POLICY & PRACTICE

Lipitor Personal Injury Suits

The top-selling statin Lipitor (atorvastatin) is being blamed for causing a suicide, peripheral neuropathy, memory loss, and severe muscle damage in two suits filed against the drug's maker, Pfizer Inc., by a New York–based plaintiff's attorney, Mark Jay Krum. The complaint, filed in New York State Supreme Court, alleges that after using Lipitor for 17 months, 60-year-old Charles M. Wilson experienced peripheral neuropathy, inflammatory demyelinating polyneuropathy, and memory loss. Three years after ceasing the medication, Mr. Wilson still has loss of balance, fatigue, and burning in his extremities, according to the suit. In the second case, 47-year-old Michael Mazzariello claimed that Lipitor use led to neuropathy, weakness in his extremities, and short-term memory loss. Both suits claim that Pfizer failed to adequately warn physicians and patients about the drug's risks. At a press briefing, another potential plaintiff alleged that Lipitor caused her teenage son to commit suicide. Pfizer said in a statement that it would "vigorously challenge in court all the baseless claims made in these lawsuits."

Guidant Price Disclosure Sought

Advocacy group Public Citizen has filed a lawsuit in Pennsylvania federal court seeking to force the medical device maker Guidant Inc. to disclose its prices to ECRI, a nonprofit organization that collects cost-effectiveness and safety data on procedures and devices for hospitals, group purchasing organizations, health plans, and health agencies worldwide. ECRI has published a database of cardiac rhythm management devices since 1996. In 2001, Guidant, a division of Boston Scientific, began requiring customers to keep prices confidential. ECRI continued to publish the data because it was not aware of the contractual agreement, according to the suit. After several years of silence, Guidant contacted ECRI in 2004 and asked it to immediately stop publishing the data and urged hospitals to stop supplying information—demands that have been made repeatedly under threat of litigation. The Public Citizen complaint was filed in response and alleges that ECRI's database is noncommercial speech that is protected by the First Amendment. Boston Scientific said confidentiality is an accepted practice in heart rhythm management and essential to its business. "We simply don't want the price negotiated privately with one hospital based on one set of circumstances used against us in negotiations with another hospital with an entirely different set of circumstances," said Paul Donovan, Boston Scientific senior vice president of corporate communications, in a statement.

Licensure for Drug Sales Reps?

A proposal making its way through the Massachusetts legislature would require that pharmaceutical company sales representatives be licensed by the state and complete continuing education programs to renew that license. The proposal passed as an amendment to the state budget and was in a joint House-Senate conference report. State Senator Mark C. Montigny, a Democrat from New Bedford, has sought to pass such a licensure requirement several times over the past few years, without success. Under the latest proposal, pharmaceutical companies—and their representatives—would also be prohibited from giving gifts, entertainment, travel, honoraria, or anything of value to physicians or public officials. Violators would be subject to a $5,000 fine and up to 2 years in jail. In a statement, Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers Association, said that licensing was unnecessary because the Food and Drug Administration already regulates promotional and educational materials and that the legislation is wrongheaded because it "seeks to impose criminal penalties on what should be viewed as the important sharing of information between pharmaceutical companies and physicians regarding the risks and benefits of medicines."

Survey: FDA Influenced by Politics

A majority of Americans—82%—believe the FDA is greatly influenced by politics when making decisions about the safety and efficacy of new prescription drugs, according to a Wall Street Journal online Harris Interactive poll. The finding was similar across parties, with 87% of Democrats, 77% of Republicans, and 88% of Independents saying they thought that politics outweighed science greatly or to some extent in decision making. The survey of more than 2,300 adults was conducted in mid-May. In addition, almost 60% said the agency is doing a fair or poor job in ensuring the safety and efficacy of new drugs. Only 36% said it was doing an excellent or good job. That is a reversal from 2 years ago, when 56% had a positive view and 37% a negative view of the FDA. Opinions have not changed much on the agency's performance in bringing innovative drugs to market quickly. In 2004, 62% said the FDA was not doing well on that front, compared with 70% in the latest poll.

—Alicia Ault