

POLICY & PRACTICE

Botox Promotions Investigated

The U.S. Attorney's office for the northern district of Georgia has subpoenaed Allergan, seeking documents that might show off-label promotion of Botox (botulinum toxin type A) for the treatment of headache. The company confirmed the inquiry in a statement, and said that while Allergan currently has Botox in phase III studies for headache, "it is Allergan's policy to promote its products only in a manner consistent with the FDA-approved product labeling." Allergan also intends to comply "with all applicable laws, rules, and regulations," according to the statement. Botox is Allergan's second-biggest-selling product, with \$1.2 billion in sales in 2007. The company is projecting sales of about \$1.3 billion this year.

Galderma Buys CollaGenex

Two dermatology powerhouses are about to combine—that is, if U.S. regulatory authorities approve the merger of Galderma Laboratories and CollaGenex Pharmaceuticals. Galderma proposes to purchase all of CollaGenex's outstanding shares for about \$420 million. Galderma, a subsidiary of the Swiss drugmaker Galderma Pharma based in Newtown, Pa., has such products as Clobex, Tri-Luma, Cetaphil, and Pliaglis. It is also seeking U.S. approval for Dysport, a botulinum toxin type A injection sold in Brazil and Argentina. CollaGenex's flagship therapy is Oracea and the company is testing a vitamin D analogue for mild to moderate psoriasis. Galderma said that it expects to complete the merger before the end of the second quarter.

Supreme Court Limits Device Suits

The U.S. Supreme Court has bolstered medical device manufacturers' argument that FDA approval confers special protection against liability suits. The justices voted 8-1 in finding that the Medical Device Amendments of 1976 supersede state law. That federal law regulates devices that have gone through the premarket approval process, the most rigorous path to approval. Plaintiff Charles Riegel's estate had sued Medtronic Inc., alleging that a catheter that ruptured during cardiac surgery was designed, labeled, and manufactured in violation of New York law. But the justices said that FDA approval "bars common-law claims challenging the safety or effectiveness of a medical device. . . ." They upheld two previous lower court decisions; Justice Ruth Bader Ginsburg was the sole dissenter. Members of Congress involved in crafting the original amendments were not pleased. "Congress never intended that FDA approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices," said Sen. Ted Kennedy (D-Mass.) in a statement. "Congress obviously needs to correct the court's decision," he said.

Woodcock Named CDER Head

Dr. Janet Woodcock has been named director of the FDA's Center for Drug

Evaluation and Research. Dr. Woodcock, a rheumatologist, served as director of CDER once before, in the 1990s, and has served as acting director since October 2007. The drug industry's chief lobbying group, PhRMA, welcomed the appointment. Dr. Woodcock "has demonstrated willingness to work with diverse partners, including researchers, Congress, the White House, patients, and pharmaceutical research companies," said a statement from the group. But Public Citizen's health research group director Dr. Sidney Wolfe said in an interview that he's "not terribly hopeful" that Dr. Woodcock will lead the center well, because she doesn't like conflict or controversy. "I don't think she's the kind of CDER director we need right now," Dr. Wolfe said. "She's aware of a number of drugs on the market that should be taken off the market, but I don't think she has the fortitude to do something about it."

Drug, Device Promotion May Expand

FDA last month proposed draft guidance that would allow drug and medical device makers to distribute medical or scientific journal articles and reference publications that involve unapproved uses of FDA-approved drugs and medical devices. Drug and device makers had been allowed to disseminate such materials under guidelines set by the FDA, but that authority expired in September 2006. The FDA's new "Good Reprint Practices" draft guidance states that the article or reference should be published by an organization that has an editorial board and fully discloses conflicts of interest. In addition, articles should be peer reviewed, and manufacturers should not distribute special supplements or publications funded by product manufacturers. Rep. Henry Waxman (D-Calif.), chairman of the House Committee on Oversight and Government Reform, blasted the FDA for its proposal, which he said in a statement "is great news for the drug industry but terrible for the public health."

Rx Abuse Worries Americans

The abuse of prescription drugs is as big a problem as the abuse of illegal drugs, according to respondents to a Wall Street Journal/Harris Interactive poll. Even so, less than half of those surveyed said they keep prescription medicines in a place where others can't access them. Seventy percent said they were somewhat or very concerned about the risk of addiction associated with some prescription pain medications. The vast majority of the 2,027 adults surveyed voiced the same level of concern about drug side effects and potentially harmful interactions between pain medications and other prescriptions. About 60% of the respondents said they discuss with their physician other prescriptions they are taking when they are prescribed a new medication. Smaller numbers said they told their physician about over-the-counter medications or nutritional supplements.

—Alicia Ault

Rule for Patient Safety Organizations Proposed

BY DENISE NAPOLI

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Draft federal regulations more than 2 years in the making aim to give hospital networks, physician groups, and similar organizations the ability to help doctors reduce medical errors and improve the quality of care they provide to patients.

The 72-page proposed rule offers the government's first pass on how to implement the Patient Safety and Quality Improvement Act of 2005 and gives guidance on how to create confidential patient safety organizations (PSOs).

First called for by the Institute of Medicine in its 1999 report "To Err is Human," PSOs will be entities to which physicians and other health care providers can voluntarily report "patient safety events" with anonymity and without fear of tort liability. PSOs will collect, aggregate, and analyze data and provide feedback to help clinicians and health care organizations improve on those events in the future, according to the law and proposed rule.

In an interview, Dr. Bill Munier, director of the Center for Quality Improvement and Patient Safety at the Agency for Health Care Research and Quality, said that patient safety events can be anything from health-care associated infections and patient falls to adverse drug reactions and wrong-site surgery.

According to the proposed rule, "a patient safety event may include an error of omission or commission, mistake, or malfunction in a patient care process; it may also involve an input to such process (such as a drug or device) or the environment in which such process occurs."

The term is intentionally more flexible than the more commonly used "medical errors" to account for not only traditional health care settings, but also for patients participating in clinical trials, and for ambulances, school clinics, and even locations where a provider is not present, such as a patient's home, according to the rule.

Until now, there has been no clear guidance on how an organization can become a PSO. But according to the proposed rule, public and private entities, both for-profit and not-for-profit, can seek listing as a PSO. This includes individual hospitals, hospital networks, professional associations, and almost any group related to providers with a solid network through which safety information can be aggregated and analyzed, said Dr. Munier.

"We know that clinicians and health care organizations want to participate in efforts to improve patient care, but they often are inhibited by fears of liability and sanctions," said Dr. Carolyn M. Clancy, AHRQ director. "The proposed regulation provides a framework for [PSOs] to facil-

itate a shared-learning approach that supports effective interventions that reduce risk of harm to patients."

Dr. Munier said that the rule took a long time to issue partly because its authors had to be sure it didn't conflict with state reporting requirements and the Health Insurance Portability and Accountability Act (HIPAA).

Dr. Bruce Bagley, medical director for quality improvement at the American Academy of Family Physicians, said in an interview that back in 2005, the AAFP had convened a work group to determine whether the academy ought to become a PSO. The proposed rule on what it would take to be a PSO was expected within the year, he said. But as implementation of the law languished, those plans were abandoned.

Now, Dr. Bagley said, he expects that the AAFP will once again look into becoming a PSO for its members, but he

thinks that big institutions such as large hospital systems or the Mayo Clinic will be the best candidates for PSOs. Nevertheless, he said, "This is something that's been long needed, to be able to have medical professionals and other clinicians be open about reporting errors that can be analyzed in a systematic way."

In a statement, Rich Umbdenstock, president and CEO of the American Hospital Association, said that

his group was in strong support of the creation of PSOs. "Hospitals have already waited 2 years for this rule and this is only a first step in the process toward establishing PSOs. We will continue to work with HHS to ensure the timely creation of PSOs," he said.

Dr. J. James Rohack, a board member of the American Medical Association, agreed. In a statement, he said, "Since the passage of patient safety legislation in 2005, the American Medical Association and other patient safety advocates have eagerly awaited guidance for implementation from the administration. The proposed rule. . . will allow health care professionals to report errors voluntarily without fear of legal prosecution and transform the current culture of blame and punishment into one of open communication and prevention."

Also in a statement, the American College of Surgeons said that it was in the process of reviewing the proposed rule and it planned on submitting comments. "Along with these other health care system stakeholders, the college has been waiting with eager anticipation for the guidance and protections these regulations should offer," a representative said. ■

To view the proposed rule and learn how to comment, go to www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=AHRQ-2008-0001.