

Can Off-Label Use of Medical Devices Lead to Baltimore Medical Malpractice?

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In some cases, the off-label use of medical devices can lead to a [Baltimore medical malpractice lawsuit](#). However, in other situations, the unapproved use may actually represent a medically recognized standard of care. Therefore, it is important to understand the difference.

The Food and Drug Administration defines “off-label use” as the use of a medication or medical device for an indication, dosage amount or regimen, patient population, or other considered use not listed in the approved labeling. Because the FDA has not stringently tested the safety of off-label uses, they can pose higher risks to patients.

Under existing regulations, physicians are permitted to use medical devices for purposes other than those that the FDA approved. However, if physicians use a medical device for in a way not described in the approved labeling, they have the responsibility to be well informed about the product, to base its use on sound medical evidence, and to maintain records of the product’s use and effects off-label uses of medical devices.

When it comes to medical malpractice, the standard of care is what other similarly trained physicians would do. In other words, would they use the medical device in similar circumstances?

For example, if there is no scientific or medical evidence to support the specific unapproved use of the medical device, a patient could have grounds for a Baltimore medical malpractice lawsuit. Doctors are also required to explain the risks of the off-label use and obtain the patient’s written consent. The failure to do so could also constitute medical malpractice.

The Baltimore medical malpractice attorneys of [Hyatt & Weber, P.A.](#) understand the potentially devastating impact of a serious medical mistake. If you or someone you love has been injured due to someone else’s negligence, we are here to help. Our injury attorneys are experienced and dedicated to pursuing the compensation you deserve.