# Proctor v. Davis, 291 Ill. App. 3d 265 (1997)

July 11, 1997 · Illinois Appellate Court · Nos. 1—92—3151, 1—92—3513 cons.

291 Ill. App. 3d 265

## Case outline

* Majority — Presiding Justice Hartman
* [Dissent](https://cite.case.law/ill-app-3d/291/265/#b305-10) — Justice Divito

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MEYER PROCTOR et al., Plaintiffs-Appellants and Separate Appellees and Cross-Appellants,*v.*MICHAEL J. DAVIS, Defendant-Appellee (The Upjohn Company, Separate Defendant-Appellant and Cross-Appellee)

First District (5th Division)

Rehearing denied July 24, 1997.

*\*267*DIVITO, J., dissenting.

Goldberg & Goldberg (Barry Goldberg and Ann Herbert, of counsel), and David Novoselsky & Associates (David Novoselsky and Linda Bryceland, of counsel), both of Chicago, for appellants Meyer Proctor and Marjorie Proctor.

Hinshaw & Culbertson (Stephen Swofford, of counsel), and Bollinger, Ruberry & Garvey (Maurice Garvey, of counsel), both of Chicago, for appellee.

Mayer, Brown & Platt, of Chicago (Alan Salpeter and Laurie Gallancy, of counsel), Mayer, Brown & Platt, of Washington, D.C. (Andrew Frey, Clifford Sloan, and Alan Untereiner, of counsel), and Todd Kingma, of Upjohn Company, of Kalamazoo, Michigan, for appellant Upjohn Company.

[*\*268*](https://cite.case.law/ill-app-3d/291/265/#p268)PRESIDING JUSTICE HARTMAN

delivered the opinion of the court as modified upon rehearing:

Plaintiffs Meyer Proctor and Marjorie Proctor (sometimes collectively Proctor) filed this medical malpractice and products liability action against Dr. Michael J. Davis (Dr. Davis) and the Upjohn Company (Upjohn), alleging serious injury resulting from Dr. Davis’ injection of the corticosteroid Depo-Medrol, manufactured by Upjohn, directly into Meyer Proctor’s left eye on November 7, 1983. A jury exonerated Dr. Davis, but found against Upjohn, awarding Proctor compensatory damages of $3,047,819.76, and punitive damages of $124,573,750, the latter of which the circuit court remitted to $35 million. Proctor and Upjohn appealed from that judgment. Proctor also cross-appealed the denial of their motion for sanctions and attorney fees.

On June 28, 1994, a unanimous opinion was filed by this court affirming the jury’s decision as to Dr. Davis and its award as to Upjohn, but reducing the punitive damages to $3,047,819.76. Upjohn’s motion for rehearing was allowed and further oral argument ensued. The June 28, 1994, opinion was withdrawn. Two members of this court issued another opinion, affirming the verdict as to Dr. Davis, but reversing outright the jury’s award as to Upjohn (Proctor v. Davis, 275 Ill. App. 3d 593, [656 N.E.2d 23](https://cite.case.law/citations/?q=656%20N.E.2d%2023) (1995)), with a lengthy dissent. Proctor, 275 Ill. App. 3d at 613-27 (Hartman, J., concurring in part and dissenting in part). Our supreme court invalidated that opinion because one of the majority judges, Justice McCormick, had retired before the opinion was to become effective. This court was directed "to enter a constitutionally valid opinion or order disposing of the matters raised, briefed and argued subsequent to Upjohn’s unanimously allowed rehearing petition.” Proctor v. Upjohn Co., [175 Ill. 2d 394](https://cite.case.law/ill-2d/175/394/#p397), 397, 677 N.E.2d 918 (1997). Our opinion and companion Supreme Court Rule 23 order follow.

Upjohn’s claims regarding its duty to warn and punitive damages will be considered, in part, in this opinion. All remaining issues and contentions will be determined in a separate Supreme Court Rule 23 order disseminated contemporaneously with this opinion.

In 1959, the Food and Drug Administration (FDA) approved Upjohn’s "New Drug Application” (NDA) for Depo-Medrol, a sterile, aqueous suspension containing methyl prednisone acetate, a corticosteroid, for treatment of various inflammatory bodily disorders. The FDA’s approval was limited to intramuscular (in the muscle), intraarticular (in the joint), and intralesional (in a lesion) injections. According to the evidence, Depo-Medrol is an insoluble, toxic material, which is intended to be released in the body over a period of six to [*\*269*](https://cite.case.law/ill-app-3d/291/265/#p269)eight weeks in human tissue with adequate blood supply; however, the human eye does not possess such a blood supply. Depositing Depo-Medrol into the eye meant that the drug would remain in the eye for a relatively long time. Because of its insolubility, its crystals had an effect on the body’s response to it when inserted, including increased intraocular pressure and other trauma. It became a foreign body in the eye, which was very difficult, if not impossible, to remove once injected into the eye.

Shortly after Depo-Medrol’s FDA limited approval, two ophthalmologists contacted Upjohn independently, each wishing to use the drug clinically for the treatment of ophthalmic conditions through an unapproved method of administration—periocular (near the eye) injections.**1** This use of Depo-Medrol was neither approved by the FDA nor listed on Depo-Medrol’s label (off-label use). Nevertheless, Upjohn immediately provided both with vials of Depo-Medrol without cautioning them that no animal studies had been initiated to test the reaction of the drug upon living tissue before embarking upon human use. Instead, Dr. Porter Crawford, an Upjohn employee responsible for monitoring Depo-Medrol at the time, encouraged this unapproved off-label use, as follows:

"Thank you very much for \*\*\* your interest in Depo-Medrol for subconjunctival injection in the treatment of uveitis. We do not have any reports concerning this use for the preparation and we would very much like for you to evaluate it in this way.” (Emphasis added.)

Dr. Crawford sent vials of Depo-Medrol to the inquiring doctor and asked him to let him know when he needed additional supplies. Dr. Crawford also noted that Upjohn would "be anxious to learn how it performs when used this way.”

Upjohn dispensed not only vials of Depo-Medrol but, also, financial assistance to doctors who would use Depo-Medrol for the unapproved off-label use of periocular injections, granting one in 1959, $3,000. This doctor later wrote Upjohn that he had given two talks in Chicago in the fall of 1960, extolling the use of Depo-Medrol [*\*270*](https://cite.case.law/ill-app-3d/291/265/#p270)for subconjunctival injections, although he knew otherwise, having written in the same letter that the "experimental work \*\*\* fell flat since we are unable to find anything in the aqueous.” (Emphasis added.) In response, Upjohn wrote back that the FDA "has not approved this use of Depo-Medrol because we have had no clinical work to show to them.” Upjohn asked the doctor to prepare a write-up of his cases or publish an article in order to document this off-label use for possible FDA approval. Upjohn noted that "not too many people are actually using this type of therapy and your good results suggest that the work should be scattered about.”

Upjohn itself undertook the task of "scattering about” the unapproved off-label use of Depo-Medrol to the medical community. In 1961, an article on the use of Depo-Medrol was written by the experimenting doctor to whom Upjohn had given $3,000. This doctor informed Dr. Crawford, on August 31, 1961, of the completion of the article, noting separately, however, that he was unable to use any of his animal experiments because the results were "very unsatisfactory.” (Emphasis added.) Proctor’s expert, Dr. Philip Walson, who reviewed this correspondence, believed the omission of the animal studies created a serious problem because collected data was ignored, and the animal studies, although "unsatisfactory,” should have been included in the article touting this use of Depo-Medrol.

Upjohn nevertheless ordered and distributed 2,500 reprints of the article, 500 for "hospital sales” and 2,000 for "sales education,” thus becoming part of the "literature” to which the ophthalmic community was exposed.**2** On November 16, 1961, Upjohn requested reprints of another experimenting doctor’s article for distribution, which also mentioned the use of subconjunctival injections of Depo-Medrol.[**3**](https://cite.case.law/ill-app-3d/291/265/#footnote_1_3) More "fodder” priming the sales pump.

On March 8, 1963, Upjohn’s Dr. Samuel Stubbs wrote to a differ*\*271*ent experimenting doctor, requesting case histories on the patients he had treated with Depo-Medrol, which Upjohn would use to supplement its original NDA. Dr. Stubbs informed him that Upjohn would compensate him for his time, and that of his secretary, in preparing the case reports. In response, by letter dated March 14, 1963, the doctor stated that he would begin working on the case reports and requested that Upjohn meanwhile send him more Depo-Medrol, which, on March 19, 1963, Upjohn did without mentioning the information and precautions suggested by its Dr. Gerard to its salesmen in 1962. E.g., 291 Ill. App. 3d at 270-71 n.3.

Harry P. Davis, Jr., an Upjohn sales representative, wrote to Mr. Crissman at Upjohn on June 12, 1963, informing him that two Ohio physicians were using Depo-Medrol for "severe, chronic or acute, uveitis by retrobulbar injection,” but that neither physician was aware that anything had been published on the use of this drug. Dr. Stubbs wrote to these two Ohio doctors on June 26, 1963, informing them of Upjohn’s interest and asking for case reports of their experience with the drug. Further, if they were interested in publishing their work, Dr. Stubbs would make the "services of The Upjohn Writing Staff” available to them, would pay for their secretary’s time, and would compensate the doctors for work on the case reports, admittedly intending to "plant the seed” in those doctors’ minds about publishing an article.

On July 1, 1963, the Ohio doctors responded with eight case reports, which Dr. Stubbs referred to Harold Tucker, one of Upjohn’s medical writers, for potential publication.[**4**](https://cite.case.law/ill-app-3d/291/265/#footnote_1_4) An article written as a result of Upjohn’s "expert assistance” proclaimed that positive *\*272*results from the subconjunctival injection of Depo-Medrol had been confirmed by others[**5**](https://cite.case.law/ill-app-3d/291/265/#footnote_1_5) All the while, Upjohn’s own expert, Dr. Stubbs, himself questioned the validity of the so-called studies. On September 19, 1963, he wrote to Jack Toole, Upjohn’s hospital representative, criticizing the data, stating:

"I’m enclosing a copy of the letter I have written to him, and it is a mild rebuff for the lousy data he sent us. This sort of thing may have gone through before the new [FDA] regulations, but it certainly doesn’t go now, and at the risk of not getting any more data at all I feel it’s time to start setting down on some of these rather loose individuales [szc], I think [this doctor] is a good friend of ours and I don’t have to [sic] many qualms that he is going to be upset, but really the stuff that he let you send to me is almost worthless for reasons as I mentioned in the letter to him.” (Emphasis added.)**6**

Dr. Stubbs nevertheless forwarded more vials of Depo-Medrol to this doctor, followed by another supply of Depo-Medrol, on January 21, 1964.

The practice of publicizing unapproved uses of drugs, when [*\*273*](https://cite.case.law/ill-app-3d/291/265/#p273)sponsored by the pharmaceutical company, is not approved by the FDA as proper advertising; it results in continuing, unapproved, potentially dangerous use. Dr. Stubbs was aware that those experimenting physicians would subsequently write publications that appeared in medical journals,**7** for which Upjohn paid secretarial and editorial expenses. These writings, of course, would be addressed to the medical community and become available to ophthalmologists, thereby becoming, incredibly, part of the current medical literature attempting to establish the standard of medical expertise.

In 1965, Dr. Stubbs collected articles in the medical literature and prepared a report for internal use by Upjohn.[**8**](https://cite.case.law/ill-app-3d/291/265/#footnote_1_8) Based on that report, he and his immediate supervisor recommended that Upjohn consider filing a supplemental NDA to obtain FDA approval for periocular administration of the drug. Without FDA approval, Upjohn could not include that use of Depo-Medrol as an approved method of administration on the drug’s labeling. In order to supple*\*274*ment the NDA to provide for periocular administration of Depo-Medrol, Upjohn knew that it was "likely that animal tissue tolerance studies” would have to be performed.

Upjohn elected not to pursue a supplemental NDA for periocular administration. A corporate memorandum recommended that "no further Medical Development work be done with Depo-Medrol administered by [periocular] injection,” and that "tissue tolerance studies in animals not be undertaken by Biomedical Research unless a request for [an NDA] supplement is initiated by Marketing, and approved in accordance with the currently effective Pharmaceutical New Product System procedures.”

Upjohn stipulated that prior to November 7, 1983, it "had the capacity to perform in-house or refer out-of-house [experiments] to be done by private consultants’ research in the form of animal studies and all four phases of human studies.” Upjohn had in its employ, or available to it, physicians, toxicologists, pharmacologists, statisticians and epidemiologists. Dr. Stubbs admitted that the animal tissue tolerance studies could have been performed if the company had wanted to do them and had the funding to do so. Such studies were already ongoing with other applications of the drug. If Upjohn had begun the animal tissue tolerance studies on the periocular use of Depo-Medrol in 1969 or 1970, it would have had the results well in advance of the casualty involved in this and, perhaps, other cases. Dr. Stubbs acknowledged that the decision whether to go forward with animal studies and supplements on Depo-Medrol for subconjunctival use was left to Upjohn’s marketing staff. Dr. Walson believed that marketing should not have been allowed to decide a medical safety and scientific issue.

Upjohn knew of potential adverse reactions to the drug, of which it learned over a period of preceding years from drug experience reports (DERs),[**9**](https://cite.case.law/ill-app-3d/291/265/#footnote_1_9) yet its labeling never referred to unapproved periocular injection of the drug, neither listing it as an appropriate *\*275*method of administration, including any recommended dosages, nor stating any warnings regarding periocular use. Ophthalmologists, not having been advised of adverse reactions, began making extensive use of periocular injections of Depo-Medrol because the benefits seemingly outweighed the risks. Defendant Dr. Davis, himself, and four others testified to routine periocular administration of the drug.

In October 1980, in response to the FDA’s global restructuring of labeling for all corticosteroids, Upjohn proposed a revised Depo-Medrol package insert. The proposed insert included the following statement:

"ADVERSE REACTIONS REPORTED WITH NONRECOMMENDED ROUTES OF ADMINISTRATION \*\*\*

Ophthalmic: (Subconjunctival)—Redness and itching, obtuse, slough at injection site, increased intraocular pressure, decreased vision. (Retrobulbar)—Blindness.”

In September 1983, the FDA informed Upjohn that it should not make its proposed changes but, rather, should "continue using currently approved labeling” until it received "notification” from the agency. The FDA also told Upjohn that "[i]f important new labeling information becomes available, you should revise your approved product labeling under 21 C.F.R. 314.8.” The circuit court excluded this evidence.[**10**](https://cite.case.law/ill-app-3d/291/265/#footnote_1_10)

In April 1983, Meyer Proctor, a retired public relations worker, consulted Dr. Davis with complaints of blurred vision. Dr. Davis diagnosed Proctor’s condition as uveitis, an inflammation of the eye, which can be chronic and can lead to permanent blindness. Dr. Davis began treating this condition with steroid medications applied to both of Proctor’s eyes by means of eye drops, which proved to be of only limited value. In May 1983, Proctor developed cystoid macular edema (CME) as a complication of the uveitis, and the vision in his left eye deteriorated to the level of legal blindness. Dr. Davis referred him to a retinal-vitreal specialist for further evaluation and treatment, who concurred in the diagnosis of CME and prescribed Nalfon, a nonsteroidal anti-inflammatory medication. Some improvement in Proctor’s vision occurred, but his sight was not restored to normal. After treating Proctor for several months, the specialist referred him back to Dr. Davis, recommending the use of a nonsteroidal anti-inflammatory drug (such as Nalfon), or the systemic or periocular administration of a steroid (such as Depo-Medrol) if continued impairment of vision made further treatment necessary.

*\*276*On August 1, 1983, Dr. Davis examined Proctor and reinstituted treatment with Nalfon; however, his vision again began to deteriorate. On August 9, 1983, Dr. Davis decided to use periocular injections of Depo-Medrol to treat Proctor’s condition, one shot around each eye. Within several weeks, Proctor’s vision improved almost to normal, but in November 1983, Proctor experienced renewed problems with the vision in his left eye. In response, on November 7, 1983, Dr. Davis administered another periocular injection of Depo-Medrol near that eye.

All the ophthalmologists who testified at trial regarding the standard of care concluded that Dr. Davis’ decision to administer Depo-Medrol via periocular injection both in August and again in November of 1983 was appropriate and within the applicable standard of care. None suggested that anything known at the time, or subsequently discovered, would have made this treatment inappropriate. There were risks associated with this treatment, however. Dr. Davis himself testified that in November 1983 he knew that an inadvertent intraocular injection was a risk of any periocular injection; Depo-Medrol could be "toxic” if inadvertently injected into the eye and cause damage to the eye, including blindness; he had never penetrated the globe of the eye (made an intraocular injection) in more than 1,600 prior periocular injections of Depo-Medrol in his entire career; and he believed he would be able to deliver the drug to its intended location without incident in this instance.

During the November 7, 1983, injection, however, Dr. Davis mistakenly inserted the needle and Depo-Medrol into Proctor’s left eye. Dr. Davis then referred Proctor to a specialist for evaluation and treatment, who determined that the appropriate treatment was observation, waiting for the drug to clear from the eye, and watching for possible retinal detachment, which eventually occurred. Proctor underwent surgery on November 23, 1983, the Depo-Medrol was removed from Proctor’s left eye, and the retina was reattached. The retina again detached, however, and two subsequent operations, on December 13 and 29, 1983, failed to reattach it. In April 1984, Proctor’s left eye, having become blind and painful, was surgically removed.

Proctor filed suit on February 14, 1984, against Dr. Davis and Upjohn. Discovery proceeded over a period of seven years, and trial began on September 4, 1991.

Proctor alleged that Dr. Davis violated the standard of care in one or more ways, directly and proximately causing the injury. Also alleged was negligence based on res ipso loquitur and loss of consortium. Proctor’s allegations against Upjohn were based on strict [*\*277*](https://cite.case.law/ill-app-3d/291/265/#p277)product liability, claiming that Depo-Medrol was defective, unsafe, and unreasonably dangerous, and that Upjohn’s failure to warn Dr. Davis about the potential harm resulting from an intraocular injection directly and proximately caused the injury. Also alleged was loss of consortium and willful, wanton, or reckless acts or omissions that would support punitive damages.

On October 18, 1991, the jury returned verdicts in favor of Dr. Davis and against Upjohn. The jury awarded Meyer Proctor $3,047,819.76 in compensatory damages and $124,573,750 in punitive damages, and Marjorie Proctor $100,000 in compensatory damages. On September 3, 1992, the circuit court entered an order remitting the punitive damages to $35 million, but otherwise leaving the verdict intact. Proctor filed a notice of appeal as to the Dr. Davis verdict; Upjohn then filed its notice of appeal; and Proctor filed a notice of cross-appeal against Upjohn.

I

Upjohn first argues that, after considering all the evidence in the case in the light most favorable to Proctor, it was entitled to either judgment notwithstanding the verdict or a new trial because Proctor failed to prove that a warning was required, because the risk was too remote to require a warning, and because the specialized medical community was already aware of the risks. The standards for judgment notwithstanding the verdict (see Pedrick v. Peoria & Eastern R.R. Co., 37 Ill. 2d 494, [229 N.E.2d 504](https://cite.case.law/citations/?q=229%20N.E.2d%20504) (1967) (Pedrick)) and for a new trial (see Maple v. Gustafson, 151 Ill. 2d 445, [603 N.E.2d 508](https://cite.case.law/citations/?q=603%20N.E.2d%20508) (1992) (Maple)) differ; Upjohn’s contentions will be considered under both standards.

In Illinois, there is no duty to warn of a risk that is already known by those to be warned. Kokoyachuk v. Aeroquip Corp., 172 Ill. App. 3d 432, [526 N.E.2d 607](https://cite.case.law/citations/?q=526%20N.E.2d%20607) (1988). A duty to warn exists only when there is "unequal knowledge and the defendant, possessed of such knowledge, knows or should know that harm might occur if no warning is given.” Kokoyachuk, 172 Ill. App. 3d at 439. In the context of prescription drug litigation, this principle means that a drug manufacturer need not provide a warning of risks known to the medical community. See Wooten v. Johnson & Johnson Products, Inc., [635 F. Supp. 799](https://cite.case.law/f-supp/635/799/) (N.D. Ill. 1986). Further, pharmaceutical warnings for prescription drugs are given to physicians as "learned intermediaries.” Northern Trust Co. v. Upjohn Co., 213 Ill. App. 3d 390, [572 N.E.2d 1030](https://cite.case.law/citations/?q=572%20N.E.2d%201030) (1991).

From the evidence it is clear that Upjohn knew or should have known that Depo-Medrol is an insoluble, toxic material which, *\*278*because of its insolubility, when inserted in the eye, became a foreign body, and was very difficult, if not impossible, to remove. Upjohn, its manufacturer, must be held to the standard of an expert in the field (McEwen v. Ortho Pharmaceutical Corp., [270 Or. 375](https://cite.case.law/or/270/375/), 528 P.2d 522 (1974)) and had a "continuous duty \*\*\* to warn physicians of the dangers incident to prescribing the drug, to keep abreast of scientific developments touching upon the manufacturer’s product and to notify the medical profession of any additional side effects discovered from its use.” (Emphasis added.) Schenebeck v. Sterling Drug, Inc., [423 F.2d 919](https://cite.case.law/f2d/423/919/#p922), 922 (8th Cir. 1970). If Upjohn did not know what it should have known, it failed in its duty as an expert. It could not fulfill that duty merely by waiting for what it considered sufficient proof of a cause-effect relationship before advising the medical profession with an appropriate alert or warning of the possibility of risk in the use of one of its products. See Mahr v. G.D. Searle & Co., 72 Ill. App. 3d 540, 564, [390 N.E.2d 1214](https://cite.case.law/citations/?q=390%20N.E.2d%201214) (1979) (Mahr). Nor can failure to do so be excused merely by the fact that the potentially endangered users are few in number. Mahr, 72 Ill. App. 3d at 560; Crocker v. Winthrop Laboratories, Division of Sterling Drug, Inc., [514 S.W.2d 429](https://cite.case.law/sw2d/514/429/#p432), 432 (Tex. 1974). The injury here clearly was within the scope of the dangerous propensities of the drug for which Upjohn must be held accountable. See McMahon v. Eli Lilly & Co., *774*[F.2d 830](https://cite.case.law/f2d/774/830/#p835), 835 (7th Cir. 1985).

The evidence revealed that Upjohn knew of Depo-Medrol’s dangerous propensities before the instant occurrence took place in 1983 (e.g., 291 Ill. App. 3d at 270-71 n.3); yet, there was no reference in the 1983 label or insert that subconjunctival use of Depo-Medrol as practiced upon Proctor in this case was not recommended by Upjohn, nor that FDA approval was never secured for such application. There was no mention on the label that one cubic centimeter (cc) amount of the drug for use about and around the eye was an excessive dosage, according to one of its own experts. E.g., 291 Ill. App. 3d at 271 n.3. Tissue atrophy developed in some patients after injection, which could be considered as evidence of a toxic effect, also known by Upjohn before 1983. E.g., 291 Ill. App. 3d at 271 n.3. The 1983 package insert made no reference to the fact, known by Upjohn, that the drug should be administered intramuscularly as " 'probably the predominant steroid effect is going to be a systemic effect anyway.’ ” E.g., 291 Ill. App. 3d at 271 n.3. Nor did it point out that this preparation was a suspension and not a solution, and that the crystalline material in the area of sensitive subconjunctival tissue could be the cause in itself for injury. E.g., 291 Ill. App. 3d at 271 n.3. Dr. Walson, Proctor’s expert, was of the opinion that, given Upjohn’s knowledge of the foregoing facts in 1962, the drug company should have warned *\*279*that periocular use of the drug was not recommended, and under the adverse reaction section of the warning, should have listed the toxicity of the drug.

As previously noted, the FDA had approved the use of Depo-Medrol only for certain other uses, involving three specific means of administration: intramuscularly, intra-articularly, and intralesionally; none of those approved uses included the periocular use to which the drug was put in this case. Federal law required Upjohn to include package inserts and labeling recommendations which referred only to the three approved forms of administration for its product. Upjohn should have warned Dr. Davis and others of its potentially harmful effects about which Upjohn knew soon after it went on the market.

The record demonstrates that, by 1961, Upjohn had learned that some ophthalmologists were administering Depo-Medrol through periocular injection as an "off-label” use. Upjohn fostered and encouraged this unapproved use as experimentation on human beings with no prior basic scientific studies having been made. This unauthorized use, encouraged by Upjohn, became more widespread in the next two decades, although Upjohn never secured FDA approval for it and never set forth the use, warnings or directions for such periocular injections on its labels or in its literature. None of the dangers attendant to such use, or any reported deleterious side effects which may have developed of which Upjohn was apprised through DERs, were made known to the prescribing or treating physicians who made this unauthorized off-label use of it. Dr. Davis testified that he did not know of the drug’s dangerous propensities, or he would not have used it. Dr. Thomas Deutsch, Upjohn’s own expert, asserted that, until he testified in this case, he did not know Depo-Medrol would be difficult or impossible to remove once injected into the eye.

Under such circumstances, physicians could not be deemed "learned intermediaries” who were aware of these dangers of Depo-Medrol; they required warnings because the medical community in 1983 was not aware of the risk of serious injury, including vision loss. See Mahr, [72 Ill. App. 3d at 560](https://cite.case.law/ill-app-3d/72/540/#p564). No physician or expert witness testified that the medical community knew what Upjohn knew with respect to dangérous toxicity and irremovability of this drug, but shared with no one except its own employees.**11** There is no record evidence to support the hypothesis that the medical community knew of these [*\*280*](https://cite.case.law/ill-app-3d/291/265/#p280)dangerous propensities. See Tongate v. Wyeth Laboratories, 220 Ill. App. 3d 952, 963, [580 N.E.2d 1220](https://cite.case.law/citations/?q=580%20N.E.2d%201220) (1991) (Tongate). The record supports the jury’s determination in this regard.

A drug such as Depo-Medrol may be deemed unreasonably dangerous absent an adequate warning accompanying the product because the product may be "unavoidably unsafe” without such a warning. Kirk v. Michael Reese Hospital & Medical Center, 117 Ill. 2d 507, 517, [513 N.E.2d 387](https://cite.case.law/citations/?q=513%20N.E.2d%20387) (1987); Lawson v. G.D. Searle & Co., 64 Ill. 2d 543, 550-51, [356 N.E.2d 779](https://cite.case.law/citations/?q=356%20N.E.2d%20779) (1976). A manufacturer of ethical drugs cannot evade its responsibilities of warning physicians of dangers and risks attendant to the use of its products, by hoping, as in the present case, that the doctors will learn of the dangers themselves. Upjohn’s duty to warn was nondelegable; the failure of prescribing and treating physicians to learn of the risks of a drug from other sources does not relieve the manufacturer of liability for harm resulting from its own failure to adequately warn. Mahr, 72 Ill. App. 3d at 566. This point was explicated in Mahr, [72 Ill. App. 3d at 561-62](https://cite.case.law/ill-app-3d/72/540/#p564).**12** Here, Upjohn knew of the risks, yet did not share this knowledge with members of the profession acting in decision-making [*\*281*](https://cite.case.law/ill-app-3d/291/265/#p281)capacities in administering drugs to their patients, and encouraged unapproved use and misleading publicity.**13** When doctors are properly warned of the possibility of side effects and advised of the symptoms accompanying them, the chances that injury to the patient can be avoided are enhanced, particularly if it takes place slowly, as in the case with the injury in question here. Sterling Drug, Inc. v. Cornish, [370 F.2d 82](https://cite.case.law/f2d/370/82/#p85), 85 (8th Cir. 1966).

Significantly, Upjohn knew how to warn, and did warn doctors against certain uses of Depo-Medrol by advising them, for example, against intrathecal administration of this drug, which it printed on *\*282*the insert distributed with the drug in 1983, before the instant insertion of Depo-Medrol into Proctor’s eye. Upjohn, in another line or two of print on the insert, easily could have mentioned potential adverse reactions to the drug when injected intraocularly, of which it had learned over a period of preceding years from the DERs. See 291 Ill. App. 3d at 274-75 n.9. Information regarding questionable reactions or side effects to this Upjohn product contained in DERs in Upjohn’s possession was not shared by it with the medical community by any other means.[**14**](https://cite.case.law/ill-app-3d/291/265/#footnote_1_14) According to Dr. Walson, being on notice of that kind of information from the 1960s up to 1983, there were methodologies and scientific means available to Upjohn to confirm or disaffirm the toxicity of the drug. In his opinion, Upjohn should have included a warning on its label or package insert which said, in effect, do not use the drug in that way, and if so used, this is what may be seen.**15** This was never done. In light of this imbalance of access to information about adverse propensities of Depo-Medrol, it cannot be [*\*283*](https://cite.case.law/ill-app-3d/291/265/#p283)concluded that physicians had knowledge of the risks equal to Upjohn’s.

The jury heard Upjohn’s Dr. Stubbs testify. He was in charge of Depo-Medrol development. He did not know about the pharma-kinetic effects of Depo-Medrol when used in a local injection rather than systemic. He did not know how difficult it would be to remove Depo-Medrol from the eye. He did not have anyone investigate by animal studies whether the drug would be toxic if it got into the eye. Prior to November 7, 1983, Dr. Stubbs never asked any Upjohn in-house personnel whether or not it would be difficult to remove the substance once it was injected into the eye.

A drug company cannot absolve itself from the duty to warn by pointing to the unauthorized use of its drug by physicians with whom it has not shared its knowledge of dangerous side effects and injury. Violation of its duty to warn is even more egregious in this case since, as the evidence heard by the jury demonstrated, Upjohn encouraged and participated in disseminating misleading information concerning the use of its drug to the "learned intermediaries,” through financial support, technical assistance, and abundant supplies of the drug during the period when Upjohn was receiving adverse information concerning this use of the drug. Ironically, some of these very reports became part of the literature that was supposed to inform the "learned intermediaries” about application of the drug intraocularly. Proctor’s expert testified that ophthalmologists were not aware of the true facts but believed that periocular use of Depo-Medrol was safe and efficacious. Significantly, in fact, Upjohn’s own expert, Dr. Thomas Deutsch, an ophthalmologist, testified he did not learn that periocular injections of Depo-Medrol were difficult or impossible to withdraw and were an unlabeled use until after he became an expert in this case. Doctors who have not been sufficiently warned of the harmful effects of a drug cannot be considered "learned intermediaries” and the adequacy of warnings is a question of fact, not law, for the jury to determine, as it did in the instant case. Tongate, 220 Ill. App. 3d at 963; Batteast v. Wyeth Laboratories, Inc., [137 Ill. 2d 175](https://cite.case.law/ill-2d/137/175/#p192), 192-94, 560 N.E.2d 315 (1990).

The evidence convincingly supports the conclusion that Upjohn promoted, encouraged and advertised the off-label use of Depo-Medrol by providing financial and technical assistance to a limited number of members of the medical community without attempting to communicate to these physicians and the medical community at large [*\*284*](https://cite.case.law/ill-app-3d/291/265/#p284)the dangers and risks attendant to this use.**16** Although it is assumed that physicians will keep abreast of current medical literature, here, part of the flawed literature was generated by Upjohn. Upjohn even sought to "plant the seed” in doctors’ minds about contributing to the literature, and thereby help to mislead the specialized ophthalmic community as to the potential harmful effects attendant to the intraocular injection of a drug which could be impossible to remove. To conclude that the existence of literature in such a case constitutes knowledge on the part of doctors and the medical community equal to that of a drug’s manufacturer would encourage more writings of the type found in this case, fostered by the very defendant upon whom responsibility should be fixed. Such an insidious situation as here existed should be neither countenanced, encouraged nor condoned. The evidence demonstrates that Upjohn knew or should have known of the risks and dangers attendant to the use of Depo-Medrol, thereby requiring warning. Woodill v. Parke Davis & Co., [79 Ill. 2d 26](https://cite.case.law/ill-2d/79/26/#p35), 35, 402 N.E.2d 194 (1980). Upjohn simply failed to do so.

Upon this record, the jury had the right to conclude that Upjohn violated its duty to adequately warn and that it be held accountable under these circumstances. The evidence on this point, when "viewed in its aspect most favorable to [Proctor, does not] so overwhelmingly favor[ ] [Upjohn] that no contrary verdict based on that evidence could ever stand” (Pedrick, [37 Ill. 2d at 510](https://cite.case.law/ill-2d/37/494/)), so as to have warranted judgment notwithstanding the verdict entered in this case. Nor was the grant of a new trial authorized under Maple, 151 Ill. 2d at 455, on this point since the jury’s verdict was well supported by the evi[*\*285*](https://cite.case.law/ill-app-3d/291/265/#p285)dence and Upjohn was not denied a fair trial. Upjohn’s contentions are rejected.**17**

II

Upjohn next contests the punitive damages judgment, asserting: (1) there was insufficient evidence to support liability for punitive damages; (2) a new trial must be awarded with respect to punitive damages; and (3) the punitive damages award is grossly excessive.

Illinois courts have long been concerned that punitive damages not be awarded improperly or unwisely. Cornell v. Langland, [109 Ill. App. 3d 472](https://cite.case.law/ill-app-3d/109/472/#p475), 475, 440 N.E.2d 985 (1982). The purpose of punitive damages is not compensation of plaintiff, but punishment of defendant and deterrence; therefore, these damages can be awarded only for conduct that is outrageous either because defendant’s acts are done with an evil motive or a reckless indifference to others’ rights. Loitz v. Remington Arms Co., [138 Ill. 2d 404](https://cite.case.law/ill-2d/138/404/#p415), 415-16, 563 N.E.2d 397 (1990), quoting Restatement (Second) of Torts § 908, Comment b, at 464-65 (1979).

Punitive damages are similar to criminal penalties (Deal v. Byford, [127 Ill. 2d 192](https://cite.case.law/ill-2d/127/192/#p203), 203, 537 N.E.2d 267 (1989)) and are permissible only in cases in which torts "are committed with fraud, actual malice, deliberate violence or oppression, or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others.” Kelsay v. Motorola, Inc., [74 Ill. 2d 172](https://cite.case.law/ill-2d/74/172/#p186), 186, 384 N.E.2d 353 (1978). The initial decision whether punitive damages may be imposed in a particular case is a matter usually reserved to the circuit court (Loitz, [138 Ill. 2d at 415](https://cite.case.law/ill-2d/138/404/#p415)), and its decision will not be reversed absent an abuse of discretion. Levy v. Markal Sales Corp., 268 Ill. App. 3d 355, 379, [643 N.E.2d 1206](https://cite.case.law/citations/?q=643%20N.E.2d%201206) (1994). A reviewing court "may reverse the amount of punitive damages only where 'it is apparent that the award is the result of passion, partiality, or corruption.’ ” Levy, 268 Ill. App. 3d at 379, quoting Deal, [127 Ill. 2d at 204](https://cite.case.law/ill-2d/127/192/#p203).

There was evidence presented here that Upjohn not only knew of the adverse effects of periocular use of Depo-Medrol, but promoted and developed this off-label use through financial and technical assistance to doctors. After those doctors wrote up their case reports with Upjohn’s assistance, Upjohn distributed them, thereby helping to create the literature touting the periocular use of Depo-Medrol. There *\*286*was sufficient evidence of willful and wanton conduct to justify the imposition of punitive damages.

Upjohn’s contention that the jury instructions on punitive damages were inadequate is not persuasive. The jury was instructed that "willful and wanton conduct” means "a course of action which shows an utter indifference to or conscious disregard for the safety of others.”[**18**](https://cite.case.law/ill-app-3d/291/265/#footnote_1_18) Given the status of Illinois law on punitive damages discussed above, we cannot say that the instructions do not state the law accurately. The circuit court did not abuse its discretion in giving these punitive damages instructions to the jury.

Upjohn also maintains the court erred in permitting argument concerning Upjohn’s net worth. Upjohn, however, cannot show the court abused its discretion in admitting evidence of its net worth. See E.J. McKernan Co. v. Gregory, 252 Ill. App. 3d 514, 536, [623 N.E.2d 981](https://cite.case.law/citations/?q=623%20N.E.2d%20981) (1993), quoting Deal, 127 Ill. 2d at 204-05. Upjohn has failed to demonstrate that the evidence was irrelevant and prejudicial with respect to either compensatory or punitive damages.

Upjohn’s most persuasive argument is that the punitive damages awarded are excessive and should be reduced.

In reviewing punitive damage awards, the question of excessiveness turns on whether the amount is so large that it outruns the justification for exacting punitive damages, namely, retribution and deterrence of future outrageous conduct. Marek v. Stepkowski, [241 Ill. App. 3d 862](https://cite.case.law/ill-app-3d/241/862/), 608 N.E.2d 285 (1992). A reviewing court considers the degree of reprehensibility of defendant’s conduct, the relationship between the punitive damage award and the harm caused by the conduct, defendant’s gain from the misconduct, and the financial condition of defendant. See Pacific Mutual Life Insurance Co. v. Haslip, [499 U.S. 1](https://cite.case.law/us/499/1/), 113 L. Ed. 2d 1, [111 S. Ct. 1032](https://cite.case.law/us/499/1/) (1991); Deal, 127 Ill. 2d at 203-04. This court’s inquiry is thus one of degree: when arrayed along the spectrum of wrongful acts, was the conduct at issue here so extraordinarily outrageous as to justify extraordinary punitive damages? The circuit court, in its review of the punitive damages awarded, answered that question in the affirmative, although it [*\*287*](https://cite.case.law/ill-app-3d/291/265/#p287)remitted the jury’s award by almost 75%. The original award of more than $124 million amounted to precisely 7% of Upjohn’s net worth; the remitted amount is still more than 2% of the company’s net worth and more than eleven times the amount of compensatory damages awarded.

When we consider the factors set out by the United States Supreme Court and Illinois courts, we find that the amount of punitive damages awarded in this case far outruns the justification for imposing punitive damages. We agree with the circuit court that Upjohn’s conduct was sufficiently reprehensible to support an award of punitive damages; however, there is no reasonable relationship between the amount of the punitive damages and the harm caused by the conduct. Further, although Upjohn is a large corporation with a net worth of approximately $1.7 billion, punishment in the amount of 2% of its net worth is excessive in the extreme.

Illinois courts have recognized that the level of compensatory damages may be an appropriate measure of punitive damages. See Brown v. Farkas, 158 Ill. App. 3d 772, 780, [511 N.E.2d 1143](https://cite.case.law/citations/?q=511%20N.E.2d%201143) (1986). It is important, however, not to belittle the meaning of the jury’s decision and the determination of the circuit court that a $35 million award was proper given Upjohn’s willful and wanton conduct. We believe that a punitive damage award twice that of the compensatory damage award will send a strong message to pharmaceutical manufacturers of the necessity to warn of the known potential adverse effects of their drugs. The twin goals of retribution and deterrence would both be met by such an award. Pursuant to Supreme Court Rule 366, we enter a remittitur of the punitive damages to $6,095,639.52. 134 Ill. 2d R. 366.

For the foregoing reasons the judgment of the circuit court is affirmed in part; vacated in part; and remittitur is entered as noted above.

Affirmed in part; vacated in part; and remittitur entered.

TULLY, J., concurs.

**1**

At trial, defendant Dr. Davis testified that he believed that by 1983, the technique of periocular injections was widely used in the medical community; he believed physicians were using this technique an estimated 1 million times each year. Physicians had previously used periocular injections with other steroids to avoid the side effects from other methods of administration and to provide more direct action on the point of inflammation in the eye. As a new, longer-acting steroid, Depo-Medrol appeared to offer advantages for this type of use. Dr. Davis did not then know of the drug’s dangerous propensities, or he would not have used it.

[**2**](https://cite.case.law/ill-app-3d/291/265/#ref_footnote_1_2)

Dr. Samuel Stubbs, Upjohn’s Depo-Medrol expert, admitted that if a doctor wanted information about periocular injections of Depo-Medrol, Upjohn would forward a copy of this article.

**3**

Yet, on January 9, 1962, when Bob Fuoto, one of Upjohn’s salesmen in Manhattan, sent an inquiry to Upjohn’s medical department, asking why the eye became "very red,” and whether that condition could be prevented, following subconjunctival injections in cataract surgery patients, Dr. Gerard, an Upjohn employee, responded, in a letter dated February 14, 1962:

"I know of no way of giving a definite answer \*\*\* as to why the eye becomes red after the subconjunctival use of Depo-Medrol. I do think that it should be pointed out, however, that it has never been recommended that Depo-Medrol be used this way. Our recom[*\*271*](https://cite.case.law/ill-app-3d/291/265/#p271)mendations for Depo-Medrol is that the injection be given deep intramuscularly or if used for intralesional treatment of the skin, that the injections be kept as small as possible. It seems to me that 1 cc. of Depo-Medrol subconjunctivally is a rather large dose to place in this area. When this amount is given subcutaneously in other areas of the body, it can occasionally cause tissue atrophy. I would think that our best recommendation \*\*\* would be that at this dosage level of Depo-Medrol, \*\*\* the medication [should be given] intramuscularly, as probably the predominant steroid effect is going to be a systemic effect anyway. This preparation is a suspension and not a solution, and it may well be that the crystalline material in the area of such a sensitive tissue as a subconjunctiva is the cause in itself for the redness.” (Emphasis added.)

**4**

PlaintifFs expert, Dr. Philip Walson, testified that so few cases did not constitute sufficient experience with the drug. Further, the material received from these doctors did not provide complete data for purposes of making any [*\*272*](https://cite.case.law/ill-app-3d/291/265/#p272)scientific use according to accepted principles. No double blind studies were done (for example, making it difficult to evaluate whether the patient had improved spontaneously or because of the therapy or treatment received), although that scientific methodology was available to do these kinds of studies.

**5**

Dr. Walson also testified that those papers could not be used to justify the statement, because they were merely anecdotal, not scientific studies, and there was no proof for the claim that the procedure they employed was "simple and effective in those inflammatory ocular processes for which steroids are indicated.”

[**6**](https://cite.case.law/ill-app-3d/291/265/#ref_footnote_1_6)

Dr. Stubbs knew what was needed for FDA approval, but what he did not get, from these reports, writing on September 19, 1963:

"I would be most happy to pay your secretary a little bit extra for these case reports if she would be willing to re-work them, perhaps with an occasional word from you to cover the following points: patient’s identification; age; sex; diagnosis; duration of illness; therapy used, and in this instance Depo-Medrol; the strength of the Depo-Medrol, in other words how many milligrams per cc; the amount given; the frequency of injection, with dates as you have done to a certain extent; the results of therapy; and finally any side effects. This information is what the [FDA] requires as a minimum and is certainly not my idea, although I think that their requirements are [] minimal particularly for a type of therapy which is not completely accepted in a general way as yet.” (Emphasis added.)

**7**

One such article, published in 1964, stated:

"Maximum local response may be expected with only minimal or no systemic steroid effects. A voluminous mass of reports testifies to the efficacy and safety of this report in general medicine and in surgery!!]” (Emphasis added.)

The article went on to state:

"Similarly, an ophthalmologist has recently reviewed indications for and the fine results to be expected from some subconjunctivally injected steroids. This experience has been confirmed by others.” (Emphasis added.)

Dr. Stubbs admitted that this article did not mention the need to conduct double blind studies to assess the effectiveness of subconjunctival injections with Depo-Medrol; that the article, which had been written by Upjohn staff writers and submitted by Upjohn for publication, was already stating to the ophthalmic community that the use of this drug for subconjunctival injections was "safe, simple and effective,” without performing double blind or animal studies by Upjohn for the subconjunctival use of Depo-Medrol and without FDA approval.

[**8**](https://cite.case.law/ill-app-3d/291/265/#ref_footnote_1_8)

Much of the material Dr. Stubbs collected, however, was supported and promoted by Upjohn. Additionally, Dr. Stubbs knew that one doctor’s case reports omitted animal studies. Proctor’s expert, Dr. Walson, criticized the studies that Dr. Stubbs relied upon, maintaining that they were unstandardized, did not refer to animal studies, and failed to demonstrate Depo-Medrol’s efficacy. Notwithstanding the many infirmities in the underlying information and case reports, which were initially developed based upon Upjohn’s promotion and sponsorship, Dr. Stubbs concluded that there were no reports of Depo-Medrol’s toxicity.

**9**

When a pharmaceutical company receives a report about an adverse reaction associated with the use of its product, it records it in a DER and forwards it to the FDA. Between the first marketing of Depo-Medrol and the injection of Meyer Proctor that led to this suit, Upjohn received 23 reports indicating adverse experiences associated with its use. The DERs based on these communications were forwarded to the FDA, usually accompanied by a cover letter stating that the use involved was not recommended. Three of these reports (one in 1977 and two in 1983) concerned vision loss following periocular injections with unintentional intraocular injection. Additionally, the medical literature had reported other instances of accidental intraocular injections of corticosteroids like Depo-Medrol, some of which were followed [*\*275*](https://cite.case.law/ill-app-3d/291/265/#p275)by vision loss.

**10**

A more expanded discussion of this incident appears in the contemporaneously issued Rule 23 order, point IV.

[**11**](https://cite.case.law/ill-app-3d/291/265/#ref_footnote_1_11)

The dissent, in concluding that "Proctor’s injury was the result of an accident involving Dr. Davis’ use of a needle, and Upjohn could not have prevented, nor was it responsible for, the doctor’s mistake” (291 Ill. App. 3d at 287), usurps the role of the finder of fact. Such appropriation is *\*280*particularly unwarranted where Upjohn seeks judgment notwithstanding the verdict. See Pedrick, [37 Ill. 2d at 510](https://cite.case.law/ill-2d/37/494/). In reaching its conclusion, the dissent reasons that the medical community was aware of the risks associated with periocular injections of Depo-Medrol, but reduces the risks to the "inadvertent intraocular injection of Depo-Medrol” (291 Ill. App. 3d at 288), whereas our decision also is based upon the insolubility and toxicity of Depo-Medrol of which Upjohn knew or should have known. 291 Ill. App. 3d at 277-78. The dissent’s failure to recognize this issue leads it to proclaim that the medical community was aware of "the risks associated with periocular use of Depo-Medrol” (291 Ill. App. 3d at 289) while ignoring the abundant evidence, including Dr. Walson’s acknowledgement that Upjohn should have warned that periocular use of the drug was not recommended. 291 Ill. App. 3d at 278-79. Finally, in discussing the removability of Depo-Medrol, the dissent overlooks critical testimony of Drs. Stubbs and Walson. E.g., 291 Ill. App. 3d at 282-83 nn.14, 15. The dissent’s repeated omissions, in Upjohn’s favor, refute its assertion that it viewed the evidence in the light most favorable to plaintiffs. 291 Ill. App. 3d at 290.

**12**

The Mahr court stated:

"The nature of prescription drugs and the ethics involved in the professional practice of medicine are such that it is a physician who decides what medications, if any, a patient is to take. Thus, while the manufacturer’s duty to warn is for the benefit of the ultimate consumer of its products, the physician, in the role of a learned intermediary, is the person to whom the warnings are to be communicated. [Citations.] [*\*281*](https://cite.case.law/ill-app-3d/291/265/#p281)Contrary to Searle’s position, however, the adequacy of the communication of the warning is not judged solely by reference to the information supplied by the manufacturer to the prescribing physicians. \*\*\* Searle had the duty to adequately communicate the adverse effects of Enovid to all members of the medical profession who came into contact with [the patient] in a decision-making capacity during the time she was using the drug.” (Emphasis added.) 72 Ill. App. 3d at 561-62.

[**13**](https://cite.case.law/ill-app-3d/291/265/#ref_footnote_1_13)

The dissent disagrees with our conclusion that plaintiffs established that Upjohn’s failure to warn was a proximate cause of Proctor’s injuries apparently because "Dr. Davis’ treatment decision would have been the same had he received the warnings plaintiffs contend were required.” 291 Ill. App. 3d at 290. This assertion is, as the dissent acknowledges, contrary to Dr. Davis’ testimony. Nevertheless, the dissent believes that Dr. Davis’ remaining testimony contradicts his statement "that he would not have treated Proctor with periocular injection of Depo-Medrol if he had received” warnings. 291 Ill. App. 3d at 290. Inexplicably, the dissent demonstrates a willingness to disregard direct testimony, usurp the role of the fact finder, and dismiss the standard of review in reaching its desired end. Notwithstanding the dissent’s outright rejection of Dr. Davis’ statement, the fact that Dr. Davis found periocular injection of Depo-Medrol to be safe and effective prior to using it on Proctor does not contradict his testimony that had he known of the risks of Depo-Medrol, he would not have used it; there is no basis to conclude that he would adhere blindly to his belief in Depo-Medrol’s safety and efficacy when confronted with contradictory evidence. The dissent would have Dr. Davis assume its mantle of omission, but such a conclusion is contrary to common sense, contravenes the standard of review, and opposes Dr. Davis’ testimony. Contrary to the dissent, Dr. Davis testified that there were alternative treatments available. He specifically stated that systemic administration of Depo-Medrol was an alternative for Proctor that was not contraindicated. The dissent’s focus on Dr. Davis’ testimony regarding "accidental intraocular injection and blindness” (291 Ill. App. 3d at 291) further distorts the issue and reveals the dissent’s misunderstanding of our decision and the risks of Depo-Medrol. E.g., 291 Ill. App. 3d at 279-80 n.11.

**14**

From June of 1963 through September of 1983, Upjohn received numerous adverse DERs relating to repository Depo-Medrol therapy for intraocular disorders. Some of these are abstracted in the Appendix attached to the Rule 23 order. It should be noted, however, that in Dr. Walson’s experience, the frequency of DERs is less than the adverse effects that actually occur; in other words, not every adverse reaction was reported. He noted that the observations contained in DERs to Upjohn, such as abscesses at the injection site, sloughing at the subconjunctiva, swelling at the injection site, residue being left in the area where the eye was injected, increased ocular pressure after the injection, blurred vision, anaphylaxis, and sudden blindness, could be evidence of the toxicity of the drug. He held the opinion that loss of vision, small white spots of residue, diminished vision, and any kind of allergic response could also indicate toxicity of the drug.

[**15**](https://cite.case.law/ill-app-3d/291/265/#ref_footnote_1_15)

Dr. Stubbs, one of Upjohn’s Depo-Medrol overseers, testified that the book "Drug Induced Ocular Side Effects and Drug Inter-reactions” by Fraunfelder was in Upjohn’s medical library in Kalamazoo. In the 1976 edition, it states "inadvertent intraocular steroid injections have caused blindness probably as a result of direct drug toxicity to the retina or optic nerve.” (Emphasis added.) Dr. Stubbs admitted that it was part of his duties and responsibilities to be aware of this kind of information. Dr. Stubbs also knew that there had been several articles reporting the accidental injection of Depo-Medrol into the eye itself. Dr. Stubbs admitted that prior to the incident, he knew that if Depo-Medrol got into the eye, its white substance might obscure a physician’s ability to identify any damage from the injection. He was aware of articles which reported that the substance remained in the eye. None of this information was contained in Upjohn’s labels or inserts.

Another writing concluded that Depo-Medrol remains active as long as it is visible. This text was dated 1978. Neither the package nor the label *\*283*insert for Depo-Medrol stated, to November 7, 1983, how long the drug remained active around the eye.

[**16**](https://cite.case.law/ill-app-3d/291/265/#ref_footnote_1_16)

The dissent claims our analysis is unfair, but this proclamation is itself unfair when carefully scrutinized. First, we noted Upjohn’s actions of aggressively promoting and advertising the off-label use of Depo-Medrol despite evidence known to Upjohn of its risks. The dissent claims that off-label use of drugs is not unusual or illegal, but this does not address nor contradict our analysis; rather, it speaks past our assertion and distorts the basis and reasoning of our holding. Next, the dissent states that Upjohn’s actions of funding research into off-label uses and distributing reprints of articles discussing off-label uses is a common practice among drug manufacturers. 291 Ill. App. 3d at 295-96. This criticism misses the point; Upjohn’s actions may have been a common practice among drug manufacturers, but its actions assume a pernicious quality when coupled with its knowledge of the dangers of the off-label use of Depo-Medrol. E.g., 291 Ill. App. 3d at 270-71 n.3, 282-83 nn.14, 15.

**17**

The dissent’s arguments concerning alleged errors in evidentiary rulings places itself into the position of circuit judge and decides the issues de nova. The standard of review, however, does not permit a reviewing court to reverse absent an abuse of discretion.

[**18**](https://cite.case.law/ill-app-3d/291/265/#ref_footnote_1_18)

The jury also was instructed:

"If you find that the defendant Upjohn Company’s conduct was willful and wanton and proximately caused injury to the plaintiff, and if you believe that justice and the public good require it, you may in addition to any damages to which you find the plaintiff entitled, award an amount [which] will serve to punish the defendant, Upjohn Company, and to deter others from the commission of the like offenses.”

JUSTICE DiVITO,

dissenting:

Meyer Proctor suffered a painful and tragic injury. For that, however, Upjohn bears no responsibility. Succinctly stated, Proctor’s injury was the result of an accident involving Dr. Davis’ use of a needle, and Upjohn could not have prevented, nor was it responsible for, the doctor’s mistake. Judgment notwithstanding the verdict *\*288*should have been granted because Upjohn had no duty to warn and, even if it did, there was no showing that any alleged failure to warn was a proximate cause of Proctor’s injury. Alternatively, reversal and a new trial are warranted because the circuit court improperly excluded critical evidence favorable to Upjohn.

DUTY TO WARN

In the 1995 opinion filed in this case (Proctor v. Davis, [275 Ill. App. 3d 593](https://cite.case.law/ill-app-3d/275/593/), 656 N.E.2d 23 (1995), invalidated by Proctor v. Upjohn Co., [175 Ill. 2d 394](https://cite.case.law/ill-2d/175/394/#p397), 677 N.E.2d 918 (1997)), I wrote that Upjohn had no duty to warn. For the reasons I expressed in that opinion, incorporated by reference here, some of which I reiterate in this dissent, I continue to believe that Upjohn had no duty to warn.

The majority holds that Upjohn is liable for Proctor’s injury because it knew that Depo-Medrol was toxic and difficult to remove if injected into the eye, and it failed to warn ophthalmologists of these risks. 291 Ill. App. 3d at 279-81. The record, however, does not justify that conclusion because it contains ample evidence that the medical community, including Dr. Davis, was aware of the risks associated with periocular injection of Depo-Medrol.

Drs. Walson, Deutsch, Giles, and Fagman testified that the possibility of intraocular injection was a well-known risk of periocular use of Depo-Medrol. Dr. Walson, plaintiffs’ own expert, also testified that he thought that, in 1983, ophthalmologists were aware that inadvertent intraocular injection of Depo-Medrol had caused the loss of an eye for some patients.

In addition, there were several reports in the medical literature describing incidents in which vision loss resulted from an inadvertent intraocular injection of Depo-Medrol. Physicians are held to a standard of medical expertise (see, e.g., Kirk v. Michael Reese Hospital & Medical Center, [117 Ill. 2d 507](https://cite.case.law/ill-2d/117/507/#p517), 517-18, 513 N.E.2d 387 (1987)) and may be expected to have knowledge of current medical literature (see, e.g., [40 Fed. Reg. 15394](https://cite.case.law/citations/?q=40%20Fed.%20Reg.%2015394) (April 7, 1975)).

Included in the literature of which ophthalmologists would be expected to be aware was a 1981 article, which reported that a patient became legally blind as a result of an intraocular injection of Depo-Medrol. K. Zinn, Iatrogenic Intraocular Injection of Depot Corticosteroid and Its Surgical Removal Using the Pars Plana Approach, 88 Ophthalmology 13 (1981). A 1974 article discussed six cases in which corticosteroids were accidentally injected intraocularly. Four of these cases involved Depo-Medrol, and in two of those four cases, the patients suffered a complete loss of vision. In the two cases involving the injection of the other corticosteroid, the patients also suffered se*\*289*vere vision loss. T. Schlaegel & F. Wilson, Accidental Intraocular Injection of Depot Corticosteroids, 78 Transactions—American Academy of Ophthalmology & Otolaryngology 847 (1974). A 1969 article by Moschini reported that a patient suffered a complete loss of vision following an inadvertent intraocular injection of Depo-Medrol. G. Moschini, Accidental Introduction of Sustained-Action Corticosteroid in the Vitreous Humor, 48 Bollettino D’Oculistica 426 (1969) (as translated). Several other articles and texts in the literature discussed the general dangers associated with the intraocular injection of steroids; still others reported no long-term adverse effects or reported adverse effects less severe than blindness following the intraocular injection of Depo-Medrol. A 1976 textbook also contained the information that inadvertent intraocular injections of steroids had caused blindness. F.T. Fraunfelder, Drug-Induced Ocular Side Effects and Drug Interactions (1976).

Not only were the risks associated with periocular use of Depo-Medrol well-known to the medical community, they were also evident to Dr. Davis. Although he testified that he did not know that Depo-Medrol could not be easily removed once injected into the eye, Dr. Davis knew that injecting it into the eye could lead to blindness. From reading medical literature, he knew that accidental intraocular injection was possible and that piercing of the eyeball could cause damage, including blindness. He also testified that he knew Depo-Medrol was toxic to the eye. Even as a medical resident, he and his fellow medical residents were well aware of the drug’s toxicity and knew that it should not be used intraocularly.

The majority asserts that Upjohn had superior knowledge of the risks associated with periocular use of Depo-Medrol because physicians did not know of Depo-Medrol’s toxicity and did not know that it could not be removed once injected. 291 Ill. App. 3d at 279. The record, however, does not support a conclusion that ophthalmologists were unaware in 1983 that Depo-Medrol could be toxic if injected into the eye. No ophthalmologist testified that he was unaware that the drug could be toxic if used in this way, and Dr. Giles and Dr. Davis both testified that they were aware in 1983 that Depo-Medrol could be toxic if injected into the eye.

With respect to the removability of the drug, the relevant question is whether Upjohn had greater knowledge than the medical community about any difficulty in removing Depo-Medrol from the eye. Dr. Stubbs, Upjohn’s medical monitor for Depo-Medrol, testified that, based on information in the medical literature available in 1983 and information in drug experience reports sent to Upjohn, he did not believe that Depo-Medrol would be particularly difficult to remove [*\*290*](https://cite.case.law/ill-app-3d/291/265/#p290)from the eye. Likewise, in the course of testifying about instances reported in the literature concerning the injection of Depo-Medrol into the eye, Dr. Walson made a similar statement concerning the removability of the drug. In addition, two of the three drug experience reports received by Upjohn that described an intraocular injection of Depo-Medrol reported that the Depo-Medrol had been removed by performing a vitrectomy. Thus, the record before us does not support the conclusion that Upjohn had greater knowledge than the medical community of any difficulty in removing the drug in the event of an inadvertent intraocular injection.

Even with the evidence viewed in the light most favorable to plaintiffs, therefore, Upjohn had no duty to warn in this case. The record demonstrates that the medical community and Dr. Davis were well aware of the potential danger associated with periocular injections of Depo-Medrol and that Upjohn did not have superior knowledge of these risks.

FAILURE TO WARN AS PROXIMATE CAUSE

Also, there is no basis for the majority’s conclusion, in its unpublished Rule 23 order, that plaintiffs established that Upjohn’s failure to warn was a proximate cause of Proctor’s injuries. Proctor v. Davis, No. 1—92—3151, slip op. at 5-8 (July 11, 1997) (unpublished order under Supreme Court Rule 23) (hereinafter Rule 23 order). As the majority states, in order to prove proximate cause, plaintiffs were required to show that Dr. Davis’ treatment decision would have been altered if he had received the warning they argue Upjohn should have provided. Rule 23 order, at 5, citing Ashman v. SK&F Lab Co., 702 F. Supp. 1401 (N.D. Ill. 1988).

Dr. Davis did testify that he would not have given Proctor a periocular injection of Depo-Medrol had he known it was difficult to remove and might cause blindness. Certainly, it was the role of the jury to evaluate his credibility and to resolve conflicts in the evidence. See Maple v. Gustafson, [151 Ill. 2d 445](https://cite.case.law/ill-2d/151/445/), 452-53, 603 N.E.2d 508 (1992). Nevertheless, judgment notwithstanding the verdict was appropriate because, even viewing the evidence in the light most favorable to plaintiffs, it is clear that, despite his testimony to the contrary, Dr. Davis’ treatment decision would have been the same had he received the warnings plaintiffs contend were required.

Dr. Davis’ testimony that he would not have treated Proctor with periocular injection of Depo-Medrol if he had received these warnings was completely contradicted by the remainder of his testimony. For example, he testified that he had found this treatment to be safe and effective and had used it without problem on 1,600 occasions [*\*291*](https://cite.case.law/ill-app-3d/291/265/#p291)prior to the accidental injection of Proctor’s eye. In fact, he had used it to restore Proctor’s vision when no other treatment had worked.

Also contrary to his testimony that he would not have used Depo-Medrol periocularly if he had known the risks, Dr. Davis testified that, at the time he treated Proctor, he was aware that accidental intraocular injection and blindness were possible consequences of periocular injection of Depo-Medrol. Perhaps the best indicator of how knowledge of these risks would have affected his treatment decision was his testimony that, even after he accidentally penetrated Proctor’s eye, he continued to treat patients with periocular injections of Depo-Medrol.

Dr. Davis’ testimony that periocular injection of Depo-Medrol was the only treatment alternative for Proctor also contradicted his testimony that warnings would have changed his treatment decision. The majority states that there were alternative treatments available (Rule 23 order, at 6), but the record does not support this conclusion. Dr. Davis explained that further use of Nalfon was not a feasible alternative because it had been used without success to treat Proctor’s condition. Dr. Davis also explained that intramuscular, that is, systemic, administration of steroids was contraindicated by certain health conditions Proctor had. As for the majority’s suggestion that Dr. Davis could have used a different formulation of Depo-Medrol, the record does not indicate that a different formulation would have been effective. By contrast, Dr. Davis knew that periocular injection was an effective treatment for Proctor because it had restored his vision in the past and it was not contraindicated by Proctor’s other medical conditions.

The testimony of other ophthalmologists also indicated that the warning plaintiffs claim was required would not have changed Dr. Davis’ treatment decision. Expert witnesses, Drs. Giles, Fagman, and Deutsch, all testified that Davis’ decision to inject Depo-Medrol periocularly was in accordance with the applicable standard of care. Dr. Giles also testified that, even after he accidentally injected Depo-Medrol intraocularly, he continued to treat patients using periocular injection of the drug and found it to be safe and efficacious.

It is clear from this evidence that the ophthalmologic community, including Dr. Davis, considered Depo-Medrol to be an appropriate treatment for Proctor’s condition and found periocular injection of this drug to be safe and effective despite the possibility of intraocular injection and vision loss.

This uncontradicted evidence compelled the jury to conclude that Upjohn’s alleged failure to warn was not a proximate cause of Proctor’s injury. The only proximate cause of Proctor’s loss of his eye *\*292*was Dr. Davis’ accidental injection of Depo-Medrol into the eye rather than periocularly. Consequently, the circuit court should have granted the motion for judgment notwithstanding the verdict.

ERRORS IN EVIDENTIARY RULINGS

Upjohn was prevented from presenting compelling evidence both on the issue of proximate cause and on the issue of punitive damages.

1. Post-1983 Usage of Depo-Medrol

The circuit court excluded evidence of post-1983 usage of Depo-Medrol, but Upjohn made offers of proof that, after 1983, Drs. Giles, Deutsch, and Fagman continued to use periocular injection of Depo-Medrol to treat their patients. The evidence that, even after 1983, ophthalmologists continued to view periocular injection of Depo-Medrol as a safe and efficacious treatment severely undermines the argument that Dr. Davis would have treated Proctor differently had he known more about the drug. Moreover, such evidence was highly relevant to the issue of punitive damages. The circuit court erred in excluding this evidence.

The majority holds that this evidentiary ruling was proper because it was consistent with the court’s exclusion of post-1983 labeling changes. Rule 23 order, at 13-14. The majority’s "consistency” rationale, however, is not persuasive because, although there are public policy considerations that support the exclusion of the evidence of post-1983 labeling changes, there is no legitimate basis for the exclusion of the evidence of post-1983 usage.

Generally, evidence of subsequent remedial measures is inadmissible in negligence and product liability actions for public policy reasons: courts do not want to discourage defendants from making safety improvements, evidence of subsequent remedial measures is not probative, and the jury may view this evidence as proof of negligence. See Herzog v. Lexington Township, [167 Ill. 2d 288](https://cite.case.law/ill-2d/167/288/#p300), 300-01, 657 N.E.2d 926 (1995); Smith v. Black & Decker (U.S.), Inc., [272 Ill. App. 3d 451](https://cite.case.law/ill-app-3d/272/451/#p456), 456, 650 N.E.2d 1108 (1995). These policy concerns supported the circuit court’s exclusion of the post-1983 labeling changes, but they do not justify the exclusion of the post-1983 usage of Depo-Medrol. Despite the discretion accorded to trial courts in ruling on the admissibility of evidence, because this evidence was highly probative with respect to the issue of proximate cause and to the issue of punitive damages, the circuit court erred in excluding it.

2. Upjohn’s Effort to Add a Warning

Also troubling is the circuit court’s exclusion of evidence of Upjohn’s attempt to add a warning to its labeling and its exclusion of [*\*293*](https://cite.case.law/ill-app-3d/291/265/#p293)evidence of FDA labeling controls. The majority acknowledges that, in Rucker v. Norfolk & Western Ry. Co., 77 Ill. 2d 434, [396 N.E.2d 534](https://cite.case.law/citations/?q=396%20N.E.2d%20534) (1979), Moehle v. Chrysler Motors Corp., 93 Ill. 2d 299, [443 N.E.2d 575](https://cite.case.law/citations/?q=443%20N.E.2d%20575) (1982), and Hatfield v. Sandoz-Wander, Inc., 124 Ill. App. 3d 780, [464 N.E.2d 1105](https://cite.case.law/citations/?q=464%20N.E.2d%201105) (1984), Illinois courts have held that evidence of compliance with federal requirements, including FDA requirements, is admissible. The majority distinguishes these cases, however, on the basis that the parties in those cases demonstrated compliance, and Upjohn did not prove that it complied with FDA requirements in this case. The majority, therefore, concludes that Upjohn was not entitled to present evidence of its attempted labeling change or of FDA labeling requirements because these were not relevant either to its duty to warn or to punitive damages. Rule 23 order, at 11.

Although, unlike this case, in Rucker, Moehle, and Hatfield there was never any question as to the defendants’ compliance with federal standards, these cases do not support the exclusion of the FDA evidence in this case. In those cases, the courts held that evidence of compliance with federal standards is admissible; they did not hold that evidence of federal standards is inadmissible absent a showing of compliance. Evidence is relevant if it tends to prove a fact at issue or shows that a matter in dispute is more or less probable. Herman v. Will Township, 284 Ill. App. 3d 53, 61, [671 N.E.2d 1141](https://cite.case.law/citations/?q=671%20N.E.2d%201141) (1996). Even absent proof of compliance, the evidence of Upjohn’s attempted labeling change and FDA labeling requirements was highly relevant to the issue of punitive damages because it tended to show that Upjohn’s conduct was not willful and wanton.

Even assuming, as the majority does, that Upjohn should have interpreted the FDA letter as requiring it to "submit its proposed change in the proper manner” (Rule 23 order, at 11), evidence of Upjohn’s attempt to add a warning should have been presented to the jury. This evidence was relevant to the issue of punitive damages because it would have permitted the jury to conclude that Upjohn did not disregard the safety of its customers because it had attempted, albeit improperly and unsuccessfully, to add a warning to its label.

Furthermore, there was no basis for concluding from the record that Upjohn was not complying with an FDA directive when it continued to use labeling that did not contain a warning with respect to ophthalmic use. In response to the FDA’s request for format changes to all corticosteroid labels, Upjohn submitted a supplemental application, in which it proposed to revise the Depo-Medrol label to, among other things, include a new warning for ophthalmic uses. In September 1983, the FDA informed Upjohn that it was conducting further review of the labeling format and instructed it to continue to *\*294*use existing labeling until the FDA notified it of the status of its supplemental application. The FDA further instructed Upjohn to revise its labeling through another supplemental application (see [21 C.F.R. § 314.8](https://cite.case.law/citations/?q=21%20C.F.R.%20%C2%A7%20314.8) (1984)) if "important new labeling information becomes available.”

Unlike the majority, I do not interpret the FDA letter as requiring Upjohn to submit an additional supplemental application in order to add a warning to its label. At the time it received this letter, Upjohn had a supplemental application that included ophthalmic warnings pending before the FDA, and it did not have any "new” information about ophthalmic uses to add to the warning it had already submitted for approval. It was, therefore, logical for Upjohn to wait for the FDA to act on its pending application and to follow the FDA’s instruction to use its existing labeling until the FDA notified it of the status of its application. Had the jury been allowed to consider this letter, it might have reached the same conclusion as to Upjohn’s actions.

3. Evidence Concerning FDA Labeling Controls

Upjohn also should have been allowed to present evidence of FDA labeling controls. The jury heard Dr. Walson’s testimony that the format of the Depo-Medrol labeling was misleading, but Upjohn was not permitted to counter this testimony with evidence that the FDA dictates the format of prescription drug labels. The exclusion of this evidence unfairly prejudiced Upjohn in its ability to justify its failure to warn of the risks associated with ophthalmic use of Depo-Medrol and likely contributed to the jury’s punitive damage award.

The majority opinion itself demonstrates the prejudice that resulted from the exclusion of evidence of FDA requirements. According to the majority, Upjohn knew how to warn because it had warned against intrathecal use, and "Upjohn, in another line or two of print on the insert, easily could have mentioned potential adverse reactions to the drug when injected intraocularly” (291 Ill. App. 3d at 282). This statement ignores the restrictions that the FDA places on labeling. See W. Viscusi, Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense, 24 Seton Hall L. Rev. 1437, 1440 (1994) ("the FDA possesses virtually total control over the content of the package inserts that accompany all prescription drugs”); L. Noah, The Imperative to Warn: Disentangling the "Right to Know” from the "Need to Know” about Consumer Product Hazards, [11 Yale J. on Reg. 293](https://cite.case.law/citations/?q=11%20Yale%20J.%20on%20Reg.%20293), 359 (1994) ("Although in theory drug manufacturers are .free to add warnings in advance of FDA approval, they may not enjoy any real flexibility to *\*295*alter previously approved labeling”). The Depo-Medrol labeling included a warning against intrathecal use because the FDA required this warning. It is not clear what sort of warnings, if any, the FDA would have permitted for periocular use. The FDA must approve all post-marketing labeling changes (see Viscusi, at 1447 n.48) and, therefore, would not necessarily have permitted Upjohn to "easily” include a warning involving periocular use of the drug. In fact, the record demonstrates that when Upjohn submitted such a warning, it took the FDA several years to respond, and the response instructed Upjohn to continue to use its existing labeling.

This evidence was relevant; there was no legitimate basis for its exclusion. The circuit court erred in refusing to allow Upjohn to present it, and its ruling unfairly prejudiced Upjohn.

UP JOHN’S INVOLVEMENT IN THE OFF-LABEL USE OF DEPO-MEDROL

Finally, the majority’s description of Upjohn’s activities with respect to the off-label use of Depo-Medrol must be addressed. The majority suggests that Upjohn acted improperly when it provided financial assistance, writing support, and free Depo-Medrol to ophthalmologists who wished to put the drug to an off-label use. See 291 Ill. App. 3d at 268-73, 283-84. The majority also criticizes Upjohn for ordering and distributing reprints of articles discussing the periocular injection of Depo-Medrol. 291 Ill. App. 3d at 270. According to the majority, "The practice of publicizing unapproved uses of drugs, when sponsored by the pharmaceutical company, is not approved by the FDA as proper advertising; it results in continuing, unapproved, potentially dangerous use.” 291 Ill. App. 3d at 272-73.

These comments are unfair. Off-label use of drugs is not unusual or illegal (see Note, A Meaningful Choice: Two FDA Approved Drugs Are Combined to Perform Medical Abortions, 18 Women’s Rights L. Rep. 49, 56 n.116 (1996) (the American Medical Association estimates that 40% to 60% of all prescriptions in America are for off-label uses of drugs), and even the FDA has acknowledged that off-label use of a drug may be appropriate and rational (see Use of Approved Drugs for Unlabeled Indicators, FDA Drug Bulletin (Public Health Service, Md.) April 1982, vol. 12, No. 1, 4-5).

In addition, contrary to the majority’s implication that Upjohn acted improperly by funding research into off-label uses and distributing reprints of articles discussing off-label uses, these practices have been common among drug manufacturers. See Comment, Products Liability and ''Off-Label” Uses of Prescription Drugs, [63 U. Chi. L. Rev. 275](https://cite.case.law/citations/?q=63%20U.%20Chi.%20L.%20Rev.%20275), 279 (1996) (Comment). Dr. Stubbs testified that it was not *\*296*unusual to supply drugs to physicians who requested them, that fulfilling reprint requests was part of normal sales education, and that, in 1963 and 1964, it was normal for drug manufacturers to compensate doctors for secretarial help in preparing case reports and to supply writing support services.

The FDA has recently restricted the manner in which manufacturers may communicate with physicians about off-label uses, but its policy with respect to such communications was not as strict during the period of time relevant to this suit. See W. Christopher, Off-Label Drug Prescription: Filling the Regulatory Vacuum, [48 Food & Drug L.J. 247](https://cite.case.law/citations/?q=48%20Food%20%26%20Drug%20L.J.%20247), 249-54 (1993); Comment, at 279. The majority offers no authority for its suggestion that Upjohn’s activities would not have been approved by the FDA and the record does not permit such a conclusion.

RESPONSE TO MAJORITY’S REPLY TO THIS DISSENT

In four footnotes (see 291 Ill. App. 3d at 279-80 n.11, 281 n.13, 284 n.16, 285 n.17), the majority replies to what I have said in this dissent. For example, in footnote 11, after pointing out what I have said about the medical community being aware of the risks associated with periocular injections of Depo-Medrol, the majority states that its "decision also is based upon the insolubility and toxicity of Depo-Medrol of which Upjohn knew or should have known.” 291 Ill. App. 3d at 279-80 n.11. The majority then accuses me of "fail[ing] to recognize this issue.” This accusation is surprising given the considerable amount of space I have dedicated to the matter (see 291 Ill. App. 3d at 288-90). Moreover, as the majority itself recognizes (see 291 Ill. App. 3d at 270), there is no duty to warn of a risk that is already known by those to be warned. Kokoyachuk v. Aeroquip Corp., 172 Ill. App. 3d 432, [526 N.E.2d 607](https://cite.case.law/citations/?q=526%20N.E.2d%20607) (1988), appeal denied, 123 Ill. 2d 559, [535 N.E.2d 402](https://cite.case.law/citations/?q=535%20N.E.2d%20402) (1988). I repeat: in this off-label use of Depo-Medrol, the risks were known to the medical community. Dr. Davis and every ophthalmologist who testified knew that an accidental penetration of the eye was a risk inherent in periocular injections. They, and the entire ophthalmological community, were well aware of the risk of vision loss following the accidental intraocular injection of the drug.

Regarding the connection of the alleged failure to warn to the issue of proximate cause, the majority claims that I have disregarded the standard of review and have "usurpfed] the role of the fact finder.” (291 Ill. App. 3d at 281 n.13.) The majority insists that this court is required to uphold the jury verdict because Dr. Davis testified that he would not have treated Proctor with the periocular injection if he had received warnings and his statement that systemic use of Depo-Medrol was not contraindicated.

*\*297*The majority’s reliance on these isolated statements demonstrates a failure to view them in the context of the entire record. Although the standard of review requires us to view the evidence in the light most favorable to the nonmoving party, it does not require us to accept evidence that the remainder of the record demonstrates is implausible.

As I have explained, except for the single statement on which the majority relies, Dr. Davis’ testimony overwhelmingly demonstrated that warnings would not have changed his treatment decision because he was already aware of the relevant risks and because, even after accidentally causing Proctor’s eye loss, he continued to use Depo-Medrol periocularly. In addition, although he may have testified that systemic use of Depo-Medrol was not contraindicated, he also testified that systemic use was contraindicated by Proctor’s medical conditions. The evidence in this case, therefore, does not support a finding of proximate cause.

In footnote 17 (291 Ill. App. 3d at 285 n.17), the majority accuses me of not applying the proper standard of review concerning the circuit court’s evidentiary rulings. Let there be no doubt: the abuse of discretion standard is the one I applied in concluding that the circuit court had erred in making these rulings. The excluded evidence was highly relevant to the issue of proximate cause. Can its relevance to the issue of punitive damages be seriously questioned—in this case where the jury was not informed that a drug was deemed so efficacious that, at the time of trial, ophthalmologists were still using it in exactly the same way the majority deems so pernicious as to warrant over $6 million in punitive damages, and where the jury, not having information so relevant to Upjohn’s effort to counter evidence of its alleged willful and wanton conduct, returned a verdict of almost $125 million?

CONCLUSION

For the reasons given, the judgment against Upjohn should be reversed. Alternatively, because of the rulings that denied admissibility of evidence highly relevant both to the issue of proximate cause and to the issue of punitive damages, the judgment should be reversed and a new trial should be required. Accordingly, I respectfully dissent.

APPENDIX

Plaintiff’s exhibit 120 was a list prepared by Dr. Samuel Stubbs from 1965 until 1983 containing drug experience reports (DERs) with various patients of which Upjohn had notice, abstracted in part as follows:

[*\*298*](https://cite.case.law/ill-app-3d/291/265/#p298)June 18, 1963—five abscesses developed in three patients given subconjunctival injections of Depo-Medrol; abscesses resulted from increased particle size in the suspension.

June 20, 1963—patient developed a sterile abscess around the Depo-Medrol which was lying subconjunctivally; abscess ruptured; Depo-Medrol removed and the abscess evacuated; no side effects after removal.

October 21, 1964—patient’s sloughing of conjunctiva at the site of subconjunctival injection, with a gradual decrease in reaction; not completely restored through surgery, which necessitated cutting through involved tissues.

February 18, 1965—three patients exhibited pain, upper lid swelling, sheets of subconjunctival hematoma, and marked chemosis. The symptoms cleared slowly.

March 20, 1967—more than five different patients with "swelling, redness and fluctuation.”

May 1968—patient developed gray-white residue, which remained subconjunctivally six to eight weeks after injection.

September 26, 1968—whitish residue left behind after Depo-Medrol injected; persists for many weeks after steroid activity ceased, gradually disappeared; similar reports noted by many other people.

February 21, 1971—injection led to red, swollen eyelid and blurred vision.

May 1971—adverse reactions filed—report of subconjunctival injection site inflammation and report of increased intraocular pressure.

May 1972—deposit remaining at the injection site; report of a glaucoma-like picture in association with subconjunctival administration of Depo-Medrol.

July 1974—several patients exhibited white precipitate that remained in the injection site for a period of one or two months. White deposit caused sufficient concern that physician stopped using the drug.

September 25, 1974—injection of 1 cc. Depo-Medrol resulted in an immediate loss of vision.

"21/a hours later had NLP in both eyes. Paralysis of upgaze. No pupillary response. White material in arterioles of fundus. Mental confusion. 36 hr. later vision began to return. Fundus showed scattered retinal edema. Vision now OD-CF at 10-12 degrees OS-CF at 18-20 degrees. Atrophy of temporal iris OD. Cloudy vitreous OD.”

February 1976—increase in intraocular pressure; patient discharging Depo-Medrol "through three sites in necrotic conjunctiva *\*299*in the lower fornix”; injection site incised—piece of soft, off-white tissue was removed; acute inflammatory reaction to the drug. Following removal of this material, the corneal oedema cleared almost immediately and patient made a good recovery.

September 1977—accidental injection of Depo-Medrol into the eye of a patient when trying to inject subconjunctivally; patient lost vision.

December 1977—blindness in one eye following an injection of the drug into the turbinate area of the nose.

September 1978—small white spot developing following subconjunctival injections of Depo-Medrol; spot remained for a long time at the injection site in the mucosal.

November 1978—temporary blindness accompanied by severe pain, following the injection of Depo-Medrol into the nose.

November 1979—intense swelling around the eyes and nose; blockage of the ears following injection of Depo-Medrol subconjunctivally.

September 1980—diminished vision in one eye following an injection of Depo-Medrol in the turbinates after nasal surgery.

May 1983—conjunctival necrosis overlying the area of the injection 17 days after a conjunctival injection of Depo-Medrol.

July 1983—blindness and eye damage following an implant into the eye with subconjunctival injection of Depo-Medrol.

September 1983—inadvertent injection of Depo-Medrol into the vitreous of the eye instead of the retrobulbar space; vitrectomy performed and patient regained partial vision.

**Plain English summary:**

Plaintiff Meyer Proctor was severely injured when his doctor accidentally injected a corticosteroid, Depo-Medrol, into his eye, during an eye operation. Depo-Medrol is manufactured by Upjoin, the defendant company. Plaintiffs sued defendant for medical malpractice. The jury found in favour of plaintiffs, and defendant appealed. The appellate court affirmed the jury’s decision, finding that the jury had a right to conclude that defendant violated its duty to warn in this case.