US Supreme Court Case: A Victory for Patients over Industry

Public Citizen's *Allison Zieve* examines the implications for patients of the US Supreme Court's decision in the *Warner-Lambert v Kent* case.

Last month, the US Supreme Court affirmed a decision rejecting the drug industry's claim to immunity from lawsuits in the state of Michigan.

The 4-4 decision in *Warner-Lambert v Kent*[1], affirming a ruling of the court of appeals in New York, has no precedential value. However, it is a great victory for the 18 patients involved in the case, all of whom suffered very serious liver damage because of Warner-Lambert's diabetes drug Rezulin (troglitazone), which has been withdrawn from the market. Those patients and their families now have hope of obtaining compensation from the company.

The Supreme Court's decision means the plaintiffs have hope of obtaining compensation from the company

Unique Michigan liability statute

At issue in the case was a product liability statute unique to Michigan. Traditional state tort law allows a manufacturer, alleged to have sold a defective product, to use compliance with federal standards or regulations as evidence that the product was not defective or that the manufacturer acted non-negligently. In most states, a jury can consider that evidence, but it is not controlling.

However, a Michigan statute enacted in 1995 provides that a drug manufacturer generally cannot be held liable to patients for injuries caused by its products if the drug is marketed with Food and Drug Administration approval and complied with FDA approval requirements. The statute also provides that, if a drug manufacturer did not comply with FDA disclosure requirements and the non-compliance affected the FDA's approval decision, the statutory defence does not apply and the patient can sue, as in any other state.

In the Rezulin litigation, Warner-Lambert argued that the non-compliance exception to Michigan's statutory defence is pre-empted because it interferes with the FDA's authority to police fraud committed by drug companies during the regulatory process. Essentially, the company was seeking to have the exception severed from the statute, so that the law provided a virtual immunity for drug manufacturers from liability to patients harmed by FDA-approved drugs. In response, the patients-plaintiffs pointed out that the Michigan law does not police or enforce compliance with FDA regulations. Rather, the state law assumes that FDA approval demonstrates that drug companies have satisfied state-law duties of care owed to patients and recognises that the basis for that assumption disappears when the basis for the approval is unreliable because the company was not honest with the FDA.

Warner-Lambert argued that the non-compliance exception interferes with the FDA's ability to police fraud by companies during the regulatory process

In accordance with its practice when a decision is evenly divided, the court issued a one-sentence decision affirming the Second Circuit decision, which had held that the exception to the Michigan statute was not pre-empted. (Chief Justice Roberts did not participate because he owns stock in Pfizer, which owns Warner-Lambert.)

The case highlights the very harsh nature of the Michigan law, which allows patients to hold companies liable in only the most egregious cases. A bill to repeal the Michigan law has been pending in the state legislature since February 2007, but a state senator is reportedly preventing the bill from coming up for a vote.

In the meantime, although Michigan plaintiffs can pursue Rezulin cases, the vast majority of Michigan patients injured by prescription drugs have no opportunity even to seek compensation for their impaired health, lost wages or other damages.

Industry's effort to obtain immunity

The *Warner-Lambert* case, which posed a narrow question about Michigan law, is part of a broad effort by the US pharmaceutical industry to obtain immunity from liability for injuries caused by approved drugs. For years, the pharmaceutical industry sought to convince Congress to pass legislation to restrict patients' traditional right to sue companies for compensation for injuries caused by drugs. No bill passed. Accordingly, with the help of the Bush administration, drug manufacturers (as well as manufacturers of other consumer products) have become increasingly aggressive in pushing pre-emption arguments in the courts, seeking to achieve through the judicial branch what they have been unsuccessful in obtaining from the legislative branch.

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Patients' ability to hold drug companies accountable is crucial because the FDA is less independent than ever before. Under the Prescription Drug User Fee Act, a company seeking FDA approval to market a new drug pays the agency a fee, which pays for more FDA review staff so that drugs can get to market more quickly. As a result, the FDA's funding depends in significant part on the companies the agency is charged with regulating. In fiscal year 2006, the drug industry paid the FDA more than $300 million in user fees[2].

Regulators under pressure

One in five FDA physicians and scientists reported pressure to recommend approval, even if they had doubts about safety, effectiveness or quality

It is perhaps not surprising, then, that in response to a 2003 survey by the FDA's parent, the Department of Health and Human Services, one in five FDA physicians and scientists reported pressure to recommend that drugs be approved, even when they had reservations about safety, effectiveness or quality[3].

Evidence suggests that the pressure to approve drugs undermines public health. Thirteen drugs approved by the FDA since 1997 have been withdrawn from the market for safety reasons. Furthermore, the FDA sometimes takes months or years after becoming aware that an approved drug is causing serious harm before trying to remove the drug from the market. Rezulin, the pain reliever Vioxx (rofecoxib) and the allergy medication Seldane (terfenadine) provide a few examples.

Most serious adverse effects are not fully discovered until a drug has been on the market for several years. The reality is that patients will be injured in the interim. At a time when the FDA is – by its own admission – underfunded and lacking the expertise to adequately protect the public health, the ability of injured patients to hold drug companies liable for injuries caused by their products is particularly important.

References

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