



FDA, the manufacturers said they worried that highlighting some of the major potential effects over others would leave the companies open to arguments that they did not adequately warn patients of the other possible negative effects. To ease the drug makers' concerns, the FDA introduced language to the rule that said a federal labeling standard would take precedence over state law, thereby exempting drug makers from state product liability laws.

That move was attacked by a variety of groups, including state legislatures and trial lawyers.

In a January 13 letter to Michael Leavitt, secretary of the Department of Health and Human Services, Steven J. Rauschenberger, president of the National Conference of State Legislatures, wrote, "This preemption language is a thinly veiled attempt on the part of FDA to confer upon itself authority it does not have by statute and does not have by way of judicial rulings."

Ken Suggs, president of the Association of Trial Lawyers of America, in a release said, "The fact that the drug industry can get the FDA to rewrite the rules so that CEOs can escape accountability for putting dangerous and deadly drugs on the market is the scariest example yet of how much control these big corporations have over our political process."

INSERT INFORMATION

The most significant change physicians will find in the new inserts is a "highlights" section at the top of the page. This section will typically be half a page in length and will contain concise summaries of such information as indications and usage, dosage and administration, and (if applicable) a boxed warning.

Other new features include a table of contents that references detailed safety and efficacy information, the date of initial product approval, and a toll-free telephone number for physicians to use to report suspected adverse events.

The FDA will also be using the Internet to keep prescription information up to date. The package insert information will be available in a new inter-

agency online health information clearinghouse called "DailyMed" (<http://dailymed.nlm.nih.gov>) that provides medication information free to health care professions and consumers.

The American Medical Association praised the revised labeling format, saying the group hoped it will help physicians better access and communicate important drug information to their patients. Public Citizen, a health advocacy group, said that while the new inserts should benefit physicians, patients who are filling a prescription will only receive (unless they visit DailyMed on the Internet) a commercially produced leaflet, the content of which is not scrutinized by the FDA.

Kenneth Shine, MD, the former president of the Institute of Medicine, while endorsing the new package insert, said improving on the information provided in those commercially produced leaflets should be the next step the FDA takes to improve patient safety.

"We know in many instances patients read the package inserts and can get information from the Internet option," said Shine, who is now executive vice chancellor for health affairs for the University of Texas System. "I want to see the package insert changes extended to create a paper that is easily understood by patients. It's the next logical step." □

Not All Placebos Are Equal

Tracy Hampton, PhD

NOT ALL PLACEBOS ARE EQUIVALENT in their effects, scientists have discovered from a study of sham acupuncture vs an oral inert pill to treat pain. The research is the first to investigate how the placebo effect varies in specific clinical environments (Kaptchuk TJ et al. *BMJ*. doi:10.1136/bmj.38726.603310.55 [published online ahead of print February 2, 2006]).

The study of 270 individuals with chronic arm pain due to repetitive use included two phases. First, half of the patients were given sham acupuncture and half were given a placebo pill for 2 weeks. Pain decreased to a similar extent in both groups. Next, participants were randomized to continue their placebo treatment or to begin active treatment of the same type: half of the patients were randomized to sham vs real acupuncture twice a week for 4 weeks, and half were randomized to placebo pill vs amitriptyline once daily for 6 weeks. Patients receiving sham acupuncture reported a more significant decrease in pain and symptom severity than did those receiving a placebo pill. At 2 weeks, 75% of participants in the acupuncture group be-

lieved they were receiving active treatment compared with 48% in the pill group, a difference that continued to the end of the study. However, differences between the two groups were not significant in objective measures such as arm function and grip strength.

Interestingly, the two groups reported different adverse effects, which may have been influenced by information provided to them prior to participation. Informed consent forms alerted participants to the possibility of experiencing temporary aggravation of pain from acupuncture or sleepiness, dry mouth, dizziness, and restlessness from the pills. Of those receiving placebos, 25% of patients undergoing sham acupuncture and 31% of patients given placebo pills reported experiencing those respective adverse effects. No reported effects were serious, although three participants withdrew from the placebo pill group because of fatigue or dry mouth. A comparison of the active treatments and the placebos will be reported in the future.

The authors concluded that this study indicates that placebo effects persist over time and "seem to be malleable and depend on the behaviors embedded in medical rituals." □