

No. 1-05-2332

GORDON GREDELL,	)	Appeal from the
	)	Circuit Court of
Plaintiff-Appellant,	)	Cook County
	)	
v.	)	
	)	
WYETH LABORATORIES, INC., and AMERICAN	)	
HOME PRODUCTS COMPANY,	)	Honorable
	)	Dorothy Kirie Kinnaird,
Defendants-Appellees.	)	Judge Presiding.

JUSTICE KARNEZIS delivered the opinion of the court:

Plaintiff Gordon Gredell appeals from an order of the circuit court dismissing his class action consumer fraud suit against defendants Wyeth Industries, Inc., and American Home Products Company. Plaintiff's suit alleges that defendants fraudulently marketed and sold five prescription drug products, known as the Phenergan Expectorants, as cough and cold remedies which would provide expectoration and anesthetic relief of sore throat knowing that they had no scientific support for making either representation. The court originally dismissed plaintiff's and the class's claims in 2001, finding that, because plaintiff failed to prove defendants fraudulently concealed his cause of action, his claims were time barred pursuant to the statute of limitations for

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the Illinois Consumer Fraud and Deceptive Business Practices Act (815 ILCS 505/1 *et seq.* (West 2002) (formerly Ill. Rev. Stat. 1991, ch. 1211/2, par. 261 *et seq.*) (the Consumer Fraud Act or the Act). The court also found the claims were preempted by the Federal Food, Drug and Cosmetic Act of 1938 (21 U.S.C. § 301 *et seq.* (2000)) (the FDCA).

In *Gredell v. Wyeth Laboratories, Inc.*, 346 Ill. App. 3d 51, 803 N.E.2d 541 (2004), we affirmed the court's finding that plaintiff failed to prove defendants' fraudulent concealment but reversed the court's dismissal of the cause of action as time barred and preempted because the preemption issue had not been before the court and the court failed to consider application of the discovery rule to the statute of limitations issue. We remanded for further proceedings. On remand, in the order at issue here, the court again dismissed plaintiff's and the class's cause of action. Plaintiff argues on appeal that the court erred in finding (1) the claim barred by the statute of limitations, notwithstanding application of the discovery rule; (2) the claim preempted by federal law; and (3) plaintiff failed to prove his claim under the Consumer Fraud Act. We affirm.

#### Background

The salient facts and history of the case are little changed since our exposition in *Gredell*, 346 Ill. App. 3d 51, 803 N.E.2d 541. In short, on February 9, 1973, the Food and Drug Administration (FDA) published its proposal to withdraw its approval of the Phenergan Expectorants in the Federal Register because, defendants having performed no clinical studies for the drugs' effectiveness for expectoration or soothing

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anesthetic relief, the FDA panel investigating the Phenergan Expectorants' efficacy claims could not substantiate those claims. Rather than perform the studies necessary to meet FDA approval, defendants obtained FDA approval of reformulated versions of the drugs and, on August 15, 1984, took the Phenergan Expectorants off the market.

Plaintiff's third amended complaint, filed individually and on behalf of all others similarly situated, alleged defendants engaged in false and deceptive conduct in their marketing of the Phenergan Expectorants in violation of the Consumer Fraud Act and similar statutes existing in other states by misrepresenting the effectiveness of the Phenergan Expectorants for the period from February 9, 1973, to approximately August 15, 1984. Plaintiff asserted defendants falsely represented that each of the five products was an effective expectorant as well as an effective sore throat anesthetic through package inserts, labels and other marketing materials, despite having no reasonable basis for making the effectiveness claims nor scientific evidence to support the claims. Plaintiff also alleged defendants' conduct was unfair and deceptive because they failed to disclose that the FDA had determined defendants had no substantial evidence for the efficacy claims and had failed to include FDA-mandated disclosures of the FDA's findings on their marketing materials. Plaintiff asserted that he and the class members were damaged as a result of defendants' unfair and deceptive practices because the drugs were prescribed for and bought by plaintiff and the class members on the basis of the false claims.

The court bifurcated the trial, holding a hearing to determine whether defendants

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fraudulently concealed plaintiff's cause of action from him such that the applicable statute of limitations for his claim was tolled. After a four-month trial on that issue and a five-year deliberation period, the court dismissed plaintiff's case with prejudice, finding that the case was barred by the statute of limitations because plaintiff failed to prove fraudulent concealment of his cause of action such that the Consumer Fraud Act's three-year statute of limitations (815 ILCS 505/10a (e) (West 2004)) was tolled and because it was preempted by federal law. We reversed and remanded, ordering the court to consider plaintiff's assertion that the discovery rule tolled the statute of limitations and to give plaintiff an opportunity to be heard on the preemption issue. *Gredell*, 346 Ill. App. 3d 51, 803 N.E.2d 541 . On remand, with both parties standing on the evidence previously submitted but submitting additional briefs, the court again dismissed the action as barred by the statute of limitations and preempted by federal law and also held that plaintiff failed to prove his claim under the Consumer Fraud Act. Plaintiff timely appealed each of the court's bases for dismissal.

#### Analysis

In his third amended complaint, plaintiff argued defendants lacked a reasonable basis for claiming that the Phenergan Expectorants were effective for cough relief and expectoration as claimed on the drugs' package inserts, labels, advertising and marketing materials and such unsupported claims of effectiveness constituted false and deceptive conduct in violation of the Consumer Fraud Act. The legislature enacted the Consumer Fraud Act as "a regulatory and remedial statute for the purpose of protecting

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consumers and others against fraud, unfair methods of competition, and unfair or deceptive acts or practices in the conduct of any form of trade or commerce." *Price v. Philip Morris, Inc.*, 219 Ill. 2d 182, 233-34, 848 N.E.2d 1, 32-32 (2005). Pursuant to section 2 of the Act:

"Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act', approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby." 815 ILCS 505/2 (West 2004).

Section 10a (a) of the Act authorizes a private cause of action for any person who suffers actual damage as a result of practices proscribed by section 2. 815 ILCS 505/10a (a) (West 2004); *Avery v. State Farm Mutual Automobile Insurance Co.*, 216 Ill. 2d 100, 179, 835 N.E.2d 801, 849-50 (2005).

To prove a private cause of action under the Act, plaintiff must establish: (1) a deceptive act or practice by defendants, (2) defendants' intent that plaintiff rely on the deception, (3) the deception occurred in the course of conduct involving trade or commerce, and (4) actual damage to plaintiff (5) proximately caused by the deception.

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*Avery*, 216 Ill. 2d at 180, 835 N.E.2d at 850. Plaintiffs must prove these elements by a preponderance of the evidence, *i.e.*, each element must be found to be more probably true than not true. *Avery*, 216 Ill. 2d at 191-92, 835 N.E.2d at 856-57. We review the trial court's decision that plaintiff failed to prove these elements under the manifest weight of the evidence standard (*Avery*, 216 Ill. 2d at 190, 835 N.E.2d at 856) and affirm the court's finding.

In order to sustain a cause of action under the Act, plaintiff must show that he suffered damage as a result of defendants' violation of the Act. 815 ILCS 505/10a (a) (West 2004). Plaintiff alleged that defendants' violation consisted of fraudulently and falsely representing the Phenergan Expectorants' effectiveness for cough relief and as an expectorant without a reasonable basis or valid scientific evidence for those claims and, therefore, marketed a product for which they had no scientific evidence of its value as they had represented it. Plaintiff also alleged that defendants failed to disclose that the FDA determined that there was no substantial evidence of the effectiveness claims and they, therefore, engaged in unfair and deceptive acts or practices, as a result of which drugs were prescribed and purchased by plaintiff and the class for which there was no valid scientific evidence supporting their efficacy and plaintiff and the class were damaged as a result. However, plaintiff proved no such damage. Plaintiff believed the drugs were effective and never complained to anyone that the drugs did not work. He stated he based his belief on the fact that the products were on the market and his doctor, Dr. Brooks, prescribed them but, when asked at trial whether he got relief when

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he took the Phenergan Expectorants, plaintiff responded "I guess so, yes. I don't know." If plaintiff got relief from taking the Phenergan Expectorants, what is his damage?

Plaintiff did not claim that the drugs were ineffective. Indeed, he admits he did not and could not prove they were ineffective. Rather, his claim was that defendants violated the Act because they could not support their claim of the drugs' effectiveness with "scientific" tests proving that effectiveness. Lack of substantiation is deceptive only when the claim at issue implies there is substantiation for that claim, *i.e.*, if defendants had claimed something along the lines of "tests show that Phenergan Expectorant Plain is effective for cough suppression" or "Phenergan Expectorant Plain is more effective for cough suppression than XYZ Expectorant." See *Bober v. Glaxo Wellcome, PLC.*, 246 F.3d 934, 939 fn.2 (7th Cir. 2001), citing *BASF Corp. v. Old World Trading Co.*, 41 F.3d 1081, 1088-91 (7th Cir. 1994) (discussing a plaintiff's burden of proof in the context of a challenge to allegedly false/unsubstantiated advertising claims under the Lanham Act). Merely because a fact is unsupported by clinical tests does not make it untrue

This is especially true where, as here, there was testimony that the ingredients in the Phenergan Expectorants were effective for the claimed relief. Plaintiff's physician Dr. Brooks, an ear, nose and throat specialist, testified that he had prescribed Phenergan Expectorant for expectoration and sore throat relief more than 10,000 times and had never received a complaint that the product did not work as desired. Dr. Lasagna, a physician and professor of pharmacology serving as an advisor to the FDA

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on drug development policy, testified that it is not possible to conclude that a drug is ineffective or lacks the claimed therapeutic benefits merely because a manufacturer does not have two clinical trials to support the claims. Dr. Deitch, vice president of medical affairs for Wyeth in 1989, agreed with Dr. Lasagna that absence of clinical data does not make a drug ineffective, noting there is a difference between actual clinical effectiveness (a drug's effect on patients) and legal effectiveness (whether clinical effectiveness is supported by sufficient clinical studies to support regulatory approval). Dr. Crout, a physician and pharmacologist and erstwhile director of the FDA's Bureau of Drugs, and Dr. O'Donnell, a pharmacologist and pharmacist, testified that, given the active ingredients in the Phenergan Expectorants, defendants could reasonably believe that the products had antitussive and anesthetic properties. Credibility of witnesses, the weight to be accorded their testimony and reasonable inferences therefrom are for the trial court to determine. *People v. Milka*, 211 Ill. 2d 150, 178, 810 N.E.2d 33, 49 (2004). The court stated that it found Drs. Lasagna, Crout and O'Donnell extremely persuasive and the evidence does not show otherwise. Accordingly, if plaintiff admitted getting relief from use of the drugs and could not otherwise show the drugs were ineffective, he has suffered no actionable damage.

Moreover, although a plaintiff's reliance on an alleged fraud is not an element of statutory consumer fraud, a valid consumer fraud claim must show that the alleged fraud proximately caused the plaintiff's injury. *Connick v. Suzuki Motor Co.*, 174 Ill. 2d 482, 501, 675 N.E.2d 584, 593 (1996). In order to show proximate cause under the Act,

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plaintiff must establish that he was " 'in some manner, deceived' " by defendants' alleged misrepresentations regarding the Phenergan Expectorants' effectiveness. *Avery*, 216 Ill. 2d at 200, 835 N.E.2d at 861, *quoting Oliviera v. Amoco Oil Co.*, 201 Ill. 2d 134, 155, 776 N.E.2d 151, 164 (2002). Plaintiff cannot and did not establish that here. Since the Phenergan Expectorants were marketed to doctors and pharmacists directly, not to individual consumers, the alleged misrepresentations and/or omissions on the Phenergan Expectorants' labels, packaging inserts and advertising materials were not seen by the public at large. Plaintiff testified he was not aware of defendants' claims regarding the drugs besides the fact that the word "expectorant" was in the products' name. To his knowledge, he had not received any materials regarding the Phenergan Expectorants. If plaintiff never saw the alleged misrepresentations, he cannot have been deceived by them and any misrepresentation cannot have proximately caused him injury.

The evidence supports the court's finding that plaintiff failed to prove his Consumer Fraud action because he failed to prove he suffered damage from defendants' alleged deceptive conduct or that this conduct proximately caused his damage. Because we affirm the court's holding that plaintiff failed to prove damages and proximate cause under the Consumer Fraud Act, we need not belabor the issue of whether defendants committed a deceptive act under the Act. Similarly, because we affirm the trial court on its finding that plaintiff failed to prove an action under the Consumer Fraud Act, we need not address plaintiff's remaining assertions on appeal.

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For the reasons stated above, we affirm the order of the circuit court.

Affirmed.

HOFFMAN, P.J., and THEIS, J., concur.