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Study Examines Impact of FDA Drug Risk Communications

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A recurring topic here at *MassTortDefense* is the role of hazard communications in product safety, and the related issues of a consumer reading, heeding, or relying on such warnings. This is particularly true in the area of prescription drug litigation, focused on over at <u>Drug and Device Law</u>.

So, that makes a recent study in *Medical Care* interesting reading: Dusetzina, et al., <u>Impact of</u> <u>FDA Drug Risk Communications on Health Care Utilization and Health Behaviors: A</u> <u>Systematic Review</u>.

The paper reviews the literature of the past 20 years on the impact of FDA drug risk communications on medication utilization, health care services use, and health outcomes. These 50 or so studies covered roughly 16 therapeutic classes; most used medical or pharmacy claims and a few examined patient-provider communication, decision making, or risk perceptions.

The authors concluded that although some FDA drug risk communications had immediate and strong impacts, many had either delayed or no impact on health care utilization or health behaviors. These data demonstrate the complexity of using risk communication to improve the quality and safety of prescription drug use, and suggest the importance of continued assessments of the effect of future advisories and label changes, according to the authors.

Although not the focus of the article, the findings are relevant to those of us who need to think about the learned intermediary doctrine, preemption, and other legal warning doctrines.