IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

No. S233898

T. H. and
CARDWELL HAMILTON,

Plaintiffs and Appellants,

v.

NOVARTIS
PHARMACEUTICALS CORPORATION,

Defendant and Respondent.

After an Opinion by the Court of Appeal,
Fourth Appellate District, Division One
(Case No. D067839)

On Appeal from the Superior Court of San Diego County
(Case No. 37-2013-00070440-CU-MM-CTL, Hon. Joan M. Lewis, Judge)

APPLICATION TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF DEFENDANT-RESPONDENT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Page

Rules of Court

Miscellaneous

Page

Page

APPLICATION TO FILE BRIEF AMICUS CURIAE

Pursuant to California Rule of Court 8.520(f),[1] Pacific Legal Foundation requests leave to file the attached brief amicus curiae in support of Defendant-Respondent Novartis Pharmaceuticals Corp. Amicus is familiar with the issues and scope of their representation, and believes the attached brief will aid the Court in its consideration of the issues presented in this case.

INTEREST OF AMICUS CURIAE PACIFIC LEGAL FOUNDATION

PLF is widely recognized as the most experienced nonprofit legal foundation devoted to promoting limited government, individual rights, and free enterprise. PLF's Free Enterprise Project engages in litigation, including the submission of amicus briefs, in cases affecting America's economic vitality, and in particular in cases involving the expansion of tort remedies in ways that harm businesses, burden entrepreneurialism, and stifle job creation. PLF filed amicus briefs in *Moradi v. Marsh USA, Inc.*, 219 Cal. App. 4th 886 (2013), *pet. denied* No. S214248; *O'Neil v. Crane Co.*, 53 Cal. 4th 335 (2012); and *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008), *pet. denied* No. S169116. PLF attorneys also have published scholarly articles discussing

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[1] Pursuant to California Rule of Court 8.520, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than Amicus Curiae, its members, or its counsel made a monetary contribution to its preparation or submission.

how the expansion of tort liability can hinder the vitality of the free enterprise system. *See, e.g.*, Deborah J. La Fetra, *A Moving Target: Property Owners' Duty to Prevent Criminal Acts on the Premises*, 28 Whittier L. Rev. 409 (2006); Deborah J. La Fetra, *Freedom, Responsibility, and Risk: Fundamental Principles Supporting Tort Reform*, 36 Ind. L. Rev. 645 (2003).

BRIEF AMICUS CURIAE

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Every act has a potentially infinite number of effects, so that if a defendant were held liable for every possible wrong resulting from an action, economic enterprise simply could not go on. Tort law recognizes this fact and, accordingly, requires line-drawing. Courts do not impose liability regardless of how tangential the person's involvement. Instead, they impose liability only where the risk of harm is reasonably foreseeable, and where necessary to compensate victims and deter unreasonably dangerous conduct. *Thompson v. Cnty. of Alameda*, 27 Cal. 3d 741, 750 (1980). Without such line drawing, tort law would unduly deter socially beneficial businesses, and become fundamentally unfair. *See Mega Life & Health Ins. Co. v. Superior Court*, 172 Cal. App. 4th 1522, 1527 (2009) (unbridled tort liability would unfairly redress "injur[ies] without wrong").

In this case, the plaintiffs ask the Court to go further than it has ever gone before in applying the tort of negligent misrepresentation, and to hold

that a brand pharmaceutical manufacturer owes a duty to a plaintiff that consumed a generic version of the product years after the manufacturer left the market and sold the production rights to someone else. This would end any limits on brand manufacturers' duties to users of generic drugs under the tort. Such a duty is not justified by existing case law, nor by considerations of public policy or fairness. Imposing liability when the harm is so attenuated to the defendants' actions would not promote the goal of deterrence, would unfairly impose liability for conduct only tangentially related to the harm, and would stifle worthy economic enterprises—including the production of potentially life-saving drugs. It would also undercut the goal of the tort of negligent misrepresentation by decreasing the flow of useful information. For these reasons, the decision below should be reversed.

ARGUMENT

I

THE THEORY ADOPTED BELOW CONTAINS NO LOGICAL STOPPING POINT

Plaintiffs seek to hold Novartis liable under negligent misrepresentation for making statements about a product the plaintiffs did not use, years before the plaintiffs were injured, and years after Novartis sold the rights to make its product to someone else—on the theory that the plaintiffs' injury was "foreseeable." *T.H. v. Novartis Pharm. Corp.*, 245 Cal. App. 4th 589, 605 (2016). This theory would eliminate even the permeable boundaries

established in *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008)—the closest a California court has come to imposing the type of innovator liability sought in this case. Plaintiffs' theory would invert the concept of foreseeability, which is meant to "limit the otherwise potential[] infinite liability which would follow every negligent act." *Dillon v. Legg*, 68 Cal. 2d 728, 739 (1968).

In *Conte*, the court of appeal held a brand pharmaceutical manufacturer liable for negligent misrepresentation even though the plaintiff had ingested a generic version of the drug manufactured by a different company. 168 Cal. App. 4th 89 at 105. The court reasoned that, because pharmacists can fill prescriptions for a brand drug with the generic version, it was foreseeable that a doctor might rely on the brand company's statements and prescribe a brand drug, and the pharmacist would fill the prescription with the generic version. *Id.* Alternatively, because brand and generic drugs are bioequivalent, it was foreseeable that a doctor might rely on the brand's statements when prescribing the generic drug.[2] *Id.*

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[2] Nearly every other court to consider the issue has held exactly the opposite. *See, e.g., In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917, 938 (6th Cir. 2014) ("[A]n overwhelming majority of courts" including at least fifty-five decisions from twenty-two states "have rejected 'the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug.'"); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013) ("[T]he overwhelming national consensus—including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a

(continued...)

After *Conte*, there is little a brand manufacturer can do to shield itself from liability to users of generic versions of their drugs. For instance, manufacturers cannot limit their liability at the outset by using a disclaimer that says that its statements only apply to the product at hand, because the Food and Drug Administration (FDA) requires generic drugs' labels to mimic their brand counterpart.[3] Nor can brand manufacturers limit their liability later by informally withdrawing from the marketplace after the patent expires, because withdrawing does not change the manufacturer's regulatory responsibilities to the FDA.[4] Some commentators have assumed then, at the very least, a manufacturer could limit its liability by transferring ownership to someone else who would assume responsibility for the drug.[5] *Conte* itself

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[2] (...continued)
product."); *see also* James M. Beck & Mark Herrmann, *Scorecard: Innovator Liability in Generic Drug Cases*, Drug & Device Law Blog (Nov. 12, 2009), https://www.druganddevicelawblog.com/2009/11/scorecard-non-manufacturer-name-brand.html.

[3] James M. Beck, *A Thought Experiment on* Conte v. Wyeth, Drug and Device Law Blog (Feb. 23, 2009), https://www.druganddevicelawblog.com/2009/02/thought-experiment-on-conte-v-wye.html.

[4] Eric G. Lasker, et al., *Taking the "Product" Out of Product Liability: Litigation Risks and Business Implications of Innovator and Co-Promoter Liability*, Defense Counsel Journal, July 2015, at 306-07, https://www.hollingsworthllp.com/uploads/1353/doc/EGL_SAK_TFB_Taking_Product_out_of_Product_Liability_DefenseCounselJournal_July2015.pdf.

[5] *See, e.g., id.* at 306-06 (When a manufacturer transfers ownership, the "new owner assumes regulatory responsibilities for the drug." At that point, the old manufacturer has no more power to change the label than the generic manufacturer, and "the theory underpinning innovator liability would no (continued...)

implied that transferring ownership constituted a limit on manufacturers' liability. 168 Cal. App. 4th at 107. When the defendants argued that accepting innovator liability would result in "permanent and uncontrolled liability . . . in perpetuity," the court responded that the allegation could not be true, because "Wyeth no longer has primary responsibility for Reglan-related claims arising after March 31, 2002," the date Wyeth sold off its production line. *Id.* This case, then, seeks to impose exactly the type of never-ending liability disclaimed in *Conte*, and to foreclose the only opportunity brand manufacturers have to ensure that their liability for statements on their labels does not continue "in perpetuity."

Not only was the result below disclaimed by *Conte*, it is unlike any California court case that the *Conte* opinion relied on. For example, the *Conte* court found *Garcia v. Superior Court*, 50 Cal. 3d 728 (1990), "instructive." In *Garcia*, this Court held that a parole officer owed a duty of care to a parolee's victim when he told her that the parolee would "not com[e] looking for her." *Id.* at 731. The Court noted that, once the officer chose to communicate information to the victim, he had a duty to use reasonable care in doing so. *Id.* at 736. But here, the defendant never communicated any information to the plaintiff or the plaintiff's doctor. It chose to stop communicating altogether by leaving the market and relinquishing

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[5] (...continued)
longer obtain.)

responsibility for the drug to someone else. Imposing liability in this case would be akin to saying that the parole officer in *Garcia* was liable even if he never spoke to the plaintiff and retired, but a subsequent officer relied on the retired officer's notes when making a statement to the victim.

The same is true of *Hanberry v. Hearst Corp.*, 276 Cal. App. 2d 680, 686 (1969). In that case, Mrs. Hanberry sued the Hearst publishing company after she slipped and fell on the vinyl floor of her kitchen while wearing a pair of shoes guaranteed by a Hearst-published magazine. The court held that the publisher had "voluntarily involved itself in[] the marketing process" by "in effect loan[ing] its reputation to promote and induce the sale of a given product." *Id.* at 684. The *Hanberry* Court emphasized the voluntary business relationship that the defendant entered when it published the magazine, thus putting itself "in the position where public policy imposes . . . the duty to use ordinary care." *Id.* By contrast, there is no voluntary business relationship in this case, because defendants left the market and sold the business to a new manufacturer. Imposing liability in this case would be akin to holding Hearst liable even after it sold the magazine to a different publisher that continued to run the endorsement on which the plaintiff relied. In both cases, the defendant did not intend to profit from the plaintiff, or even to communicate with the plaintiff. It ceased communicating altogether by leaving the market.

Even *Randi W. v. Muroc Joint Unified Sch. Dist.*, 14 Cal. 4th 1066, 1081 (1997), which held that a party owed a duty of care to a third person who

did not receive the information at issue, did not go as far as the decision below. In that case, the Court held that a school district that wrote a letter of recommendation for a former employee owed a student later assaulted by the employee a duty not to misrepresent the facts. *Id.* Imposing liability here would be akin to holding a person liable for writing a recommendation letter intended for a certain job application, even after the applicant uses it for a different application years after the author changes job and is no longer responsible for writing such letters.

In sum, the decision below cannot be squared with *Conte*, nor with any case *Conte* relied on. By holding that once an innovating manufacturer labels a prescription drug in compliance with federal law, not even selling the company will relieve it of potential liability, the court below has imposed a type of limitless tort liability never before sanctioned by California courts.

II

POLICY CONSIDERATIONS WEIGH AGAINST EXTENDING A DUTY IN THIS CASE

Even if this Court decides that the plaintiffs' injury was foreseeable, "policy considerations may dictate a cause of action should not be sanctioned . . . for the sound reason that the consequences of a negligent act must be limited in order to avoid an intolerable burden on society." *Elden v. Sheldon*, 46 Cal. 3d 267, 274 (1988). Public policy considerations, including promoting deterrence, ensuring fundamental fairness, supporting socially

beneficial enterprises, and increasing the flow of useful information, weigh against imposing liability in this case.

A. Imposing Liability in This Case Would Not Promote Deterrence, and Is Fundamentally Unfair

An important consideration when deciding whether or not to impose a tort duty is promoting deterrence. *Foley v. Interactive Data Corp.*, 47 Cal. 3d 654, 711 (1988) (the "proper and traditional function of tort law" is to "deter and demand redress"). Imposing liability on a party that has relinquished control of the product, and therefore no longer has any ability to avert the harm, cannot serve deterrence. Only those entities that can monitor, label, test, or otherwise control a product have an incentive to make that product safer.[6]

In *Taylor v. Elliott Turbomachinery Co., Inc.*, 171 Cal. App. 4th 564, 595 (2009), the appellate court refused to hold a company whose products were often used with asbestos-containing products for failing to warn of the dangers of asbestos. The court noted that doing so would not "serve the policy of preventing future harm" because it was "doubtful [defendants] had any ability to control the types of products that were used with their equipment." *Id.*; *accord O'Neil v. Crane Co.*, 53 Cal. 4th 335, 365 (2012) (refusing to hold manufacturer liable for failing to warn of dangers of asbestos merely because

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[6] *See* Lasker, et al., *supra*, at 307 (Noting the practical concerns with making a brand manufacturer responsible for its products after divestiture. For example, unlike the generic manufacturers themselves, brand manufacturers will have difficulty "obtaining meaningful and complete safety data from generic manufacturers" second-hand.)

product was used with asbestos-containing components; manufacturer had no control over how the asbestos-containing products were used); *see also Romito v. Red Plastic Co., Inc.*, 38 Cal. App. 4th 59, 66-67 (1995) (skylight manufacturer owed no duty to electrician killed by falling through skylight three years after sale of product; ability to prevent future harm limited by lack of control over external factors affecting risk of harm). The obvious and most efficient defendant for deterrence purposes is the party that has the ability to control the product. Richard C. Ausness, *When Warnings Alone Won't Do: A Reply to Professor Phillips*, 26 N. Ky. L. Rev. 627, 640 (1999).

The *Taylor* court emphasized that, not only would imposing liability on a party with no control over the product that causes injury fail to prevent future harm, it would be fundamentally unfair. The court explained: "[L]ittle moral blame can be attached to" failing to warn of *another*'s products. If the injuries had to be attributed to "morally blameworthy conduct, it is the conduct of the manufacturers and suppliers of the asbestos-containing materials [the plaintiff] actually encountered, who were in the best position to investigate and warn of the dangers posed by their products." *Taylor*, 171 Cal. App. 4th at 595; *see also Lineaweaver v. Plant Insulation Co.*, 31 Cal. App. 4th 1409, 1418 (1995) ("[I]it serves no justice to fashion rules which allow responsible parties to escape liability while demanding others to compensate a loss they did not create.").

It is exactly these considerations which led this Court to reject imposing liability on property owners for injuries that occur after they relinquish control of their properties. *See Preston v. Goldman*, 42 Cal. 3d 108, 125 (1986). For example, landowners' inability to predict future uses of their land means that any injuries that happen after the land is transferred are not foreseeable. *Id.* Moreover, "the greater 'blame' should be placed on those in present control of the circumstances." *Id.* That person can "make changes, take needed precautions, and control the entry of persons on the land." *Id.* The subsequent owner is also in the best position to insure against potential losses. Holding the original landowner liable would only make insurance more difficult to get. *Id.* at 126.

Notably, even proponents of innovator liability admit that the doctrine is often unfair to the defendants. *See* Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 Duke L.J. 1123, 1181 (2011) (Holding brand, but not generic, manufacturers liable results in an "asymmetry" that is "particularly unfair given that the brand-name manufacturers make substantial investments in developing new drugs from which generic producers profit by copying."); *see also* Wesley E. Weeks, *Picking Up the Tab for Your Competitors: Innovator Liability After* PLIVA, Inc. v. Mensing, 19 Geo. Mason L. Rev. 1257, 1259 (2012) (Conceding that innovator liability "is far from ideal" and "could provide drug developers with a negative incentive, reducing the number

of beneficial drugs developed in this country."). After an innovator sells a product line, it relinquishes both the moral responsibility and the practical ability to change the label on its product. It is therefore both unfair, and unwise, to hold them liable for statements on their labels.

B. The Decision Below Will Deter Useful Enterprises Beyond the Pharmaceutical Industry

Expansive theories of tort liability drive up the cost of doing business. The result is higher prices for poorer products, as companies are forced to divert funds to "settlements, damage awards, insurance, lawyers, and legal-defense costs" rather than "product and process improvements." Lawrence J. McQuillan, et al., *Jackpot Justice: The True Cost of America's Tort System* 23 (Pacific Research Institute) (2007). Depleted resources and a fear of lawsuits might also cause companies to rationally withhold products from the market altogether. *See* AMA Board of Trustees, *Impact of Product Liability on the Development of New Medical Technologies* 12 (June 1988) (Noting that products have been pulled from the market, not for safety reasons, "but because product liability suits have exposed manufacturers to unacceptable financial risks."); Cass R. Sunstein, et al., *Assessing Punitive Damages (With Notes on Cognition and Valuation in Law)*, 107 Yale L.J. 2071, 2077 (1998) (Limitless tort liability like that imposed by the court below "is likely to produce excessive caution," because "unpredictable awards create both unfairness and (on reasonable assumptions) inefficiency, in a way that

may overdeter desirable activity."). If developers of pharmaceuticals are forced to shoulder never-ending tort liability for their drugs, it will drive up the cost of medical research and development, to the detriment of the consumers.

As Justice O'Connor observed, the threat of enormous awards "has a detrimental effect on the research and development of new products," particularly pharmaceuticals. *Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part). In response to expanding theories of tort liability, prescription drug manufacturers have "decided that it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market." *Id.* Potential tort liability has chased pharmaceutical companies away from developing products designed for use by children and pregnant women. Joseph F. Petros III, *The Other War on Drugs: Federal Preemption, the FDA, and Prescription Drugs After* Wyeth v. Levine, 25 Notre Dame J.L. Ethics & Pub. Pol'y 637, 661-62 (2011) (also noting that tort law has impeded development of a vaccine for the AIDS virus). Similar considerations explain why most courts reject the theory of innovator liability. *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 377 (Iowa 2014) (Innovator liability "discourage[s] investments necessary to develop new, beneficial drugs by increasing the downside risks.").

The decision below threatens more than just the pharmaceutical industry. While the theory of innovator liability was developed in the context

of pharmaceuticals, there is "no principled barrier" to prevent the doctrine from extending to "deficient representations or design defects made by developers of other types of popular products copied by competitors." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 707 (Ala. 2014). Identical issues arise with other types of goods, "ranging from nonprescription drugs and foods to household chemicals and appliances." Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 Tort Trial & Insurance Prac. L.J. 673, 694 (2010). Under the appellate court's rationale, any name-brand company that faces competition by a knock-off brand risks innovator liability, even after it leaves the market. A consumer of Mr. Pibb might rely on statements from Dr. Pepper cans. A person who uses a knock-off replacement head for a Swiffer might rely on the original Swiffer head's packaging. An owner of two cars may rely on government mandated warnings in just one of the car's manuals.[7] The prospect of liability will be especially likely for companies whose names have become synonymous with a product, like Kleenex, Xerox, Band-aid, and Clorox bleach. It will also be a risk for products that—like pharmaceuticals—have what are essentially bio-equivalents (i.e., brands of sugar). Several companies could face the type of

[7] *See* James M. Beck, *More Thoughts on* Conte v. Wyeth, Drug and Device Law Blog (Nov. 13, 2008), https://www.druganddevicelawblog.com/2008/11/more-thoughts-on-conte-v-wye.html.

liability sought in this case, and the effects of the decision will be felt by consumers served by each of these industries.

This Court has long been sensitive to extending tort liability where the result would be to burden socially beneficial endeavors. *See Parsons v. Crown Disposal Co.*, 15 Cal. 4th 456, 466-68 (1997) (operators of socially beneficial machinery not liable when it startles horses and causes injuries). The Court should therefore refrain from extending liability in this case, which would not only affect the production of potentially life-saving drugs, but a wide-range of useful products.

C. The Decision Below Will Deter the Flow of Useful Information

Although the negligent misrepresentation cause of action is intended to increase the flow of truthful information, expansive applications of the tort *reduce* that flow. For example, since this Court expanded liability for misrepresentation in the context of recommendation letters, *see Randi W. v. Muroc Joint Unified Sch. Dist.*, 14 Cal. 4th at 1070, most employers have adopted a strict "no comment" policy to avoid potential litigation and liability for inadvertent misrepresentations. *See, e.g.*, John Ashby, *Employment References: Should Employers Have an Affirmative Duty to Report Employee Misconduct to Inquiring Prospective Employers?*, 46 Ariz. L. Rev. 117, 119 (2004). Faced with liability for even well-intentioned statements, "[o]nly those employers dull-witted enough to issue free-wheeling assessments

without calling their lawyers would supply any but the most rudimentary information." *Passmore v. Multi-Management Services, Inc.*, 810 N.E.2d 1022, 1028 (Ind. 2004); *see also Kadlec Medical Center v. Lakeview Anesthesia Assocs.*, 527 F.3d 412, 422 (5th Cir. 2008) ("[A]lthough the defendants might have had an ethical obligation to disclose their knowledge of Dr. Berry's drug problems, they were also rightly concerned about a possible defamation claim if they communicated negative information about Dr. Berry.").

Because the plaintiffs' theory of negligent misrepresentation vastly expands liability under the tort, it might have a similar stifling effect—which would not be confined to pharmaceuticals. The lower court in *Conte*, for example, partially relied on *Randi W.*—an employment reference case—to justify its holding in the pharmaceutical context. The decision below might similarly be used to expand negligent misrepresentation in other areas, which would chill the exchange of valuable information in a wide array of situations. If publishers like the defendant in *Hanberry*, 276 Cal. App. 2d 680, can be held liable for its endorsements even after a new publisher takes over, or if people like the parole officer in *Garcia*, 50 Cal. 3d 728, can be held liable for statements they make in their official capacity even after they leave their job, these parties may choose to censor themselves rather than risk a lawsuit. Negligent misrepresentation is meant to foster the provision of useful speech, not encourage producers to censor it altogether.

CONCLUSION

The decision below would unmoor liability for negligent misrepresentation from all conceivable rationales normally employed in tort, and impose never-ending liability on brand manufacturers. For the foregoing reasons, the decision below should be reversed.

DATED: November 29, 2016.

Respectfully submitted,

DEBORAH J. LA FETRA
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CERTIFICATE OF COMPLIANCE

Pursuant to California Rule of Court 8.204(c)(1), I hereby certify that the foregoing APPLICATION TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF DEFENDANT-RESPONDENT, is proportionately spaced, has a typeface of 13 points or more, and contains 3,998 words.

DATED: November 29, 2016.

ANASTASIA P. BODEN

DECLARATION OF SERVICE BY MAIL

I, Barbara A. Siebert, declare as follows:

I am a resident of the State of California, residing or employed in Sacramento, California. I am over the age of 18 years and am not a party to the above-entitled action. My business address is 930 G Street, Sacramento, California 95814.

On November 29, 2016, true copies of APPLICATION TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF DEFENDANT-RESPONDENT, were placed in envelopes addressed to:

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which envelopes, with postage thereon fully prepaid, were then sealed and deposited in a mailbox regularly maintained by the United States Postal Service in Sacramento, California.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed this 29th day of November, 2016, at Sacramento, California.

Barbara A. Siebert
BARBARA A. SIEBERT