

# A path toward more effective drug safety labeling

July 24 2019, by Patricia Green

---



Credit: CC0 Public Domain

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

Citation: A path toward more effective drug safety labeling (2019, July 24) retrieved 26 April 2024 from <https://medicalxpress.com/news/2019-07-path-effective-drug-safety.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--