FDA approves many drugs that predictably increase heart and stroke risk

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The agency charged to protect patients from dangerous drug side effects needs to be far more vigilant when it comes to medications that affect

blood pressure.

Robert P. Blankfield, MD, MS, a clinical professor of family medicine, issues this call to the U.S. Food and Drug Administration (FDA) in an editorial published recently in an online edition of the *Journal of Cardiovascular Pharmacology and Therapeutics*; the print version of the article is expected to appear this autumn.

The editorial notes that several medications survived FDA scrutiny, only to be pulled from the market after reports of increased heart attacks and strokes related to use of the drugs. These include rofecoxib (Vioxx), valdecoxib (Bextra), and sibutramine (Meridia). What these drugs have in common is that they raise blood pressure. Other medications approved by the FDA, including some antidepressant medications as well as medications used to treat attention deficit hyperactivity disorder, also raise blood pressure but remain on the market despite inadequate safety data.

At issue is the apparent disconnect between what patients and doctors might consider "clinically significant" risk and the standards that some FDA reviewers apply when evaluating the safety of new therapeutics. When it comes to medications that affect blood pressure, a few FDA reviewers only classify "clinically significant" blood pressure spikes as those that raise systolic blood pressure by 20 mm Hg (milliliters of mercury) or diastolic blood pressure by 10 to 15 mm Hg.

Increases in systolic blood pressure of more than 2 mm Hg or increases in diastolic blood pressure of more than 1 mm Hg raise the risk for heart attack by 10 percent and stroke by 7 percent in middle-aged adults, according to an epidemiological study published in *Lancet* in 2002. Younger individuals have less risk. For example, studies published in 2011 in the *New England Journal of Medicine* and the *Journal of the American Medical Association* indicate that attention deficit hyperactivity

disorder medications are safe when used by young adults. While different populations differ in terms of cardiovascular risk, Blankfield believes one point should draw broad agreement: unless one is a healthy, young adult, clinicians and patients should have adequate cardiovascular safety data before they make prescription decisions.

"It is unwise to allow medications that predictably increase risk to be marketed without adequate safety data," said Blankfield, also a family physician at University Hospitals Berea Health Center. "Risk should be quantified, and the product label should accurately communicate the risk."

Blankfield, who has published other editorials recommending that the FDA require safety data for drugs that raise blood pressure, advocates a three-step solution. First, the FDA needs to establish specific guidelines regarding what degree of blood pressure elevation constitutes a risk for different populations (i.e. young adults, middle aged adults, older adults, diabetics, hypertensives, etc.). Then the agency should require pharmaceutical companies to provide cardiovascular safety data on medications that increase blood pressure. Finally, the agency should require pharmaceutical companies to post relevant data and/or warnings on medication labels.

"This would allow physicians and patients to make informed decisions about medications," he said. "Physicians and the general public may assume that if a drug is approved by the FDA, it is safe. Yet even modest elevations in blood pressure increase the risk of heart attacks and strokes."

Blankfield was moved to write this editorial now because of the public health importance of the issue.

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