The Supreme Court then rejected the lower court's formulation of the requirement of supervision. The lower court found that the requirement was satisfied if the state program was staffed and funded, was assigned the duty to supervise, was afforded means of judicial enforcement, and provided some basic level of activity. In these cases, however, this formulation was inadequate since the states exercised only the right to veto an agreement reached through the rating bureaus. Under these circumstances, the defendants must show that the states took the necessary steps to determine the specifics of the rates. The mere potential of state supervision was not enough. The Court added that the requirement of action in fact was necessary since the charge was horizontal price fixing by the insurers. Since the state agencies did not take any apparent action to review the filings, the Court concluded that the state immunity defense was not available.

Two dissenting opinions stressed that the majority opinion failed to describe the level of state activity that would suffice. Further, the dissenters suggested that the majority's approach would reduce the flexibility of state regulation as more companies chose to file individually to avoid the perception of price fixing.

Medical Device Amendments Preempt State Product Liability Claim

Slater v. Optical Radiation Corp., Case No. 91-1544 (7th Cir., decided Apr. 22, 1992) (Lexis, genfed lib.)

The Seventh Circuit in the first appellate case raising the issue decided that a products liability claim alleging defective design of a medical device subject to an FDA experimental exemption was preempted. The Medical Device Amendments of 1976 amended the Food, Drug and Cosmetics Act of 1938 and gave the FDA comprehensive authority over medical devices. One of the provisions forbids states from regulating medical devices in any manner concerning safety or effectiveness different or in addition to that provided by the agency. Pursuant to the act, the FDA in 1977 issued regulations providing for an exemption for investigations of intraocular lenses. The lenses are implanted in the eyes of persons who have had surgery for cataracts. After signing a waiver required by the regulation, Slater, the plaintiff, had a lens made by the defendant, Optical Radiation, implanted in his eye after cataract surgery. The treatment failed, apparently due to the design of the lens, the lens was removed, and Slater suffered additional permanent damage to his eye. He sued, but the trial court dismissed the case on the theory that it was preempted by the amendments. On appeal, the Seventh Circuit Court of Appeals agreed.

In the appeal, Slater conceded that he could not argue for a different level of testing but urged that the claim based on defective design was not preempted since the regulations did not specify a particular design. The court rejected that argument. Since the device was experimental, the regulation could not dictate the design. An effective and safe design was the desired outcome of the experimental exemption. Therefore, the rules could relate only to the procedures and these would preclude the claim.

Apparently recognizing the limitations of its first rationale, the court went on to assert that the approval for an exemption also constituted an initial determination that the design was safe enough to justify the risks of further experimentation. To allow the suit thus would require additional design characteristics, a result not permitted by the amendments' preemptive section.

Finally, the court rejected the argument that the result of preemption would deny Slater a remedy for his injury. The court noted that Slater had alternatives to the experimental treatment and assumed the risk of an experimental procedure. It further noted that the notice he received and signed provided an informed consent.

Maryland Court Modifies Punitive Damages Standard

Owens-Illinois, Inc. v. Zenobia, 325 Md. 420, 601 A.2d 633 (Md. Ct. App. 1992).

The Maryland Court of Appeals substantially revised its standards for assessing punitive damages in negligence and products liability. In this case, Zenobia sued several manufacturers and installers for asbestosis injuries. He received a judgment based on strict liability of $1.2 million in compensatory damages and over $200,000 in punitive damages. The jury awarded the punitive damages based on an instruction that permitted them if it found by a preponderance of evidence that a defendant acted with gross negligence. On appeal, Owens-Illinois argued for a higher standard of intent and a heavier burden of proof. Maryland's highest court agreed and remanded the case for further evidence.

Initially, the court abandoned a distinction between injuries that occurred before or after a contract between the plaintiff and the defendant. Under the prior rule in Maryland, the plaintiff had to show only gross negligence to claim punitive damages if the injury occurred before the parties entered a contract, but he had to show actual malice if the injury happened after contracting. The court found that the rule was unprincipled. Punitive damages were to relate to the defendant's conduct, not the timing of the injury. Therefore, the court eliminated the distinction.

The court then adopted an actual malice standard for punitive damages. Under the prior rule, punitive damages were available on a showing of implied malice. Under the court's definition of implied malice, a plaintiff could recover on a showing of gross negligence. The court felt this standard had lead to inconsistent awards and confusion about the scope of actions covered by punitive damages. The court, therefore, adopted a requirement of actual malice. It defined actual malice as a showing of evil motive, intent to injure, or fraud. Recognizing the difficulty of extending the doctrine to products liability cases, the court went on to explain that actual malice in a products case could be shown if the seller had actual knowledge of a dangerous defect and deliberately disregarded the safety of others. The court characterized this standard as a bad faith decision to market the product.