POLICY & PRACTICE

FDA Seeks Data on Older Devices

The Food and Drug Administration has ordered manufacturers of 25 class III medical devices that were approved before 1976 to submit safety and effectiveness data to the agency by Aug. 7. The devices include an intra-aortic balloon and its control system, a ventricular bypass assist device, generators, materials for pacemakers, automated external defibrillators, and some types of hip joints. Depending on the data it gets on each device, the FDA will decide whether to require a full approval application or reclassify the device to a lower-risk regulatory category. The Advanced Medical Technology Association issued a statement saying it was pleased the agency is moving ahead with the process, but that "it needs to be clearly understood that the device types subject to the FDA notice have already been thoroughly reviewed by the agency," based either on technologic and performance data or, in some cases, clinical data.

Device Staff Decries FDA Politics

The FDA is a mess of politics, abuse, and misdeeds, according to members of the agency's Office of Device Evaluation, who sent a six-page letter to President Obama in early April. The staff members called on the president to enact sweeping measures "to end the systemic corruption and wrongdoing that permeates all levels of FDA." FDA managers have "abused their power and authority" and "engaged in illegal retaliation against those who speak out," the staffers said. "The culture of wrongdoing is nothing new but is part of a longstanding pattern of behavior," they stressed. The letter, with all of the signers' names redacted, was released at a congressional hearing.

Bristol-Myers Squibb Fined

Bristol-Myers Squibb Co. will pay $2.1 million—the largest fine allowed by law—for failing to report an agreement it reached with Apotex Inc. on generic competition for its blockbuster cardiovascular drug Plavix (clopidogrel), the Federal Trade Commission reported. Bristol-Myers Squibb did not disclose that in 2006 the two companies made a deal to schedule the releases of their generic versions of the drug to reduce competition, according to the FTC. The agency said that failing to disclose the oral agreement violated both a 2003 FTC order and the Medicare Modernization Act, which requires that certain drug company agreements be accurately reported to both the FTC and the U.S. Department of Justice. In 2007, Bristol-Myers Squibb paid $1 million to settle a criminal complaint that the company had lied about the Plavix agreement with Apotex. The name-brand manufacturer has also settled several state actions arising from the generic-timing agreement, the FTC said.

FDA Warns on Internet Ads

The FDA has warned 14 drug makers against using brief Internet ads to promote drugs, saying the ads are misleading because they fail to provide full information about risks and indications. The ads typically appear on search engines such as Google as "sponsored links" when patients search for information on medical conditions. The ads cited by the FDA include promotions for multiple sclerosis drug Tysabri (natalizumab), the cardiovascular drug Plavix (clopidogrel), and the diabetes treatment Avandia (rosiglitazone). The sponsored links generally contain only a dozen or so words—not enough to convey detailed treatment or risk information, according to the FDA. The Pew Prescription Project, a nonprofit drug-safety group, has asked the FDA to articulate the rules regulating online advertising and to advise manufacturers on where risk disclosures may appear in Internet ads.

EHR Applications Rise

By a March 31 deadline, 64 companies applied for certification of their electronic health record (EHR) products, one-third more than the number that applied by the same time last year, the Certification Commission for Healthcare Information Technology reported. In addition, nearly 40% of the applications were for new EHR products, rather than renewals, according to the federally recognized commission. Nearly two-thirds of the applicants qualified as small businesses, the commission noted. So far, 25 of the products have been certified, the commission said.

Issues of Drug Class Pending

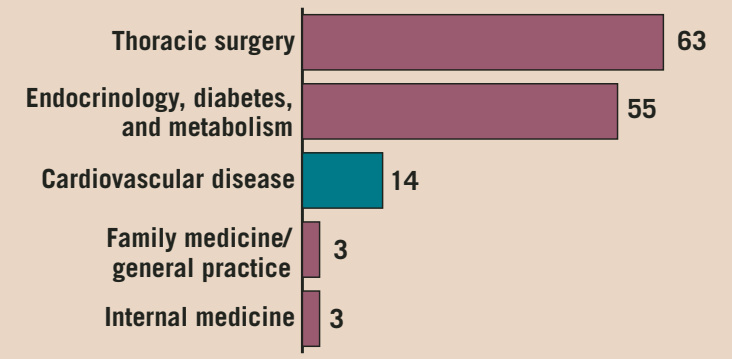
Logistic and cost issues must be addressed before a behind-the-counter class of nonprescription drugs can be established officially in the United States, the U.S. Government Accountability Office said in a report on so-called BTC drugs. The GAO stressed that pharmacists must be ready to provide BTC counseling and that pharmacies must physically protect consumer privacy. In addition, policy makers should address cost issues, such as the availability of third-party coverage for BTC drugs and pharmacists' compensation for providing associated services. GAO researchers studied the experiences of five countries, including Italy and the Netherlands, that have a behind-the-counter or similarly restricted drug class.

—Alicia Ault

DATA WATCH

Number of People per Active Physician By Specialty, 2007

(In thousands)



Source: 2008 Physician Specialty Data, Association of American Medical Colleges

CLASSIFIEDS

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