PRODUCT LIABILITY: NEGLIGENCE

Fact Pattern:

Vassallo underwent breast implant surgery in 1977. Fifteen years later, she underwent a mammogram after suffering from chest pains under her left armpit. The mammogram showed that the breast implants had possibly ruptured. The silicone gel implants were removed and replaced with saline implants. During the surgery the surgeon noted severe, permanent scarring of Vassallo's pectoral muscles that was attributed to the silicone gel. The left implant had ruptured and the right had several pinholes through which the silicon could escape. During trial, evidence indicated that by 1977, Heyer-Schulte, the manufacturer, knew its implants were not consistent as far as durability or destructibility. Heyer did not warn of the consequences of gel migration in the body, also, Heyer-Schulte conducted few animal and no clinical studies regarding the safety of its silicone gel implants. While Heyer-Schulte did furnish warnings to doctors, they did not address the possibility of gel bleed, ruptures or the consequences of silicon gel escaping into the body. Vassallo stated that if she had known that the implants could cause permanent scarring, chronic inflammation and problems to her immune system, she would not have gone ahead with the procedure.

Question:

Is the manufacturer liable under the tort theory of negligence?

Rule

A manufacturer will be held liable under rules of negligence if he fails to use reasonable care in designing, manufacturing, or marketing the product.

Discussion

Plaintiffs basing a product liability claim on negligence must prove that a manufacturer failed to use reasonable care in designing, manufacturing or marketing the product. In order to recover under a theory of negligence, a plaintiff must prove five basic elements, including the following: (1) the manufacturer owed a duty to the plaintiff; (2) the manufacturer breached a duty to the plaintiff; (3) the breach of duty was the actual cause of the plaintiff's injury; (4) the breach of duty was also the proximate cause of the injury; and (5) the plaintiff suffered actual damages as a result of the negligent act. In a products liability case, the law requires that a manufacturer exercise a standard of care that is reasonable for those who are experts in manufacturing similar products. However, even if a plaintiff can prove that a manufacturer has failed to exercise the

proper standard of care, the plaintiff cannot recover without proving two aspects of causation. The plaintiff must first show that but for the manufacturer's negligence, the plaintiff's would not have been injured. The plaintiff must also show that the defendant could have foreseen the risks and uses of the product at the time of manufacturing.

Historically, the use of negligence theory for such purposes was drastically limited by the requirement of privity, the requirement that , in order to maintain an action, the plaintiff must show that he contracted directly with the defendant. The courts have modified the privity rule to permit negligence suits where personal injury occurred from an inherently dangerous defective product. For example, a consumer who is made sick by contaminated food can sue the manufacturer, even though she made her purchase from a retailer.

Design Defects: All products manufactured by the defendant are the same, and they all bear a feature whose design is itself defective and unreasonably dangerous. Ordinarily, the plaintiff will have to prove that there existed a reasonable alternative design that would have been materially safer. However, this does not require that the plaintiff must produce a prototype in order to prove the existence of a reasonable alternative design—one of the best ways for a plaintiff to show the existence of a reasonable alternative design is to show that similar products from other manufacturers already have such an alternative design.

Most cases claiming design defects fall within three general categories, which sometimes overlap: (1) structural defects, (2) absence of safety features; and (3) suitability for unusual purposes. In the Vassallo case, there was evidence of a structural design defect and that Heyer-Schulte was aware that their implants were rupturing, having received 129 complaints of ruptured gel implants in 1976. By 1975, Heyer-Schulte also knew that, even without a rupture of the implant shell, the silicone gel could leak through to the exterior surface of the implant.

Manufacturing Defects: A defectively manufactured product does not conform in some significant aspect to the intended design, nor does it conform to the great majority of products manufactured in accordance with that design. Stated differently, the particular item that injures a person is different from the other ones manufactured by the defendant because something went wrong with the manufacturing process. A manufacturing defect is, in essence, a mistake in the manufacturing process. Under products liability, even if the manufacturer was extremely careful in manufacturing the product, it will still be held responsible for any manufacturing defect in the product.

Improper Marketing: Marketing defects include improper labeling, insufficient instructions, and/or inadequate safety warnings. The duty to warn is an extra obligation placed on a manufacturer. In other words, a manufacturer who has otherwise produced a defective product cannot render the product un-defective by giving an adequate warning. A warning will not shield a manufacturer from liability for a defective design. In the Vassallo Case, there was extensive testimony as to

Heyer-Schulte's knowledge of the risks of silicone gel breast implants up to the time of Mrs. Vassallo's implant surgery. According to Heyer-Schulte's own internal correspondence, the company was aware of a „Talk Paper," issued by the United States Food and Drug Administration in 1976, that documented migration to the brain, lungs, and heart, and death following injections of liquid silicone into the human body. In 1976, Heyer-Schulte received a report of an animal study, partially funded by Heyer-Schulte and conducted using miniature silicone gel implants supplied by Heyer-Schulte, that documented migration of gel from ruptured implants to the surrounding connective tissues and local inflammatory responses with fibroblastic activity and giant cell formation. This is in addition to the reports of implants rupturing and leaking that Heyer-Schulte was aware of prior to Mrs. Vassallo's implant surgery.

Heyer-Schulte did furnish warnings to physicians concerning their silicone gel implants in a product insert data sheet (PIDS). The 1976 version of the PIDS that accompanied Mrs. Vassallo's implants included warnings that the implant shell could be easily cut or ruptured by excessive stresses, and that Heyer-Schulte could not guarantee gel containment in the case of a rupture. The warnings did not address the issue of gel bleed, the fact that a rupture could result from normal stresses and could persist undetected for a significant time period, or the consequences of gel migration in the body. The PIDS also contained a list of potential complications associated with breast implants, but this list did not address the risks of chronic inflammation, permanent tissue scarring, or possible effects on the immune system.

In the Vassallo case, the manufacturer will be held liable on the basis that the implants were negligently designed accompanied by negligent product warnings.