Patients deserve data about drugs

Peaceful, restful sleep" promises an ad for the sleep drug Lunesta. Yet nowhere in the fine print of the ad (or the drug’s package insert) is there any data about how many people who take the drug are helped by it or how much sleep they get when taking it. Such “benefits data” is not currently required by the Food and Drug Administration (FDA).

The ad, says DMS’s Steven Woloshin, M.D., suggests that popping a Lunesta leads to eight hours in dreamland. “But if you actually look at the data, and this is real data, you fall asleep 15 minutes faster and sleep 37 minutes longer than [with a] placebo.”

Common: He and other DMS researchers are also concerned that the information on side effects in drug ads can be confusing. Ads have “huge laundry lists of side effects, and oftentimes they’re not highlighting the ones that are more common than placebo’s [side effects],” notes DMS’s Lisa Schwartz, M.D. Ads also don’t make it clear which side effects may be life threatening and which are merely bothersome.

So Woloshin, Schwartz, and H. Gilbert Welch, M.D., created a “drug facts box,” to help patients (and physicians) better understand drugs’ capabilities. The top part of the box describes what the drug is designed to do, who should consider taking it, and what monitoring is recommended. In the middle is a table with study data showing the drug’s benefits and side effects compared to a placebo. At the bottom is its FDA approval date.

Facts: The DMS team then recruited 274 volunteers and presented them with a drug facts box about tamoxifen (a breast cancer preventative) and a survey to test their comprehension of the data.

“People did quite well,” says Woloshin. “That was very gratifying.” The vast majority, 89%, correctly determined what percentage of women given tamoxifen got a blood clot in their legs or lungs; 71% calculated the absolute difference in the proportion of women who got breast cancer in the tamoxifen group versus the placebo group. Over 66% chose the better drug in two scenarios that called for comparing percentages. Half of those with only a high-school degree and two thirds of those with some college correctly answered at least four out of five questions based on the study data table. The results were published in Medical Decision Making.

FDA reviewers have expressed interest in the concept and are now working with Schwartz and Woloshin. The researchers’ goal is to have the box included in drug package inserts, says Woloshin. They’re optimistic about the prospect. The FDA reviewers “really are dedicated public servants,” says Schwartz. The researchers are all affiliated with the Center for Medicine, the Media, and the Public at the Dartmouth Institute for Health Policy and Clinical Practice. Matthew C. Wiencke