DRI The Voice™ of the Defense Bar
55 West Monroe Street ▪ Suite 2000 ▪ Chicago, Illinois 60603
(312) 795-1101 ▪ Fax: (312) 795-0747 ▪ E-Mail: dri@dri.org ▪ Website: www.dri.org

January 16, 2009

The Honorable Chief Justice and Associate Justices
The Supreme Court of California
350 McAllister Street
San Francisco, CA 94102-4797

Re: **Amicus Curiae Letter in Support of Petition for Review by Wyeth in *Elizabeth Ann Conte v. Wyeth, Inc.*, No. S169116**

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, DRI respectfully requests that the Court grant the petition for review filed by Wyeth, Inc., in *Elizabeth Ann Conte v. Wyeth, Inc.*, No. S169116.

Identity and Interest of *Amicus Curiae*

DRI is the "Voice of the Defense Bar," a 22,500-member international association of defense lawyers who represent individuals, corporations, and insurance carriers involved in civil litigation. Committed to enhancing the skills, effectiveness, and professionalism of defense lawyers, DRI seeks to address issues germane to defense lawyers and the civil justice system, to promote appreciation of the role of the defense lawyer, and to improve the civil justice system. DRI has long been a voice for a fair and just system of civil litigation, seeking to ensure that it operates to effectively, expeditiously, and economically resolve disputes for litigants. To that end, DRI participates as amicus curiae in cases that raise issues of vital concern to its membership. This is such a case.

DRI's interest in this appeal stems from its concern about the unprecedented departure from well-established common law principles governing the concept of duty in products liability and other tort litigation, and the policy implications of the rule of

law adopted by the Court of Appeals in this case. Since its members are involved in litigation in state and federal courts all over the country, DRI is well-positioned to assist the Court by offering insight into the impact of the decision at issue here.

The Court of Appeals held that "the common law duty to use due care owed by a name-brand prescription drug manufacturer when providing product warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug." Opn. at 1. The Court of Appeals also held that a jury-submissible factual dispute exists regarding whether the plaintiff's doctor relied on the name-brand manufacturer's warnings despite the doctor's statement that "[a]t no time did I rely in any way on representations made in the PDR monograph, package insert, labeling materials or other information from Wyeth regarding the medication Reglan® in order to formulate my course of care and treatment for Ms. Conte." Opn. at p 7. Because the doctor testified that "he 'probably' read Wyeth's monograph on Reglan in the PDR during his residency training; that the PDR was one of the sources he generally refers to in his clinical practice when he considers prescribing Reglan for his patients; and that he believe the information it contained was accurate," the Court of Appeals held that there was a fact question as to the accuracy of the doctor's recollection and as to whether "information he had previously garnered from the PDR was a substantial factor in his decision to prescribe Reglan for her." Opn. at 7.

This novel and expansive approach to tort liability cannot be reconciled with longstanding principles of California tort law, runs counter to the basic notion of personal responsibility that provides the foundation for traditional tort law, threatens to complicate

litigation, will drastically increase the expense of litigation by adding additional parties, and will force many brand-name manufacturers to undergo the rigors and expenses of trials in order to prove they are strangers to the plaintiff, and to the product ingested by the plaintiff.

DRI has long supported a balanced civil justice system that facilitates the just, speedy, and inexpensive resolution of disputes through litigation. Under such a system, plaintiffs are fairly compensated for genuine injuries by those who caused them. At the same time, defendants who are strangers to the plaintiff or whose conduct is causally unrelated to the plaintiff's injuries can expeditiously establish that they are not liable. The Court of Appeals decision in this case, if left undisturbed, severely threatens the goal of a fair and balanced civil justice system by foisting liability onto defendants with no relationship to the plaintiff or to the purportedly injurious conduct. The decision is therefore of great interest to DRI and its members. Since its members have first-hand experience with litigation involving similar issues, DRI is well-suited to address the consequences of allowing the decision of the Court of Appeals to stand without review.

Reasons for Granting Review

The issues presented in Wyeth's petition for review are important questions of law worthy of this Court's consideration. Because the Court of Appeals decision will establish precedent governing future cases, this Court should grant the petition to consider whether such a novel and expansive approach to tort liability should be adopted in California. DRI submits that a reversal is warranted because of the many detrimental consequences that would flow from leaving the Court of Appeals decision undisturbed.

At the core, the decision deviates from traditional product liability principles that have governed such suits for many years. California served as a leader in the developing

area of product liability law when it decided *Greenman v. Yuba Power Products* 59 Cal.2d 57, 63 (1963), holding that the "purpose of liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market." Id. A fundamental element of product liability law, and of tort law generally, is that a litigant may recover against an entity only for injuries arising from the entity's product; no recovery is allowed for injuries arising from a competitor's product. The rationale for this approach has long been that the manufacturer may fairly be held liable for its conduct in marketing an unsafe product and that the manufacturer is well-situated to spread the cost of injury from the individual plaintiff to the consuming public through the purchase of insurance or participation in other risk-spreading measures. See *Anderson v. Owens-Corning Fiberglas Corp.* 53 Cal.3d 987 (1991); *Brown v. Superior Court*, 44 Cal.3d 1049, 1062 (1988); *Daly v. General Motors*, 20 Cal.3d 725, 739 (1978); *Ray v. Alad Corp.* 19 Cal.3d 22, 31 (1977).

In the past, California courts have required a litigant to prove that a purportedly defective product was manufactured by the defendant except in that narrow category of cases where it is impossible to identify the manufacturer through no fault of the plaintiff. See *Sindell v. Abbott Laboratories* 26 Cal.3d 588, 611 (1980). Although a market-share theory was not applicable or necessary here, the Court of Appeals dispensed with the well-established obligation of a plaintiff to show that the purportedly injury-causing product was put into the market by the defendant. *Cadlo v. Owen-Illinois, Inc.*, 125 Cal.App.4th 513, 523-25 (2005). The Court of Appeals recognized a new theory of law by which a brand-name manufacturer may be held liable for injuries to a plaintiff caused not by that manufacturer's product, but by a generic drug manufactured by a different entity with its own duty regarding the products it puts on the market. See 21 U.S.C. §

301 et seq.; Abbreviated New Drug Application Regulations, Final Rule, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992); 21 C.F.R. §§ 314.80-314.81. This expansive approach to liability undermines a foundational principle of tort law, which is that a defendant's potential liability is based on the defendant's conduct.

The Court of Appeals approach will have numerous detrimental effects on the civil justice system. First, it will make already complicated litigation more complex, expensive, and difficult by adding numerous potential additional defendants. This problem will be exacerbated by the Court of Appeals holding that a trial is necessary despite a physician's affirmative testimony that he did not rely on brand-name product information in prescribing the generic drug. If a fact question exists notwithstanding such affirmative testimony, it is hard to conceive of cases in which summary judgment will be granted. Most treating physicians will testify to reviewing the PDR or product labeling for brand name drugs at some point. Thus, brand-name defendants with no connection to the plaintiff will nevertheless be forced to participate in expensive and time-consuming discovery and often in trial. The rule means that brand-name manufacturers will be forced to disprove that a physician ever saw their product information or will be forced to undergo the rigors and uncertainties of trial in the absence of any evidence supporting the kind of relationship traditionally required in a negligence or product liability action or the reliance ordinarily required to show misrepresentation.

Second, it will mean that brand-name manufacturers will no longer have control over the potential liability that they face. Under the Court of Appeals approach, brand-name manufacturers may be held liable, not only for injuries from products that they place on the market, but for products placed on the market by generic manufacturers with

whom they have no relationship and against whom they compete for market share. This indirect liability creates exposure that is difficult to predict and potentially limitless. As a result, brand-name manufacturers are likely to face difficulty obtaining insurance to cover the risk. In addition, these expenses will further discourage the research and development necessary for the production of new medical products by transferring costs properly allocated to generic drug manufacturers onto brand-name drug manufacturers. Wyeth has no relationship with the plaintiff in this case and the plaintiff's physician explicitly testified that he did not rely on Wyeth's product information. Under the Court of Appeals novel theory, Wyeth and other brand-name manufacturers may be held liable for injury-causing generic products put on the market by their competitors without knowledge or involvement of the brand-name manufacturers. Courts in other jurisdictions have routinely rejected such an extension of liability. See e.g., *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994)("[t]here is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer has no control.") Courts have recognized the unfairness of foisting liability onto the brand-name manufacturer when it lacked any involvement in production or sale of the generic drug, and when "the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising." *Foster*, 29 F.3d at 170.

Third, brand-name manufacturers face liability under a theory of misrepresentation that is based on recognizing a duty although they played no role in the manufacture or sale of the products. Contrary to this Court's teaching about the limits of an actionable duty, see e.g., *Thing v. La Chusa*, 48 Cal.3d 644 (1989)(recognizing that

foreseeability alone is insufficient as a template for determining the limits of tort liability), the Court of Appeals invoked a limitless foreseeability principle without analyzing the other factors that this Court has required to impose an actionable duty. See *Rowland v. Christian*, 69 Cal.2d 108 (1968). Duty is a question of policy, and is generally based on "a matter of some specific relation between the plaintiff and the defendant without which there could be no liability." Prosser and Keeton On Torts (5th ed. W. Page Keeton ed. 1984) at 357 citing Winfield, *Duty in Tortious Negligence,* 34 Colum. L. Rev. 41 (1934). Although foreseeability is an element of the duty analysis, other factors are equally and often more important. See e.g., *Buczkowski v McKay*, 441 Mich. 61, 490 N.W.2d 330, 336 (1992). The policy considerations that form the underpinnings for recognizing a duty were ignored by the Court of Appeals.

Fourth, the Court of Appeals theory will have a distorting effect on the civil justice system by transferring potential liability of generic drug manufacturers to brand-name manufacturers when the brand-name manufacturers had no control over the products purportedly causing the injury and were strangers to the plaintiff and the plaintiff's physician. This Court has acknowledged that the Legislature is better suited to imposing broad new tort duties when doing so "involve[s] complex policy decisions." *Mirkin v. Wasserman*, 5 Cal.4th 1082, 1104-05 (1993). That is particularly true in the context of prescription drugs, which provide critically important societal benefits. Tort litigation, if allowed in the absence of traditional requirements, can have a deleterious effect on necessary economic activity such as the research and development of new drugs. The Legislature, with all its ability conduct broad inquiries and to weigh and balance competing societal needs, is better-situated than the judiciary to recognize such

broad new liability. Thus, this Court should grant the petition for review and reverse the Court of Appeals decision.

Conclusion and Relief

The decision in *Elizabeth Ann Conte v. Wyeth, Inc.*, No. S169116, threatens to create broad new liability for drug product manufacturers. It conflicts with fundamental principles of fault and responsibility based on an entity's own conduct that have been accepted by California courts for decades. The decision interferes with basic goals of the civil justice system including its effort to connect liability with a defendant's conduct and to expeditiously and fairly resolve disputes. For the reasons set forth in Wyeth's petition for review and those set forth in this letter, DRI urges this Court to grant review to resolve the important questions of public policy and law that are presented in this appeal.

Respectfully Submitted,

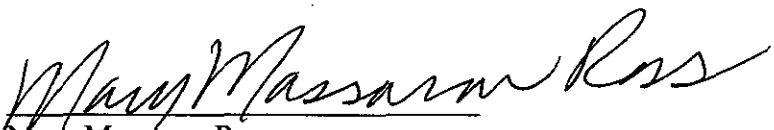
DRI, the Voice of the Defense

Marc E. Williams /mmr

Marc E. Williams
President
611 Third Avenue
Huntington, WV 25701
(304) 691-8306

John R Kouris /mmr

John R. Kouris
Executive Director
55 West Monroe Street, Suite 2000
Chicago, IL 60603
(312) 698-6201



Mary Massaron Ross
Of Counsel for DRI, The Voice of the Defense
Plunkett Cooney
Buhl Building
535 Griswold, Suite 2400
Detroit, MI 48226
(313) 965-3900

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DRI The Voice™ of the Defense Bar
55 West Monroe Street ▪ Suite 2000 ▪ Chicago, Illinois 60603
(312) 795-1101 ▪ Fax: (312) 795-0747 ▪ E-Mail: dri@dri.org ▪ Website: www.dri.org

PROOF OF SERVICE

Re: *Conte v. Wyeth, Inc., et al.,*
Cal. Sup. No. S169116 (Cal. App. 1/3 Nos. A117353, A116707)

I am a resident of the State of Michigan, over the age of eighteen years, and not a party to the within action. My business address is Buhl Building, 535 Griswold, Suite 2400, Detroit, Michigan 48226. On **January 16, 2009**, I served the following document(s) by the method indicated below:

AMICUS CURIAE LETTER TO CALIFORNIA SUPREME COURT JUSTICES IN SUPPORT OF PETITION FOR REVIEW BY WYETH IN *ELIZABETH ANN CONTE v. WYETH, INC.*, NO. S169116

☒ by placing the document(s) listed above in a sealed envelope(s) addressed as follows and placing the envelope(s) for collection and mailing following our ordinary business practices. I am readily familiar with the firm's practice of collection and processing of correspondence for mailing. Under that practice, it would be collected and deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in this Declaration.

Laurence Oliver Masson
Law Office of Laurence O. Masson
2625 Alcatraz Ave #206
Berkeley, CA 94705

Counsel for Plaintiff and Appellant Elizabeth Ann Conte

Valerie Maria Nannery
Center for Constitutional Litigation, PC
777 6th Street NW, Suite 520
Washington, DC 20001-3723

Counsel for Plaintiff and Appellant Elizabeth Ann Conte

Ralph David Pittle
Medical Legal Consultants Of Washington
14205 SE 36th Street - Suite 100
Bellevue, WA 98006

Counsel for Plaintiff and Appellant Elizabeth Ann Conte

Brian Wolfman
Public Citizen Litigation Group
1600 20th Street, NW
Washington, DC 20009

Counsel for Plaintiff and Appellant Elizabeth Ann Conte

Elizabeth F. Stone
Goodwin Procter LLP
3 Embarcadero Center
24th Floor
San Francisco, CA 94111

Counsel for Defendant and Respondent Teva Pharmaceuticals USA, Inc.

Merton A. Howard
Eric William Junginger
Jill Noel Cartwright
Hanson Bridgett
425 Market St. 26th floor
San Francisco, CA 94105

Counsel for Defendant and Respondent Pliva

Richard A. Dean
Kristen Mayer
Tucker, Ellis & West LLP
1150 Huntington Building
925 Euclid Avenue
Cleveland, OH 44115-1414

Counsel for Defendant and Respondent Purepac Pharmaceutical, Inc.

Michael C. Zellers
Tucker Ellis & West LLP
515 S Flower Street, 42nd Floor
Los Angeles, CA 90071

Counsel for Defendant and Respondent Purepac Pharmaceutical

Ralph J. Smith
Donnelly & Nelson LLP
2401 Shadelands Drive, Suite 120
Shadelands Point
Walnut Creek, CA 94598

Counsel for Defendant and Respondent Robert J. Elsen, M.D.

Stuart M. Gordon
James R. Reilly
Fletcher C. Alford
Gordon & Rees
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111

Counsel for Defendant and Respondent Wyeth, Inc.

Jeffrey R. Pilkington
Davis Graham and Stubbs LLP
1550 Seventeenth Street
Suite 500
Denver, CO 80202

Counsel for Defendant and Respondent Wyeth, Inc.

Michael T. Scott
James C. Martin
Paul D. Fogel
Dennis Peter Maio
REED SMITH LLP
Two Embarcadero Center, Suite 2000
San Francisco, CA 94111-3922

Counsel for Defendant and Respondent Wyeth, Inc.

Sandra Pizarro
Vice-President of Government Affairs
California Healthcare Institute
1215 K Street, Suite 970
Sacramento, CA 95814

Counsel for California Healthcare Institute, amicus curiae

Robert Hunter, President
International Association of Defense Counsel
One North Franklin, Suite 1205
Chicago, IL 60606

Counsel for International Association of Defense Counsel, amicus curiae

Patrick J. Gregory
Shook, Hardy & Bacon, L.L.P.
333 Bush Street, Suite 600
San Francisco, CA 94104

Counsel for Chamber of Commerce of the United States of America, amicus curiae

Victor Schwartz
Cary Silverlman
Philip S. Goldberg
Shook, Hardy & Bacon, L.L.P.
600 14th Street, NW, Suite 800
Washington, DC 20005

Counsel for Chamber of Commerce of the United States of America, amicus curiae

Robin S. Conrad
Amar D. Sarwal
National Chamber Litigation Center, Inc.
1615 H Street, NW
Washington, DC 20062

Counsel for Chamber of Commerce of the United States of America, amicus curiae

Harvey M. Grossman
Law Offices of Harvey M. Grossman
P.O. Box 360919
Los Angeles, CA 90038-1419

Counsel for Product Liability Counsel, amicus curiae

Clerk of the Court of Appeal
First Appellate District, Division 3
350 McAllister Street
San Francisco, CA 94102

Clerk of the Calif. Superior Court
County of San Francisco
Attn: Honorable Robert L. Dondero
400 McAllister Street
San Francisco, CA 94102-4514

I declare under penalty of perjury under the laws of the State of Michigan that the above is true and correct. Executed on January 16, 2009, at 38505 Woodward Avenue, Suite 2000, Bloomfield Hills, Michigan 48304.

MARY MASSARON ROSS

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