PRODUCT LIABILITY: STRICT LIABILITY

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 strict liability?

Rule

Under the doctrine of strict liability, the manufacturer is liable if the product is defective even if the manufacturer was not negligent in making the defective product.

Discussion

Virtually all states apply the doctrine of strict product liability, which states that a seller of a product is liable without fault for personal injuries or other physical harm caused by the product if the product is sold: (1) in a defective condition that is (2) unreasonably dangerous to the user of the consumer. Strict liability applies not only to the product's manufacturers, but also to it retailer, and any other person in the distributive chain. A product will not give rise to strict liability if it is unavoidably unsafe. For instance, if a prescription drug causes side effects or allergies in some patients, and there is no way to avoid these, the drug is considered unavoidably unsafe and thus not defective. A product may become defective because the manufacturer has failed to issue a warning concerning its use. In general, even if a product is properly designed and properly

manufactured, the manufacturer must provide a warning if there is a non-obvious risk of personal injury from using the product. Similarly, the manufacturer must give instructions concerning correct use, if incorrect use would cause a danger.

Why not apply Implied Warranty?: Implied warranty suits also provide for liability without fault, in the sense that negligence does not have to be proven. However, these actions have many contract aspects that are illogical where there is no privity between the plaintiff and the defendant. For this reason, many courts have abandoned the language of implied warranty and have allowed recovery for strict tort liability.

Why not apply Negligence?: The difficulty with negligence is that it still requires the plaintiff to prove that the defendant's conduct fell below the relevant standard of care. However, if an entire industry tacitly settles on a somewhat careless standard of conduct, then the plaintiff may not be able to recover even though he or she is severely injured, because although the defendant's conduct caused his or her injuries, such conduct was not negligent in the legal sense. As a practical matter, with the increasing complexity of products, injuries, and medical care (which made many formerly fatal injuries survivable), it is quite a difficult and expensive task to find and retain good expert witnesses who can establish the standard of care, breach, and causation.

Restatement Third of Torts: Products Liability: In 1997 the law of product liability underwent a massive evolution and expansion when the "Third Restatement" was published by the American Law Institute.

§ 1. Liability of Commercial Seller or Distributor for Harm Caused by Defective Product

One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.

§ 2. Categories of Product Defect

A product is defective when, at the time of the sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

(a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

(c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

The Third Restatement drops the requirement that to be defective, a product must be "unreasonably dangerous," at least with respect to manufacturing. It does not abandon the concept of unreasonable dangerousness in the case of design or warning defects. The Third Restatement also takes a different approach to the issue of the unavoidably unsafe product, such as a prescription drug, which may cause side effects or a handgun, which may fire unintentionally. Under the Third Restatement, it still makes a difference whether a product is unavoidably unsafe, but the issue becomes a balance between the utility of the product versus danger. If the utility of the product outweighs the risks, the product is not defective. If the dangers outweigh the unavoidably risks, the logic of the risk-utility is that they are defective. Also, a product will be deemed defective it if it not accompanied by a reasonable warning where one is feasible.

Prescription drugs and medical devices present a special case of the unavoidably unsafe problem. Such drugs and devices are usually of very high social utility, yet often have very serious, completely unavoidable side effects. Courts have tended to give an automatic exemption from liability for such drugs and devices, assuming that they have been approved by the FDA and that the warnings given with them are adequate. The Third Restatement says that a defective design claim can be brought in the case of a prescription drug or medical device only if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to it foreseeable therapeutic benefits, and that knowing of such foreseeable risks, healthcare providers would not prescribe the drug or medical device for any class of patients. In other words, if there is even a single group of patients for whom the drug or device could sensibly be prescribed, then no patient may bring a design-defect against the maker. Given this very demanding objective standard, liability is likely to be imposed only under unusual circumstances. Under the Third Restatement, manufacturers of drugs and related products need not exercise reasonable care under a risk-utility balance to make a safer drug.

What about unknowable dangers? Suppose at the time a product is designed and manufactured, there is simply no way to know that a particular danger lurks within a product.
Will a manufacturer be held liable for defective design or for failure to warn of the unknown defect? The answer is "no." There is no duty to design around or warn against a danger that could not have reasonably been foreseen at the time of design and manufacture.
This idea is often expressed as the "state of the art" defense.

The Third Restatement says that there is no duty to warn of unknowable risks and that the plaintiff bears the burden of establishing that the risk in question was known or should have been known by the manufacturer. Testing prior to putting a product on the market, however, especially

of drugs and medical devices is required. A seller is charged with knowledge of what reasonable testing would reveal. If testing is not undertaken or is performed in an inadequate manner, and this failure results in a defect that causes harm, the seller is subject to liability for harm caused by such defect.

The duty to warn in a strict liability case is similar to the duty to warn in a negligence case. Most product liability suits brought against drug companies are premised upon a failure to warn. If the product is sold over-the-counter to consumers via a mass-media campaign, then warnings must be made to the consumer via packaging inserts and/or on TV ads in addition to the physicians who might recommend the product to patients. These warnings must be provided in language comprehensible to a lay person—a warning conveying a fair indication of the nature, gravity and likelihood of the known or knowable risks of the drug. Additionally, the warning itself must be adequately intense and not obscured by surrounding advertising and publicity.

A manufacturer also has a post-sale duty to warn about dangers of which the manufacturer was not aware at the time of manufacture. Also, courts have held that the manufacturer has a duty not only to warn about dangers or defects that it learns about, but also a duty to monitor the performance and safety of its products after sale. In cases involving prescription drugs, courts traditionally impose a continuing duty of reasonable care to test and monitor after sale in order to discover product-related risk.

Proving the Case: The Plaintiff in a strict liability case must prove much of the same things as what would be necessary to prove in a negligence case:

(1) That the item was made or sold by the defendant

(2) That the product was defective

(3) That the defect caused the plaintiff's injuries

(4) That the defect existed when the product left the defendant's hands

To prove that the product was defective, particularly in cases of alleged design defect, the plaintiff will often try to show that the defendant subsequently redesigned the product to make it safer. Most courts apply a general rule that such evidence is inadmissible to prove the defectiveness, on the grounds that to allow it would discourage manufacturers from doing such redesigning.
In the category of "mass toxic torts," it is often especially difficult for the plaintiff to prove that the product was defective because of the difficulty in proving that some toxic substance is damaging to human beings. A plaintiff typically must present epidemiological studies or provide expert testimony in order to show that a certain condition is more prevalent when the substance is used.

The plaintiff also must demonstrate causation and potentially rebut the defendant's suggestion that alternative events were the sole cause in fact of his or her injuries. Causation is especially important in cases involving a plaintiff's claim that exposure to a toxic substance caused a disease or illness. Such "toxic torts" frequently require the plaintiff to use epidemiological proof of causation.

In the Vassallo case, the manufacturer is strictly liable for failure to warn of the risks and associated dangers of the breast implants. 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.
Heyer-Schulte was also aware that some of 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. Despite this knowledge of the possible adverse long-term consequences of leaking silicone in the body, Heyer-Schulte conducted few animal, and no clinical, studies to document the safety and efficacy of its silicone gel implants. On the basis of this evidence, Vassallo will be able to prove that the product was defective, that the defects caused her injuries and that the manufacturer knew or should have known that the product was defective when it was placed on the market.