients

BY PATRICE WENDLING

Chicago Bureau

TUCSON, ARIZ. — Physicians and patients seldom discuss new medication costs and other acquisition issues, Dr. Derjung Mimi Tarn and associates reported in a poster presentation at the annual meeting of the North American Primary Care Research Group.

The investigators audiotaped the clinic visits of 185 patients who were receiving 243 new medication prescriptions and found that discussions about cost occurred in only 28 of the encounters. Patients rarely initiated conversations about cost, doing so for only four new prescriptions.

Physicians talked about cost or insurance for 12% of the 243 prescriptions, mentioned whether the medication was generic or brand name for only 2% of the prescriptions, talked about how to obtain the medication for 19%, about how long the supply would last for 9%, and about refills for 5%.

The analysis was based on the taped clinic visits that were conducted in 1999 at the University of California's Davis Medical Group and Kaiser Permanente, both in Sacramento, Calif., as part of the Physician Patient Communication Project. The project included 15 family physicians, 18 internists, and 11 cardiologists. The patients' mean age was 55 years, 83% were Caucasian, and more than 75% paid less than half of prescription drug costs. Overall, 31% were seen by family physicians, 47% by internists, and 23% by cardiologists (percentages do not total 100 because of rounding).

As patient age increased, the chances of physicians discussing cost decreased, according to a multivariate analysis that adjusted for medication class, over-the-counter and as-needed medication status, patient gender and race, prescription drug coverage, number of continued medications, and number of new medica-

tions prescribed. One possible explanation for that finding may be that time constraints and multiple health concerns were a factor, Dr. Tarn said in an interview.

Patients with a yearly income of less than \$20,000 had significantly more conversations about medication costs than did those with an annual income of \$40,000-\$60,000 (odds ratio 8.27 vs. 0.29, respectively).

Family physicians (OR 0.003) and internal medicine physicians (OR 0.02) were less likely to discuss cost than were cardiologists. The investigators suggested that cardiologists may encounter more patients with chronic conditions and thus are more aware of cost issues, or perhaps that in this setting, they were prescribing more brand name or expensive medications and have had more problems with insurers not covering these drugs, said Dr. Tarn, department of family medicine, David Geffen School of Medicine, University of California, Los Angeles.

The results don't necessarily mean that primary care physicians are really doing that much worse, as the study did not evaluate previous interactions. It may be that primary care physicians have been seeing these patients for years, have a much closer relationship, and have had these types of discussions with their patients in previous visits, she said.

Other study results have also shown that physicians and patients seldom discuss cost because they are uncomfortable about raising the subject. However, both parties need to be more aware of the issue, because high medication costs are strongly associated with medication underutilization and noncompliance, she said.

"Patients really shouldn't be scared to ask if there are cost issues" or to ask if it's the cheapest medication available, Dr. Tarn said. "On the flip side, previous studies have shown that doctors aren't very good at recognizing whether patients are having trouble with costs. A simple exchange can bring out a lot of concerns with patients." ■

## Liability Parameters of Information Technology in Health Care Need Defining

WASHINGTON — From a liability perspective, health information technology remains a double-edged sword whose parameters still need to be spelled out, experts said at a meeting sponsored by eHealth Initiative and Bridges to Excellence.

"It's going to provide protection in some places and increase liability in others," said attorney Marcy Wilder, a partner with Hogan & Hartson.

When it comes to electronic clinical decision support (CDS) tools, Jud DeLoss, vice chair of the HIT Practice Group at the American Health Lawyers Association, recommended that physicians document their reasoning when they disregard the tool's suggestion.

Although it would be "difficult to pull off," attorneys could create a class of victims for whom they argue that CDS was not followed, leading to detrimental results, he said. Conversely, attorneys could charge that a physician overly relied on the tool.

Ms. Wilder pointed out another gray area created by HIT: delineating who contributed what sections to an electronic health record. "Look at the paper system. We have handwriting and signatures, which are simple tools to identify who's responsible for which clinical applications, which provider made the diagnosis, who authorized the medication change. It is both easier and more difficult to do that with electronic health records."

Although systems are in place to address identity authentication in health care institutions, problems may arise when data from shared information warehouses such as a regional health information organization are incorporated into an electronic medical record, Ms. Wilder said.

Physicians also are concerned about the validity of the portion of an electronic medical record that they did not make, Mr. DeLoss added.

—Nellie Bristol