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SUPREME COURT COPY

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IN THE SUPREME COURT OF CALIFORNIA

T.H. AND CARDWELL HAMILTON

Plaintiffs and Appellants,

v.

NOVARTIS PHARMACEUTICALS CORP.,

Defendant and Respondent

Review of a Decision of the Court of Appeal, Fourth Appellate District, Division One, Case No. D067839 (McConnell, P.J.)

From a Decision of the Superior Court San Diego County, Case No. 37-2013-00070440-CU-MM-CTL (Lewis, J.)

APPLICATION BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF NOVARTIS PHARMACEUTICALS CORP.

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December 7, 2016

Attorneys for Amicus Curiae Pharmaceutical Research and Manufacturers of America

Pursuant to Appellate Rule 8.520(f), the Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully seeks leave to file the accompanying *amicus curiae* brief in support of Defendant Novartis Pharmaceuticals Corp.[1]

PhRMA is a voluntary, nonprofit association comprised of the leading pharmaceutical research and technology companies. PhRMA members are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. In 2015 alone, PhRMA members invested $58.8 billion in discovering and developing new medicines. (PhRMA, *2016 Profile: Biopharmaceutical Research Industry* (2016) p. ii <http://phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf>.)

PhRMA frequently files amicus briefs on issues that affect its members, and the issue presented in this case is especially crucial to them. Every brand-name company faces generic competition. By expanding the already substantial litigation risks that brand-name companies face to encompass the risks created by their generic competitors' products, the Court of Appeal's outlier holding subjects each of PhRMA's members to unpredictable and potentially immense liability. PhRMA is uniquely positioned to address the unfairness to its members of the Court of Appeal's decision and the accompanying effect that the decision could have on innovation and the public health. PhRMA believes its views will assist the

[1] No party's counsel authored this brief in whole or in part. No party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief, and no person other than amicus curiae, its members, or its counsel made such a monetary contribution. Although Defendant is a member of PhRMA, it has not contributed financially to the preparation of this brief.

Court in resolving this case by providing a unique perspective on the practical implications of affirming the decision below.

Respectfully submitted,

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Dated: December 7, 2016

PROOF OF SERVICE

I, Romeo Berana, am a resident of the State of California and over the age of 18 years. Neither I, nor my client, the Pharmaceutical Research and Manufacturers of America, are a party to this action. My business address is Covington & Burling LLP, One Front Street, San Francisco, CA 94111.

On December 7, 2016, I caused the following document entitled:

APPLICATION BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF NOVARTIS PHARMACEUTICALS CORP.

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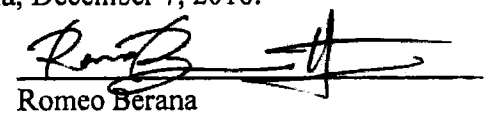
I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed in San Francisco, California, December 7, 2016.



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December 7, 2016

CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

Pursuant to Appellate Rule 8.208, the Pharmaceutical Research and Manufacturers of America ("PhRMA") states that it is a trade association with no parent corporations. No entity or person has a 10% or greater ownership interest in PhRMA. PhRMA does not know of any person or entity, other than the parties themselves, that has a financial or other interest in the outcome of the proceeding that the justices should consider in determining whether to disqualify themselves. A list of PhRMA's member companies can be found at http://www.phrma.org/about/member-companies.

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SUMMARY OF ARGUMENT

Plaintiffs seek to hold Novartis responsible for the alleged injuries of a child whose mother ingested a generic version of its former brand-name medicine Brethine, notwithstanding that Plaintiffs' mother never took the brand-name version of Brethine and that Novartis had stopped marketing Brethine many years earlier. In allowing their claims to proceed, the Court of Appeal embraced several outlier theories that, in addition to being inherently unfair, carry significant public health implications. Faced with uncertain and unlimited liability tethered neither to their own products nor to their financial returns, brand-name companies who face potential liability for alleged injuries sustained while using generic copies of their products years after leaving the market may be forced to cabin that liability in at least two ways that will frustrate the aims of the federal regulatory scheme governing pharmaceuticals and harm public health.

First, by subjecting the companies engaged in innovation to liability that bears no relation to their products or revenues (and that instead follows directly from the measure by which their revenues are reduced by generic competition), the Court of Appeal's holding substantially disrupts innovators' ability to recapture investments and shrinks the resources that can be invested in future innovation.

Second, by creating a remarkable risk profile for brand-name companies, the Court of Appeal's decision encourages companies to prophylactically warn of every conceivable risk, which in turn could erode the meaningfulness of scientifically-justified warnings and deter beneficial uses of medications.

In light of these significant public health concerns, the Court of Appeal's decision should be reversed.

ARGUMENT

I. The Costs of Researching and Developing Innovative Medicines Are Borne Almost Entirely by Brand-Name Companies

A. Innovator Companies Invest Immense Resources in Researching and Developing New Medicines

Bringing a new medicine to market is a lengthy and expensive process. Before studying a new medicine in humans, a pharmaceutical company must conduct a series of laboratory and animal studies to test how the medicine works and assess its safety. (21 C.F.R. § 312.23(a)(8).) If the results are promising, the company submits an Investigational New Drug application ("IND") to the FDA, outlining the preclinical study results and offering a plan for clinical trials in humans. (21 U.S.C. § 355(i)(2); 21 C.F.R. § 312.20(a)–(b).) Upon FDA approval of the IND, the company conducts three phases of clinical trials, each of which must be completed successfully before the potential new medicine may undergo FDA review and approval. (21 C.F.R. § 312.21.) On average, the clinical trial phase takes six to seven years to complete. (PhRMA, *Biopharmaceutical Research & Development: The Process Behind New Medicines* (2015) p. 10 <http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf>.) If clinical trial results show that the medicine's benefits outweigh its risks, the sponsoring company can seek the FDA's approval to market the medicine by submitting a New Drug Application ("NDA"). (21 U.S.C. § 355(b).) The NDA, which must contain, among other things, the results of the clinical and pre-clinical testing, proposals for manufacturing, and proposed labeling for the new medicine (21 U.S.C § 355(b)(1)), often exceeds 100,000 pages in length (PhRMA, *Biopharmaceutical Research & Development*, *supra*, at p. 14).

Innovative companies undertake this process at tremendous expense and risk. On average, developing and obtaining FDA approval of a new medicine takes ten to fifteen years and costs $2.6 billion. (PhRMA, *2016*

Profile: Biopharmaceutical Research Industry (2016) p. ii <http://phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf>.) Pharmaceutical companies spend even more money developing compounds that are never approved: just one out of every 5,000 to 10,000 compounds under development, and just one out of every eight medicines entering clinical trials, obtains FDA approval. (*Ibid.*; PhRMA, *Biopharmaceutical Research & Development*, *supra*, at p. 10; see also PhRMA, *2016 Profile*, *supra*, at p. 36 [reporting that in 2013, pharmaceutical companies sponsored 6,199 clinical trials involving 1.1 million participants].) PhRMA's member companies invest approximately one quarter of their total annual domestic sales on research and development — an estimated $58.8 billion in 2015. (*Ibid.*)

These costs do not end with approval. Once a new medicine is brought to market, NDA holders are required to monitor, review, and report to the FDA all adverse events received from any source, "including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." (21 C.F.R. § 314.80(b); see also Food & Drug Administration, *Reports Received and Reports Entered into FAERS by Year* (2015) <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm> [stating that the FDA received over 1.2 million adverse event reports from pharmaceutical companies in 2014].) NDA holders must also submit to the FDA annual reports summarizing all information received about their medicines, including adverse drug events and clinical trial results. (21 C.F.R. § 314.81(b)(2).)

Apart from adverse-event reporting, the FDA frequently requires NDA holders to undertake additional clinical studies after approval. (See

21 U.S.C. § 355(o)(3).) According to one estimate, more than three quarters of all new medicine approvals are accompanied by a commitment by the sponsor to conduct one or more post-marketing, or "Phase IV," studies. (Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?* (2006) 61 Food & Drug L.J. 295, 300.) PhRMA's member companies spend more than $7.5 billion annually conducting these studies. (PhRMA, *Annual Membership Survey* (2015) p. 6 table 4 <http://www.phrma.org/sites/default/files/pdf/2015-phrma_profile_membership_results.pdf>.)

B. The Hatch-Waxman Amendments Enable Generic Manufacturers to Copy Innovative Medicines at Minimal Expense

Prior to the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417 (Sept. 24, 1984) 98 Stat. 1585), commonly known as the Hatch-Waxman Amendments, virtually all companies were required to conduct pre-clinical and clinical trials as a prerequisite to obtaining the FDA's approval to market a medicine. Recognizing that this procedure was a hindrance to the launch of generic medicines — in 1984, approximately 150 medicines with expired patents lacked generic competition — Congress amended the FDA approval process to "make available more low cost generic drugs." (H.R. Rep. No. 98-857, pt. 1, 2d Sess., p. 14 (1984), reprinted in 1984 U.S. Code Cong. & Admin. News, p. 2647.)

The Hatch-Waxman Amendments left in place the multi-step approval process for innovative new medicines, but it streamlined that process for generic versions of those medicines. Under Hatch-Waxman, a company may seek approval to market a generic medicine by filing an abbreviated new drug application ("ANDA") demonstrating that the generic version is biologically equivalent to an already-approved medicine. (21

U.S.C. § 355(j)(2)(A)(iv); 21 C.F.R. § 314.92(a)(1).) An ANDA applicant need not independently perform extensive and costly studies to prove that the generic is safe and effective; instead, it can rely on "a prior agency finding of safety and effectiveness based on the evidence presented in [the] previously approved new drug application." (57 Fed. Reg. 17950, 17953 (April 28, 1992).)[1]

Due to these streamlined procedures, researching and developing a generic version of an FDA-approved medicine costs under $2 million today — less than one-tenth of one percent of the cost of developing the innovative medicine itself. (U.S. Department of Health and Human Services, Office of Science and Data Policy, *Expanding Use of Generic Drugs* (2010) pp. 4–5 <https://aspe.hhs.gov/sites/default/files/pdf/76151/ib.pdf>.) Generic manufacturers pass these cost savings onto consumers. (See PhRMA, *Biopharmaceuticals in Perspective: Spring 2016* (2016) p. 54 <http://phrma.org/files/dmfile/chart-pack-biopharmaceuticals-in-perspective4.pdf>.)

II. The Duties Created by the Court of Appeal Would Expose Brand-Name Companies to Limitless Liability

Plaintiffs take great pains to portray this case as unique. In truth, there is nothing particularly unusual about the allegations presented here. After generic entry, the market share of generic copies of medicines dwarfs the brand's market share. (See, e.g., Grabowski, *Updated Trends in US Brand-Name and Generic Drug Competition* (2016) 19 J. Med. Econ. 836 [reporting that for brand medicines facing generic entry in 2013-2014, generics captured an average of 93 percent of the market (by volume)

[1] Because a generic medicine must contain "the same" active ingredient(s), delivered in "the same" dosage form, strength, and route of administration, in a formulation that is bioequivalent to an approved brand-name medicine, it must bear identical warnings. (28 U.S.C. § 355(j)(2)(A)(ii)–(v).)

within the first year].) If allowed to stand, the Court of Appeal's decision will expose brand-name manufacturers to virtually unlimited liability for injuries allegedly sustained while using generic versions of their current and former branded products.

The scope of litigation against pharmaceutical companies is immense. Between 2000 and 2006, more than 65,000 product liability lawsuits were filed against pharmaceutical companies. (See Schmit, *More Drugs Get Slapped with Lawsuits* (Aug. 23, 2006) USA Today <http://usatoday30.usatoday.com/money/industries/health/drugs/2006-08-23-drug-lawsuits-usat_x.htm>.) And as of last year, one quarter of all pending multidistrict litigation proceedings involved product liability claims, the majority involving medicines or medical devices. (See U.S. Judicial Panel on Multidistrict Litigation, Calendar Year Statistics: January Through December 2015, p. 11 <http://www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2015.pdf>.)

Lawsuits seeking to impose innovator liability on brand-name pharmaceutical companies already number in the thousands. (See *Neeley v. Wolters Kluwer Health, Inc.* (E.D. Ky. 2015) 311 F.R.D. 427, 429 [noting that "thousands" of cases have been filed against "against various generic and brand-name companies responsible for manufacturing Reglan®/metoclopramide"].) Courts have ruled on this issue in lawsuits involving treatments for allergic reactions, asthma, bacterial infections, cardiac arrhythmias, depression, enlarged prostate, heartburn, insomnia, menopausal symptoms, migraine headaches, obesity, and panic disorder, to name just a few.[2] Cases seeking to hold brand-name companies liable

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[2] See, e.g., *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, 168–71 [Phenergan (promethazine hydrochloride)]; *Tsavaris v. Pfizer, Inc.* (S.D. Fla. 2016) 154 F.Supp.3d 1327, 1339–41 [Activella (continued...)

under a theory of innovator liability persist, even though the concept has been rejected by the overwhelming majority of courts that have considered it. (See Opening Brief on the Merits pp. 32–33.)

Should innovator liability gain acceptance, the number of lawsuits would multiply exponentially. A creative advocate can always sketch out a scenario where some action (or inaction) by the brand-name company years earlier could impact the subsequent generic labeling. There is virtually no limiting principle to this "butterfly effect" rational endorsed by the Court of Appeal, as clever lawyers can trace almost any safety issue back to the original brand holder, given the overwhelming amount of safety data the innovator company amasses over the decades of development and marketing of a medicine before generic entry. Lawyers can almost always make incendiary allegations of "off-label" promotion for unapproved uses, to conceive of new or stronger warnings that they allege companies should have added to their labeling, or to claim in hindsight that existing warnings should have been added sooner. (See, e.g., Brief for the United States as

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(estradiol/norethindrone acetate)]; *Neeley v. Wolters Kluwer Health, Inc.*, *supra*, 311 F.R.D. 427, 432–34 [Reglan (metoclopramide)]; *Anselmo v. Sanofi-Aventis Inc. USA* (Kan. Dist. Ct., Oct. 13, 2014, No. 10-CV-77) 2014 WL 8849464, at *1 [Ambien (zolpidem)]; *Barnhill v. Teva Pharmaceuticals USA, Inc.* (S.D. Ala., Apr. 24, 2007, No. CIV A 06-0282-CB-M) 2007 WL 5787186, at *2 [Keflex (cephalexin)]; *Goldych v. Eli Lilly & Co.* (N.D.N.Y., July 19, 2006, No. 5:04CV1477(GLS/GJD)) 2006 WL 2038436, at *3–8 [Prozac (fluoxetine)]; *Colacicco v. Apotex, Inc.* (E.D. Pa. 2006) 432 F.Supp.2d 514, 539–43 [Paxil (paroxetine)]; *DaCosta v. Novartis AG* (D. Or., Mar. 1, 2002, No. CV 01-800-BR) 2002 WL 31957424, at *8–9 [Migranal (ergot alkaloid)]; *Rafferty v. Merck & Co., Inc.* (Mass. Super., May 23, 2016, No. 2013–04459) 2016 WL 3064255, at *4–6 [Proscar (finasteride)]; *Stanley v. Wyeth, Inc.* (La. Ct. App. 2008) 991 So.2d 31, 33–35 [Cordarone (amiodarone)]; *Flynn v. American Home Products Corp.* (Minn. Ct. App. 2001) 627 N.W.2d 342, 350–52 [Pondimin (fenfluramine)].

Amicus Curiae Supporting Petitioner p. 25, *Wyeth v. Levine* (2009) 555 U.S. 555 (No. 06-1249) <http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_07_08_06_1249_PetitionerAmCuUSA.authcheckdam.pdf> [noting the "post hoc imagination of lawyers" in pursuing pharmaceutical lawsuits challenging safety labeling].) And because nine out of every ten U.S. prescriptions are filled with generics, the number of potential plaintiffs is enormous. (PhRMA, *2016 Profile*, *supra*, at p. ii).

As this case demonstrates, a broad interpretation of such allegations can permit even the most outlandish claims to survive demurrer, forcing companies to expend significant resources and years in discovery to fend off frivolous claims. For example, Plaintiffs claim that Novartis failed to warn of the "serious side effects on newborns whose mothers consumed Terbutaline while pregnant" (AA016–58, at ¶ 130), notwithstanding that more than three years after T.H.'s mother ingested terbutaline, the FDA concluded that "the available human data regarding an association between terbutaline sulfate and autism" — the specific disorder from which T.H. allegedly suffers — "are not sufficient to conclude that there is 'positive evidence of human fetal risk.'" (Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, to James P. Reichmann (Feb. 17, 2011) p. 13 <http://www.fda.gov/downloads/drugs/drugsafety/ucm243797.pdf>.) Plaintiffs further complain that Novartis "aggressively marketed" Brethine for an off-label use (Answer Brief on the Merits p. 12), notwithstanding that the FDA has never challenged Novartis's marketing of Brethine.[3]

[3] While Plaintiffs contend that off-label promotion "goes dramatically under-regulated by the FDA" (Answer Brief on the Merits p. 40), the truth of the matter is that the federal government and state attorneys general (continued...)

Indeed, the allegations that Plaintiffs claim make this case unique — that (1) the medicine at issue causes a serious injury, (2) the manufacturer knew or should have known of the risk but failed to warn about it on its labeling, and (3) the former manufacturer knew or should have known that upon selling the rights to market the medicine, the purchaser would not update the medicine's labeling (Answer Brief on the Merits p. 61) — are hardly rare. The first two "unusual facts" are essential elements of any negligent failure-to-warn claim. (See, e.g., *Chavez v. Glock, Inc.* (2012) 207 Cal.App.4th 1283, 1304–05 [144 Cal.Rptr.3d 326, 345].) And Plaintiffs' brief makes little attempt to conceal their belief that *every* former manufacturer should anticipate that the purchaser will not update the medicine's labeling, because warnings might temper future sales. (See Answer Brief on the Merits p. 61.) Indeed, even Plaintiffs admit that the

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actively investigate such allegations, which have resulted in many high-profile cases against pharmaceutical companies in recent years. (See, e.g., U.S. Department of Justice, *Endo Pharmaceuticals and Endo Health Solutions to Pay $192.7 Million to Resolve Criminal and Civil Liability Relating to Marketing of Prescription Drug Lidoderm for Unapproved Uses* (Feb. 21, 2014) <https://www.justice.gov/opa/pr/endo-pharmaceuticals-and-endo-health-solutions-pay-1927-million-resolve-criminal-and-civil>; U.S. Department of Justice, *Wyeth Pharmaceuticals Agrees to Pay $490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses* (July 30, 2013) <https://www.justice.gov/opa/pr/wyeth-pharmaceuticals-agrees-pay-4909-million-marketing-prescription-drug-rapamune-unapproved>; U.S. Department of Justice, *Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote* (May 7, 2012) <https://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote>; U.S. Department of Justice, *U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx®* (Nov. 22, 2011) <https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-pay-nearly-one-billion-dollars-over-promotion>.)

Court of Appeal's holding affects "hundreds, perhaps thousands" of potential claimants. (*Id.* at p. 68).

III. The Court of Appeal's Massive Expansion of Tort Liability Will Harm Innovation

Shifting liability to innovators for injuries allegedly sustained by individuals who ingest generic manufacturers' products is likely to chill innovation and impair public health. When a company is exposed to liability that bears no relationship to its products, sales, or revenue, it is both prevented from recapturing its research and development investment in that medicine and discouraged from making future investments. Such a result not only undermines the purposes of the Hatch-Waxman Amendments, which "careful[ly] balance" the interest in lower-cost medicines against the need to "encourag[e] research and innovation" (57 Fed. Reg. 17950, 17951 (April 28, 1992)),[4] but is also incompatible with California's established public policy, which "favors the development and marketing of beneficial new drugs" (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063 [245 Cal.Rptr. 412, 420, 751 P.2d 470, 479]). The Court should decline to contort basic tort principles in such a manner. (See *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 782 [122 Cal.Rptr.3d 313, 327, 248 P.3d 1170, 1182] [holding that "the undesirable

[4] See also H.R. Rep. No. 98-857, *supra*, at p. 15 ["The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval."]. To encourage brand-name companies to continue engaging in research and development in the face of greater competition from lower-priced generics, the Hatch-Waxman Amendments restore up to five years of the patent life lost during clinical testing and NDA review. (See 35 U.S.C. § 156(a), (c), (g)(6)(A).) Extending the period of market exclusivity allows companies that bring innovative medicines to market to begin to earn back their research and development costs.

consequences of allowing potential liability" are a key consideration in deciding whether to impose a tort duty].)

Given the enormous costs associated with researching and developing a new medicine, the scope of litigation risk bears heavily on a company's decision to invest in innovation. (See *Brown v. Superior Court*, *supra*, 44 Cal.3d 1049, 1065 n.10 [recognizing the "connection between the cost and availability of pharmaceuticals and the liability imposed on their manufacturers for injuries"]; Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989* (1994) 24 Seton Hall L.Rev. 1418, 1419 ["[T]he net effect of the surge in liability costs ha[s] been to discourage innovation in the pharmaceutical industry."]; Epstein, *Legal Liability for Medical Innovation* (1987) 8 Cardozo L.Rev. 1139, 1153–54 ["If in the aggregate the net gains are wiped out by the liability costs, then the product will no longer be made."].)

The anti-nausea drug Bendectin, used to treat severe morning sickness in pregnant women, illustrates why. After Bendectin was named as the cause of birth defects in thousands of lawsuits, its manufacturer withdrew the medicine from the market in 1983, only later to be vindicated by scientific studies showing that Bendectin posed no risks to either mothers or fetuses. (See Bernstein, *The Breast Implant Fiasco* (1999) 87 Cal. L.Rev. 457, 460; Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs* (2003) 54 S.C. L.Rev. 741, 760–61; Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases* (1993) 46 Stan. L.Rev. 1, 7; Brent, *Medical, Social, and Legal Implications of Treating Nausea and Vomiting of Pregnancy* (2002) 186 Am. J. Obstetrics & Gynecology S262, S262–63.) In 2013, after nearly thirty years off the market, Bendectin returned under a new name. (See Food & Drug Administration, *FDA Approves Diclegis for Pregnant Women Experiencing Nausea and Vomiting* (Apr. 8, 2013)

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm347087.htm>.) In the interim, however, hospital admissions for excessive vomiting during pregnancy had doubled, costing the U.S. economy $1.7 billion annually in time lost from work, caregiver time, and hospital expenses. (See Nuangchamnong & Niebyl, *Doxylamine Succinate–Pyridoxine Hydrochloride (Diclegis) for the Management of Nausea and Vomiting in Pregnancy: An Overview* (2014) Int'l J. Women's Health 401, 401–02 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3990370/pdf/ijwh-6-401.pdf>.)

Similarly, by 1990, eight of the nine major U.S. pharmaceutical companies that had been involved in researching and developing new contraceptives had abandoned their efforts. (National Research Council, Committee on Contraceptive Development, & Institute of Medicine, Division of International Health, *Developing New Contraceptives* (1990) p. 59 <www.nap.edu/download/1450#>.) According to the National Research Council and the Institute of Medicine, "recent products liability litigation and the impact of that litigation on the cost and availability of liability insurance have contributed significantly to the climate of disincentives for the development of contraceptive products." (*Id.* at p. 141.) In 1989, the inventor of the birth control pill, Carl Djerassi, recommended changes to the product liability regime, commenting that "the United States is the only country other than Iran in which the birth control clock has been set backward during the past decade." (Djerassi, *The Future of Birth Control* (Sept. 10, 1989) Wash. Post <https://www.washingtonpost.com/archive/opinions/1989/09/10/the-future-of-birth-control/7e25f2cc-ae35-4a79-8daf-031db02f81be/?utm_term=.dd4d8bbcf626>.) The executive director of the Society for the Advancement of Women's Health Research similarly testified before Congress that "the current liability climate is preventing

women from receiving the full benefits that science and medicine can provide." (S. Rep. No. 104-69, 1st Sess., p. 7 (1995).)

The country's experience with vaccines is also illustrative. Lawsuits in the late 1970s alleging that the whooping-cough component of the DPT vaccine caused permanent brain damage led nearly all of its manufacturers to cease production, resulting in nationwide shortages. (See Willett, *Litigation as an Alternative to Regulation: Problems Created by Follow-on Lawsuits with Multiple Outcomes* (2005) 18 Geo. J. Legal Ethics 1477, 1488 n.60; see also *Brown v. Superior Court*, *supra*, 44 Cal.3d 1049, 1064 ["One producer of diphtheria-tetanus-pertussis vaccine withdrew from the market, giving as its reason 'extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance.' [citation] There are only two manufacturers of the vaccine remaining in the market, and the cost of each dose rose a hundredfold from 11 cents in 1982 to $11.40 in 1986, $8 of which was for an insurance reserve."].) Although the allegation that the DPT vaccine causes neurological harm was subsequently "discredited" (Sugarman, *Cases in Vaccine Court – Legal Battles Over Vaccines and Autism* (2007) 357 N. Eng. J. Med. 1275, 1276), by 1986, there was only one American manufacturer of the polio vaccine, one manufacturer of the measles, mumps, and rubella vaccine, and two manufacturers of the DPT vaccine (H.R. Rep. No. 99-908, 2d. Sess., p. 7 (1986), reprinted in 1986 U.S. Code Cong. & Admin. News, p. 6344). Congress, realizing the "inadequacy — from both the perspective of vaccine-injured persons as well as vaccine manufacturers — of the current approach to compensating those who have been damaged by a vaccine" (*id.* at p. 7), passed the National Childhood Vaccine Injury Act of 1986 (Pub. L. No. 99-660 (Nov. 14, 1986) 100 Stat. 3743), which removed many personal-injury cases involving vaccines from the state-law tort system. Congress hoped that once "manufacturers ha[d] a better sense of their

potential litigation obligations, a more stable childhood vaccine market w[ould] evolve." (H.R. Rep. No. 99-908, *supra*, at p. 7.) And, in fact, the Act appears to have "succeeded in stabilizing prices and stemming further exit from the market" for listed vaccines. (Noah, *Triage in the Nation's Medicine Cabinet*, *supra*, at p. 761.)

In short, the past 40 years have repeatedly demonstrated that dramatic increases in potential liability — particularly unpredictable, long-enduring liability — can drive biopharmaceutical companies to abandon the research and production of medicines, especially those that treat populations like children and pregnant women where the liability risks are especially significant. (See, e.g., *Brown v. Superior Court*, *supra*, 44 Cal.3d 1049, 1063 [recognizing that "fear of large adverse monetary judgments" makes pharmaceutical companies "reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial"].) Yet the unpredictable liability that would follow from the theory of innovator liability is worse by an order of magnitude: all of the examples discussed above took place in a legal landscape where companies were potentially liable for injuries to plaintiffs who used medicines that they themselves manufactured. Under the Court of Appeal's logic, a brand-name company could be subjected to decades of liability for a medicine manufactured by its competitor years after the innovative company stops earning any significant revenue from its innovation.[5] The impact of this

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[5] Plaintiffs insist that *Carlin v. Superior Court* (1996) 13 Cal.4th 1104 [56 Cal.Rptr.2d 162, 920 P.2d 1347] "rejected the argument that imposition of tort liability on brand-name manufacturers will deter innovation." (Answer Brief on the Merits p. 45.) But *Carlin*'s careful balance — pharmaceutical companies could be held strictly liable for failing to warn of risks presented by their own products that were known or reasonably knowable at the time of distribution, but not those that were unknown or unknowable — was designed to minimize the impact of tort liability on innovation. (See *id.* at (continued...)

unpredictable and potentially limitless liability on innovation, and correspondingly on public health, would be profound.[6]

The biopharmaceutical industry funds nearly half of all U.S. biomedical research, accounting for the largest share of public or private funding. (PhRMA, *Biopharmaceuticals in Perspective*, *supra*, at p. 27.) Its investments have produced dozens of major scientific breakthroughs. For example, over the past two decades, innovative diagnostic techniques and treatments have reduced the death rate from cancer by 23 percent, saving over 1.5 million lives. (PhRMA, *2016 Profile*, *supra*, at p. 9.) Innovations have reduced the death rates from heart disease and stroke by nearly 40 percent compared to ten years ago. (*Id.* at pp. 7–8.) And innovative treatments for HIV/AIDS have contributed to a nearly 87 percent decline in death rates since the mid-1990s, preventing over 862,000 premature deaths. (PhRMA, *Biopharmaceuticals in Perspective*, *supra*, at p. 8.) Without

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1117.) *Carlin* hardly repudiates the importance of incentivizing innovation in the pharmaceutical industry or suggests that allowing an entirely new class of claims by users of another manufacturer's medicine would not adversely impact innovation.

[6] Nor would innovator liability increase consumer access to medicines. (See *Brown v. Superior Court*, *supra*, 44 Cal.3d 1049, 1063 [holding that "the broader public interest in the availability of drugs at an affordable price must be considered" in deciding liability standards]; *Sloan v. Wyeth* (N.J. Sup. Ct. Oct. 13, 2004, No. MRS-L-1183-04) 2004 WL 5767103 [rejecting innovator liability because it would not "advance the affordably of drugs, one of the main policy foundations for the Hatch-Waxman amendments"]; Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects* (2013) 81 Fordham L. Rev. 1835, 1870 ["Saddling 10 percent of a market with 100 percent of its liability is certain to create new and significant financial pressures on brand-name drugs, the effects of which would harm health care consumers."]

ongoing investments from pharmaceutical companies in research and development, none of these advances would have been possible.

Numerous scholars and jurists have recognized that placing liability on innovator pharmaceutical companies for injuries allegedly sustained from the use of generic medicines would negatively impact innovation.[7] Plaintiffs nevertheless insist that there would be no impact on innovation because "brand-name drug companies make enormous profits" prior to generic entry and would be loath to forego this "enormous financial windfall." (Answer Brief on the Merits p. 46.) Plaintiffs' assertion is

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[7] See *In re Darvocet, Darvon, & Propoxyphene Product Liability Litigation* (6th Cir. 2014) 756 F.3d 917, 945 [rejecting innovator liability in light of the "grave health policy consequences" it presents, including "fewer innovative drugs"]; *Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 377 (plur. opn.) ["[E]xtending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks."]; *Rossi v. Hoffmann-LaRoche* (N.J. Sup. Ct. Jan. 3, 2007, No. ATL-L690-05) 2007 WL 7632318 [holding that innovator liability "could only act to stigmatize the ability of companies to develop new and innovative drugs"]; *Sloan v. Wyeth, supra*, 2004 WL 5767103 ["Brand name manufacturers would be less likely to develop new products if liability were imposed upon these companies for injuries wrought by products of generic manufacturers."]; Laakmann, *The Hatch-Waxman Act's Side Effects: Precautions for Biosimilars* (2014) 47 Loyola L.A. L.Rev. 917, 926 [innovator liability "could further dampen the incentives to create new drugs and thus reduce overall patient welfare"]; Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product* (2010) 45 Tort Trial & Ins. Prac. L.J. 673, 688 n.69 [innovator liability "threatens to chill therapeutic product innovation"]; Schwartz et. al., *Warning, supra*, at p. 1871 [innovator liability makes it "riskier for brand-name manufacturers to dedicate resources to researching and developing potentially life-saving or life-improving medicines"]; Koopman, *Hidden Risks of Taking Generic Drugs over Brand Name: The Impact of Drug Labeling Regulations on Injured Consumers and the Pharmaceutical Industry* (2014) 34 J. Nat'l Ass'n Admin. L. Judiciary 112, 140 ["Overall, innovator liability likely results in less new drug development."].

divorced from today's reality. Since 2000, the average lifetime revenue for a new medicine has declined by over forty percent. (See PhRMA, *Biopharmaceuticals in Perspective*, *supra*, at p. 51.) Over a similar timeframe, the costs of researching and developing new medicines have more than doubled. (*Id.* at p. 34.) Consequently, four out of every five medicines today fail to earn enough revenue even to offset their up-front research and development costs. (PhRMA, *2016 Profile*, *supra*, at p. ii.) Innovator liability would shrink the number of profitable medicines even further.

IV. Holding Brand-Name Companies Liable for Injuries Allegedly Sustained from Their Generic Competitors' Products Will Impair the Usefulness of Pharmaceutical Labeling

A. The Tort Duties Invented Below Encourage Companies to Warn of Speculative and Hypothetical Risks

Liability that includes not only a company's own medicines, but also those manufactured by its generic competitors may additionally affect how companies seek to protect themselves. Because liability in pharmaceutical product liability cases hinges on whether a company's labeling sufficiently warned of potential risks, companies looking ahead to the generic phase of a medicine's lifespan may have no choice other than to "pile on warnings for every conceivable adverse reaction, no matter how remote the odds," in order to protect themselves "from the 20/20 hindsight of juries." (Comment, *Resolving Drug Manufacturer Liability for Generic Drug Warning Label Defects* (2015) 47 St. Mary's L.J. 219, 238.)[8]

[8] Limitless tort liability drives companies to add unnecessary warnings because lawsuits center on allegations that a warning was deficient in the context of an injured individual plaintiff. (See *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, 325 ["A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."]; *Cotton v. Buckeye Gas* (continued...)

This approach would harm consumers in two ways. First, physicians may disregard lengthy labeling that is filled with speculative warnings, thereby overlooking important, scientifically-founded safety information. (See *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 932 [12 Cal.Rptr.3d 262, 276, 88 P.3d 1, 13] ["'Against the benefits that may be gained by a warning must be balanced the dangers of overwarning and of less meaningful warnings crowding out necessary warnings . . . .'" (quoting *Carlin v. Superior Court*, *supra*, 13 Cal. 4th 1104, 1133) (conc. & dis. opn. of Kennard, J.)]; *Finn v. G. D. Searle & Co.* (1984) 35 Cal.3d 691, 701 [200 Cal.Rptr. 870, 876, 677 P.2d 1147, 1153] ["[I]nundat[ing] physicians indiscriminately with notice of any and every hint of danger . . . inevitably dilut[es] the force of any specific warning given."]; see also, e.g., *Robinson v. McNeil Consumer Healthcare* (7th Cir. 2010) 615 F.3d 861, 869 ["The resulting information overload [from describing every remote risk] would make label warnings worthless to consumers."]; *Thomas v. Hoffman-LaRoche, Inc.* (5th Cir. 1992) 949 F.2d 806, 816 n.40 [explaining that if warnings were cluttered with "every possible risk," then "physicians [would] begin to ignore or discount the warnings"]; H.R. Rep. No. 86-1861, 2d Sess., p. 2837 (1960), reprinted in 1960 U.S. Code Cong. & Admin. News, p. 2833 [speculative warnings "invit[e] indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness"]; 73 Fed. Reg.

Prods. Co. (D.C. Cir. 1988) 840 F.2d 935, 937–38 ["Failure-to-warn cases have the curious property that, when the episode is examined in hindsight, it appears as though addition of warnings keyed to a particular accident would be virtually cost free."]; Epstein, *Legal Liability for Medical Innovation*, *supra*, at p. 1150 ["Once the outcome is known to be bad, some further warnings of adverse side effects must be good, given that it would discourage the unfortunate course of action."].)

49603, 49605–06 (Aug. 22, 2008) [unfounded statements in FDA labeling may cause "more important warnings" to be "overshadow[ed]"].) Warnings on pharmaceutical labeling are already extensive. The average package insert today lists 49 potential adverse events, and one out of every ten labels contains over 500 warnings. (Duke et al., *A Quantitative Analysis of Adverse Events and "Overwarning" in Drug Labeling* (2011) 171 Archives of Internal Med. 944, 945 <http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/487051>.)

Second, warnings that are not grounded in science discourage the beneficial use of medicines. (See, e.g., *Dowhal v. SmithKline Beecham Consumer Healthcare*, *supra*, 32 Cal.4th 910, 934 ["[A] truthful warning of an uncertain or remote danger may mislead the consumer into misjudging the dangers stemming from use of the product, and consequently making a medically unwise decision."]; *Mason v. SmithKline Beecham Corp.* (7th Cir. 2010) 596 F.3d 387, 391–92 ["[O]verwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted . . . ."]; 73 Fed. Reg. 49603, *supra*, at pp. 49605–06 ["[O]verwarning . . . may deter appropriate use of medical products . . . ."].) All medicines have risks, and all prescribing decisions are based on a balancing of those risks against the medicine's potential benefits. Overstating risk thus keeps physicians from making optimal prescribing decisions.

The FDA has long been aware of the dangers that overwarning presents. Since 1979, the agency has stated that "it would be inappropriate to require statements in drug labeling that do not contribute to the safe and effective use of the drug, but instead are intended solely to influence civil litigation." (44 Fed. Reg. 37434, 37435 (June 26, 1979); see also 150 Cong. Rec. S8657-01 (daily ed. July 22, 2004) (statement of former FDA Chief Counsels) ["If every state judge and jury could fashion their own labeling requirements for drugs and medical devices, . . . FDA's ability to

advance the public health by allocating scarce space in product labeling to the most important information would be seriously eroded."].) Because innovator liability could produce the very result that the FDA considers in its expert scientific judgment to be "inappropriate," the concept should be rejected.

B. Existing Law Amply Incentivizes Pharmaceutical Companies to Adequately Warn of Known Risks

The Plaintiffs nevertheless argue that the expansive tort duties that the Court of Appeal fashioned are necessary to prevent brand-name companies from underwarning. According to Plaintiffs, without innovator liability, brand-name companies would have "little incentive to ensure that [their] drug labels remain accurate" upon generic entry. (Answer Brief on the Merits pp. 39–40.) Plaintiffs additionally maintain that if former manufacturers were not forced to answer for injuries allegedly sustained after they divested ownership of their innovative medicines, they would be incentivized to "sell the brand rights to the drug rather than update the drug's label." (*Id.* at pp. 65–66.) Plaintiffs' arguments fundamentally misunderstand the FDA regulatory regime and the mechanics of corporate transactions.

At all times, pharmaceutical labeling must warn of all "clinically significant hazard[s]" for which there is "reasonable evidence of a causal association." (21 C.F.R. § 201.57(c)(6)(i).) If a company learns of new evidence that meets this standard at any time after approval of its NDA, it must submit a supplement to modify the labeling. (*Id.* § 314.70(b)(2)(v), (c)(6).) A medicine that bears labeling that fails to warn of risks for which there is reasonable evidence of a causal association is "misbranded." (21 U.S.C. § 352(a), (f), (j); U.S. Department of Health and Human Services, *Guidance for Industry: Safety Labeling Changes — Implementation of Section 505(o)(4) of the FD&C Act* (2013) p. 7 n.10 <http://www.fda.gov/

downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm250783.pdf> ["To implement the statutory prohibition against marketing a misbranded product, 21 CFR § 201.57(c)(6) requires that prescription drug labeling be 'revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug.'"].)

Pharmaceutical companies have ample incentives to comply with these obligations, because the consequences for misbranding a medicine are severe. Putting aside the fact that companies can be held liable in tort by those who actually used their products if they fail to adequately warn of the known risks, if at any time after approval the FDA believes that a medicine is misbranded, it can withdraw marketing approval (21 U.S.C. § 355(e)(3)) and bring an enforcement action against the manufacturer (see *id.* § 352(a)). Upon finding that the medicine is misbranded, a court may enjoin the medicine's distribution (*id.* § 332), seize the medication (*id.* § 334), or impose criminal penalties (*id.* § 333), which can result in complete exclusion from healthcare programs such as Medicare or Medicaid and thereby eliminate a company's major distribution channel. State attorneys general can also recover large fines against companies whose medicines are mislabeled. [See Schwartz et. al., *Warning*, *supra*, at p. 1872 n.254 [citing examples of civil penalties in the amounts of $1.2 billion, $327 million, $258 million, and $158 million].) Any of the foregoing actions can lead to serious reputational harm that can negatively affect sales of a company's entire portfolio of medicines. Accordingly, additional litigation against brand-name companies is not needed to incentivize them to police their labels.

Nor would companies be incentivized to "delay the adoption of necessary warnings and then profit from their misconduct by selling the rights to the drug" at an inflated price. (Answer Brief on the Merits pp. 63–

64.) Evaluating potential product liability claims is a central component of every pharmaceutical purchaser's due diligence. (See, e.g., Wheeler, *Due Diligence in Life Sciences Mergers and Acquisitions*, Lexis Practice Advisor J. (Nov. 30, 2015) <https://www.lexisnexis.com/lexis-practice-advisor/the-journal/b/lpa/archive/2015/11/30/due-diligence-in-life-scienes-mergers-amp-acquisitions.aspx> ["Evaluating existing product liability claims and potential sources for future claims should be an important part of any due diligence effort for a life sciences transaction."]; Mannix & Gaba, *Acquiring Pharmaceutical or Medical Device Manufacturers: Due Diligence and Risk Reduction Strategies*, Practical L.J. (Sept. 2012), p. 36 <https://www.hklaw.com/files/Publication/4649d747-75f5-4165-931c-5d959869a9e3/Presentation/PublicationAttachment/0fb0d029-1301-4442-9fe4-0a9ee7e1fa6d/September2012_MA-in-Healthcare.pdf> ["In particular, during the due diligence process acquirors should evaluate: . . . Financial risks related to products liability claims, and product labeling and advertising potentially resulting in misbranding and US Food and Drug Administration (FDA) enforcement actions."].) During the diligence process, potential purchasers review, among other things, the medicine's labeling, reports of adverse events sustained while using the medicine, and the pertinent scientific literature to assess the risk of future product liability litigation. Where a medicine's labeling fails to adequately warn of its known risks, potential purchasers are likely to notice.

This case is instructive. Plaintiffs allege that Brethine's labeling failed to warn of a risk of birth defects that by the time of Novartis's sale of the medicine to aaiPharma had already been identified in nearly a dozen published studies and recognized in public pronouncements by the FDA, the Agency for Healthcare Research and Quality, and the leading professional society of American gynecologists and obstetricians.

(AA016–58, at ¶¶ 30–31, 33–36, 38–39, 41, 46, 48, 51–54.) Accepting these allegations as true, it is hardly plausible that aaiPharma would have been completely unaware of this evidence before finalizing its purchase.

Moreover, a company that hides material risk information within its unique possession can expect to face liability to the purchaser in both contract and tort. (See *Warner Construction Corp. v. City of Los Angeles* (1970) 2 Cal.3d 285, 294 [85 Cal.Rptr. 444, 449, 466 P.2d 996, 1001] ["In transactions which do not involve fiduciary or confidential relations, a cause of action for non-disclosure of material facts may arise . . . [where] the facts are known or accessible only to defendant, and defendant knows they are not known to or reasonably discoverable by the plaintiff . . . ."]; *Belasco v. Wells* (2015) 234 Cal.App.4th 409, 424 [183 Cal.Rptr.3d 840, 852] [non-disclosure of a material fact can trigger rescission of a contract].) In short, the supposed need to prevent companies from "toss[ing] the 'hot potato' of a dangerously mislabeled drug" does not justify the detrimental consequences to the public of the Court of Appeal's holding. (Answer Brief on the Merits p. 6.)

V. The Duties Created by the Court of Appeal Are Fundamentally Unfair

Having paid nearly all of the costs associated with researching and developing a new medicine, brand-name companies would, under the Court of Appeal's decision, also have to pay for the harm allegedly caused by generic manufacturers' products. Making matters worse, a brand-name company would continue to face liability years (or even decades[9]) after it

[9] Plaintiffs maintain that "it is difficult to imagine a scenario in which a brand-name manufacturer is sued an extended period of time . . . after it divested a drug." (Opening Brief on the Merits p. 69.) Yet that scenario is already playing out across the country. In 2001, Wyeth, Inc., sold Reglan, a medicine used to treat gastroesophageal reflux disease, to Schwartz (continued...)

sold all ownership of the medicine and lost all ability to change its labeling.[10] No modern conception of fairness would tolerate a company being held liable for injuries caused by a product it did not make years after it ceased all sales of its own product.

This case starkly illustrates the unfairness of the Court of Appeal's decision. Ever since generic Brethine entered the market in June 2001 (Press Release, *Impax Receives FDA Approval to Market Terbutaline Sulfate Tablets* (June 27, 2001) <http://www.evaluategroup.com/Universal/View.aspx?type=Story&id=44249>), sales of brand-name Brethine have steadily declined. Indeed, all of the brand-name manufacturers of Brethine have left the market: Novartis sold all rights to AAIPharma in December 2001 (Press Release, *Novartis Divests Brethine in US* (Dec. 13, 2001) <http://www.evaluategroup.com/Universal/View.aspx?type=Story&id=16955>), and AAIPharma ceased selling Brethine in August 2006 (see 72 Fed. Reg. 39629, 39630 (July 19, 2007)). Novartis is thus being subjected to decades of potential liability for a competitor's product, even when that product was manufactured years after

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Pharma Inc. In the years that followed, thousands of lawsuits were filed against Wyeth alleging that Reglan should have warned of the risk of tardive dyskenia. Wyeth continues to face new lawsuits, over a decade after it divested Reglan. (See, e.g., *Nicely v. Wyeth, Inc.* (Mo. Ct. App. 2014) 451 S.W.3d 694, 695 [complaint filed in June 2012].)

[10] The only way for a company to change a medicine's labeling is by submitting a "prior approval supplement" or a "changes being effected supplement" to its NDA. (21 C.F.R. § 314.70(b)(2)(v), (c)(6).) Since only the NDA holder may "submit a supplement to an application," former manufacturers have no control over the labeling for medicines they no longer own. (*Id.* § 314.71(a); see also *Lyman v. Pfizer, Inc.* (D. Vt., July 20, 2012, No. 2:09-CV-262) 2012 WL 2970627, at *16 [recognizing that upon the sale of the medicine at issue, its former manufacturer "lost any ability to change the . . . label"].)

it (and its successor) stopped earning *any* revenue from that product, and even when Novartis long ago lost the ability to make changes to the labeling.

Plaintiffs respond that it is equally unfair to deny consumers monetary relief "simply because their pharmacy happen[ed] to have filled their prescription with a generic version of the drug." (Answer Brief on the Merits p. 43.) But "[t]he brand-name manufacturer plays no role in the generic manufacturer's decision to enter the market, and it is not responsible for crafting the regulatory and legal framework within which the generic manufacturer chooses to do so." (*Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649, 694 n.27 (dis. opn. of Murdock, J.) [recognizing that any perceived unfairness was "created by Congress and the Food and Drug Administration . . . in return for the perceived societal benefit of less expensive generic drugs, or perhaps instead by the manner in which the United States Supreme Court subsequently has applied the preemption doctrine to the legislative and regulatory scheme structured by those entities"]). Accordingly, the fact that "the consumer of a competitor's product is . . . blocked from imposing on that competitor the costs that would normally accompany the rewards attendant to the sale of that product" does not make it any less unfair to shift liability onto the brand-name company for injuries suffered from a product it never sold. (*Id.* at p. 701 n.33.)

CONCLUSION

For the foregoing reasons, the Court of Appeal's decision should be reversed.

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

This brief complies with the type-volume limitations of Appellate Rule 8.200(c)(1) because it contains 7,303 words, as counted by the Microsoft Word word-processing program used to prepare the brief, excluding the parts of the brief exempted by Appellate Rule 8.200(c)(3).

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PROOF OF SERVICE

I, Romeo Berana, am a resident of the State of California and over the age of 18 years. Neither I, nor my client, the Pharmaceutical Research and Manufacturers of America, are a party to this action. My business address is Covington & Burling LLP, One Front Street, San Francisco, CA 94111.

On December 7, 2016, I caused the following document entitled:

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF NOVARTIS PHARMACEUTICALS CORP.

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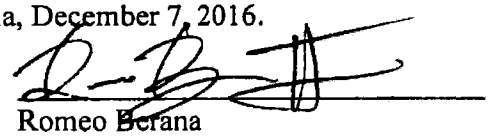
I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed in San Francisco, California, December 7, 2016.



Romeo Berana