

FDA Considers Easing Curbs on Sharing Off-Label Research with Doctors

By Christopher Lee Washington Post Staff Writer December 1, 2007

The Food and Drug Administration is considering allowing pharmaceutical makers to provide doctors with medical journal studies of unapproved uses for drugs, a move critics say would undermine long-standing restrictions on marketing medicines for "off-label" purposes.

Under a draft "guidance" prepared by the FDA, drug and medical device manufacturers could distribute unabridged reprints of peer-reviewed research from reputable medical journals as long as the articles were not written, edited or otherwise "significantly influenced" by the manufacturers or people with financial ties to them. No other promotional materials could be attached to the reprints, which would have to be labeled as describing uses for the products that have not been approved by the FDA.

The proposal would be a break with the FDA's prohibition on the marketing of drugs and medical devices for unapproved purposes, which dates to 1938. It is legal for doctors to prescribe approved drugs for off-label uses, however, and the practice is common for some types of drugs.

In 1997, Congress created a temporary exception allowing companies to distribute reprints so long as they submitted them to the FDA for advance review and had formally asked the FDA to approve the new use. That exception expired in 2006. In recent years, the marketing restrictions have been the subject of legal challenges on free speech grounds.

Rep. Henry A. Waxman (D-Calif.), chairman of the House Committee on Oversight and Government Reform, said creating a new path to promote off-label uses could improperly influence doctors' prescribing habits. In a letter yesterday, Waxman urged FDA Commissioner Andrew C. von Eschenbach to suspend drafting of the new guidance and cooperate with a committee inquiry into the issue.

The draft guidance "would open the door to abusive marketing practices that will jeopardize safety, undermine public health, and lead to an increase in unapproved uses of powerful drugs," Waxman wrote.

Companies would be less likely to conduct definitive scientific studies and seek formal FDA approval for alternative uses of drugs and devices if they could promote and profit from off-label uses anyway, Waxman contended. He said the proposal could grant undue influence to incomplete or distorted studies, some of them industry-funded. And he pointed to several high-profile cases in which drugs such as Vioxx and Celebrex were trumpeted in flawed journal articles that either underreported dangers or overstated benefits.

"While there may need to be a balance between First Amendment and protection of the public health," Waxman wrote, "the answer is not to open the door to unrestricted dissemination of potentially questionable information about drug safety and effectiveness."

FDA spokeswoman Rita Chappelle said the agency does not comment on letters from Congress.

Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, said it is "premature" to comment specifically on the FDA draft, but that providing the articles to doctors could help them make better prescribing decisions.

"These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care," the guidance says.

Some people depend on off-label uses of drugs, said Diane Dorman, vice president for public policy at the National Organization for Rare Disorders.

"There are nearly 30 million people in the United States affected by almost 7,000 known rare diseases," Dorman said. "Consequently, most of those disease states are treated off-label because there is no therapy specific for their disease. So getting that information to physicians, I would consider to be very, very important for the patient."