Stanford researchers call for drug labels to disclose lack of comparison with existing medications

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The labeling information that comes with prescription drugs tells you what's known about the medication, but researchers from the Stanford University School of Medicine think it's high time that the labeling tell you what isn't known.

The researchers want the U.S. Food and Drug Administration to require drug manufacturers to state how new medications compare with similar, existing treatments. In many instance, these statements would indicate that there is no evidence that a new drug is more effective than older ones. They believe this information would make patients and health-care insurers less likely to pay for newer treatments without evidence that they lead to improved patient outcomes. It would also spur drug and medical-device companies to design more informative clinical trials to test a new product's superiority over existing therapies.

"Drug and device manufacturers benefit from an unacknowledged information gap that develops as more and more products are tested against placebo, but not each other," said Randall Stafford, MD, PhD, associate professor of medicine at the Stanford Prevention Research Center.

Stafford is the lead author of an essay that will be published online Aug. 12 in the New England Journal of Medicine, calling on the FDA to require more informative labeling of new drugs and medical devices. His

co-authors are Philip Lavori, PhD, professor of health research and policy, and Todd Wagner, PhD, health economist at the Veterans Affairs Palo Alto Health Care System and consulting assistant professor of health research and policy at the medical school.

The researchers note that the FDA doesn't require the inclusion of statements regarding how a new drug or device compares with existing treatments. Instead, treatments are simply required to perform better than a placebo without harmful side effects. "The problem is that the public, including physicians, often view FDA approval as constituting more than it does," Stafford said. "There's an inherent tendency for physicians and patients to want the newest thing and to assume that newer and more expensive means better, although this is often not the case."

That would be fine if the new drugs were the same price as those already on the market, but new therapies "are almost always more costly than previously approved treatments, particularly so when existing drugs are available in generic form," the essay says.

The public's appetite for the latest drugs might be curbed if patients understood that new treatments aren't necessarily more effective than existing ones. The Stanford researchers recommend that the FDA require new treatments to carry a label that would read, for instance: "Although this drug has been shown to lower blood pressure more effectively than placebo, it has not been shown to be more effective than other members of the same drug class."

While some might argue that the FDA's primary role is informing the public about the safety of drugs and devices, the researchers believe that developing more informative labels is consistent with the agency's recently invigorated function as a public health agency.

Source: Stanford University Medical Center (news : web)