POLICY & PRACTICE

$13 Million Accutane Verdict

Hoffmann-La Roche has been ordered to pay $13 million to three plaintiffs who claimed that they developed inflammatory bowel disease from taking Accutane (isotretinoin). The New Jersey State Superior Court jury agreed that Roche did not provide adequate warning and awarded damages to the three patients. Their attorneys, at New York–based Seeger Weiss, said that the three developed Crohn's disease, ulcerative colitis, or another form of IBD while taking the drug or shortly afterward. "This is an important outcome and consistent with the recognition by the medical community that Accutane is a trigger for IBD," plaintiffs' attorney David Buchanan said in a statement. Roche said in its own statement that it was disappointed in the jury's decision and that it planned to appeal. The company added that even though Accutane labeling "has contained a warning about IBD for more than 20 years … there is no reliable scientific evidence that Accutane actually causes IBD."

FDA Sunscreen Rules Being Sought

The Skin Cancer Foundation, Ciba Corp., Fallene Ltd., and Rep. Nita Lowey (R-N.Y.) join a growing list of organizations, sunblock manufacturers, and lawmakers calling on the Food and Drug Administration to finalize sunscreen standards. "The American public is underprotected and operating with a false sense of security in the face of the life-threatening dangers of sun exposure," Rep. Lowey said at a briefing. The two companies and several dermatologists then submitted a Citizen's Petition to the FDA seeking final standards and approval of sunscreen ingredients that protect against UVA—specifically, Ciba's Tinosorb. Last summer, Sen. Christopher Dodd (D-Conn.) and Sen. Jack Reed (D-R.I.) introduced a bill to require final sunscreen rules by next month. The legislation is supported by the American Cancer Society, the Melanoma Research Foundation, Citizens for Sun Protection, the Environmental Working Group, and sunscreen manufacturers Banana Boat and Hawaiian Tropic. Connecticut Attorney General Richard Blumenthal also has petitioned the FDA to implement standards.

Benzoyl Peroxide Recall

CSI USA Inc. is recalling all lots of its over-the-counter 10% benzoyl peroxide acne cream because it's contaminated with *Burkholderia cepacia* bacteria. The company and the FDA said that consumers—especially those who have cuts, scrapes, or rashes, or who have weakened immune systems—should stop using the products because of infection risk. The brands are DG Maximum Strength Acne Medicated Gel (sold at Dollar General), Kroger Acne Gel 10% Benzoyl Peroxide Acne Medication (sold at Kroger), and Equate: Medicated Acne Gel (sold at Wal-Mart). There has been no report of an adverse event so far. More information is available at www.acnemedrecall.com.

MedPAC Calls for Disclosure

Congress should pass legislation to require drug, device, and medical supply makers and distributors, along with hospitals, to disclose their financial ties to physicians and physician groups, the Medicare Payment Advisory Commission has decided. The companies also should be required to disclose financial relationships with pharmacies, pharmacists, health plans, pharmacy benefit managers, hospitals, medical schools, continuing medical education organizations, patient organizations, and professional organizations. MedPAC said it will urge Congress to require drug manufacturers to post to a Web site all details about free drug samples given to providers. MedPAC advises Congress on Medicare issues, but lawmakers are not required to implement the commission's recommendations.

Pharmaceutical Sales Outlook

The U.S. pharmaceutical market is expected to grow 1%-2% in 2009, resulting in sales of $292 billion to $302 billion, according to analysis from the health care market research firm IMS Health. This latest projection is down from the 2%-3% increase projected by IMS earlier this year and reflects the expected impact of patent expirations, fewer launches of new products, and the slowing U.S. economy. Worldwide pharmaceutical sales are expected to grow 4.5%-5.5% in 2009, similar to growth this year. "The market will continue to contend with a number of forces—among them the shift in growth from developed countries to emerging ones, specialist-driven products playing a larger role, blockbuster drugs losing patent protection, and the rising influence of regulators and payers on health care decisions," Murray Aitken, a senior vice president at IMS, said in a statement.

—Alicia Ault