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Prescription Drugs Harms and Benefits: What the Labels Don't Tell You

Lebanon, NH -- Drug labels - the main way that the Federal Drug Administration (FDA) communicates the prescribing information physicians need - frequently don't include basic information required to fully understand the harms and benefits of these products, according to a commentary in today's issue of the New England Journal of Medicine.

Authors Lisa M. Schwartz, MD and Steve Woloshin, MD argue that the FDA needs to improve its drug labeling information. Specifically, FDA needs to systematically improve access to the results of its internal drug reviews to foster informed decision-making about prescription drugs. FDA reviewers – independent experts -- spend as much as a year evaluating benefit and harm data from drug trials, but, they write, "in many cases, information gets lost between FDA review and the approved label."

Schwartz and Woloshin, faculty at The Dartmouth Institute for Health Policy and Clinical Practice, and physicians with the White River Junction, VT VA hospital, note that drug labels - the pages and pages of dense text that come with prescription medications – are written by the pharmaceutical companies and then approved by the FDA. But a full summary of the results of the studies reviewed in these lengthy documents may be missing in the approved label.

An example cited by the authors is Zometa, a drug prescribed for use in patients with an abnormal amount of calcium in their blood, an important complication faced by some cancer patients. Two clinical trials analyzed by the FDA showed that 8 mg of Zometa was no more effective than 4 mg in reducing calcium levels. Moreover, the higher dose increased the incidence of kidney damage and death. Although FDA reviewers noted both of these serious risks in their review, the higher death rate was not noted in the Zometa label.

Dr. Woloshin said "FDA has known about problems with drug labeling for some time. We are very hopeful that FDA's new leadership will try and take on this issue. Better labeling is critical-- clinicians -

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and their patients - need access to credible, complete information about prescription drugs without the filter of industry. FDA is the logical choice to provide this information".

In the article, Schwartz and Woloshin recommended the FDA introduce a standardized executive summary of every drug review, to include data tables of main clinical trials results, highlight any reviewer uncertainties (often expressed in the body of the reviews, but absent from product inserts) and whether approval was conditional on further study. They encourage the FDA to use the structured approach they have developed and tested -called the "drug facts box"- a simple standardized table presenting benefit and harm data for prescription drugs.

In February of this year, FDA's Risk Communication Advisory Committee unanimously recommended that the FDA adopt drug facts boxes as their format for communications to the public. The proposal to incorporate drug facts boxes into the label has also been included in health reform legislation under consideration in the Senate.

"Whatever approach the agency adopts, it needs a better way of communicating drug information to clinicians. We don't need to wait for new comparative-effectiveness results in order to improve practice. We need to disseminate what is already known," conclude the authors.

Lisa Schwartz and Steve Woloshin are physicians and researchers who have written widely about the importance of understanding risks and benefits of health procedures and treatments. Their most recent book, with Dr. H. Gilbert Welch, is *Know Your Chances: Understanding Health Statistics: How to See Through the Hype in Medical News, Ads, and Public Service Announcements*.

The article, "Lost in Transmission – FDA Drug Information That Never Reaches Clinicians" appears in the October 29th edition of the [New England Journal of Medicine](#). Copies can be accessed at <http://nejm.org>.

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