FDA Proposes New Guidelines on Advisers' Conflicts of Interest

BY ALICIA AULT
Associate Editor, Practice Trends

The Food and Drug Administration is proposing to beef up its conflict-of-interest guidelines for experts who serve on its advisory committees, the agency announced in a teleconference.

Proposed guidelines would bar experts with stock or other financial interests worth more than $50,000 in a particular company from reviewing that manufacturer's product, and ban voting by those who receive or own less than $50,000.

The $50,000 rule would be applied to any holdings or interest within 12 months of an advisory panel meeting.

The proposal was billed by FDA officials as an upgrade of guidelines that have been in effect since 2000 and were made partly in response to public demands for more accountability, according to Randall Lutter, FDA acting deputy commissioner for policy.

"[The] FDA is committed to making the advisory committee process more rigorous and transparent so that the public has confidence in the integrity of the recommendations made by its advisory committees," said Mr. Lutter in a statement issued by the agency.

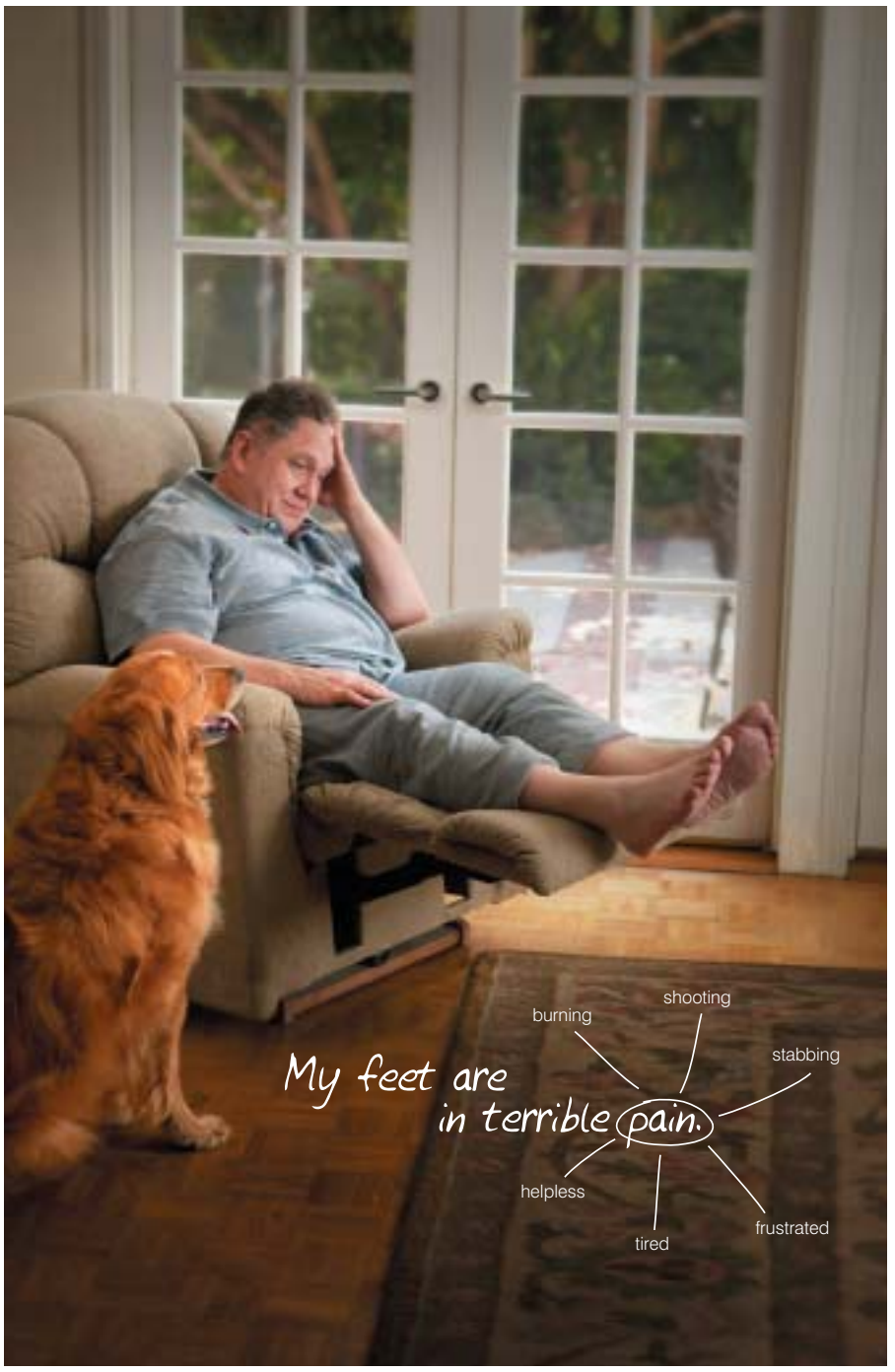
However, in the briefing, he said the FDA "was not aware of any instances where decision making has been adversely affected by conflicts members might have."

The new guidance attempts to balance the quest for transparency with the need for qualified experts, said Mr. Lutter.

As in the past, the guidelines are not legally binding. They are offered as suggestions to staff evaluating potential conflicts of interest by both government and nongovernment employees. It is rare for staff to make decisions that fall outside of the guidance, though, and waivers will likely only rarely be granted, said Mr. Lutter.

For instance, if a panel member has received an individual grant or other fee of less than $50,000 from a company for work in the hematology area, but is reviewing the company's cardiology drug or device, that person might be allowed to participate in the panel meeting.

The guidance document was posted on the FDA's Web site on March 21. ■



Employer-Based Health Coverage Dwindling

BY JOEL B. FINKELSTEIN
Contributing Writer

WASHINGTON — Companies both large and small are finding it increasingly difficult to afford the health insurance coverage they have traditionally provided to their workers, experts warned at a conference sponsored by AcademyHealth.

Employer-based insurance remains the dominant source of coverage in the American health care system. However, the proportion of companies that provide health benefits dropped from 70% in 2000 to 60% in 2005. Small businesses, those with only a handful of employees, have been especially hard hit by rising premiums, said Todd McCracken, president of the National Small Business Association.

"We have reached a point in the past couple of years where for the first time in memory, most of these companies now do not provide health benefits to their employees," he said.

Of the small companies that can still offer health coverage, few can give their workers a choice of health plans, and they are often not happy with the plans they can offer. In any given year, 60% of small companies are shopping around for another health plan, but only 24% make a switch, according to data from the Kaiser Family Foundation.

"Small businesses are constantly in the marketplace looking for a better deal, sure that there's something out there for them that can bring prices in line, when in fact, they don't find much or they find choices that are even worse," he said.

When they come up empty, most companies have few options other than shifting more of the cost of premiums to their workers or reducing benefits, a trend that will continue over the next 5 years, according to projections by the Bureau of Labor Statistics.

"The share that employees will be asked to bear simply outstrips any realistic ability they may have to pay," Mr. McCracken said.

Large companies also face rising health insurance premiums and are passing them on to their employees, said Mary Kay Henry, who leads the health systems division of the Service Employees International Union.

The union represents 700,000 workers worldwide. About half of them have no health coverage and the other half are being asked to share more of the cost of their health insurance. Over the past few years, SEIU has increasingly found itself in difficult negotiations with employers over health benefits at both the level of collective bargaining and that of individual workers.

"Beyond the bargaining problem, we also had a crisis happening for individual workers, which was [that] they were, by virtue of no coverage, having to face not getting the medical care they needed in order to live," she said. ■

FDA Issues Final Rule Outlining Stricter Medical Glove Standards

The Food and Drug Administration has issued a final rule that would require medical glove makers to improve their products' ability to serve as a barrier against pathogens.

Manufacturers are being given 2 years to comply with the new regulations.

The goal is to reduce the risk of transmission of bloodborne pathogens such as HIV and hepatitis B, according to the FDA. The agency estimated that approximately 2.4 HIV infections occur each year due to "problems with the barrier protection properties" of medical gloves.

The FDA estimates that 140 health care workers are infected with the hepatitis B virus (HBV) on the job each year. About a third, or 40 cases, may be due to glove defects, according to the agency.

There is less evidence that glove defects are associated with hepatitis C, said the agency, noting that most occupational exposures are from needle sticks.

The agency has inspected gloves—used for patient examinations and surgical procedures—since 1990. At that time, the International Organization for Standardization (ISO), ASTM International, and the FDA had the same standards for glove quality. A few years later, the ISO and ASTM began requiring higher standards.

The FDA has allowed a defect rate of 4% for gloves used during patient exams and 2.5% for gloves used in surgery.

With more and more brands of gloves being marketed and sold, the agency hopes to maintain that defect rate. To do so means increasing the quality standards, said the agency.

—Alicia Ault

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