ILLINOIS OFFICIAL REPORTS

Appellate Court

***DiCosolo v. Janssen Pharmaceuticals, Inc.*, 2011 IL App (1st) 093562**

Appellate Court Caption	JOHN DiCOSOLO, as Administrator of the Estate of Janice V. DiCosolo, Deceased, Plaintiff-Appellee, v. JANSSEN PHARMACEUTICALS, INC. and ALZA CORPORATION, Defendants-Appellants.
District & No.	First District, Fifth Division Docket No. 1–09–3562
Filed	June 30, 2011
Held (*Note: This syllabus constitutes no part of the opinion of the court but has been prepared by the Reporter of Decisions for the convenience of the reader.*)	In a wrongful death product liability case alleging that a transdermal patch manufactured and distributed by defendants malfunctioned and delivered a lethal dose of fentanyl to plaintiff's decedent, the judgment for plaintiff was affirmed, where plaintiff presented sufficient evidence to show that the patch worn by decedent was defective, including evidence that the decedent had a fentanyl level in her system greatly in excess of the level the patch was designed to deliver, the source of which was the patch, and the patch came from a lot that had been recalled.
Decision Under Review	Appeal from the Circuit Court of Cook County, No. 04–L–005351; the Hon. Thomas E. Flanagan, Judge, presiding.
Judgment	Affirmed.

Counsel on Appeal

John Dames and David B. Sudzus, both of Drinker Biddle & Reath LLP, of Chicago, and Irene C. Keyse-Walker, *pro hac vice*, Rita A. Maimbourg, *pro hac vice*, and Tariq M. Maeem, *pro hac vice*, all of Tucker Ellis & West LLP of Cleveland, Ohio, for appellants.

F. John Cushing III, of Law Offices of F. John Cushing III, P.C., and Michael J. Kralovec, of Kralovec Meenan LLP, both of Chicago, and Eric D. Pearson, James Craig Orr, Michael Heygood, and Charles Miller, all of Heygood, Orr & Pearson, of Dallas Texas, for appellee.

Panel

JUSTICE EPSTEIN delivered the judgment of the court, with opinion.
Justices J. Gordon and Howse concurred in the judgment and opinion.

OPINION

¶ 1 Defendants, Janssen Pharmaceuticals, Inc., and ALZA Corporation, appeal from an $18 million judgment in favor of plaintiff, John DiCosolo, as administrator of the estate of Janice V. DiCosolo, deceased, for noneconomic damages entered in a wrongful death product liability case involving the Duragesic® prescription transdermal patch that they manufactured and distributed. Defendants raise several arguments on appeal: (1) they were entitled to a judgment notwithstanding the verdict because plaintiff presented insufficient evidence that the product "malfunctioned" to permit the legal inference of a "nonspecific" defect; (2) in the alternative, multiple errors in evidentiary rulings entitle them to a new trial; (3) an improper and inflammatory closing argument resulted in a grossly excessive verdict that requires reversal; and (4) if the judgment is not reversed, the case should be remanded for a substantial remittitur. We affirm.

¶ 2 BACKGROUND

¶ 3 On February 15, 2004, 38-year-old Janice DiCosolo died while using a Duragesic® skin patch designed, manufactured, and distributed by defendants. DiCosolo was survived by her husband, John DiCosolo (plaintiff) and three children: John, Kristina, and Anthony. The active ingredient in Duragesic® is fentanyl, a strong narcotic painkiller. The fentanyl is mixed with a gel and ethanol and sealed within the patch. The patch is placed on the skin and the fentanyl travels through a rate-controlled membrane into the skin. Once through the skin, the fentanyl collects just beneath the skin and then enters the bloodstream through capillaries.

¶ 4 The Duragesic® skin patch is prescribed for chronic, severe pain that is otherwise unrelieved. DiCosolo suffered from a nerve root problem in her neck that was "exceedingly painful." After numerous painkillers and a spine stimulator implant failed to manage her pain, DiCosolo began treatment with Dr. Gene Neri. In July 2003, Dr. Neri prescribed a 50

micrograms per hour (mcg/hr) Duragesic® patch and increased the prescription to a 75 mcg/hr patch in September 2003. In addition to using the Duragesic® skin patch, DiCosolo was taking several other medications prescribed by her physician.

¶ 5 An autopsy performed by Dr. Lawrence Cogan of the Cook County Medical Examiner's office on February 16, 2004, which was more than 24 hours after DiCosolo's death, showed that DiCosolo's blood contained a fentanyl level of 28.2 nanograms per milliliter (ng/mL). A properly functioning 75 mcg/hr Duragesic® patch, according to defendants' package insert, should have delivered a fentanyl level of approximately 1.7 ng/mL.

¶ 6 Although DiCosolo had access to 11 central nervous system (CNS) depressants immediately prior to her death, plaintiff provided only eight of these for the "First Call List" that the Cicero police department provided to the medical examiner. Plaintiff did not list Avinza (an opiate), clonazepam (a sedative), or butalbital (a barbiturate). The medical examiner did not test DiCosolo's blood for the presence of Avinza or clonazepam, but he did test for butalbital, which was present in the blood. Although plaintiff listed Bextra (a sedative) and Topamax (a sedative) on the First Call List, the medical examiner decided not to test for those drugs. The medical examiner concluded that DiCosolo's cause of death was from "Fentanyl and Gabapentin and Venlafaxine" and that the manner of death was "suicide."

¶ 7 On February 16, 2004, the day after DiCosolo died, defendants announced an "Urgent Class I Drug Recall" of lot control No. 0327192 (Lot 192). DiCosolo's patch came from this lot. The recall notice stated, in part, that "[a] small percentage of these patches may leak medication along one edge." The notice further stated that exposure to the patch's gel "could result in an increased exposure to the active opioid component, fentanyl" and that "[s]uch increased exposure can lead to increased drug effect including nausea, sedation, drowsiness, or potentially life-threatening complications."

¶ 8 Plaintiff received a letter regarding the recall shortly after DiCosolo's death. After receiving information from plaintiff's attorney that DiCosolo's patch had come from the recalled lot, the medical examiner changed his conclusions regarding DiCosolo's manner of death from "suicide" to "accident."

¶ 9 On May 12, 2004, plaintiff filed a complaint alleging strict products liability against defendants and asserting defects in the manufacture, design, and labeling of Duragesic®. On March 28, 2005, plaintiff amended his complaint. Both complaints alleged that the patch that DiCosolo was wearing at the time of her death caused her respiratory arrest and death.

¶ 10 On June 21, 2006, the director of process engineering for defendant ALZA Corporation examined the preserved patch that DiCosolo had been wearing at the time of her death and determined that it did not leak and contained no defect. On December 28, 2006, plaintiff filed a second amended complaint that deleted the allegation regarding the patch she was wearing at the time of her death. With respect to the patch that had been removed and discarded on February 14, 2004, the day before DiCosolo's death (the penultimate patch), in an affidavit dated November 17, 2007, plaintiff stated that when he removed the penultimate patch from his wife's back, he "noticed that it slid from her skin, and almost fell off, almost as if all the adhesive material from the patch and large adhesive overlay bandage was gone, leaving a

slick film behind on [her] skin." Plaintiff filed a third amended complaint on July 18, 2008 alleging negligence and strict products liability, and further alleging that "one or more of the two" patches worn by DiCosolo prior to her death contained a manufacturing defect. At trial, plaintiff's theory was that the penultimate patch was defective and the sole cause of DiCosolo's death. The jury returned a verdict in favor of plaintiff. The trial court denied defendants' posttrial motions. This appeal followed.

¶ 11 ANALYSIS

¶ 12 I. Judgment Notwithstanding the Verdict

¶ 13 Defendants argue that the trial court erred in denying their motion for judgment notwithstanding the verdict. Specifically, they contend that plaintiff presented insufficient evidence of product "malfunction" to support a jury verdict based on inferences of a "nonspecific" product defect.

¶ 14 A judgment notwithstanding the verdict (judgment *n.o.v.*) presents a question of law that we review *de novo*. *Knauerhaze v. Nelson*, 361 Ill. App. 3d 538, 547 (2005). A judgment *n.o.v.* should be "entered only in those cases in which all of the evidence, when viewed in its aspect most favorable to the opponent, so overwhelmingly favors movant that no contrary verdict based on that evidence could ever stand." *Pedrick v. Peoria & Eastern R.R. Co.*, 37 Ill. 2d 494, 510 (1967); accord *Maple v. Gustafson*, 151 Ill. 2d 445, 452 (1992). A trial court should not "enter a judgment *n.o.v.* if there is any evidence, together with reasonable inferences to be drawn therefrom, demonstrating a substantial factual dispute, or where the assessment of credibility of the witnesses or the determination regarding conflicting evidence is decisive to the outcome." *Maple v. Gustafson*, 151 Ill. 2d at 454. "[T]he standard for obtaining a judgment notwithstanding the verdict is a very difficult standard to meet and limited to extreme situations only. [Citation.]" (Internal quotation marks omitted.) *Knauerhaze v. Nelson*, 361 Ill. App. 3d 538, 548 (2005). As the Illinois Supreme Court has explained:

> "A trial court cannot reweigh the evidence and set aside a verdict merely because the jury could have drawn different inferences or conclusions, or because the court feels that other results are more reasonable. [Citations.] Likewise, the appellate court should not usurp the function of the jury and substitute its judgment on questions of fact fairly submitted, tried, and determined from the evidence which did not greatly preponderate either way." *Maple v. Gustafson*, 151 Ill. 2d at 452-53.

Additionally, where a jury is presented with the testimony of experts with conflicting opinions, "our task is not to reweigh the evidence and make our own determinations." *Knauerhaze v. Nelson*, 361 Ill. App. 3d 538, 550 (2005).

¶ 15 A plaintiff in a products liability case, must prove three elements: (1) the injury resulted from a condition of the product; (2) the condition was an unreasonably dangerous one; and (3) the condition existed at the time it left the defendant's control. *Suvada v. White Motor Co.*, 32 Ill. 2d 612 (1965). A plaintiff is not required to present expert testimony that the product contained a specific defect. *Tweedy v. Wright Ford Sales, Inc.*, 64 Ill. 2d 570, 574 (1976). In *Tweedy*, our supreme court held that "[a] *prima facie* case that a product was

defective and that the defect existed when it left the manufacturer's control is made by proof that in the absence of abnormal use or reasonable secondary causes the product failed 'to perform in the manner reasonably to be expected in light of [its] nature and intended function.' [Citations.]" *Tweedy v. Wright Ford Sales, Inc.*, 64 Ill. 2d 570, 574 (1976); see also *Erzrumly v. Dominick's Finer Foods, Inc.*, 50 Ill. App. 3d 359, 363 (1977) (noting that *Tweedy* eased plaintiff's burden of proof in a strict liability case).

¶ 16 The *Tweedy* doctrine has been analogized to the *res ipsa loquitur* doctrine in negligence cases. *Id.*; *St. Paul Fire & Marine Insurance Co. v. Michelin Tire Corp.*, 12 Ill. App. 3d 165, 177 (1973). "After *Tweedy*, courts in this State have generally held that a plaintiff need not pinpoint the specific defect in a product in order to recover under strict liability." *Doyle v. White Metal Rolling & Stamping Corp.*, 249 Ill. App. 3d 370, 377 (1993) (and cases cited therein).

¶ 17 Defendants contend that the *Tweedy* doctrine does not apply to the facts of the instant case because plaintiff did not present sufficient evidence of a product "malfunction," *i.e.*, that the penultimate Duragesic® patch did not perform in the manner reasonably expected in light of its nature and intended function. Defendants contend that the questions on appeal are: "(1) what is the nature and quantum of evidence required for a *Tweedy* inference of nonspecific defect when there is no clear evidence of malfunction; and (2) did plaintiff's evidence meet that threshold standard?" Plaintiff does not address defendants' specific argument that he failed to present the required evidence of a "malfunction" but, instead, contends that he presented sufficient evidence of a "nonspecific defect."

¶ 18 At the outset, we note that the product alleged to be defective here, the penultimate patch worn by DiCosolo, was not available because it was discarded by plaintiff. Nonetheless, Illinois courts have acknowledged that the unavailability of the product does not preclude a plaintiff from proving that a product was defective through circumstantial evidence. See, *e.g.*, *Samansky v. Rush-Presbyterian-St. Luke's Medical Center*, 208 Ill. App. 3d 377, 389 (1990) ("the absence of the product at trial is not fatal to the plaintiff's [claim for strict liability]"); *Ralston v. Casanova*, 129 Ill. App. 3d 1050, 1059 (1984) ("it may indeed be possible to introduce sufficient evidence to establish a *prima facie* case of strict liability even in the absence of the allegedly defective product itself"); *Weedon v. Pfizer, Inc.*, 332 Ill. App. 3d 17, 19 (2002) (involving case where physician explanted the allegedly defective device, discarded it before any tests could be conducted for extravasation, *i.e.*, leakage, and the device was never recovered); *Mateika v. La Salle Thermogas Co.*, 94 Ill. App. 3d 506, 510 (1981) (noting generally that "[i]t is possible to introduce sufficient evidence to establish a *prima facie* case of strict liability even in the absence of the allegedly defective product"); *Neighbors ex rel. American States Insurance Co. v. City of Sullivan*, 31 Ill. App. 3d 657, 659 (1975) ("there are numerous cases holding that failure of a machine may be shown by circumstantial evidence and that the machine itself need not be produced at trial"). None of these cases, however, refer to a "malfunction doctrine" or "malfunction theory."

¶ 19 Other jurisdictions have addressed the situation where the actual product is unavailable and have made direct reference to a "malfunction." Under Pennsylvania law "a plaintiff pursuing a case under the *malfunction theory* can assert a successful strict product liability claim based purely on circumstantial evidence in cases where the allegedly defective product

has been destroyed or is otherwise unavailable." (Emphasis added.) *Barnish v. KWI Building Co.*, 980 A.2d 535, 539 (Pa. 2009); see also *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1150 (Fla. Dist. Ct. App. 1981) (noting that the inference has been applied to cases in which the malfunction was such as to cause the product's disappearance); *Living & Learning Centre, Inc. v. Griese Custom Signs, Inc.*, 491 A.2d 433, 436 (Conn. App. Ct. 1985) (defect may be circumstantially proved from the fact of the malfunction).

¶ 20 Defendants argue that *Tweedy* did not change fundamental product liability law or the rule that a defect "cannot be established by the mere fact that an accident or injury has occurred" and contend also that the *Tweedy* doctrine allows an inference of defect from a malfunction, but does not allow an inference of the malfunction itself. Defendants note that "[h]ere, there is no exploding coffee pot, collapsed ladder, or brake pedal that goes all the way to the floor to show malfunction." Defendants assert that, absent this threshold requirement that there be direct evidence of a malfunction in the product at issue, the *Tweedy* doctrine did not apply and the trial court should not have allowed circumstantial evidence of the nonspecific defect. They further argue that plaintiff conflates the distinct concepts of malfunction and inferred nonspecific defect. They assert that "[p]laintiff's formulation of the malfunction doctrine eliminates 'defect' from a *prima facie* product liability case." As noted earlier, plaintiff has not addressed defendants' argument that he failed to meet the threshold requirement of showing that the patch "malfunctioned" and was, therefore, not entitled to any inference of nonspecific defect.

¶ 21 In *Weedon v. Pfizer, Inc.*, 332 Ill. App. 3d 17 (2002), a case involving summary judgment, the plaintiff had a venous access device surgically implanted in his chest for the administration of chemotherapy. The site became inflamed and physicians explanted the device and discarded it before any tests could be conducted for extravasation (leakage). The plaintiff's condition continued to deteriorate and he was left with a large hole in his chest. The plaintiff alleged that the device improperly leaked and allowed the chemotherapy drugs to come in contact with tissues in his chest. The plaintiff did not present evidence of a specific "malfunction" or a specific defect and the circuit court granted summary judgment in favor of the defendants. The plaintiff appealed claiming that he produced "sufficient circumstantial evidence to create a reasonable inference that the product was defective." *Weedon*, 332 Ill. App. 3d at 19. The appellate court agreed.

¶ 22 The appellate court noted that "[a] plaintiff may establish a nonspecific defect claim by circumstantial evidence." *Weedon*, 332 Ill. App. 3d at 22. The court, although not using the term "malfunction," addressed the defendants' argument that the plaintiff had failed to "demonstrate that the device failed to perform in a manner reasonably expected in light of its nature and intended function." *Weedon*, 332 Ill. App. 3d at 30. Acknowledging that the plaintiff had not produced any expert witness to testify "regarding any *specific* defect in the venous access device," the court reviewed the evidence presented by each party and concluded that summary judgment was precluded because the court could not say that "no issue of material fact exist[ed]." (Emphasis added.) *Weedon*, 332 Ill. App. 3d at 30.

¶ 23 Although the procedural posture of *Weedon* differed from that of the instant case, we believe it stands for the principle that a plaintiff need not show a malfunction such as an "exploding coffee pot, collapsed ladder, or brake pedal that goes all the way to the floor" in

order to prove a products liability claim involving a nonspecific defect. As the *Weedon* court noted, "The evidence must be weighed by the finder of fact in order to determine whether the device failed to perform in a manner reasonably to be expected." *Id.*

¶ 24 Defendants now assert that *Weedon* is an "aberration." We believe *Weedon* recognizes the difference between a defect in a medical device residing in, or on, a patient as compared to those defects in products that are actively used and whose operation or performance is clearly observable as might be any performance "failure," *i.e.*, malfunction, such as is observed with an "exploding coffee pot, collapsed ladder, or brake pedal that goes all the way to the floor." Given the nature of the product at issue here, the Duragesic® skin patch, and the way it functions, the patch's "operation" or "performance" is not observable. Thus, it is difficult to envision how a "malfunction" in a patch could ever be observable. Arguably, an observable malfunction might be excessive gel on the skin, and we note that plaintiff testified that he did observe a slick film on DiCosolo's skin when he changed the penultimate patch. Another observable malfunction might be a markedly elevated blood fentanyl level such as 28.2 ng/mL when the only source of fentanyl is the patch that is designed to deliver a level of 1.7 ng/mL.

¶ 25 The requirement that a product "malfunction" before circumstantial evidence of a defect is permitted has been addressed in other jurisdictions. A Florida court has held that absolute positive proof of product malfunction is not necessary where the product is destroyed, provided plaintiff can point to evidence that the cause of the accident most probably originated in the product. *Cassisi v. Maytag Co.*, 396 So. 2d 1140 (Fla. Dist. Ct. App. 1981); see also *Worsham v. A.H. Robins Co.*, 734 F.2d 676, 683 (11th Cir. 1984) (Because the inference of a defect may be applied to cases in which the subject product is lost or destroyed, making even the requirement of proving malfunction difficult, in such cases "absolute positive proof of product malfunction is not necessary."); *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1259 (11th Cir. 2002) (same). Noting that a plaintiff may prove its product liability case, so long as there is sufficient evidence from which the jury could reasonably infer the existence of a defect, a Pennsylvania court decided that "[e]vidence of a malfunction is but one piece of circumstantial evidence that can be used to elicit the inference that a product was in a 'defective condition' " and that a defect could also "be inferred from unexplained occurrences." *Cornell Drilling Co. v. Ford Motor Co.*, 359 A.2d 822, 827 (Pa. Super. Ct. 1976), *overruled on other grounds, REM Coal Co. v. Clark Equipment Co.*, 563 A.2d 128, 134 (Pa. Super. Ct. 1989).

¶ 26 The *Cornell* case involved a truck that caught on fire and the plaintiff was not only unable to point to a specific defect but, because the truck was not in operation when the fire occurred, it could not be said that a "malfunction" had occurred. *Cornell*, 359 A.2d at 826. Therefore, the trial court had dismissed the case. In reversing that decision, the *Cornell* court stated:

> "We refuse to adopt the superficial distinction that proof of a malfunction is the only circumstantial evidence available from which a 'defective condition' in a product can be inferred. ***
>
> Evidence of a malfunction is but one piece of circumstantial evidence that can be

> used to elicit the inference that a product was in a 'defective condition.' '(A) defect can be inferred from unexplained occurrences and need not be directly proved.' [Citation.] As previously noted by Dean Prosser other circumstantial evidence ((1) expert testimony as to possible causes; (2) the occurrence of the accident a short time after the sale; (3) same accidents in similar products; (4) the elimination of other causes of the accident; (5) the type of accident that does not happen without a defect) may permit the inference that the product was defective. [Citation.]" *Cornell*, 359 A.2d at 827.

See also *Barris v. Bob's Drag Chutes & Safety Equipment, Inc.*, 685 F.2d 94, 101 (3d Cir. 1982) (evidence of a malfunction is *one* type of circumstantial evidence that can be used in establishing a defective condition).

¶ 27 An older Illinois case stands for the proposition that proof of a malfunction is only one type of proof that a product did not perform as expected. *Bollmeier v. Ford Motor Co.*, 130 Ill. App. 2d 844 (1970). As the court stated:

> "[D]irect *or* circumstantial evidence which tends to prove that the product failed to perform in the manner reasonably to be expected in the light of its nature and intended function, *such as* proof of a malfunction which tends to exclude other extrinsic causes, is sufficient to make a *prima facie* case on this issue. And the rule in a products liability case as to the proof of a defective condition within the meaning of *Suvada* and *Dunham* does not differ from the rule in other cases as established in *Lindroth v. Walgreen Company*, 407 Ill. 121 at 134, that 'reasonable inferences may be drawn from established facts and all that can be reasonably required to establish controverted facts, whether the evidence be direct or circumstantial, is that the evidence creates a greater or less probability leading, on the whole, to a satisfactory conclusion.' " (Emphasis added.) *Bollmeier*, 130 Ill. App. 2d at 851-52.

¶ 28 Another Illinois court has explained that it is *not* the rule in Illinois that, absent the *Tweedy* doctrine, a case in strict tort liability could be established only through expert testimony. *Millette v. Radosta*, 84 Ill. App. 3d 5, 21 (1980). As the court explained: "The plaintiff may rely on direct or circumstantial evidence to establish his case or on expert testimony [citations]; indeed, expert testimony is merely one kind of circumstantial evidence. [Citation.]" *Id.*

¶ 29 Thus, we conclude that evidence of an obvious malfunction is one type, but not the only type, of evidence that a plaintiff may use to prove that a product failed to perform in the manner reasonably to be expected in the light of its nature and intended function. Plaintiff presented sufficient evidence to show that the Duragesic® skin patch worn by DiCosolo was in a defective condition. We reject the defendants' argument that plaintiff failed to provide the fundamental evidentiary basis that the patch "malfunctioned" entitling defendants to a judgment *n.o.v.*

¶ 30 In addition to other evidence presented by plaintiff, the evidence showed that: the Duragesic® skin patch worn by DiCosolo was designed to deliver a blood fentanyl level of 1.7 ng/mL, which is a drastically lower level than the 28.2 ng/mL found in her system at the time of her death; the medical examiner concluded that DiCosolo died from an overdose of

fentanyl; the source of the fentanyl was defendants' product, the 75 mcg/hr Duragesic® skin patch; and the patch came from a lot that had been recalled by defendants due to the presence of a defect in some of the patches. Although defendants have correctly noted that an accident or injury alone is not sufficient to establish a defect, as one court has explained: "Saying that the patch was defective *because it delivered more fentanyl than intended* is not the same as saying the patch was defective because [the patient] died ***." (Emphasis added.) *Kunnemann v. Janssen Pharmaceutica Products, L.P.*, No. 05 C 3211, 2008 WL 5101116 at 13 (N.D. Ill. Dec. 2, 2008). In view of the evidence presented at trial, defendants have failed to show that "all of the evidence, when viewed in its aspect most favorable to the opponent, so overwhelmingly favors movant that no contrary verdict based on that evidence could ever stand." *Pedrick v. Peoria & Eastern R.R. Co.*, 37 Ill. 2d 494, 510 (1967).

¶ 31 II. Evidentiary Rulings

¶ 32 Having determined defendants have failed to meet their burden for a judgment *n.o.v.*, we next address defendants' alternative argument that they should be granted a new trial because of erroneous evidentiary rulings. Defendants argue that these errors, both standing alone and when combined with plaintiff's improper closing argument, "resulted in an unjust and grossly excessive verdict." Evidentiary rulings are within the sound discretion of the trial court and will not be reversed absent an abuse of discretion. *Cetera v. DiFilippo*, 404 Ill. App. 3d 20, 36-37 (2010). An abuse of discretion occurs only if " 'no reasonable person would take the view adopted by the trial court.' [Citation.]" *Id* at 37. As defendants note, however, when the trial court's decision to admit evidence is based solely on the interpretation of case law the question presented is one of law and our review is *de novo*. *Nolan v. Weil-McLain*, 233 Ill. 2d 416, 429 (2009). An error in the exclusion or admission of evidence does not require reversal unless one party has been prejudiced or the result of the trial has been materially affected. *Cetera*, 404 Ill. App. 3d at 36.

¶ 33 A. Evidence of CNS Depressants Possibly Taken by DiCosolo

¶ 34 Defendants argue that the trial court "gutted [their] causation defense and contributory fault claim by broadly excluding evidence of both prescribed and discontinued central nervous system (CNS) depressants that were available to DiCosolo." The trial court granted plaintiff's motion *in limine* that sought to exclude all evidence or argument regarding drugs that were not found in DiCosolo's system at autopsy. Defendants state that, "[h]ad the trial court not excluded it, [defendants] would have presented evidence that plaintiff picked up a prescription for one of the discontinued drugs–clonazepam–on February 12, 2004, just three days before DiCosolo died." Defendants contend that this evidence "was essential to [defendants'] right to rebut plaintiff's evidence that DiCosolo was on a stable pain regimen that had not changed, and thereby rebut the inference that only a Duragesic® patch could have caused her death." They additionally argue that this evidence "was also critical to support [defendants'] expert opinion evidence that the synergistic effect of several CNS depressants was the cause of DiCosolo's hypoventilation."

¶ 35 Clonazepam was not found in DiCosolo's system at autopsy, nor was it tested for, by the

Cook County medical examiner. Clonazepam had been discontinued by DiCosolo's physician on December 18, 2003. Defendants note that plaintiff did not list clonazepam on the "First Call List" that the Cicero police department provided to the medical examiner. However, clonazepam was listed in plaintiff's lawyer's letter of July 27, 2004 to the medical examiner as a medication that had been prescribed to DiCosolo at the time she died. After receiving the letter, the medical examiner did not take steps to determine if clonazepam was in DiCosolo's blood. Clonazepam was also listed in plaintiff's answers to interrogatories that were filed prior to his deposition that was taken on June 27, 2006.

¶ 36 During plaintiff's deposition, defense counsel asked him whether he had any of DiCosolo's medications or their containers to which plaintiff responded, "I have some of her medications, yes ... which ones, I don't know. I have them locked up." Plaintiff also stated, "The drugs are locked up. That's just in a closet somewhere. I'd have to try to find it." Defense counsel said: "I would ask if you could provide a list of what is there by name, and we'll work it out with counsel here in Chicago. And we'll get pictures or something so we know what's there; okay?" As the trial court noted, in its ruling on defendants' posttrial motions, "After the deposition ***, defendants apparently did not proceed with any action to have pill containers and any remaining pills produced for some months. On September 27, 2006, plaintiff produced empty bottles for inspection. Plaintiff's answers to interrogatories on October 27, 2006, stated that plaintiff threw the remaining pills out within the first few months after his wife died.

¶ 37 At trial, defendants' counsel questioned plaintiff regarding the medications that had been picked up on February 12, 2004. Plaintiff explained that, during his work hours, he would "run in" the pharmacy, ask the pharmacist to refill his wife's medications, and tell the pharmacist he would return to pick them up in 30 to 45 minutes. He stated that he did not request specific medications but, instead, would ask the pharmacist to refill those medications that were due for a refill. Plaintiff stated that the pharmacy would then refill those medications that the computer indicated needed refilling. Plaintiff testified that he did not keep track of which medications his wife was taking and there were times that he had picked up prescriptions that the physician had discontinued. He also testified that his wife knew what medications she was taking and that he recalled one time when his wife had asked him why he had filled a medication that she no longer took.

¶ 38 Plaintiff now argues that to find evidence of the clonazepam refill relevant, "the trial court would have had to indulge at least two major inferences: (1) that Janice DiCosolo actually took the clonazepam shortly before her death; and (2) that the level of clonazepam in her blood at the time of death was a 'substantial factor' in causing her death." Plaintiff asserts that "[e]ach of these inferences was entirely speculative and was unsupported by reliable, admissible evidence" because there is no evidence that DiCosolo ingested clonazepam on any of the three days before her death. Plaintiff further argues that also speculative was the "expert testimony" that defendants proffered that DiCosolo *had* taken the clonazepam. Plaintiff notes, "in none of the cases cited by defendants did a court hold that mere evidence that a person had access to a drug was sufficient to infer [the person] had taken the drug."

¶ 39 It is undisputed that there was no evidence of clonazepam in DiCosolo's blood at the

time of her death. It is equally undisputed, however, that DiCosolo may have had "access" to certain medications, including clonazepam. As defendants note, in addition to this access, "there was a host of circumstantial evidence supporting an inference that a patient who reported a few weeks before that she was 'entering [an] hallucination period' took a familiar pain and sleep aid obtained three days earlier." We agree with defendants that this evidence was relevant to their causation defense that DiCosolo's death was the result of the synergistic effect of several CNS depressants. See, *e.g.*, *Troyan v. Reyes*, 367 Ill. App. 3d 729, 732 (2006) ("Relevant evidence, which tends to prove a fact in controversy or renders a matter in issue more or less probable, is generally admissible."). Moreover, because plaintiff's experts were allowed to testify that nothing had changed in DiCosolo's drug regimen, which permitted the jury to infer that the Duragesic® patch was the cause of her death, the admission of the barred evidence regarding clonazepam would have allowed defendants an opportunity to rebut causation by showing that DiCosolo was *not* "on a stable pain regimen that had not changed." Thus, although there was no direct evidence that DiCosolo ingested these medications, we conclude that the trial court abused its discretion in excluding any evidence of drugs not found in DiCosolo's system at autopsy.

¶ 40 Nonetheless, a party is not entitled to a new trial unless a trial court's erroneous evidentiary ruling was substantially prejudicial and affected the outcome of the trial. *Simmons v. Garces*, 198 Ill. 2d 541, 566-67 (2002). The burden of establishing prejudice and showing that the trial court's error affected the outcome of the trial is on the party seeking reversal. See *Dienstag v. Margolies*, 396 Ill. App. 3d 25, 40 (2009) (citing *Jackson v. Pellerano*, 210 Ill. App. 3d 464, 471 (1991)). Defendants have not met their burden.

¶ 41 Although admission of evidence related to clonazepam may have rendered a matter in issue more or less probable, *i.e.*, whether DiCosolo was on a stable pain regimen that had not changed or whether a synergistic combination of CNS depressants, including clonazepam, was a cause of DiCosolo's death, we do not believe that it would have affected the outcome of the trial. There was overwhelming evidence regarding the defective Duragesic® skin patch causing DiCosolo's death. As plaintiff notes, defendant's expert, Dr. Kearney, conceded that he "did not know one way or the other whether she had clonazepam or Topiramate in her blood." Nor could he state with certainty whether it actually contributed to her death. More importantly, even if the jurors could have inferred that DiCosolo ingested the clonazepam, it would not have changed the undisputed fact that no clonazepam was found in her system.

¶ 42 We further note that, despite their defense theory that DiCosolo's death was caused by a synergistic combination of CNS depressants, as opposed to the markedly elevated blood fentanyl level, defendants themselves never asked for a postmortem blood level for clonazepam or any other drug that was not tested for. An actual blood level result for clonazepam, assuming it existed, would have allowed defendants' experts to rely on a "fact" as opposed to an inference (which was itself based on an inference of ingestion). Despite being informed of the clonazepam access, defendants took no steps to seek a postmortem blood level for clonazepam. This belies their claim that the existence of clonazepam in DiCosolo's blood was *so* crucial to their defense that the trial court's exclusion of the evidence related to clonazepam "gutted" their causation defense. Of course, had defendants taken such steps and had the postmortem blood level of clonazepam been shown to be

negative, their causation defense may have been "gutted" much sooner. In any event, there was no evidence of clonazepam being present in DiCosolo's blood. Thus, any hypothetical question of causation and any expert opinion based upon the presence of clonazepam in DiCosolo's blood would have been based on sheer speculation. The trial court's exclusion of the evidence of drugs not found in DiCosolo's blood, including clonazepam, does not entitle defendants to a new trial.

¶ 43 B. Evidence Regarding Recalls of Defective Duragesic® Patches

¶ 44 Defendants next argue that they were deprived of a fair trial as a result of the trial court's admission of improper recall evidence which "rewarded plaintiff's strategy of abandoning claims based on a patch which could be *proved* to be nondefective, in favor of a claim based on a destroyed patch that could never be examined." (Emphasis added.) Defendants contend that: (1) recall evidence cannot support an inference of a *nonspecific* defect, and (2) only *after* a plaintiff has provided the requisite proof of product malfunction and proof that the malfunction was consistent with the defect triggering the recall, can recall evidence be offered to support an inference of *specific* defect. They assert that plaintiff failed to establish a foundation for the admission of the recall letter because there were only "assumptions" of both malfunction and defect based on the recall letter.

¶ 45 It is undisputed that the Duragesic® patch at issue was from Lot 192, which was recalled the day after DiCosolo's death. Defendants argue, however, that "Illinois law follows federal precedent in allowing recall evidence after plaintiff presents evidence of a product malfunction that is consistent with a defect found in *all* products with that design and that was the subject of the recall." Citing *Calhoun v. Honda Motor Co.*, 738 F.2d 126, 131-33 (6th Cir. 1984), defendants contend that "recall evidence cannot sustain a jury finding of defect absent adequate evidence of a malfunction that is both consistent with the defect that caused the recall and broadly present in the recalled product." Defendants also argue that here, as in *Calhoun*, assumptions provided an "insufficient foundation" to support the introduction of defendants' recall as circumstantial evidence of defect.

¶ 46 In *Calhoun*, the plaintiff brought a products liability claim against the manufacturer of the motorcycle that the decedent was operating at the time of his accident. The district court admitted evidence of a recall letter sent to all owners of the motorcycle as proof of a defect that reduced braking performance when the brakes were exposed to heavy rain. Plaintiff's expert assumed that the brakes on decedent's motorcycle were wet because the motorcycle had gone through a car wash prior to the accident. The Sixth Circuit held that the expert's testimony was insufficient to establish causation, noting that "[a]lthough plaintiff's expert opined that the brakes were wet at the time of the accident, the evidence does not support his conclusion." *Calhoun*, 738 F.2d at 131. The court also stated that the recall letter was inadmissible to establish the existence of a defect because the plaintiff "never submitted evidence independent of the recall letter." *Calhoun*, 738 F.2d at 134.

¶ 47 Plaintiff correctly notes that the *Calhoun* court did not hold that a recall letter was inadmissible because the plaintiff could not prove that the defect was "broadly present in the recalled product." Nonetheless, this concept was discussed in *dicta* in *Millette v. Radosta*,

84 Ill. App. 3d at 20:

> "In several of the cited cases it appears that the letter indicated a defect *might* exist in some cars. Obviously in such instances the letter could not be used to make the transition from the general to the particular and to prove that the vehicle in question contained the defect. [Citation.] But it would be absurd to say that if a letter says all named vehicles without exception contained a defect, the plaintiff cannot use the letter as an admission that the named vehicle was *in fact* defective." (Emphasis added.)

However, as plaintiff here notes, the recall letter here which showed that DiCosolo's patches came from a specific lot that was recalled by defendants due to a leak defect was not used for the purpose of claiming the patch was *in fact* defective. Rather, the recall letter was strong compelling evidence of a defect, *along with the additional evidence of a defect* including DiCosolo's excessive, lethal fentanyl blood level, and the "slick film" plaintiff saw on DiCosolo's skin when he removed her patch, which, according to plaintiff's expert, was "consistent with a patch leaking."

¶ 48 We conclude that the trial court did not abuse its discretion in admitting evidence of defendants' recall of the patches. Admission of the recall evidence did not deprive defendants of a fair trial.

¶ 49 C. Testimony of Plaintiff's Expert, Professor Prausnitz

¶ 50 Defendants also contend that the trial court erroneously allowed plaintiff's expert witness Dr. Mark Prausnitz, to opine on medical issues and to testify that DiCosolo's penultimate patch must have leaked based on medical evidence he was unqualified to analyze. As plaintiff correctly notes, defendants did not object to Dr. Prausnitz's trial testimony on this basis. Plaintiff further notes that the defendants do not "quote or even cite the testimony at issue." We note that defendants addressed Dr. Prausnitz's testimony in some detail, but that was in support of their argument that no malfunction occurred here, an issue we have already addressed.

¶ 51 Plaintiff notes that Dr. Prausnitz, an engineering professor, "has a Ph.D. in chemical engineering that focused on transdermal drug delivery, that he has studied transdermal drug delivery for more than 20 years, that he holds more than 20 patents in the area of transdermal drug delivery, that he teaches courses on transdermal drug delivery, that he has published more than 100 articles on transdermal drug delivery, and that he sits on the editorial boards of the two leading journals in the area of drug delivery." Moreover, as plaintiff correctly notes, "Dr. Prausnitz testified at length regarding the numerous bases for his opinion that the patch at issue leaked." Plaintiff further notes that Dr. Prausnitz's "opinion was based on his analysis of the facts, his education, his experience and training, his review of numerous scientific articles, the 'health hazard analysis' prepared by Defendants, the toxicology report relating to Janice DiCosolo, the history of leaking patches produced by the Defendants and the fact that Janice DiCosolo's patch came from a lot that was recalled due to leaking patches." We conclude that the trial court's decision to allow Dr. Prausnitz's testimony was not error.

¶ 52 D. Admission of E-mail and Testimony of Plaintiff's Expert, Michael Anisfeld

¶ 53 Defendants also argue that the trial court erroneously allowed Michael Anisfeld, a pharmacist, to "opine regarding [defendants'] alleged fraud on the [Food and Drug Administration (FDA)]." They further contend that the e-mail forming the basis for Mr. Anisfeld's testimony was erroneously admitted.

¶ 54 1. E-mail

¶ 55 The document at issue was defendants' internal e-mail dated January 28, 2005 which stated: "It is very difficult to partner with the FDA if we keep deceiving them. If we keep deceiving them, we can't partner with them." Defendants contend that the e-mail was "an inflammatory document that had no relevance to any claim." They also contend that the inherent prejudice of the e-mail was enhanced because the author was deceased, his comments went unexplained, and plaintiff capitalized on this during closing argument.

¶ 56 Plaintiff contends that defendants "opened the door to the e-mails at issue by stating repeatedly in opening statement that Defendants were acting as partners with the FDA, that they were working in tandem with the FDA in developing a safe product and that the FDA concluded that their labeling gave adequate information to prescribing physicians." Defendants also stated that they "were fully cooperating with the FDA" during the 2004 recall and that "the FDA was satisfied with [their] conduct and cooperation during the recall." Plaintiff asserts that this e-mail "was consistent with other e-mails, which are not mentioned in [defendants' brief], which further demonstrate that Defendants were not accurately communicating with the FDA and were instead providing the FDA with 'misinformation.' "

¶ 57 As noted earlier, a trial court's evidentiary rulings will not be reversed absent an abuse of discretion. Defendants have failed to show that the trial court abused its discretion in admitting the e-mail.

¶ 58 2. Testimony

¶ 59 Defendants additionally claim "Mr. Anisfeld's 'opinion' that '[i]t is a federal offense if you are not candid' with the FDA, and that [defendants] violated a duty of 'truth' because [defendants] allegedly 'did not shoot straight with the FDA and deceived the FDA,' was irrelevant, highly inflammatory, and erroneously admitted for at least three reasons." These three reasons can be summarized as follows: any violation of FDA regulations constitutes a legal matter and improperly invaded the province of the jury; (2) Mr Anisfeld, a pharmacist, was not qualified to opine on legal issues; and (3) whether defendants "deceived the FDA" was not relevant to any claim in this case.

¶ 60 Once defendants' internal e-mails were admitted, they were properly relied upon by Mr. Anisfeld. Plaintiff notes that the e-mails were offered to rebut defendants' "attempts to insulate themselves from liability by relying on the FDA's alleged approval of their actions." As plaintiff notes, he did not assert a claim for "fraud on the FDA." Plaintiff also notes that

Mr. Anisfeld's testimony was not offered for the proposition that defendants "had violated specific FDA regulations or federal law." Thus, defendants' contentions that the trial court abused its discretion in allowing Mr. Anisfeld's testimony regarding the FDA fails.

¶ 61 III. Closing Argument

¶ 62 Defendants also argue that they are entitled to a new trial based on plaintiff's inflammatory "punitive" closing argument. Defendants moved for a mistrial following the initial closing argument in which plaintiff's counsel repeatedly accused defendants of "killing" DiCosolo and "corporate greed run amok." Plaintiff's counsel also made a comment that defendants presented a "frivolous defense." Defendants also sought a new trial based on the allegedly improper closing argument after the jury returned a verdict that defendants state was "grossly excessive" and "punitive."

¶ 63 Defendants now argue that the trial court abused its discretion by concluding that: (1) plaintiff's argument did not "quite g[e]t to" the level of misconduct required for a mistrial, and (2) the argument did not "cross the line." Plaintiff, without citation to any authority, asserts that "where, as here, the evidence established that Janice DiCosolo died because of defendants' product *** the use of the word 'kill' is simply not improper or prejudicial." Plaintiff further notes that he never argued that the jury should punish defendants, send a message to defendants, or base their damage award on defendants' improper conduct or motives. Plaintiff also argues that defendants did not object to these remarks when they were made at trial.

¶ 64 We first address the lack of a timely objection. Plaintiffs, citing *Hubbard v. Sherman Hospital*, 292 Ill. App. 3d 148, 156-57 (1997), correctly note that "Under Illinois law, the failure to timely object to alleged errors during closing argument is deemed a waiver of any such error." Defendants argue now, without citation to authority, that this failure to timely object to plaintiff's closing argument should be excused because they raised their objection in a motion for a mistrial. This pattern of failing to take steps to allow any "corrective" action to be taken and later claiming reversible error on appeal should not be condoned. Similar to defendants' failure to timely request the blood level for clonazepam when it was available, and argue later that such evidence was so crucial that its exclusion "gutted" their defense theory, defendants failed to timely object to the closing argument and allow corrective action, but instead assert on appeal that the unobjected-to comments were so inflammatory and prejudicial that they caused a grossly excessive verdict that must be reversed. Waiver or forfeiture aside, we conclude that the comments do not warrant a new trial.

¶ 65 Defendants correctly note that it is error for counsel to make overt appeals to the emotions, passions, or prejudices of the jury. See, *e.g.*, *Pleasance v. City of Chicago*, 396 Ill. App. 3d 821, 828 (2009) (holding that the plaintiff's counsel's "repeated improper and prejudicial comments require[d] the granting of a new trial"). Plaintiff, however, notes that "a trial court is in the best position to observe the arguments of counsel and the atmosphere of trial, and to make a determination about its effect on the jury."

¶ 66 As this court recently explained:

> "Although improper argument and attorney misconduct can be the basis for

granting a new trial, that determination is left to the sound discretion of the trial court and should not be disturbed on appeal absent an abuse of discretion. [Citations.] In arguing a case to the jury, counsel is allowed broad latitude in drawing reasonable inferences and conclusions from the evidence. [Citation.]. Questions as to the prejudicial effect of remarks in closing statements are within the discretion of the trial court and the results are affirmed absent an abuse of discretion. [Citation.] Even improper arguments will not warrant reversal without a substantial showing of prejudice. [Citation.] Parties are entitled to a fair trial, not a perfect trial. [Citation.]

The standard of reviewing a claim of improper argument is whether the argument was of such a character as to have prevented a fair trial. [Citation.] The trial court is in a unique position to gauge the effects of misconduct, having heard all of the testimony and arguments and having observed the parties and their effect on the jury. [Citation.] The attitude and demeanor of counsel, as well as the atmosphere of the courtroom, cannot be reproduced in the record, and the trial court is in a superior position to assess and determine the effect of improper conduct on the part of counsel. [Citation.] Where the jury hears an improper comment by counsel, the trial court's prompt action in sustaining an objection can cure the possible error. [Citation.] Where, as here, the trial court tells the jury that closing arguments are not evidence, the scope and character of the arguments are left to the trial court and will not be reversed absent an abuse of discretion. [Citation.] In addition, if the trial was fair as a whole and the evidence was sufficient to support a jury's verdict, a case will not be reversed upon review. [Citation.]" (Internal quotation marks omitted.) *Wilbourn v. Cavalenes*, 398 Ill. App. 3d 837, 854 (2010).

With these principles in mind, although we disapprove of the comments made by plaintiff's counsel, we cannot say that they warrant a new trial.

¶ 67 IV. Remittitur

¶ 68 In the alternative to defendants' argument for a new trial, they contend that, at a minimum, they are entitled to a remittitur. Defendants cite *Mikolajczyk v. Ford Motor Co.*, 374 Ill. App. 3d 646 (2007), *rev'd on other grounds*, 231 Ill. 2d 516 (2008), in support of their argument for remittitur. In *Mikolajczyk*, a defective design action was brought against manufacturers by the widow of a driver who had been killed when his vehicle was struck from behind. The *Mikolajczyk* court concluded that the award of loss of society damages in the amount of $25 million was excessive. Instead of ordering a new trial, however, the court concluded that remittitur was the proper remedy. The case was remanded to permit the trial court to conduct a hearing to determine the appropriate amount of remittitur.

¶ 69 "Where a jury verdict ' "falls outside the range of fair and reasonable compensation or results from passion or prejudice, or if it is so large that it shocks the judicial conscience,' " a court has a duty to correct the verdict by ordering a remittitur, with the plaintiff's consent. [Citation.]" *Lebron v. Gottlieb Memorial Hospital*, 237 Ill. 2d 217, 234 (2010). Whether remittitur should be allowed is "considered on a case-by-case basis because the evidence and circumstances supporting verdicts must be carefully examined before a jury's assessment of

damages is reduced." *Best v. Taylor Machine Works*, 179 Ill. 2d 367, 413 (1997). The *Best* court noted examples of cases where courts had allowed remittitur. See, *e.g.*, *Richardson v. Chapman*, 175 Ill. 2d 98, 121 (1997) (remitting one plaintiff's $11 million award for future medical expenses by $1 million and reducing by half the other plaintiff's pain and suffering award); *Carter v. Kirk*, 256 Ill. App. 3d 938 (1993) (finding that trial court properly granted $20,000 remittitur where the jury's verdict was excessive because medical evidence failed to support the plaintiff's claims). The court also noted cases in which courts had declined to enter a remittitur, "even in cases involving large awards, because the evidence supported the jury's verdicts." *Best*, 179 Ill. 2d at 413 (citing *Holston v. Sisters of the Third Order of St. Francis*, 165 Ill. 2d 150 (1995) (declining to reduce as excessive a $7.3 million verdict in a wrongful death and survival case); *Barry v. Owens-Corning-Fiberglas Corp.*, 282 Ill. App. 3d 199, 208 (1996) (declining to apply a remittitur to $12 million verdict).

¶ 70 We cannot say that the verdict in this case "falls outside the range of fair and reasonable compensation" or "is so large it shocks the judicial conscience." We therefore deny defendants' request for a remittitur.

¶ 71 CONCLUSION

¶ 72 In accordance with the foregoing, we affirm the judgment of the circuit court of Cook County.

¶ 73 Affirmed.