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Honorable Chief Justice Ronald M. George
and Associate Justices
California Supreme Court
350 McAllister Street
San Francisco, CA 94102-4783

RE: ***Elizabeth Ann Conte v. Wyeth, Inc.***
Petition for Review Filed December 17, 2008
Supreme Court, Case No. S169116
First Appellate District, Div. 3, No. A117353
San Francisco Superior Court, No. CGC04437382

Dear Chief Justice George and Associate Justices:

Amicus curiae Chamber of Commerce of the United States of America ("the Chamber") writes pursuant to Rule 8.500(g)(1) in support of Wyeth, Inc.'s petition for review of the issue of whether a product manufacturer owes a duty to those who did not purchase its product, in this case, a name-brand prescription drug, to warn of risks faced by users of a copy of its product, here, a generic version, sold by a competitor.

The Chamber is the world's largest business federation, representing an underlying membership of more than three million companies and professional organizations of all sizes and in all industries. The Chamber advocates for its members in matters before the courts, Congress, and executive branch agencies. It regularly files amicus briefs in cases raising issues of vital concern to the nation's business community. In addition to the nearly 30,000 Chamber members located in California, countless others do business in the state and are directly affected by its litigation climate. The Chamber believes that the First Appellate District's decision violated well-established tort law and established unsound public policy through an unprecedented expansion of the duty of a manufacturer to allow claims based on an alleged failure to warn of the risks of a product that it did not manufacture and from which it did not profit. The Chamber has a strong interest in urging this Court to reverse this first-of-its-kind decision, as it may provide an unsound precedent for expansion of duty in other areas of the law or in other states.

This case should be of significant interest to this Court because the lower court's decision dramatically extends a manufacturer's duty, contradicts rulings in every other jurisdiction that has considered this novel legal question, and would lead to perverse outcomes. The Chamber does not believe such a fundamental change in the common law is appropriate, but if the law were to change in this direction, it should be supported by necessity, sound legal public policy, and the imprimatur of this Court.

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I. This Court Should Grant Review to Correct the Lower Court's Faulty Premise.

A fundamental problem with the First Appellate District Court of Appeals' decision is that the core of its holding is rooted in a faulty premise: that a defendant *who authors and disseminates information about a product manufactured and sold by another* may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury." Op. at *11 (emphasis added). The case at bar, however, does not involve any statement that the Petitioner, Wyeth, made about the *generic* drug taken by the plaintiff.

As is the norm with prescription medicines, Wyeth researched, developed and sold medication under a brand name, in this instance, Reglan™. In coordination with the United States Food & Drug Administration ("FDA"), Wyeth authored and disseminated information about Reglan, including through labeling and publication in the Physician's Desk Reference. *See* Op. at *14. There is no hint of any allegation that Wyeth veered from this path and made any representations or misrepresentations about a different product, a generic drug manufactured by another company, consumed by the plaintiff. Rather, the lower court extended Wyeth's duty to the consumer of a generic competitor solely on the basis that the plaintiff's doctor "'probably' read Wyeth's monograph on Reglan in the [Physician's Desk Reference] during his residency training," years earlier. *Id.* at *7, 14 (tying the allegations against Wyeth with regard to the generic medicine to "Wyeth's representations about Reglan").

None of the three cases that form the lynchpin of First Appellate District's decision involve liability for another's conduct or product stemming from statements made solely about one's own conduct or product. *See* Op. at *13-14. In two of these cases, liability is based on specific representations that defendants made regarding other people, not itself. *Garcia v. Superior Court* (1990) 50 Cal.3d 728; *Randi W. v. Muroc Joint Unified School Dist.* (*Randi W.*) (1997) 14 Cal. 4th 1066. In *Garcia*, the court extended a parole officer's duty of care when he "chose to communicate information about the parolee to the victim." *See* Op. at *13. He had told the victim that the parolee would "not come looking for her" after his release, but he did. *Id.* Likewise, in *Randi W.*, the court found that a school district owned a duty of care to a former employee's molestation victim because the district made specific misrepresentations about the former employee in a letter of recommendation based on which he was given his new employment. *Id.* The court's faulty reasoning also led it to improperly invoke the landmark case, *Rowland v Christian*, 69 Cal .2d 108 (1968). *Rowland* addressed the duty of landholders to people who enter the landholder's *own* property. *Rowland* does not discuss the duty of an owner of land to warn persons who are going onto *someone else's* property of potential danger.

This Court should grant review to clarify the difference between making a statement about one's own product and making a representation about another's product. This is a critical distinction that must be fully considered if California courts are to impose an entirely new tort duty that would subject all name-brand prescription drug

manufacturers to liability for injuries allegedly stemming from medicines sold by their generic competitors, and could be broadly applied to impose a duty on name-brand manufacturers of any product for the design or adequacy of warnings used on similar products created and sold by other manufacturers.

II. Should the First Appellate District's Ruling Stand, it Will Impose an Unprecedented Tort Duty on Manufacturers to Warn of Potential Dangers of Lower-Cost Copies Designed, Manufactured, and Sold by Competitors.

The fact that a generic manufacturer of prescription medicines copies the formula and labeling of a name-brand drug does not provide cause for creating an entire new tort duty between the manufacturer of the brand medicine and a consumer of the drugs made and sold by a generic competitor. In California, "the general rule is that all persons have a duty to use ordinary care to prevent others from being injured as a result of their conduct." *Randi W. v. Muroc Joint Unified Sch. Dist.* (1997) 14 Cal.4th 1066, 1077 (citing *Rowland v. Christian* (1968) 69 Cal.2d 108, 112). Under longstanding California precedent, recognized yet not applied by the First Appellate District, imposing a tort duty beyond the general rule is only warranted after a multi-factor analysis considering: (1) the foreseeability of harm to the plaintiff; (2) the degree of certainty that the plaintiff suffered injury; (3) the closeness of the connection between the defendant's conduct and the plaintiff's injury; (4) the moral blame attached to the defendant's conduct; (5) the policy of preventing future harm; (6) the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach; and (7) the availability, cost, and prevalence of insurance for the risk involved. *Rowland*, 69 Cal.2d at 112-13.

Instead of analyzing these essential factors, the lower court impermissibly took a "pass," so to speak. *See* Op. at *16. As the court reasoned:

> [W]hile there is much that could and will be said in various fora about the burdens, social consequences, costs and insurance applications of Wyeth's potential liability [in extending its duty beyond that owed to an actual consumer of its product] the limited record on summary judgment does not provide the information necessary to inform such a debate. The broader consequences of that duty we identified today cannot be considered on the limited facts in the record.

Id. at 16. The lower court's candor may be admirable, but also shows a surprising lack of interest in determining whether the proposed major extension of duty is warranted, especially when it is one that has not been embraced by any other court in the United States.

The seminal two cases in which plaintiffs who admittedly never used a name-brand drug but nevertheless sued the name-brand manufacturer for injuries allegedly stemming from the generic version are *Foster v. American Home Prods. Corp.* (4th Cir.

1994) 29 F.3d 165 and *Colacicco v. Apotex, Inc.* (E.D. Pa. 2006) 432 F. Supp.2d 514. In both cases, the court rejected plaintiff's claim against name-brand manufacturers for injuries caused by the generic drug because the branded manufacturer owed no duty to the users of other manufacturers' products. *See Foster*, 29 F.3d at 171; *Colacicco*, 432 F. Supp.2d at 539. Further, both courts agreed that "to impose a duty in [these circumstances] would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171; *Colacicco*, 432 F. Supp.2d at 540. According to the *Foster* court, "The premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a brand manufacturer when another manufacturer's drug has been consumed." *Foster*, 29 F.3d at 170. While the reasoning of the U.S. Court of Appeals for the Fourth Circuit is persuasive only, "'a review of the case law reveals that every state and federal district court which has confronted the issue of innovator-drug-manufacturer liability has either adopted the *Foster* reasoning or cited *Foster* with approval.'" *Goldylch v. Eli Lilly & Co.* (N.D.N.Y. July 19, 2006) No. 5:04-CV-1477, 2006 WL 2038436, at *5 (quoting *Colacicco*, 432 F. Supp.2d at 540). Courts continue to reject such a duty.[1]

Where existing law does not support a negligence claim and a court is to extend existing law, as is the situation in this case, the burdens, social consequences, costs, and insurance implications are the very matters that a court should carefully consider in evaluating such an expansion. Unless these factors support an extension, the "leap of change" should be rejected.

The Court should grant review in this case to examine whether the factors support placing a new duty of care on manufacturers of name-brand products to warn of dangers from similar products manufactured and sold by others. For example, the Court should consider whether there is any evidence that placing a duty on the actual manufacturer of the product used by the plaintiff, as provided by current tort law, is insufficient to assure adequate incentives to prevent risks of harm. In this instance, the manufacturers of the actual products at issue are viable defendants named in the lawsuit. They produce and profit from their own products. Under existing law, generic manufacturers have the power to seek modifications to warnings that accompanied the name-brand drug and have their own obligations to participate in post-market analysis and reporting. The addition of a name-brand defendant appears to provide only an additional and unwarranted deep pocket.

The Court might also grant review to consider the cost of the new liability to manufacturers of name-brand pharmaceutical products, the impact of the expanded duty

[1] *See, e.g., Smith v. Wyeth, Inc.* (W.D. Ky. June 30, 2008) No. 5:07-CV-18-R, 2008 WL 2677051, at *4 (finding that "Kentucky does not recognize [sic] a cause of action against a manufacturer for its representations concerning its own product, based on an injury caused from the use of another manufacturer's product"); *Stanley v. Wyeth, Inc.* (La. Ct. App. 2008) 991 So. 2d 31, 34-35 (finding brand name manufacturer owned no duty to consumer of generic drug regardless of the theory of liability); *Pustejovsky v. Wyeth, Inc.* (N.D. Tex. Apr. 3, 2008) No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (finding that a name-brand manufacturer's lack of duty to a generic drug consumer "is fatal to all her common law claims").

on insurance rates, and the disincentive such a duty would place on research and development of new, potentially life saving products. Such costs could amount to billions of dollars of new liability on name-brand manufacturers, who would remain subject to tort claims even after its patent expires and sales of their own products cease or greatly diminish due to the availability of a lower cost generic alternative. Moreover, it stands to reason that liability insurance purchased by name-brand manufacturers did not account for the risks of products sold by competitors. Manufacturers pay extremely high insurance rates for current exposure for their own name-brand products. Adding new and uncharted liability exposure for products that they did not make will lead to even higher insurance costs. Such costs would be passed on to consumers of prescription drugs and limit accessibility to needed medications for some patients. Such considerations, which were not addressed by the lower court, all demonstrate the importance of review by this Court.

III. The New Form of Vicarious Liability Created by the First Appellate District Should Be Closely Reviewed and Rejected by this Court.

It is also important this Court grant review of this case to bring it into accord with fundamental principles of vicarious liability that would not permit holding one party responsible for the acts of another when there is no control, contractual relationship, or profit sharing between the parties.

Vicarious liability permits an innocent party to be liable for the tortious conduct of another in highly limited circumstances. It is "an important exception to the usual rule that each person is accountable for his own legal fault but in the absence of such fault is not responsible for the actions of others." Dan B. Dobbs, The Law of Torts § 333, at 905 (2000); *see also Srithong v. Total Investment Co.* (1994) 23 Cal.App.4th 721, 726 (recognizing that "vicarious liability is a departure from the general tort principle that liability is based on fault"). As such, application of this principle should be strictly construed.

Vicarious liability developed based on the principle that one who controls the actions of another should be liable for the torts committed by that person under his or her direction. It was first applied in cases involving slaves and servants, and then expanded to employees and other situations. *See* W. Page Keeton et al., Prosser & Keeton on the Law of Torts § 69, at 500 (5th ed. 1984). Vicarious liability is most often placed upon employers for the acts of employees committed during the scope of employment, under the reasoning that the employer has a degree of control over the conduct of its employees and should bear the risk of injuries that occur during the course of their usual operations. Vicarious liability also applies to joint ventures, where there is an agreement between two businesses in which they agree to share profits. *See id.* § 72, at 517-18.

This Court has explicitly adopted Prosser & Keeton's "modern justification for vicarious liability," which describes vicarious liability as:

> a rule of policy, a deliberate allocation of risk. The losses caused by the torts of employees, which as a practical matter are sure to occur in the conduct of the employer's enterprise, are placed upon that enterprise itself, as a required cost of doing business. They are placed upon the employer because, having engaged in an enterprise, which will, on the basis of all past experience, involve harm to others through the torts of employees, *and sought to profit by it*, it is just that he, rather than the innocent plaintiff, should bear them; and because he is better able to absorb them, and to distribute them, through prices, rates or liability insurance, to the public, and so to shift them to society, to the community at large.

Far West Financial Corp. v. D & S Co. (1988) 46 Cal.3d 796, 813, n. 13 (quoting Prosser & Keeton on the Law of Torts, *supra*, at 500); *Hinman v. Westinghouse Elec. Co.* (1970) 2 Cal.3d 956, 959-960 . While this statement focuses on employer liability, it is salient in this case for its profit emphasis.

California courts recognized that vicarious liability is not "merely a legal artifice invoked to reach a deep pocket or that it is based on an elaborate theory of optimal resource allocation." *Alma W. v. Oakland Unified School Dist.* (1981) 123 Cal.App.3d 133, 143-144 . The public policy reason vicarious liability is invoked is to provide greater assurance of compensation to victims in circumstances where it is equitable to shift losses to the employer *because the employer benefits from the injury-producing activity* and such losses are, as a practical matter, sure to occur from the conduct of the enterprise. *Le Elder v. Rice* (1994) 21 Cal.App.4th 1604, 1610 ; *Alma W. v. Oakland Unified School Dist., supra*, 123 Cal.App.3d at 144. "It is only where a person actually acts through another to accomplish his own ends that the law will or should impose such vicarious liability." *King v. Ladyman* (1978) 81 Cal.App.3d 837, 842 .

Here, imposing what is essentially vicarious liability on the manufacturer of a name-brand product for injuries allegedly resulting from a similar product that it did not manufacture or sell does not serve the public policy underlying vicarious liability. The name-brand manufacturer has no control over another manufacturer that copies its product. There is no agreement, contract or otherwise, between name-brand and generic manufacturers that qualify their relationship as a joint venture. And, perhaps most significantly, in regard to the fundamental basis for vicarious liability, the name-brand manufacturer certainly does not profit from sales of a competitor's products. To the contrary, manufacturers of name-brand drugs stand to experience a loss of business when a generic manufacturer provides a lower-cost alternative that does not account for research, development, and marketing costs.

IV. This Court Should Grant Review to Consider the Case in the Broader Context of Similar Attempts to Expand Tort Liability.

A. Extension of Duties to Third Parties

Not only have courts rejected the extension of duty of a manufacturer of name-brand medicines to those who used or consumed competitor's generic products, courts have also refused to extend traditional duties in cases that might be more "emotionally appealing" where a plaintiff may not have a viable defendant to sue. For example, the Maryland Court of Appeals in *Gourdine v. Crews* (Md. 2008) 955 A.2d 769, recently rejected a claim in which the plaintiff argued that she should be compensated by a manufacturer of a name-brand drug where she had not consumed the drug, but was injured by a person who had done so. The case alleged that the manufacturer's failure to warn of fatigue from taking the drug led the consumer of the drug to drive negligently and injure the plaintiff.

Once again, as in the instant case, the old cliché "of foreseeability" was put forth by the plaintiff. Yes, it was foreseeable that a failure to warn a consumer of a drug about a side effect involving drowsiness could cause the user of that pharmaceutical to injure to a third party. But fundamental tort law principles and the public policy reasons we have discussed caused the Maryland Court of Appeals to firmly and unanimously reject such an extension of a duty.

Tort law does extend duties to foreseeable third parties when a defendant engages in intentional misconduct, but such extensions do not exist under the traditional tort of negligence. In this context, it is surprising that the Court of Appeals opinion relied on the famous traditional "duty" case of *Palsgraf v. Long Island RR Co.* (1928) 248 N.Y. 339. As learned Judge Cardozo said in the very quote cited by the lower court, "risk imports relation." *Id.* at 344. The only consumer with whom a manufacturer of a name brand pharmaceutical has a relation is the consumer who takes the drug the manufacturer produced. Extending a duty to unconnected parties, as the *Gourdine* court explained, would "create an indeterminate class of potential plaintiffs." 955 A.2d at 776.

Similarly, the Washington Supreme Court, in two companion cases, recently rejected the extension of liability for failure to warn of asbestos-related hazards in products made by others. *See Simonetta v. Viad Corp.* (Wash. 2008) 197 P.3d 127; *Braaten v. Saberhagen Holdings* (Wash. Dec. 11, 2008) No. 80251-3, 2008 WL 5175083. In *Simonetta*, the court held that a manufacturer may not be held liable in common law negligence or strict liability actions for failure to warn of the dangers of asbestos exposure resulting from another manufacturer's insulation applied to its products. The court found that the duty to warn of the hazards of a product fall on those in the chain of distribution of the product, such as manufacturers, suppliers, or sellers, but the court found no authority to extend the duty to warn to another manufacturer's product. 197 P.3d at 133. In *Braaten*, the court rejected failure-to-warn claims against pump and valve manufacturers relating to replacement packing and replacement gaskets made by others, concluding, "It makes no difference if the manufacturer knew its

products would be used in conjunction with asbestos insulation." 2008 WL 5175083, at *3. In both cases the court rejected plaintiffs' claims that the foreseeability of harm gave rise to a duty owed for the danger posed by the products of another.

The implications of extending tort duties of a manufacturer to manufacturers of competing or separate products have serious adverse implications. For example, manufacturers of goods where patents expire could be liable for harms caused by manufacturers of copies. Should manufacturers of products that have no patent, for example, a saw, be held liable for injuries caused by those who duplicate their products? Are original manufacturers going to be subject to liability predicated on their advertisements about the safety of their own products, when a competitor follows the same path? Should the law permit purchasers of "no name" products to bring claims against name-brand product manufacturers? Should the law subject Gucci, Louis Vuitton, or Chanel to liability for the quality or safety of replica handbags manufactured by another company based on a duty regarding its own products simply because the copies are 99% similar to the originals? This Court should grant review in this case to reaffirm that tort law does not extend so far.

Moreover, in choosing whether to take a brand name drug or a generic, the consumer has a choice. If it wants to be able to sue the brand company for any injuries caused by the medicine, then the consumer must choose to take the brand medicine. Here, as the lower court readily admits, "[i]t is undisputed that Conte took only the generic version of the medication, not Reglan." Slip Op. at *2.

B. End Runs Around Product Liability Law

This case also fits into a larger effort to evade long-established and well-reasoned requirements of product liability law through novel legal theories. As the Fourth Circuit recognized in *Foster*, "in this case the allegations of negligent misrepresentation are an effort to recover for injuries caused by a product without meeting the requirements the law imposes on product liability actions," such as a threshold showing that the defendant manufactured the product at issue and that product caused the plaintiff's injury. *Foster*, 29 F.3d at 168. Such claims also circumvent the learned intermediary doctrine, which recognizes that a prescription drug manufacturer's duty to warn runs to the patient's prescribing physician, not directly to the individual patient-consumer. *See Carlin v. Superior Court (Upjohn Co.)* (1996) 13 Cal.4th 1104, 1116] ("[I]n the case of prescription drugs, the duty to warn runs to the physician, not to the patient.").[2]

This Court should grant review to clarify that when claims sound in product liability law, as they do in this case, California law will not permit novel theories that

[2] A similar blending of the law is occurring against product manufacturers not only through negligent misrepresentation claims, as it is here, but also through actions brought under consumer protection statutes and common law public nuisance claims. *See* Victor E. Schwartz & Philip S. Goldberg, *The Law of Public Nuisance: Maintaining Rational Boundaries on a Rational Tort*, 45 Washburn L.J. 541, 551-61 (2006); Victor E. Schwartz & Cary Silverman, *Common-Sense Construction of Consumer Protection Acts*, 54 Kansas L. Rev. 1, 48-49, 63-66 (2005).

eviscerate the well-reasoned requirements for a prima facie product liability claim. It should clarify that regardless of the theory of liability asserted, a manufacturer has no duty to protect consumers of products that it did not manufacture, distribute, or sell from harm.

C. *Stare Decisis* Disfavors Abandoning Core Tenets of Tort Law

As discussed above, the First Appellate District, in recognizing a new duty on the part of a name-brand manufacturer to warn those who did not use its own product of the risks of a competitor's product, departed from longstanding principles of tort law. At minimum, such a new course should be considered by this Court, not directed by an anomalous lower court decision.

Tort law is organic and can be adjusted when appropriate. But *stare decisis* places rational limits on tort law with respect to extensions, "ensuring that change is gradual." Victor E. Schwartz et al., *Neutral Principles of Stare Decisis in Tort Law*, 58 S.C. L. Rev. 317, 319 (2006). For a court to depart from precedent regarding foundational principles of tort law, such that a manufacturer's duty to warn would extend to the consumers of separate and competing manufacturers, there must be some catalyst or "significant shift in the legal foundation underlying a rule." *Id.* at 328.

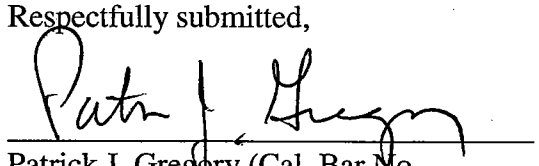
Factors which might be considered in departing from *stare decisis* include advances in science or technology requiring modification of earlier tort law doctrine; changes in the nature of modern tort litigation; prior decisions chipping away at a tort law rule; a preference for uniformity and consistency favoring abandonment of disfavored tort law doctrines universally rejected in sister states; and unintended consequences of previous departures from precedent requiring revaluation and correction of earlier rulings. *See id.*

This Court should consider whether these factors weigh in favor of departing from well-established tort law in the present case. Unless there is a demonstrated need or reason to fundamentally alter the scope of liability to hold manufacturers of name-brand products accountable for harms caused by generic copies sold by competing manufacturers, this Court should hold that *stare decisis* is appropriate and reject this unprecedented extension of duty.

CONCLUSION

For the reasons stated herein, *Amicus* respectfully request that this Court grant Wyeth, Inc.'s petition for review.

Respectfully submitted,



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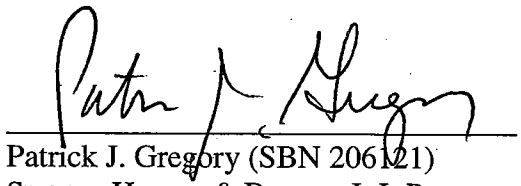

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