In Brief

Drug Companies Adopt New Advertising Guidelines

A group representing much of the U.S. pharmaceutical industry has announced a new set of voluntary guidelines for direct-to-consumer advertising of prescription drugs.

The Pharmaceutical Research and Manufacturers of America (PhRMA) approved the guiding principles on July 29, and they will go into effect January 2006. More than 20 companies have agreed to follow the guidelines.

Among the 15 principles are directives for companies to submit new television ads to the U.S. Food and Drug Administration for review—which is currently not required by law—and that companies ensure that these ads clearly state the health conditions for which the drug is approved and any major risks. Both print and television advertising should present a balanced view of the risks and benefits of a drug and make only claims supported by substantial evidence, according to the new guidelines. Furthermore, companies should begin advertising campaigns only after they have spent an “appropriate amount of time” educating health care professionals about a new product.

To monitor the advertising and compliance with the guidelines, PhRMA will establish an office of accountability that will take comments about the ads from the public and health care professionals and issue periodic reports to the public. A year after the guidelines take effect, the office will select an independent panel to review these reports.

Anastrozole After Tamoxifen May Benefit Women With Early Breast Cancer

Switching to the drug anastrozole following 2 years of tamoxifen may improve event-free survival for postmenopausal women with early-stage breast cancer, according to a new study in the August 6 issue of The Lancet.

For more than 20 years, tamoxifen has been the standard treatment for older women with early-stage breast cancer. However, long-term use has been associated with such side effects as increased risk of endometrial cancer and resistance to tamoxifen.

To compare the effectiveness of the aromatase inhibitor anastrozole against tamoxifen, Raimund Jakesz, M.D., of the Vienna Medical University in Austria, and colleagues combined data from two randomized trials of a total of 3,224 postmenopausal women being treated for early breast cancer who had received 2 years of tamoxifen. The patients were randomly assigned to an additional 3 years of either anastrozole or tamoxifen.

The researchers found that after 28 months, there were 67 cancer recurrences among the 1,618 women in the anastrozole group (about 4%), compared with 110 among the 1,606 in the tamoxifen group (about 7%). At 3 years, the anastrozole group had an event-free survival rate of 95.8%, compared with 92.7% for the women continuing with tamoxifen. Overall survival was similar in both treatment groups.

The researchers also found that the women taking tamoxifen on average experienced more thromboses as a side effect from their drug treatment. However, the anastrozole group experienced more fractures.

See related article, p. 1262.

—Elana Hayasaka and Sarah L. Zielinski