Medical Xpress

Experts challenge FDA over approval for new dose of Alzheimer's drug

March 22 2012

Approval for a new dose of a best-selling Alzheimer's drug "breached the FDA's own regulatory standard" and has led to "incomplete and distorted messages" about the drug, warn experts in the *British Medical Journal* today.

In the first of a new occasional series, "not so", highlighting the exaggerations, distortions, and selective reporting that mark some news stories, advertising, and medical journal articles, Lisa M. Schwartx and Steven Woloshin challenge the claims made for the new 23 mg dose of donepezil.

Professors Lisa Schwartz and Steven Woloshin of the Center for Medicine and the Media at The Dartmouth Institute for Health Policy and Clinical Practice argue that the new dose was approved "only over the objections of the FDA's medical and statistical reviewers" and that it offers "no meaningful added benefit, just more harm."

Donepezil was a blockbuster drug for Alzheimer's disease, with over $2bn in annual sales in the United States alone. Just before its patent expired, the US Food and Drug Administration (FDA) approved a new 23 mg dose for moderate to severe Alzheimer's disease, thereby extending its patent for three more years. Previously, the drug was only available in 5 mg and 10 mg doses.

The FDA and the manufacturer agreed that the 23 mg dose would be approved only if it was shown to be superior to the 10 mg dose on both a

cognitive and a global functioning measure.

Although the drug improved cognitive symptoms, it did not improve overall functioning, which suggests that the cognitive difference was not meaningful. Furthermore, the new dose caused more side effects, including nausea and vomiting.

Yet Schwartz and Woloshin point to "a stunningly erroneous statement" in an advertisement aimed at doctors which claims that patients on the 23 mg dose "experienced important clinical benefit on both measures [cognition and overall functioning]."

"Nowhere – not in the direct to consumer or the physician advertisements, nor even in the FDA approved label – are the great uncertainties about this drug acknowledged, uncertainties that led the FDA's own medical and statistical reviewers to recommend against approval of the 23 mg dose," they argue.

Despite this, the drug was approved over the objections of the FDA's medical and statistical reviewers and government and private insurance programmes now cover the drug. It is now, or will soon be under consideration for approval in 16 countries in Asia and South America.

Alzheimer's is an awful disease, say the authors. "Sadly, the available drugs don't work well. But that is no excuse for manipulating vulnerable patients, desperate family members, and their doctors to use a product that is most likely to cause net harm."

They conclude: "To make good decisions about drugs, doctors and patients need the evidence. The FDA should not forget to give it to them."

New material recently obtained by the authors from the FDA

acknowledge that they made an error in relation to the previous label, stating: "The offending phrase was in the original label, and we don't recall how it slipped by, but we contacted the company as soon as it was brought to our attention, and they readily agreed to remove it. We are always interested in improving the content and clarity of our labeling, and appreciate being informed of any misleading or inaccurate statements that anyone may notice."

Provided by British Medical Journal

Citation: Experts challenge FDA over approval for new dose of Alzheimer's drug (2012, March 22) retrieved 1 May 2024 from https://medicalxpress.com/news/2012-03-experts-fda-dose-alzheimer-drug.html