
**MEDICAL PRODUCTS
LIABILITY:
IMPLANTABLE DEVICES**

Honorable Kenneth L. Buettner

IMPLANTABLE DEVICES

- Learned Intermediary Doctrine
 - *McKee v. Moore*, 1982 OK 71, 648 P.2d 21
-IUD
 - *Alexander v. Smith & Nephew, PLC*,
98 F. Supp. 2nd 1310 (N.D. Okla. 2000)
-Rogozinski Spinal Rod System
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Learned Intermediary Doctrine

“It is the physician’s duty to inform himself of the qualities and characteristics of those products which he administers or prescribes for use of his patients, and to exercise his judgment, based on his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides which facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise an informed judgment in the best interest of the patient.”

McKee v. Moore, 648 P2d at 24-25

IMPLANTABLE DEVICES

- Unavoidably Unsafe Products
 - *Tansy v. Dacomed Corp.*,
1994 OK 146, 890 P.2d 881
-Penile Implant



Unavoidably Unsafe Products

While products liability law seeks to protect the public from unreasonably dangerous products, Comment k seeks to protect another facet of the public's interest-that of having available new products whose benefits are great enough to justify associated risks. It protects certain manufacturers who develop new products which at the time of manufacture are incapable of being made totally safe, and shields certain products by classifying them as "unavoidably unsafe" rather than "defective."

Tansy v. Dacomed, Corp., 890 P2d at 885

IMPLANTABLE DEVICES

- FDA Preemption

- *Riegel v. Medtronic, Inc.*,
552 U.S. _____, 128 S. Ct. 999,
169 L. Ed. 2d 892 (2008)
 - Evergreen Balloon Catheter
 - *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*,
592 F. Supp. 2nd 1147 (D. Minn. 2009)
 - Implantable Cardiac Defibrillators
-

FDA Preemption

21 U.S.C. Section 360(a):

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

FDA Preemption

In re Medtronic, Inc. Sprint Fidelis Leads Products
Liability Litigation

Plaintiffs' claims were preempted:

- manufacturing defect
 - negligence
 - negligence per se
 - failure to warn
 - design defect
 - breach of warranty
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