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Strict liability for inadequate warning applies even when vaccines are unavoidably unsafe

by Ellen Sugrue Hyman

In ***Allison v. Merck and Co.***, 878 P.2d 948 (Nev. 1994), the supreme court of Nevada held that a vaccine manufacturer may be held strictly liable in tort when it produces a vaccine that, while beneficial to the general public, may cause side effects considered "reasonable" in light of those benefits. Such liability may attach even when the product is properly prepared and marketed. Moreover, the court held that the manufacturer cannot avoid liability by delegating its duty to warn consumers of potential risks by contracting with the Center for Disease Control ("CDC").

Merck's MMR II vaccine

In December 1982, seventeen-month old Thomas Allison received the measles, mumps, and rubella vaccine ("MMR II"). Dr. Del Potter, a pediatrician at the Clark County Health District ("CCHD") prescribed the vaccine. Prior to administering the vaccine, Dr. Potter did not inform Mrs. Allison about the risks associated with the drugs because such risks were so low as to be negligible. Mrs. Allison, however, did sign an information sheet entitled "Important Information about the Measles, Mumps, and Rubella vaccines" at the CCHD. This sheet contained information about the vaccine, including the statement that one out of a million children vaccinated may develop a serious reaction to the drug, including encephalitis (inflammation of the brain). Three days after receiving the vaccine, Thomas developed encephalitis which resulted in permanent blindness, deafness, and brain damage.

Allison filed suit individually and on behalf of Thomas against Merck and Co. ("Merck"), the vaccine's manufacturer, and the CCHD. In her complaint, Allison alleged that the defendants were strictly liable for injuries sustained by Thomas. Furthermore, she alleged that the defendants had both breached their duty to give adequate warning about the potential side effects of the vaccine.

The trial court granted summary judgment in favor of the defendants. It held that the CCHD was not liable for Thomas' injuries under strict liability because it was not a seller of the vaccine. Moreover, it was not liable for any breach of its duty to warn because it had met its requisite standard of care by providing the informational sheet approved by the CDC. Similarly, the court also found that Merck was not liable for damages as the vaccine in question, while unavoidably unsafe, was beneficial to the public and not subject to strict liability. Furthermore, it held that Merck's duty to adequately warn of the inherent dangers of the vaccine had been properly delegated to the government according to a contract between the manufacturer and the CDC. Additionally, Merck was entitled to immunity under the government contractor defense. Allison then appealed the trial court's decision to the state supreme court.

Court applies strict liability

On review, the supreme court of Nevada closely examined the applicability of strict liability theory to the facts of the case. The court noted that Allison, in order to establish a claim, must prove: (1) a defect in the vaccine caused the injuries sustained by Thomas; and (2) the defect existed when the product left the control of the manufacturer. Because the court did not consider the second factor to be an issue, it held that Allison could recover if she demonstrated a defect in the vaccine had caused the child's encephalitis.

According to the supreme court, a product is defective when it failed to perform in the manner reasonably expected given the nature of the product and its intended function. Here, the court reasoned that the intended function of the vaccine was to immunize Thomas against measles, mumps, and rubella without causing blindness, deafness, and mental retardation. Because the vaccine resulted in such injuries, the court concluded that it was defective.

The court stated that its decision holding Merck strictly liable for its product was consistent with existing public policy. It observed that longstanding public policy considerations supported the principle that the manufacturer, not the consumer, should bear the responsibility for an injury caused by a defective product as the manufacturer profits from the sale of the product. Moreover, the manufacturer is clearly in the best position to reduce the risks associated with the product and therefore should bear the ultimate responsibility for injuries resulting from it.

Informed consent and application of Comment k

Merck, in defense of the MMR II vaccine, contended that it was exempt from strict liability because while the vaccine was unavoidably unsafe, it was not unreasonably dangerous in light of its utility in preventing measles, mumps, and rubella. The manufacturer, in support of its argument, relied on Comment k of Section 402A of the Restatement (Second) of Torts. Comment k states that a drug manufacturer should not be held liable for risks associated with a drug's use if: (1) the manufacturer provides the public with a useful and desirable product that has known but reasonable risk; (2) the drug is properly prepared and marketed; and (3) proper warning is given.

The supreme court rejected the application of Comment k in the present case, finding it contrary to public policy and inconsistent with the established law of products liability. It interpreted Comment k as granting immunity only if the drug consumer accepts a known danger associated with the drug in exchange for an anticipated benefit. In such cases, the court noted, the drug manufacturer is immunized from liability for potential injuries because the consumer has voluntarily taken the drug, cognizant of the dangers that are associated with her choice. In this way, the consumer waives all tort claims and accepts the risk.

In this case, the court found that Allison had not made the informed choice dictated by Comment k. On the contrary, the court reasoned that Allison had been compelled by state law to have her son vaccinated since the vaccine was required for school attendance. Refusal to comply with the state requirement would have subjected her to criminal sanctions. Moreover, the court suggested that Allison may not have consented to the vaccination had she known the possible consequences to her child.

Merck had also contended that imposing strict liability for statistically infrequent injuries, such as those Thomas suffered, would deter manufacturers from researching and developing new drugs. As a result, greatly needed vaccines would be unavailable and the incidence of serious diseases might increase. The court did not find this argument compelling. Rather, the court held that the rarity of the injury was immaterial and consideration of this factor was contrary to the basic rationale of strict liability. Moreover, the court suggested that if such considerations were paramount, the legislature, not the judiciary, should revise the law.

Failure to warn

Turning to the failure to warn issue, the court reasoned that even if Comment k applied to insulate Merck from liability, Allison would still be entitled to a trial on the merits of her claim because a jury could find that the MMR II vaccine was unreasonably dangerous as marketed. The court observed that a product is unreasonably dangerous if it is dangerous beyond an ordinary consumer's expectations. Thus, both strict liability and Comment k require that the consumer be provided with an adequate warning of the vaccine's consequences. The court observed that there was evidence that Merck had knowledge of the dangers of the MMR II vaccine, but did not share this information fully with the consumers. For example, the supreme court emphasized that neither Merck's own MMR II package circular nor the CCHD's information sheet warned the prospective vaccinees of the actual possibility of the brain damage. Therefore, Allison had no knowledge that the vaccine was associated with this risk. As a result, the court concluded that there was evidence that would allow a jury to find that the vaccine was not accompanied by an adequate warning.

Merck could not delegate its duty to warn

In reversing the lower court's holding that the defendants were entitled to summary judgment on both of Allison's claims, the supreme court of Nevada also found that Merck could not delegate its

responsibility to warn to the government through its contract with the CDC. It reasoned that regardless of whether the manufacturer or another organization actually promulgates the warning, the manufacturer retains responsibility for its contents.

Similarly, the court found that the government-contractor defense did not relieve Merck of its liability to Allison. The underlying rationale of this defense is that when a product is designed according to government specifications, the manufacturer should not be held for any resulting defect. The court rejected the application of the defense because of its uncertainty about whether it applied to products such as drugs. Additionally, the court stated that there was also a serious question of fact as to whether Merck had acted according to government specifications

Accordingly, the supreme court reversed the summary judgment in favor of Merck. It remanded the case for trial on the issues of strict liability and failure to warn.

Concurrence finds a genuine issue regarding sufficiency of warning

Chief Justice Rose concurred with the court's opinion. Although he stated that he found Comment k applicable in this case, he concluded that an issue of genuine fact remained concerning the sufficiency of the vaccine's warning. Therefore, summary judgment was inappropriate since a factual issue remained regarding the adequacy of warning. Moreover, Chief Justice Rose stated that a vaccine manufacturer should not be able to delegate its duty to warn a third party.

Dissent questions majority's analysis

Writing in dissent as to the majority's opinion of the issue of Merck's liability, Justice Young first turned to the issue of strict liability. He suggested that the majority had erred in its comparison of strict liability theory to that of *res ipsa loquitur*. In particular, he objected to the majority's conclusion that if Allison could establish that her son's injuries were caused by the vaccine, the vaccine was defective and Merck was strictly liable. Justice Young argued that this should not be the case. Rather, the plaintiff must first prove that there is a defect in the product and that this defect made the product unreasonably dangerous. Only then would the plaintiff permitted to contend that the defect was the cause of the injury. Justice Young contended that injury alone was not sufficient to establish a defect for the purpose of strict liability.

Furthermore, he concluded that Comment k should protect manufacturers whose drugs are unavoidably unsafe but beneficial to society. He recommended that the court use a balancing test to weigh the benefits and risks of such products when the manufacturer has exercised reasonable care in informing the potential user of the product's dangerousness. Applying this reasoning to the case at hand, Justice Young concluded that the warnings provided on the information sheet were reasonable in light of the medical knowledge available in 1982.

Justice Young also contended that a manufacturer's liability should depend on whether it had reasonably relied on the product's ultimate dispenser to provide an adequate warning. In the present situation, Justice Young concluded that Merck had acted reasonably in delegating its duty to warn to the CDC, an agency that possesses the most comprehensive information on the subject of drug side effects. Additionally, he noted that the CDC required that state health departments use its information sheets whenever federally funded vaccines were administered.

In his dissent, Justice Young suggested two possible defenses available to Merck. First, he observed that the learned intermediary doctrine imposes a duty on the manufacturer to warn only the physician who prescribed the vaccine. The physician then takes over the manufacturer's duty to warn in his role as the learned intermediary. Justice Young concluded that Allison's pediatrician was the learned intermediary who, in this role, had failed to warn her of the potential dangers. However, Merck had fulfilled its duty to warn the physician. Second, Justice Rose stated that the government contractor defense, rejected by the majority, should shield Merck in this case. Noting that the defense had been applied in cases involving drugs, he stated that it was applicable in Merck's situation as the government had considered the design features of the MMR II vaccine before granting approval for its nationwide use.