A path toward more effective drug safety labeling

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Changes to drug safety labeling by the Food and Drug Administration (FDA) provide patients and providers with the most up-to-date information about a product's risk.

However, too little is known about the impact of these changes and whether they have unintended consequences, such as dissuading patients from taking a medication from which they might benefit or resulting in prescribing practices that do not comply with the labeling change.

Duke-Margolis Center for Health Policy researchers examined this issue and developed a white paper with recommendations and a research agenda intended to help FDA better understand the impact of its labeling changes and its communications about drug risks. Duke-Margolis researchers undertook this work as part of a cooperative agreement with FDA and in collaboration with other experts on this topic, including Becky Briesacher, Northeastern University; Stacie Dusetzina, Vanderbilt University School of Medicine; Chester "Bernie" Good, University of Pittsburgh; Kenneth Hornbuckle, Eli Lilly and Company; and Joseph Ross, Yale University.

Several recommendations made by Duke-Margolis for the FDA's consideration included:

- improving its safety labeling changes website to ensure it provides robust and accessible information;
- announcing priority topics for study, which Duke-Margolis identified, to the research, funding and pharma communities;
- publishing FDA's intended goals for labeling changes to allow for better evaluation of those changes; and
- establishing an expert consortium to systematically evaluate the impact of labeling changes. The consortium would use real-time data on key health and behavioral outcomes, and leverage existing partnerships, including those maintained through the FDA's Sentinel initiative and other sources.

"Communicating the most up-to-date information on a product's safety to patients and providers is one of FDA's most important functions," said

Mark McClellan, MD, Ph.D., director of Duke-Margolis. "This work reflects the collaborative contributions of experts to help FDA advance its understanding of the impact of post-marketing safety efforts."

Provided by Duke University