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Medical Devices That Fail

Prescription Medical Devices Are Regulated by Food & Drug Administration (FDA).

Unlike non-prescription medical devices (e.g. thermometers, bandages, heating pads) that can be purchased by lay consumers over the counter at retail stores, in the case of prescription medical devices, the consumer is the prescribing physician, not the patient. The manufacturer of the prescription medical device has an obligation to provide the prescribing physician adequate instructions for use that include information about the intended use for the device, the precautions, warnings, risks and contraindications associated with the use of the device. It is the standard of care for the prescribing physician to inform the patient about the benefits, risks, and complications associated with the use of the medical device. Centocor, Inc. v. Hamilton, 310 S.W.3d 476 (2012)(Texas); Bakerv. Danek Medical, 35 F. Supp.2d 875 (N.D. Fla. 1998); Anderson v. Owens-Corning Fiberglas Corp., 53 Cal.3d 987 (1993). Medical devices are classified into Class I, Class II, Class III. FDA regulatory control increases from Class I to Class III. Most Class I medical devices can be sold over the counter (OTC) in the retail marketplace. Class II medical devices carry increased regulatory oversight and require Premarket Notification 510 (k) to FDA in order to be cleared for market and sale in the United States; Class II devices are prescription medical devices. Most Class III devices require Premarket Approval by FDA; all Class II devices are prescription medical devices. The increased oversight of Class II and Class III medical devices emanates from FDA's efforts to ensure that such devices are safe and effective for the manufacturer's intended use.

Physicians Who Prescribe FDA Regulated Devices Are Not Subject To FDA Oversight, But Must Comply With The Standard Of Care.

Prescribing physicians are not regulated by the FDA and can prescribe prescription medical devices for unintended uses (aka "off label" -a use that is not intended by the prescription medical device

manufacturer). It is not below the standard of care for a physician to prescribe a medical device for off label use if the off-label prescription is appropriate in the physician's exercise of medical judgment.

A Bad Outcome Is Not Always Due To The Failure Of A Prescribed Medical Device.

Medical device "failures" are not always due to a failure of the medical device, especially in instances where the device was either prescribed or used off label. Poor outcomes that are associated with the use of a prescription medical device are frequently due to factors such as poor patient selection, lack of informed consent, off label prescription, or poor patient compliance.