

POLICY & PRACTICE

Vytorin Probe Expanded

The House Energy and Commerce Committee has expanded its investigation of the circumstances surrounding the release of data from the ENHANCE trial (see article on p. 1). In December, the Committee wrote to Merck & Co. and Schering-Plough seeking more information on ENHANCE, alleging potential data fraud. Raising the specter of Vioxx, Rep. John Dingell (D-Mich.) and Rep. Bart Stupak (D-Mich.) said they want to find out what Merck and Schering-Plough knew about Vytorin's apparent lack of efficacy and when they knew it. The release of equivocal ENHANCE results last month prompted the committee to question the propriety of the Vytorin direct-to-consumer ad campaign. The companies subsequently pulled the television commercials, and modified the print ads. "We are interested in whether the Food and Drug Administration's Division of Drug Marketing, Advertising, and Communications has been involved with these Vytorin advertisements," the congressmen wrote to Dr. Andrew von Eschenbach, FDA commissioner, in a Jan. 16 letter. "Physicians

and their patients should have been made aware as soon as possible that Vytorin provided no benefit over a widely-used, cheaper, generic alternative," they said. Shortly thereafter, the panel wrote the companies seeking information on secondary end points. The committee also wrote to the Centers for Medicare and Medicaid Services to find out how much the two federal health programs have spent on Vytorin since April and to ask whether the CMS has considered withdrawing payment for the drug.

Jarvik's Endorsement Questioned

The House Energy and Commerce Committee also is investigating celebrity endorsements of prescription drugs in direct-to-consumer advertisements, with a focus on Dr. Robert Jarvik's TV ads for Pfizer's Lipitor (atorvastatin). The committee wrote to Pfizer CEO Jeffrey B. Kindler last month, seeking all correspondence, records, and contractual arrangements with Dr. Jarvik. In addition, the committee asked for "any records relating to the veracity of any claims" made by Dr. Jarvik, along with documentation of whether he

uses the drug and medical records that would indicate his diagnosis or purpose for using Lipitor. The letter stated that the ad might be misleading, since it appears that Dr. Jarvik is endorsing the drug and that he "may not be a practicing physician with a valid license in any state." The committee wrote separately to the FDA, seeking records of agency reviews of the ad or complaints relating to the campaign. Pfizer was given until the end of January to respond. A Pfizer spokeswoman said, "We intend to fully cooperate with the congressional committee's request."

FDA and Tobacco Redux

A coalition of medical professional societies and health advocates once again is pushing for approval of legislation to grant the FDA the authority to regulate tobacco. Last year, the Family Smoking Prevention and Tobacco Control Act (H.R. 1108/S. 635) garnered 216 House cosponsors but stalled in committee; the Senate companion had 54 cosponsors. American Heart Association lobbyists told reporters last month that the bill soon would be marked up by the House Energy and Commerce Committee. Dr. Clyde Yancy, speaking for the AHA, noted that tobac-

co manufacturers continue to target children, spending \$36 million a day on marketing, most of it directed at kids. Each day, 4,000 children start smoking; of those, 1,000 will become lifelong smokers, said Dr. Yancy, medical director at the Baylor Heart and Vascular Institute in Dallas. The American Medical Association also called for FDA regulation of tobacco, in response to an American Lung Association report faulting federal control policies.

Feds' Failing Tobacco Grade

A recently issued American Lung Association report gives the federal government Ds and Fs for failing to provide the FDA the authority to regulate tobacco, and for not raising taxes or putting policies into place to encourage cessation. "The State of Tobacco Control: 2007" reported that states are in many ways doing a better job than the feds: 21 states have workplace smoking bans, and 25 states have a cigarette tax of \$1 or more per pack. Twelve states received an F on taxes, however. Only nine states got an A for funding cessation and prevention programs at 90% or more of the levels recommended by the Centers for Disease Control and Prevention.

—Alicia Ault

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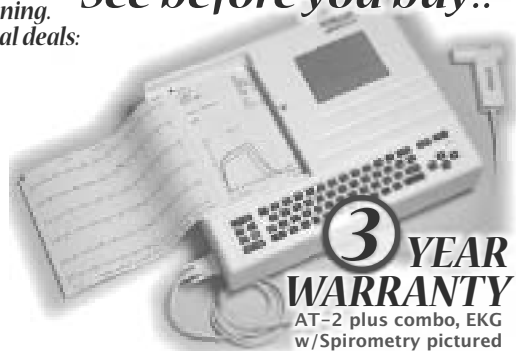
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