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FOUNDED 1866

January 5, 2008

Honorable Ronald M. George, Chief Justice,
and the Associate Justices
Supreme Court of California
350 McAllister Street
San Francisco, California 91402

Re: *Conte v. Wyeth, Inc., et al.*
Case Number S169116
Amicus Curiae Letter of Washington Legal Foundation in Support of Petition for Review

To the Honorable Chief Justice and Associate Justices of the Supreme Court of California:

Pursuant to Rule 8.500(g) of the California Rules of Court, Washington Legal Foundation submits this amicus curiae letter in support of Wyeth, Inc.'s (Wyeth) pending Petition for Review of the decision of the Court of Appeal in *Conte v. Wyeth, Inc., et al.* Washington Legal Foundation urges the Court to grant the Petition because *Conte* is a radical and unsound departure from traditional principles of tort law that will have a profound impact on legal liability and business decision-making not only for innovator drug manufacturers but potentially for manufacturers of vast numbers of other products as well.

About Washington Legal Foundation:

The Washington Legal Foundation (WLF) is a nonprofit public interest law and policy center based in Washington, D.C. with members in all 50 States, including many in California. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared before this Court and numerous other federal and state courts in support of tort reform efforts and to oppose abusive civil litigation. *See, e.g., City of Hope Nat'l Medical Center v. Genentech Inc.* (2008) 43 Cal.4th 375; *Korea Supply Co. v. Lockheed Martin Corp.* (2003) 29 Cal.4th 1134.

Reasons for Granting Review:

This Court should grant Wyeth's Petition because the Court of Appeal's ruling that Wyeth may be liable for injuries caused by a drug it did not manufacture or sell marks a sharp and unwarranted break from traditional principles of tort law. The Court of Appeal's decision

places California squarely at odds with every other state and federal appellate court to have addressed the issue, and is not compelled by California law. Such a direct rejection of previous law in California and every other jurisdiction is too critical to the legal and economic landscape of California to pass without review by this Court.

California represents an enormous portion of the national marketplace, as much as 13% of the national economy by some estimates. *See* Legislative Analysts Office, Cal Facts 2006: California's Economy and Budget in Perspective at 7, available at http://www.lao.ca.gov/2006/cal_facts/cal_facts_2006.pdf (accessed Dec. 30, 2008.) To the extent California adopts rules of tort liability that depart from national norms, those rules could profoundly affect manufacturers deciding whether, and on what terms, to do business in California.[1] Before effecting a sea-change in tort liability, this Court should be confident that such a change is well-grounded in California law and adequately considers the relevant legal and policy concerns.

The Decision Below Radically Alters Traditional Tort Law Principles.

Traditional tort law principles hold a company accountable for products it manufactures or sells, and exempt a company from liability for products it does not manufacture or sell. This Court has stated that a manufacturer defendant bears no liability for injuries caused by use of an allegedly defective product where "it demonstrates that it could not have made the product which caused plaintiff's injuries." *Sindell v. Abbott Labs.* (1980) 26 Cal.3d 588, 612. Nowhere has this Court suggested that a manufacturer's tort liability for harm caused by its representations about its own product could extend to someone who used a competitor's product instead.

In the decision below, however, the appellate court exonerated the manufacturer of the product that allegedly caused the injury, while creating a basis for imposing liability on a manufacturer that did not make or sell that product. This departure from traditional principles is unprecedented; every other state or federal appellate court, and federal trial court, to have considered the issue has reached the opposite conclusion, for good reason.[2]

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[1] *See generally, e.g., Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063-1065 [245 Cal.Rptr. 412, 751 P.2d 470] (noting the connection between manufacturer liability and the development and availability of pharmaceuticals); Michael I. Krauss & Robert A. Levy, *Can Tort Reform and Federalism Coexist?*, Cato Inst. Policy Analysis No. 514 (Apr. 14, 2004) pp. 23-24 (noting that differing likelihoods of liability in different jurisdictions affect corporations' willingness to invest in markets); Steven Garber, *Product Liability, Punitive Damages and Economic Outcomes* (1998) 1998 Wis. L. Rev. 237 at pp. 243-48 (discussing how manufacturers respond to potential product liability costs and the uncertainty caused by, *inter alia*, inter-jurisdictional variation in tort liability).

[2] *See Foster v. American Home Prods. Corp.* (4th Cir. 1994) 29 F.3d 165, 170; *Barnhill v. Teva Pharm. USA, Inc.* (S.D.Ala., Apr. 24, 2007, No. Civ. A. 06-0282-CB-M) 2007 WL 5787186, at *1; *Swicegood v. Pliva, Inc.* (N.D.Ga. 2008) 543 F.Supp.2d 1351, 1358; *Smith v. Wyeth, Inc.* (W.D.Ky., June 30, 2008, No. 5:07-CV-18-R) 2008 WL

Decisions about the scope of liability and a manufacturer's ability to affect that liability can have a significant impact on activity in the marketplace, including determinations on whether and when to introduce innovative new products or to invest in or serve a particular market.[3] While assessments of potential liability are always imprecise, under the Court of Appeal's decision, a manufacturer loses all ability to control or assess its potential scope of liability, because the Court of Appeal severed the traditional link between the manufacturer's product and the imposition of liability. A manufacturer thus now may be liable in California not only for injuries caused by its own product, but also for injuries caused by the products of competitors over whom the manufacturer has no control, and who should (and prior to the Court of Appeal's decision, did) have their own incentives to ensure the safety, efficacy, and adequate labeling of their products. As explained below, the Court of Appeal's decision makes manufacturers of innovator products the effective indemnitors of foreseeably similar competing products, raising grave implications for companies considering whether to bring new products to market, or to continue marketing or investing in existing products, in California.

The Court of Appeal's Result Is Unnecessary to Protect Consumers, But Disrupts the Incentives for Generic Manufacturers to Attend to the Warnings on Their Labels.

The impact of *Conte* is most obviously apparent in the pharmaceutical context. Sales of generic drugs may account for 80 percent or more of the total sales of a given drug. *See, e.g.*, E.R. Berndt, R. Mortimer, A. Bhattacharjya, A. Parece, E. Tuttle, *Authorized Generic Drugs,*

2677051, at *4; *Morris v. Wyeth, Inc.* (W.D.Ky. June 30, 2008, No. 1:07-CV-176-R) 2008 WL 2677048, at *4; *Wilson v. Wyeth, Inc.* (W.D.Ky., June 30, 2008, No. 3:07-CV-378-R) 2008 WL 2677049, at *4; *Demahy v. Wyeth, Inc.* (E.D.La., Oct. 27, 2008, No. 08-3616) 2008 WL 4758615, at *13-14; *Leblanc v. Wyeth, Inc.* (W.D.La., Oct. 5, 2006, No. Civ. A 04-0611) 2006 WL 2883030, at *6; *Tarver v. Wyeth* (W.D.La., June 7, 2005, No. Civ. A. 3-04-2036) 2005 WL 4052382, at *2; *Mensing v. Wyeth, Inc.* (D.Minn., Oct. 27, 2008, Civ. No. 07-3919 (DWF/SRN)) 2008 WL 4724286, at *5, 13; *Goldych v. Eli Lilly & Co.* (N.D.N.Y., July 19, 2006, No. 5:04-CV-1477 (GLS/GJD)), 2006 WL 2038436, at *6, 20; *DaCosta v. Novartis AG* (D.Or., Mar. 1, 2002, No. CV 01-800-BR) 2002 WL 31957424, at *9; *Colacicco v. Apotex, Inc.* (E.D.Pa. 2006) 432 F.Supp.2d 514, 543, rev'd in part on other grounds (3d Cir. 2008) 521 F.3d 253; *Pustejovsky v. Wyeth, Inc.* (N.D.Tex., Apr. 3, 2008, No. 4:07-CV-103-Y) 2008 WL 1314902, at *2; *Block v. Wyeth, Inc.* (N.D.Tex., Jan. 28, 2003, No. Civ. A. 3:02-CV-1077) 2003 WL 203067, at *2; *Sharp v. Leichus* (Fla.Cir.Ct., Feb. 17, 2006, No. 2004-CA-0643) 2006 WL 515532, at *7, aff'd *per curiam* (Fla.App. 2007) 952 So.2d 555; *Stanley v. Wyeth, Inc.* (La.Ct.App. 2008) 991 So.2d 31, 34-35; *Flynn v. Am. Home Prods. Corp.* (Minn.Ct.App. 2001) 627 N.W.2d 342, 350; *see also Sheeks v. Am. Home Prods. Corp.* (Colo.Dist.Ct., Oct. 15, 2004, No. 02CV337) 2004 WL 4056060; *Reynolds v. Anton* (Ga.Super.Ct., Oct. 28, 2004, No. 01A-76719-3) 2004 WL 5000272, at *8; *Kelly v. Wyeth* (Mass.Super.Ct., May 6, 2005, No. Civ. A. MICV200303314B) 2005 WL 4056740, at *4; *Beutella v. A.H. Robins Co., Inc.* (Utah Dist.Ct., Dec. 10, 2001, No. 980502372) 2001 WL 35669202, at *2-3. *But cf. Clark v. Pfizer Inc.* (Ct.C.P. of Phila. County, Pa. Mar. 14, 2008, No. 1819) [nonpub. opn. at 17] (disagreeing with the U.S. District Court for the Eastern District of Pennsylvania's holding in *Colacicco* that a name brand drug manufacturer does not owe a legal duty to consumers of a generic equivalent of its drug under Pennsylvania law, without addressing the reasoning in *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, or the other cases that have followed it).

[3] *See supra* n. 1.

Price Competition, and Consumers' Welfare (2007) 26 Health Affairs 790, 795-96. Under the decision below, therefore, the brand-name manufacturer must carry responsibility in tort law for an entire market in which that manufacturer's own sales account for only a tiny fraction. Indeed, the rationale in the opinion suggests that the innovator manufacturer may be liable for injury caused by a generic drug even if the innovator no longer sells the drug at all.

Removing the link between the manufacture of a product and tort liability is not in the public interest. Placing liability on the manufacturer of the product that allegedly caused injury provides incentives for each manufacturer to ensure the safety, efficacy and adequate labeling of its own product. The Court of Appeal's decision is poor public policy because it reduces the incentives that generic manufacturers would otherwise have to attend to the adequacy of the warnings on their labels. The decision instead provides an incentive for generic manufacturers to limit the information they distribute and defer wherever possible to the innovator manufacturer, in order to shift liability to the innovator. There is no benefit to public health or safety from excusing generic manufacturers from tort liability they would otherwise bear in order to place it on a single manufacturer that may no longer have significant interest in promoting or even manufacturing the drug.

This is especially true where, as here, a federal statutory and regulatory scheme holds generic manufacturers responsible for the safety, efficacy, and adequate labeling of their products. Under federal law, generic manufacturers, like innovator manufacturers, are subject to extensive safety monitoring and reporting requirements. *See, e.g.*, 21 C.F.R. §§ 314.80, 314.81; 314.98 (extending postmarketing reporting requirements to holders of approved abbreviated new drug applications ("ANDAs"), *i.e.*, generic drug manufacturers). When a generic drug manufacturer becomes aware of new safety information that supports a labeling change, the generic drug manufacturer, like the innovator manufacturer, must submit that information to the FDA. *See* 21 C.F.R. §§ 314.70, 314.71, 314.97 (extending requirements concerning supplemental applications to holders of approved ANDAs). The FDA then will determine whether the labeling for the generic drug *and* the branded drug should both be revised. *See Abbreviated New Drug Application Regulations: Final Rule*, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992). Thus, both innovator and generic manufacturers have equal and symmetric responsibility to seek FDA approval for labeling changes for the drugs they market under circumstances defined in FDA regulations. Generic manufacturers are obligated under federal law to ensure the adequacy of labeling for the drugs they sell, and no departure from settled principles of liability is needed to protect users of generic drugs.

The Court of Appeal's Decision Will Have a Profound Impact on the Liability and Decision-making of All Manufacturers Who Face Competition From Manufacturers of Similar Products.

This decision would be troubling enough if its impact were limited to the pharmaceutical arena. But by breaking the traditional requisite link between the manufacturer and the product that caused the injury, the Court of Appeal's opinion augurs an expansion of tort liability that is not limited to claims against pharmaceutical manufacturers.

The core of the Court of Appeal's rationale is that a claim for injury premised on a negligent representation is not necessarily a claim about the product that caused the injury. The court's opinion therefore suggests that one may pursue such a claim against a defendant manufacturer who made the representations but not the product. That broad fundamental analysis is not limited to the pharmaceutical world. Most manufacturers' products carry warnings, and many innovator manufacturers (such as manufacturers of chemical solutions or industrial machinery) face competition from those who have subsequently copied their products and warnings.

A person injured by the copycat product could readily assert that the innovator's warnings were misleading, and that the innovator had reason to know its original warnings were widely adopted by competing manufacturers and foreseeably relied upon by employees or customers. Having eliminated the requirement that the injury be caused by the defendant manufacturer's own product, the Court of Appeal's decision offers no guidance on where future courts are to draw the line on liability, and instead encourages courts to shift liability to the innovator.

As noted above, this shift in liability disrupts the incentives that manufacturers otherwise would have to ensure the safety, effectiveness, and adequate labeling of their products. Take, for example, the situation in which a contractor typically uses one manufacturer's chemical product and has become familiar with the warnings on that product. The contractor later switches to a new manufacturer's version of the same chemical product, does not read the warnings on the alternate version of the chemical product, and is injured as a result of using that product. Under the Court of Appeal's reasoning, the first manufacturer could be held liable for the injuries caused by the second manufacturer's product if the first manufacturer's warnings were defective.[4] This result would have the effect of reducing the incentives that the second manufacturer otherwise would have to ensure the adequacy of the warnings distributed with its product, because the first manufacturer will carry the costs of the inadequate warnings. Similar

[4] This result becomes even more perverse if the first manufacturer had started to warn of the risk at issue between the time the contractor became familiar with the warnings on the first product and the time the contractor started to use the copycat product.

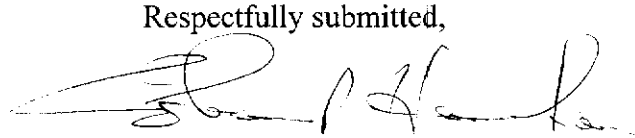
results could be seen in a host of other contexts, such as injuries allegedly caused by the use of fertilizers, pesticides, cleaning supplies, tools, industrial machinery, or medical devices.

The Court of Appeal's recognition that the record before it was limited underscores the need for review here. The court's broad ruling based on a limited understanding of the facts only confounds the necessary line-drawing that courts must undertake in future cases; future courts and litigants must guess at whether consideration of these facts would have changed the rule. By drastically extending liability for injuries caused by the use of one product to the manufacturer of a competing product, the opinion eliminates the traditional line courts have drawn in defining the scope of actionable foreseeability for conduct in the marketplace. Under this decision, the scope of future litigation for innovator manufacturers is cabined by only the limits of the imaginations of the lawyers who will seek to apply it. The inevitable costs of such litigation must now be considered by any company considering whether and on what terms to do business in California.

CONCLUSION

The decision in *Conte* has received substantial attention for good reason: it profoundly and inappropriately alters the rules that have guided manufacturers for decades in deciding how and where they conduct business. It admittedly rejects the rules that all other appellate courts have endorsed. It will undermine the goals of public health and safety that it ostensibly seeks to further, and destabilize future applications of tort law. Washington Legal Foundation respectfully urges the Court to accept the Petition and reverse this unwarranted and misguided expansion of tort liability.

Respectfully submitted,



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PROOF OF SERVICE

STATE OF CALIFORNIA)
) ss
COUNTY OF LOS ANGELES)

I am employed in the County of Los Angeles, State of California. I am over the age of 18 years and not a party to the within action. My business address is 555 West Fifth Street, Suite 4000, Los Angeles, CA 90013-1010.

On January 5, 2009, I served the foregoing document(s) described as **AMICUS LETTER IN SUPPORT OF PETITION FOR REVIEW** on all interested parties in this action as follows (or as on the attached service list):

☒ (VIA U.S. MAIL) I served the foregoing document(s) by U.S. Mail, as follows: I placed true copies of the document(s) in a sealed envelope addressed to each interested party as shown above. I placed each such envelope with postage thereon fully prepaid, for collection and mailing at Sidley Austin LLP, Los Angeles, California. I am readily familiar with Sidley Austin LLP's practice for collection and processing of correspondence for mailing with the United States Postal Service. Under that practice, the correspondence would be deposited in the United States Postal Service on that same day in the ordinary course of business.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on January 5, 2009, at Los Angeles, California.

Betty Jue

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