PRODUCT LIABILITY CONSIDERATIONS: THE LAP-BAND SYSTEM

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I. THE LAP-BAND SYSTEM

• General Information:
  o The Lap-Band System is a long-term, surgically implantable device intended to induce weight loss in morbidly obese patients by limiting food consumption.
    • The components of the device include the silicone elastomer band, an access port, and tubing used to connect the band and port.

  o How it Works: In a laparoscopic surgical procedure, a surgeon wraps the band around the upper part of the stomach, creating a small pouch that can hold only a small amount of food. The narrow opening of the stomach pouch (the stoma) limits how quickly food passes to the lower part of the stomach. Fullness and satiety is achieved with just a small amount of food.

  o “Adjustments” or “Fills”: Inside the band is a circular balloon that can be inflated and deflated by using the access port, a small button-like reservoir that is surgically placed under the skin of the abdomen. As the patient adjusts to the band, the surgeon can inflate or deflate the balloon by injecting saline solution through the access port, a procedure called an “adjustment” or a “fill.”
• Risks and Benefits:
  o Patient Requirements: The Lap-Band is indicated for severely obese patients with a Body Mass Index (BMI) of at least 40, or a BMI of 35 with at least one obesity-related health condition, or those who are 100 lbs. over their ideal weight.
    ▪ Patients must have been overweight for more than 5 years and have previously failed more conservative weight loss techniques.
    ▪ Patients who elect to have Lap-Band surgery must be prepared to make major changes in eating habits and lifestyle for the rest of their lives.
  o Surgery & Recovery Time: The Lap-Band is installed under general anesthesia. The procedure lasts about an hour. Because the Lap-Band is a laparoscopic procedure, a large incision is not required and recovery time is rapid.
  o Results: Average Lap-Band patients experience a reduction in weight of 1-2 lbs. per week. Most patients maintain their weight loss.
  o Risks: \(^1\)
    ▪ Mortality rate: 0.05%
    ▪ Total complications: 9%
    ▪ Major complications: 0.2%
    ▪ Most common risks include:
      • Standard risks associated with major surgery
      • Nausea and vomiting
      • Lap-Band slippage
      • Stoma obstruction

II. STATE OF MEDICAL DEVICE LAW GENERALLY

• Introduction: Medical devices are regulated by the Food and Drug Administration (“FDA”) under the authority of the 1976 Medical Device Amendments (“MDA”) to the Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 et seq. The FDA divides medical devices into three classes (Class I, II, and III), with Class III being the most regulated.
  o The Lap-Band System is a Class III medical device:
    ▪ Class III medical devices are those which are to be used for “supporting or sustaining human life” or that are of “substantial importance in preventing impairment of public health,” or those that “present a potential unreasonable risk of illness or injury.” See 21 U.S.C. § 360c(a)(1)(C).
    • Other examples: replacement heart valves, silicone breast implants
    ▪ Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with “reasonable assurance” that the device is both safe

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\(^1\) The following data is available at the official Lap-Band System website, see http://www.lapband.com/en/learn_about_lapband/compare_lapband/ (last accessed 9/27/2010).
and effective. The means of establishing this “reasonable assurance” is a comprehensive process known “premarket approval” (“PMA”). See 21 U.S.C. § 360(e).

- **The PMA process:**
  - Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

- **The MDA and Preemption:**
  - The MDA includes a provision that expressly preempts state law: “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. 21 U.S.C. § 360(k).
  - Key Language: “different from, or in addition to” any federal safety requirement

  - Prior to the landmark *Riegel* decision, courts disagreed whether the MDA preempted state common law claims against manufacturers of medical devices.
  - According to *Riegel*, the MDA bars all state tort claims challenging the safety of a Class III medical device that attempt to impose safety requirements “different from, or in addition to” federal requirements for PMA.
    - To apply *Riegel*, use the following two-part test to determine whether the MDA preempts a state law claim:
      - 1: Determine whether the FDA has established requirements applicable to the medical device in issue.
      - 2: Determine whether the state law claims are based on requirements “different from, or in addition to” the federal requirements relating to safety, effectiveness, labeling, or any requirement under the MDA.

- **Facts of *Riegel***:
  - *Riegel* involved a Class III catheter manufactured by defendant Medtronic that had received FDA premarket approval. The suit arose after the plaintiff’s surgeon overinflated the catheter while performing a coronary angioplasty, causing the catheter to rupture and requiring emergency coronary surgery.
  - Plaintiff filed suit in state court alleging various state product liability claims. The Supreme Court affirmed dismissal of the plaintiff’s strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims on the grounds that they were preempted by the MDA. The Court also pre-empted a negligent manufacturing claim insofar as it was not premised on the theory that Medtronic violated federal law.
State of Law Post-Riegel:

- Key Question: Which claims are preempted and which claims are available?
- “Parallel” Claims:
  - Although Riegel purportedly preempts most state law product liability claims, it leaves available the possibility of state law tort claims that "parallel" federal requirements, so far as state law does not interfere with the FDA’s regulatory scheme.
  - But since Riegel gave no definition of "parallel" claims, lower courts have been left to determine which state law claims "parallel" FDA regulations and which claims interfere. Two views have emerged, with most lower courts favoring preemption.
- Minority View: This view favors a broad reading of permissible "parallel" tort claims and allows more claims to proceed despite Riegel.
  - The most notable example is Hofts v. Howmedica, 597 F. Supp. 2d 830 (S.D. Ind. 2009), where a federal district court ruled that the MDA does not preempt a state claim based on a violation of the FDCA and a medical device manufacturer could be liable under state tort law for any failure to follow its approved PMA. Under Hofts, a state law claim must only survive this so-called “express preemption” in order to proceed. Thus, many common-law tort claims (e.g., negligence, strict liability, and breach of implied warranties) enforcing federal requirements may proceed, even though they were generally thought to be preempted by Riegel.
- Majority View: This view is deferential to the FDA's decision to approve medical devices and takes a narrow reading of “parallel” claims, which results in more claims being preempted.
  - This line of cases is represented by In re Medtronic Sprint Fidelis Leads Product Liability Litigation, 592 F. Supp. 2d 1147 (D. Minn. 2009) (“Sprint Fidelis”), and Riley v. Cordis Corp., 625 F. Supp. 2d 769 (D. Minn. 2009). Both Sprint Fidelis and Riley agree with Hofts that a state tort claim premised on conduct that is prohibited under the FDCA is “parallel” and not expressly preempted.
  - Sprint Fidelis and Riley differ from Hofts in their recognition that state law claims may also be impliedly preempted. This view is derived from Buckman Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341 (2001), where the Supreme Court found that because enforcing the FDCA is considered the province of the federal government, there is no private right of action under the FDCA. Thus, a private plaintiff cannot sue a defendant for violating the FDCA. Similarly, under Sprint Fidelis and Riley, a plaintiff cannot bring a state law tort claim against a device manufacturer when the state law claim is equivalent to a claim for violating the FDCA. Under this so-called “implied preemption,” the manufacturer’s conduct on which the plaintiff’s claim is based must give rise to liability under state law even if the FDCA did not exist.
  - Thus, in order to survive preemption under Sprint Fidelis and Riley, a state law claim must avoid both express and implied preemption.
(1) To avoid express preemption, the plaintiff must claim that the device manufacturer has violated the FDCA.

(2) To avoid implied preemption, the plaintiff must show that the manufacturer’s actions create liability under state law even if the FDCA did not exist.
   - Example: a state statute providing a remedy for a violation of FDCA requirements would possibly avoid federal preemption.

The Future of Riegel:
- Most courts agree with Sprint Fidelis and Riley and find that most state law claims are preempted.
- Key Question: What types of claims are not preempted?
  - Answer: This is still to be determined by future decisions. According to Sprint Fidelis, nearly all types of claims concerning FDA-approved medical devices are preempted. See below for a discussion on claims that may not be preempted.

- The Supreme Court may have to revisit Riegel to resolve the conflicts courts have created in defining “parallel” claims.
- Medical Device Safety Act of 2009
  - This bill, introduced in March 2009, is currently in committee and represents the Democrat legislative effort to overturn Riegel.

### III. POSSIBLE APPLICATION TO THE LAP-BAND SYSTEM

- Lap-Band Device Manufacturer Liability: Preemption is the manufacturer’s greatest defense weapon, all state-law tort claims that fall within Riegel are preempted. Consider the following possible claims:
  - Defective Design
    - Possible Claim: The Lap-Band is defectively designed and unreasonably safe for its intended use.
      - Under Hofts and Sprint Fidelis/Riley: Claim expressly preempted. Allowing plaintiff’s claim would contradict the FDA’s determination that the Lap-Band is appropriately safe.
  - Manufacturing Defect
    - Possible Claim #1: Lap-Band Manufacturer was negligent/reckless in manufacturing product despite following FDA requirements.
      - Under Hofts and Sprint Fidelis/Riley: Claim expressly preempted.
    - Possible Claim #2: Lap-Band Manufacturer defectively manufactured the device by violating FDA requirements. Plaintiff can allege either PMA-specific violations or violations of the FDA’s general “Current Good Manufacturing Practice” requirements.
• Under Hofts: Claim not preempted. Manufacturer’s violation of an FDA-approved requirement is evidence that manufacturer breached a duty owed to plaintiff.

• Under Sprint Fidelis/Riley:
  o Claim preempted when plaintiff only makes conclusory allegations of a manufacturing defect. Claim not preempted if plaintiff alleges specific device manufacturing defect that failed to comply with PMA specifications.
  o Claim must also survive implied preemption.
  o Causation Requirement: Plaintiff must also allege that violation of the PMA specifications resulted in manufacture of the defective device that was implanted in the plaintiff and caused the injuries plaintiff sustained.

  o Breach of Implied Warranties
    ▪ Possible Claim: Lap-Band is defective and not reasonably fit for the ordinary purpose for which it is intended.
      • Under Hofts: Claim not preempted at pleading stage. Riegel doesn’t apply because FDA regulations permit state law claims brought under the Uniform Commercial Code. Plaintiff must still provide evidence of violations of federal requirements to avoid express preemption.
      • Under Sprint Fidelis/Riley: Claim preempted. For plaintiff to succeed a jury would have to find that the Lap-Band manufacturer breached implied warranties of fitness or merchantability by selling a device that was unsafe in its federally approved design or manufacture.

  o Unfair Trade Practices Statutes
    ▪ Possible Claim: Lap-Band manufacturer’s trade practices are fraudulent or deceptive in violation of state consumer protection statutes.
      • Under Hofts: Claim not preempted at pleading stage. Riegel does not apply because FDA regulations permit claims based on state law unfair trade practices statutes. Plaintiff must still provide evidence of violations of federal requirements to avoid express preemption.
      • Under Sprint Fidelis/Riley: Claim preempted. Deceptive practices claims attempt to impose “additional or different” requirements on device manufacturers and interfere with federal regulatory scheme.

  o Breach of Express Warranties  [not specifically addressed by Riegel]
    ▪ Possible Claim #1: The Lap-Band manufacturer made and breached express warranties based on statements which exceeded the scope of the PMA labeling.
      • Under Hofts and Sprint Fidelis/Riley: A manufacturer’s voluntary, express warranties that exceed the scope of FDA-required labeling are not preempted.
        o Note: Plaintiff must sufficiently allege that the statements by the manufacturer became part of the “basis of the bargain.”
• Possible Claim #2: The Lap-Band device was unsafe and thus the manufacturer breached express warranties based on the labeling approved during the PMA process.
  • Under *Hofts*: Claim not preempted. The “requirements” imposed by an express warranty are not imposed under state law but are imposed by the device manufacturer on itself as the “basis of the bargain.” This contractual commitment “parallels” the federal requirements.
  • Under *Sprint Fidelis/Riley*: Claims preempted. Allowing plaintiff’s express warranty claim would contradict the FDA’s determination that the label’s representations were appropriate.

  o Failure To Warn:
    • Possible Claim #1: Lap-Band Manufacturer failed to warn physicians and patients of defects regarding the Lap-Band.
      • Under *Hofts*: court did not consider failure-to-warn claims.
      • Under *Sprint Fidelis/Riley*: Claim expressly preempted. For plaintiff to succeed, the Lap-Band manufacturer would have to provide warnings beyond the FDA-approved labeling.
        • Note: Claims based on a “post-sale” duty to warn in light of post-PMA received reports of injury are also preempted.
    • Possible Claim #2: Lap-Band Manufacturer failed to warn about the risks regarding off-label uses of the Lap-Band (*i.e.*, when the Lap-Band is installed in people who do not meet the BMI requirements indicated by the device).
      • Under *Hofts*: did not consider off-label failure-to-warn claims.
      • Under *Sprint Fidelis/Riley*: Although failure-to-warn claims are generally preempted, *Riley* discusses one failure-to-warn claim that could escape preemption:
        • Plaintiff must plead that (1) the Lap-Band Manufacturer affirmatively promoted off-label use of the Lap-Band in a manner that violated federal law, and (2) the Lap-Band manufacturer failed to include adequate warnings about the off-label use it was promoting.
        • Arguably, such a claim survives express preemption because it is based on violation of federal law. It survives implied preemption under *Buckman* because traditional state law imposes a duty to warn when a manufacturer reasonably foresees that an injury could result from use of its device.
        • Note: Plaintiff must still allege causation. Plaintiff must allege (1) that implanting the Lap-Band in an off-label way caused her injuries, and (2) the plaintiff’s physician would not have implanted the Lap-Band in the plaintiff had the physician been adequately warned about this off-label use.
Failure-To-Warn Claims and Direct-to-Consumer (“DTC”) Advertising

- The “learned intermediary” rule: Under the general rule, medical device manufacturers fulfill their duty to warn of known risks of their devices by providing warnings to prescribing physicians. Physicians, using their medical judgment, have a duty to convey the warnings to their patients.
- In the context of prescription drugs, DTC advertising may create an exception to the learned intermediary rule and create an obligation for drug manufacturers to warn patients directly.
  - For example, Perez v. Wyeth Laboratories, Inc., 161 N.J. 1 (1999), involved a suit by plaintiffs who had received Norplant implants which were the subject of a Wyeth advertising campaign directed at women rather than at doctors. In Perez, the New Jersey Supreme Court agreed that the learned intermediary rule should not apply in the case of DTC advertising.
  - To date, no other jurisdiction has adopted this exception.
- As in Perez, one could possibly foresee courts imposing on Lap-Band manufacturers the duty to warn patients who were the subject of extensive advertising campaigns. Whether such claims would be preempted remains to be determined as discussed above.

Samples of Recent Suits Against Lap-Band System Manufacturers:

- Cusack v. Allergan, Inc., 10C1372, Rutherford County Cir. Court, TN (filed 04/14/2010):
  - Plaintiff alleges that defendant Allergan, Inc. designed and manufactured a defective Lap-Band System that failed 2 years after it was implanted in the plaintiff, causing weight gain and a “different” sensation when plaintiff ate food.
  - The complaint alleges causes of action for negligent design and manufacture, failure to warn, strict liability, and breach of implied and express warranties.

- Portillo v. Allergan, Inc., BC430770, Los Angeles County Superior Court, CA (filed 01/28/2010):
  - Plaintiff alleges that she failed to lose weight due to a “spontaneous fracture” of the Lap-Band tubing that was discovered by her doctor when he removed the Lap-Band and replaced it with the “Realize Band”.
  - The complaint alleges one cause of action for strict products liability based on the Lap-Band’s defective design and/or manufacture.

Doctor & Hospital Liability:

- Preemption applies only to device manufacturers, doctors and hospitals who perform Lap-Band procedures remain liable for traditional state law tort claims such as negligence, battery, breach of contract, and violation of state consumer protection laws.