POLICY & PRACTICE

FDA Posts Guidance on Handouts

The FDA has issued updated guidance for manufacturers that distribute journal articles or other scientific publications concerning off-label uses for their FDA-approved drugs, devices, or biologics. On its Web site, the agency suggests that distributed journal articles be only from organizations using editorial boards with "demonstrated expertise in the subject of the article," independence to review articles, and fully disclosed conflicts of interest. Authors and editors should also disclose conflicts. Acceptable articles can't be from special supplements funded even partially by a manufacturer. In its presentation to practitioners, an article should not be highlighted, otherwise marked up, or attached to promotional materials.

Device Makers Update Ethics Code

The Advanced Medical Technology Association (AdvaMed) has revised its ethics code covering equipment manufacturers' dealings with health care professionals. New rules explicitly prohibit manufacturers from providing entertainment, recreation, or gifts of any type to physicians. The document also describes acceptable royalty arrangements between companies and providers. The update is the first since 2005.

FTC Alleges Price Gouging

The Federal Trade Commission has alleged that a pharmaceutical company acted illegally in buying the only two medicines approved to treat a deadly congenital heart defect in premature babies and then raising the prices for the drugs by nearly 1,300%. Ovation Pharmaceuticals Inc. bought the drug NeoProfen (ibuprofen lysine) in early 2006, when it already held the rights to Indocin IV (indomethacin). Both drugs are used to treat patent ductus arteriosus in lieu of surgical repair. After acquiring NeoProfen, Ovation raised the price of Indocin from $36 to nearly $500 a vial and set a similar price when it launched NeoProfen in July 2006, according to the FTC. Ovation said in a statement that NeoProfen and Indocin are not interchangeable and that it would fight the allegations.

Clinic Discloses Industry Ties

The Cleveland Clinic has begun public disclosure of the business relationships its staff physicians and scientists have with drug and medical device makers. The organization said its Web site will list the names of companies with which each staff professional has collaborations. It also will identify whether a physician or scientist owns equity or has the right to royalties, a fiduciary position, or a consulting relationship that pays $5,000 or more per year. "We want our patients to have abundant information about our physicians and let them decide what's relevant to their situations," said Dr. Joseph Hahn, Cleveland Clinic chief of staff. He added that to the best of his knowledge, Cleveland Clinic is the first academic medical center in the United States to disclose these ties.

Lawmaker Asks for Heparin Review

Rep. Joe Barton (R-Tex.), ranking minority member of the House Energy and Commerce Committee, has asked the Government Accountability Office for a thorough review of the Food and Drug Administration's handling of the recent problems with tainted heparin coming from China. In February 2008, Baxter Healthcare Corp. recalled several heparin products and the FDA identified a previously unknown contaminant in the heparin. According to the FDA, 246 people died after heparin administration between Jan. 1, 2007, and May 31, 2008, and 149 of those deaths involved allergic symptoms or the appearance of hypotension. Rep. Barton's letter to the FDA challenges the agency's attribution of several deaths to heparin and questions whether the FDA used "all of the tools available" to investigate the deaths.

GAO Slams FDA on Device Reviews

The FDA is allowing too many high-risk medical devices to go through its least stringent approval process, called 510(k), the GAO reported in January. After Department of Health and Human Services officials read the report, they agreed. Class III devices include pacemakers and heart valves. Under 510(k), the manufacturer simply proves that the device is substantially equivalent to one already on the market. A 1990 law gave the FDA 5 years to determine which class III devices should require premarket approval applications, which are stricter than 510(k) clearances, but the agency hasn't done so, the GAO reported. The FDA approved 228 of 342 applications for class III devices submitted through the 510(k) process during fiscal years 2003-2007.

—Alicia Ault