FDA Mulls Label Changes for Antihypertensives

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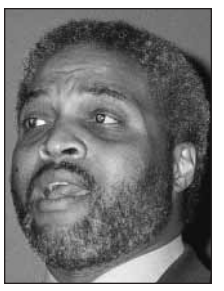
GAITHERSBURG, MD. —The Food and Drug Administration is paving the way for information on the clinical benefits of antihypertensive drugs to be included in their labels because it is concerned that hypertension is seriously undertreated.

The FDA's division of Cardiovascular and Renal Drug Products has prepared a draft guidance document for industry, which is intended as a guide for adding outcome claims to the labels of antihypertensive drugs. The draft was set to be published in the Federal Register by the end of May. Such guidance documents are considered recommendations and are not required.

Most labels of antihypertensive drugs, aimed at physicians, do not elaborate on the well-established clinical benefits that result from reducing blood pressure. But the agency "believes that, by making the connection between lower blood pressure and improved outcomes more explicit in labeling, it can encourage appropriate use of these drugs," according to a statement in the guidance document. This statement and the other elements of the draft guidance were reviewed by the FDA's Cardiovascular and Renal Drugs Advisory Committee, at a meeting of the panel in April.

The proposed indications section includes such statements as: "drug name" is indicated for treating hypertension, "to reduce the risk of cardiovascular events, primarily fatal and nonfatal strokes and myocardial infarction. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacological classes (including this drug) including the class to which this drug principally belongs."

The panel reviewed specific sections of the proposed clinical trials section of the label, which includes the statement that high systolic or diastolic blood pressure increases cardiovascular risk, and the "risk increase per mm Hg is greater at higher blood pressures." The section also says many drugs in various pharmacologic classes, "whose only common property is to lower blood pressure, have been shown to reduce cardiovascular morbidity and mortality, and it can be concluded that the blood pressure reduction is responsible for those benefits." The reduced risk of stroke is "the largest and most consistent outcome benefit … but reductions in myocardial infarction and cardiovascular mortality have also often been seen."



Adding benefits data could 'improve the use of these drugs in a very treatable but undertreated condition.'

DR. FLACK

The proposed label would also include a statement if there were no outcome trials that had been conducted for the particular drug or drug class, which had shown reductions in cardiovascular risk in hypertensive patients.

Other elements of the clinical trial section include references to the need for combination therapy in many patients, the smaller effects of some agents in black patients, and the additional effects of many antihypertensive drugs on outcomes such as angina, heart failure, or diabetic kidney disease. Among panelists' concerns were that there should be a qualifier for new drugs and an adequate amount of safety data on new drugs.

In an interview, Dr. John M. Flack, professor of medicine and physiology and interim chair and chief of translational research and clinical epidemiology at Wayne State University, Detroit, said more explicit labeling of the cardiovascular risk reduction expected from lowering blood pressure will have a positive impact on physician prescribing patterns, and "enhance the likelihood of doctors taking these drugs more seriously." Dr. Flack, a member of the FDA panel, was recused for this session, but was at the meeting.

The data strongly suggests that for a host of drugs across different classes that are mechanistically dissimilar, when they lower blood pressure, they lower cardiovascular risk as well, he said. At the very least, the enhanced label would have a neutral effect, and won't cause any harm, but adding the information on outcome claims "has the potential to improve the use of these drugs in a very treatable but undertreated condition," Dr. Flack noted. ■

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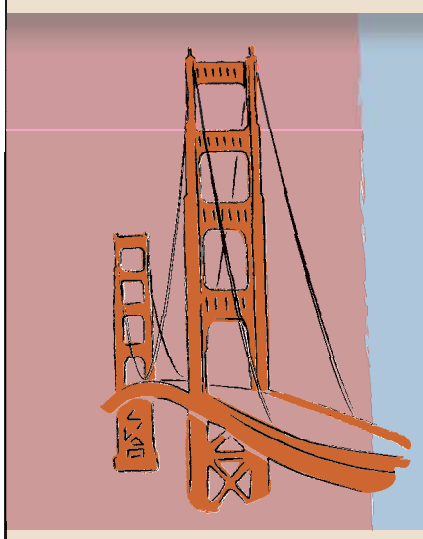

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