

FDA Revamps Drug Info, Aims to Improve Safety

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Prescription drug package inserts will soon have a new format that U.S. Food and Drug Administration officials believe will reduce the risk of medical errors.

A goal of the “major revisions” recently announced by the FDA is to prioritize warning information and provide user-friendly access to the most important prescribing information. The new inserts will contain a “Highlights” section prominently displayed at the top of the first page, Dr. Andrew von Eschenbach, acting FDA commissioner, explained during a press briefing sponsored by the agency.

The new format will provide the most up-to-date information in a clearly organized, concisely written, easily accessed format so doctors can convey this vital information to patients, he said.

Other key features of the new inserts will include a table of contents that provides reference

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to detailed safety and efficacy information, the date of initial product approval and information about any changes to the label in the past year, a patient counseling information section, and a toll-free number

and Web site for reporting adverse events.

The revisions also were designed to make prescription information more accessible via the Internet: Information will be updated in real-time to DailyMed, an interagency online health information clearinghouse, which can be accessed at <http://dailymed.nlm.nih.gov>, Dr. Scott Gottlieb, FDA’s deputy commissioner of medical and scientific affairs, said during the briefing.

This information will also be made available soon at a new Web site called Facts@FDA, which will provide comprehensive information about all FDA-regulated products, he noted.

The electronic capability aspects of the new package insert requirements are one of the most “potentially exciting opportunities” created by the new system, he said, adding that the electronic information will allow physicians to access the most up-to-date prescribing information at the point of care.

This is particularly important in this age of 12-minute patient visits, said U.S. Surgeon General Richard H. Carmona during the briefing. “We made great strides today that will benefit providers and the American public by increasing the health literacy of all those who desperately need this information.”

The final rule providing for the changes—the first changes to prescription drug package inserts in 25 years—has been in the works since 2000 when a draft rule

was released. The final version, released along with two guidance documents and two draft guidance documents to assist drug companies with implementing the revisions, differs little from the early draft, and was based largely on information from focus groups, physician surveys, a public meeting, and written comments.

The revisions will be phased in gradually and apply only to drugs approved in the last 5 years, as well as newly approved drugs and those that receive new indica-

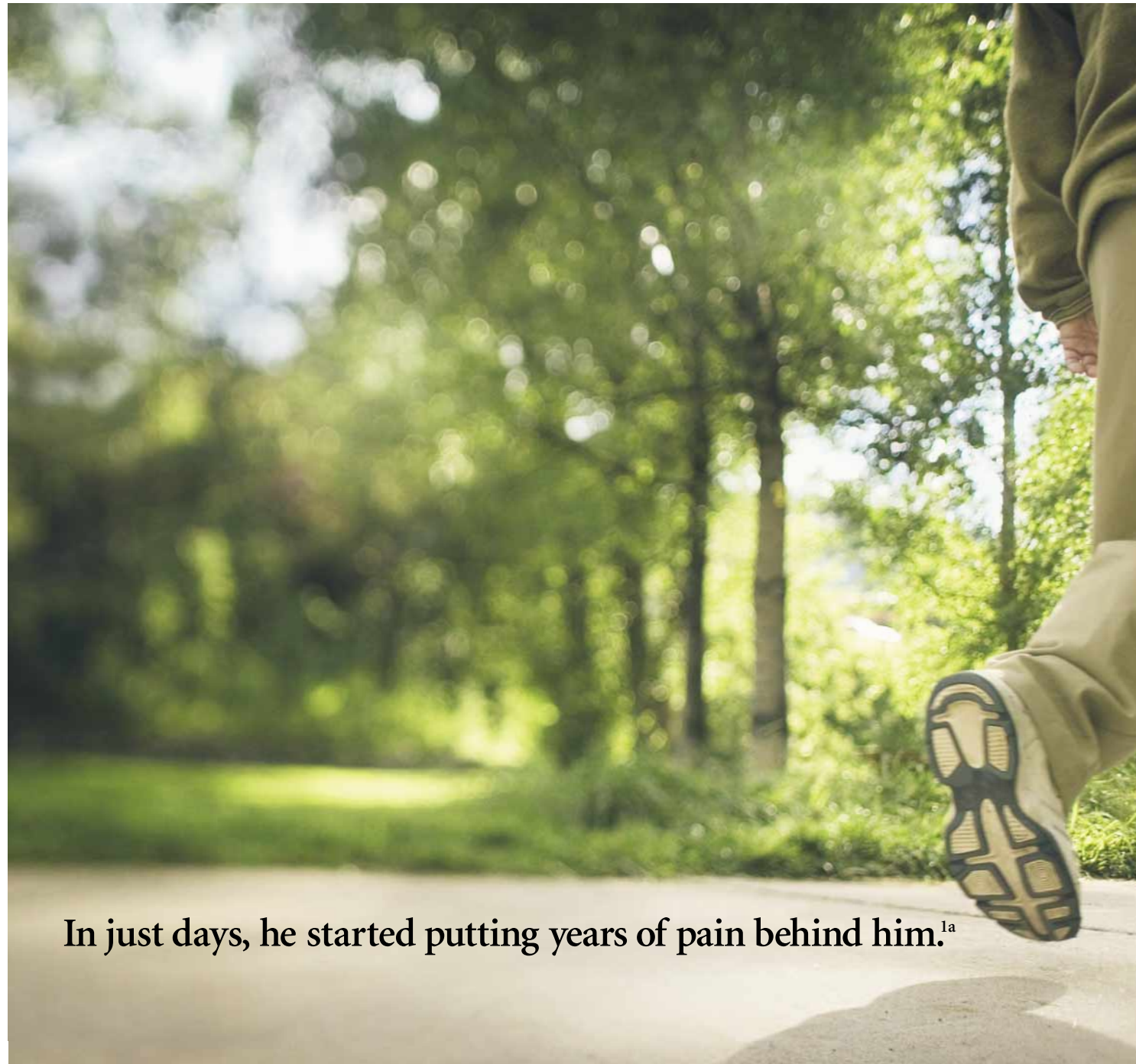
tions. However, FDA officials are encouraging voluntary industrywide application of the rule for existing drugs.

The American Medical Association applauded the rule as one that will simplify the prescribing process for physicians, but some consumer advocates, such as Washington-based Public Citizen, are critical, saying the revisions fail the patients they are purported to ultimately protect.

A preamble added to the rule is a “sneak attack” on patients’ rights designed to pre-

empt lawsuits filed by patients under state law, Public Citizen said in a statement.

Further, although the revisions simplify and prioritize labeling for doctors and patients, they don’t go far enough, according to Public Citizen. In many cases, patients will receive this information only if they request it. Otherwise they will receive only nonregulated patient information leaflets; these have been shown to lack scientifically accurate drug information, the group argues. ■



In just days, he started putting years of pain behind him.^{1a}

Important Safety Information:

- Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
- Patients started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.
- Cymbalta is not approved for use in pediatric patients.

References: 1. Data on file, Lilly Research Laboratories: a: CYM20050901A; b: CYM20050314B; c: CYM20050314D. 2. Goldstein DJ, et al. *Pain*. 2005;116:109-118.

Cymbalta should not be used concomitantly with monoamine oxidase inhibitors (MAOIs) or thioridazine and not in patients with a known hypersensitivity or with uncontrolled narrow-angle glaucoma.

Clinical worsening and suicide risk: All adult and pediatric patients being treated with an antidepressant for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially when initiating drug therapy and when increasing or decreasing the dose. A health professional should be immediately notified if the

* Cymbalta vs placebo ($P \leq .001$) by MMRM on 24-hour average pain severity score
Cymbalta vs placebo ($P \leq .009$) by MMRM on 24-hour night pain severity score
MMRM = Mixed-effects Models Repeated Measures analysis