

[Products Liability Law Daily Wrap Up, WARNINGS ISSUES—MEDICAL DEVICES—D. Neb.: Learned intermediary doctrine applies to birth control prescriptions, devices, \(Mar. 5, 2019\)](#)

Products Liability Law Daily Wrap Up

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By Rebecca Mayo, J.D.

A district court held that birth control prescriptions should be included in the learned intermediary doctrine exception to products liability actions for failure to warn.

Patients make the ultimate decision of what contraceptive to use, but still rely on physician guidance and advice to make the decision just like any other medical decision of which treatment to pursue. Therefore, a district court in Nebraska held that birth control prescriptions should be treated the same as other prescription drugs and devices under the learned intermediary doctrine. The court dismissed a failure to warn claim against the manufacturer of an intrauterine device, finding that the learned intermediary doctrine applied and the prescribing physician in the case had been adequately warned (*Ideus v. Teva Pharmaceuticals USA, Inc.*, February 19, 2016, Gerrard, J.).

Injury. A patient had a ParaGard® T380 Intrauterine Copper Contraceptive birth control device implanted. When the device was being removed four years later, a piece of the device broke off and embedded in the myometrium of the patient's uterine wall and had to be surgically removed. The patient sued the device manufacturer claiming that she was not adequately warned of the possible risks associated with the device. The manufacturer moved for summary judgment.

Learned intermediary doctrine. A manufacturer is generally subject to liability for failing to adequately warn about a risk or hazard inherent in the way a product is designed or the reasonably foreseeable uses that may be made of the product. The learned intermediary doctrine is an exception to that rule that discharges manufacturers of that duty for prescription drugs and devices so long as adequate warnings are provided to a patient's prescribing health-care provider. Courts have been divided as to whether contraceptives are distinguished from other prescription drugs when applying the doctrine. Some courts have noted that birth control is a private matter and decisions on which contraceptive to use is often dependent on factors such as effectiveness, convenience, or cost rather than medical necessity. Previous courts also have noted that manufacturers often market directly to the consumer, and further, that contraceptives often are prescribed in clinical settings with little contact between the physician and the patient.

Decision. The court here distinguished this case from previous cases, finding that the device was not directly marketed to patients and that the patient in this case had ongoing, consistent contact with her prescribing physician. Additionally, in making the decision to go with this form of contraception, the patient considered whether the contraceptive was "hormone free," reliable, and would last a long time. These factors required the knowledge and input of a physician. While the final decision of which contraceptive to use is ultimately the decision of the patient, patients are expected to look to the physician for guidance just as they do in making the decision to pursue a certain surgery or follow a particular diet. Therefore, the court held that the learned intermediary doctrine should apply in this case, and that since there was no evidence that the patient's physician would not have inserted the device had the warnings in the package insert been stronger or more specific, there was no genuine dispute as to the adequacy of the ParaGard warning. Consequently, the case was dismissed.

The case is No. [4:16-CV-3086](#).

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Companies: Teva Pharmaceuticals USA, Inc.; Teva Women's Health, Inc.

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