Off-Label Use of Medical Products

**WHY ARE THE RISKS OF OFF-LABEL USE OF MEDICAL PRODUCTS IMPORTANT?**

- For a variety of reasons, the labeled indications arising during the U.S. Food and Drug Administration (FDA) approval process may not include all conditions for which a medical product might be useful.¹
- Despite the prevalence and acknowledged benefits of the practice, by virtue of not undergoing safety and efficacy evaluation by the FDA, off-label use may be associated with potential harm in patients.
- Off-label use of medical products can increase the likelihood of a malpractice lawsuit.²
- Certain types of off-label use—prescribing significantly higher doses than approved in labeling, prescription for an unapproved indication, and prescription for patients not part of a population included in clinical trials—have been more frequently targeted in litigation following adverse events.³

**DID YOU ASK?**

- Has our organization established a committee to develop a framework to best guide off-label use of medical products?
- Is our organization aware of regulatory developments and enforcement actions regarding off-label promotion of medical products?
- Does our organization involve patients and family in a comprehensive informed consent process regarding the risks and benefits of off-label medication use?
- Are members of our organization familiar with strategies to decrease risks related to off-label prescribing?

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¹ U.S. Food and Drug Administration. Understanding investigational drugs and off-label use of approved drugs. [cited 2015 Feb 3]. http://www.fda.gov/ForPatients/Other/OffLabel/default.htm
