S233898

IN THE

SUPREME COURT OF CALIFORNIA

T.H., A MINOR, ET AL.,
Plaintiffs and Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant and Respondent.

Review of a decision of the Court of Appeal,
Fourth Appellate District, Division One
Case No. D067839

Application for Leave to File Brief as Amicus Curiae
In Support of Plaintiffs-Appellants
And Brief of Amicus Curiae Public Citizen, Inc.

CHAVEZ & GERTLER LLP
NANCE F. BECKER (SBN 99292)
42 Miller Ave.
Mill Valley, CA 94925
415-381-5599

Of counsel: Allison M. Zieve
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
202-588-1000

Attorneys for Amicus Curiae Public Citizen

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Washington, DC 20009
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Attorneys for Amicus Curiae Public Citizen

APPLICATION OF PUBLIC CITIZEN, INC., FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFFS-APPELLANTS

Public Citizen, Inc. respectfully requests leave to file the accompanying brief as amicus curiae in support of plaintiffs-appellants T.H., a minor, et al., addressing the question whether a patient should be able to hold the brand-name manufacturer accountable for injuries resulting from misrepresentations about the safety of a drug, when the patient took the generic form of the product.

INTEREST OF AMICUS CURIAE

Public Citizen is a non-profit consumer advocacy organization with members and supporters nationwide, including nearly 19,000 in California. Since its founding in 1971, Public Citizen has assessed the safety and efficacy of drugs, provided information on drug safety to the public, and advocated before the Food and Drug Administration (FDA) for product labeling and regulation to reduce safety risks. In June 2013, a Public Citizen report compiled a list of drugs for which black-box warnings—the most serious contraindications and warnings—were added after a generic equivalent entered the market. Looking at a five-year period, the report identified 53 drugs for which a black-box warning calling attention to serious or life-threatening risks was added after generic market entry. The data underscore the public health imperative of requiring pharmaceutical companies to maintain active surveillance of safety, even after a drug is also marketed in generic form.[1]

Public Citizen and its attorneys have participated, as amicus or appellate counsel, in many cases brought by patients injured by drugs that carried inadequate warnings, including *PLIVA, Inc. v. Mensing* (2011) 131 S. Ct. 2567, and *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89.

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[1] The report is available at www.citizen.org/documents/2138.pdf.

In *PLIVA*, the United States Supreme Court held that federal law preempts failure-to-warn claims against generic drug manufacturers because FDA regulations prohibit generic manufacturers from updating labeling except to mimic brand-name labeling changes or as ordered by the FDA. Public Citizen responded by petitioning the FDA to allow generic drug manufacturers to revise product labeling through the procedures already available to brand-name manufacturers. In November 2013, the FDA granted Public Citizen's petition in part by issuing a proposed rule, 78 Fed. Reg. 67985 (Nov. 13, 2013). The FDA, however, has yet to issue a final rule. Until it does so, and unlike brand-name manufacturers, generic drug manufacturers cannot initiate safety updates to product labeling. Patients and physicians therefore depend on brand-name manufacturers to provide adequate warnings for both brand-name and generic drugs. Allowing patients to pursue misrepresentation claims against brand-name manufacturers for injuries caused by inadequate warnings is important as both an incentive to be vigilant about product safety and to provide accountability to patients. For this reason, this case thus has important implications for all Californians that go well beyond the interests of the parties.

CERTIFICATION

No party's counsel authored this brief in whole or in part, and no party or party's counsel made a monetary contribution to fund the preparation or submission of this brief. No person or entity other than amici made a monetary contribution to the preparation or submission of this brief.

Dated: December 6, 2016

Respectfully submitted,
CHAVEZ & GERTLER LLP
PUBLIC CITIZEN, INC.

By: Nance F. Becker
Nance F. Becker

CERTIFICATE OF INTERESTED PARTIES

Pursuant to California Rule of Court 8.208, proposed amicus Public Citizen, Inc. makes the following disclosure regarding persons or entities having a financial or other interest in the outcome of the proceeding that the justices should consider in determining whether to disqualify themselves: There are no interested persons or entities who must be identified pursuant to Rule 8.208.

Dated: December 6, 2016

Respectfully submitted,

CHAVEZ & GERTLER LLP
PUBLIC CITIZEN, INC.

Nance F. Becker
Attorneys for Public Citizen, Inc.

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Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
202-588-1000

Attorneys for Amicus Curiae Public Citizen

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INTRODUCTION AND SUMMARY OF ARGUMENT

The primary issue presented in this case—whether brand-name drug manufacturers can be held liable for injuries caused by inadequately labeled generic drugs—is of significant and growing importance to patients. Following passage of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Amendments, sales of generic drugs have grown dramatically, fundamentally reshaping the pharmaceutical market. The increased availability of generic drugs has made many prescription drugs more affordable for patients. In 1983, only 35 percent of top-selling drugs with expired patents had generic equivalents; by 1998, nearly all did.[1] And when generics compete, they typically capture a significant part of market share and profit.[2] As of 2010, 90 percent of prescriptions for drugs with generic versions were filled with generics rather than brand-name drugs[3]—a development spurred by state laws authorizing pharmacists to substitute generic drugs when filling prescriptions.[4] Some states have gone further and now mandate generic substitution where available.[5] From 2009 through 2012, generic prescriptions' share of the prescription drug market

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[1] *How Increased Competition From Generic Drugs Has Affected Prices and Return in the Pharmaceutical Industry*, Congressional Budget Office, p. xii (1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[2] *See Research and Development in the Pharmaceutical Industry*, Congressional Budget Office, pp. 16-17 (2006), https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf.

[3] *ASPE Issue Brief: Expanding the Use of Generic Drugs*, HHS, pp. 3-4 (Dec. 2010), https://aspe.hhs.gov/basic-report/expanding-use-generic-drugs.

[4] *See Drug Product Selection: Legal Issues*, Thomas P. Christensen et al., 41 J. Am. Pharm. Ass'n 868 (2001).

[5] *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, William H. Shrank et al., 29 Health Affairs 1383 (July 2010).

increased to 84 percent of all U.S. prescriptions.[6] In 2010, generics captured more than 80 percent of the market within six months of expiration of a brand-name's patent (as compared to 55 percent in 2006).[7]

Despite these market changes, the law places responsibility for labeling firmly on brand-name manufacturers. Generic drug manufacturers cannot initiate labeling updates; the labeling of generic drugs must mirror that of the brand-name products. A patient's reliance on the brand-name labeling, regardless of whether the patient took the branded or the generic version of the drug, is thus intended by the regulatory scheme. In light of this unusual fact—that one manufacturer is required to copy the safety information provided by another—patients should be able to hold brand-name drug manufacturers accountable for injuries resulting from misrepresentations about the safety of their drugs, even if those injuries are caused by a generic version of the drug. As discussed below, allowing patients to do so makes sense under traditional tort law principles and as a matter of policy.

ARGUMENT

I. Safety concerns often do not come to light until years after a drug first comes on the market, and only brand-name manufacturers can promptly update labeling in light of newly discovered risks.

Before a manufacturer can market a drug in the United States, it must obtain FDA marketing approval. 21 U.S.C. § 355. Although the FDA

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[6] *Declining Medicine Use and Costs: For Better or Worse?*, IMS Institute for Healthcare Informatics (May 2013), http://static.correofarmaceutico.com/docs/2013/05/20/usareport.pdf; *The Use of Medicines in the United States: Review of 2010*, IMS Institute for Healthcare Informatics, pp. 11, 15, 22 (Apr. 2011), https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202010/Use_of_Meds_in_the_U.S._Review_of_2010.pdf (IMS 2011 Report).

[7] IMS 2011 Report, *supra* note 6, at p. 21.

evaluates the drug's safety and effectiveness for its intended use before granting approval, the importance of post-approval monitoring for ensuring drug safety is well-recognized. As an article in the *Journal of the American Medical Association* explained:

> Even though the evaluation of new drugs and devices is technically rigorous, the current approach of basing drug approval decisions on clinical trials of efficacy that include relatively small numbers of patients virtually guarantees that the full risks and complete safety profile of these drugs will not be identified at the time of approval. Rather, the full safety profile and effectiveness only manifest as each drug is used in the wider population of patients who are less carefully selected than participants in clinical trials.[8]

The limitations in pre-approval testing are especially salient when a drug's significant adverse effects are relatively rare or have long latency periods—forms of risk that the FDA approval process is not designed to uncover. Examples of drugs whose substantial risks were only discovered post-approval abound in the medical literature.[9] A 2013 article authored jointly by three FDA staff members and two academics reported that "[t]he most critical safety-related label changes, boxed warnings and contraindications, occurred a median 10 and 13 years after drug approval (and the range spanned from 2 to 63 years after approval)."[10] This conclusion is consistent with an earlier study's finding that "[o]nly half of

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[8] *Prescription Drugs, Products Liability, and Preemption of Tort Litigation*, Catherine D. DeAngelis & Phil B. Fontanarosa, 300 J. Am. Med. Ass'n 1939, 1939 (2008).

[9] *See, e.g.*, Brief of the Am. Med. Ass'n et al. as Amici Curiae Supporting Resp'ts, 2011 WL 794118, *PLIVA, Inc. v. Mensing* (2011) 131 S. Ct. 2567 (Nos. 09–993, 09–1039, 09–1501), at 12-17 (discussing examples of fenfluramine, propoxyphene, ibuprofen, terbutaline sulfate, and metoclopramide).

[10] *Evaluation of FDA safety-related drug label changes in 2010*, Jean Lester, et al., 22 Pharmacoepidemiology and Drug Safety 302, 304 (2013).

newly discovered serious [adverse drug reactions] are detected and documented in the *Physicians' Desk Reference* within 7 years after drug approval."[11]

Because safety risks are commonly not identified until long after a drug comes on the market, and indeed after generic versions of the drug come on the market, ongoing monitoring and labeling updates are crucial for safe use of medications. Yet as the Supreme Court recognized in *Wyeth v. Levine* (2009) 555 U.S. 555, "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Id.* at 578-79 (footnote omitted). It has therefore been "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times ... [and] ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570-71. The need for manufacturers to play a significant role is heightened by funding and staff shortages at the FDA that have prompted the Government Accountability Office (GAO) repeatedly to express concern about post-approval drug safety monitoring.[12]

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[11] *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, Karen E. Lasser, et al., 287 J. Am. Med. Ass'n 2215, 2218 (2002).

[12] *See, e.g., High-Risk Series: An Update* 271, GAO (Feb. 2015), http://www.gao.gov/assets/670/668415.pdf (expressing concern that FDA lacks resources to adequately inspect drug manufacturing facilities); *High-Risk Series: An Update* 116-17, GAO (Feb. 2011), http://www.gao.gov/assets/320/315725.pdf ("FDA staff have expressed concern about their ability to meet a growing postmarket workload, with some maintaining that their premarket responsibilities are considered a higher priority."); *Drug Safety: FDA Has Begun Efforts to Enhance Postmarket Safety, But Additional Actions Are Needed*, GAO (Nov. 2009), http://www.gao.gov/assets/300/298135.pdf; *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process*, GAO (Mar. 2006), http://www.gao.gov/new.items/d06402.pdf; *see also A Critical*

To ensure the post-approval safety of their drugs, manufacturers must "promptly review all adverse drug experience information obtained or otherwise received by the [manufacturer] from any source, foreign or domestic, including information derived from commercial marketing experience, post-marketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b). To ensure that labeling is kept up to date as information accumulates, FDA regulations require that the labeling of both brand-name and generic drugs "must 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; a causal relationship need not have been definitely established." *Id.* § 201.57(c)(6)(i) (implementing 21 U.S.C. § 352(f)(2), which provides that a drug lacking "adequate warnings" is misbranded). Yet the FDA significantly restricts generic manufacturers' ability to do so, in ways that absolve those manufacturers of responsibility for labeling updates and that reinforce the brand-name manufacturers' responsibility.

Brand-name manufacturers, who market drugs approved through the new drug application (NDA) process, may seek review and approval of revised labeling by filing a supplemental application. *Id.* § 314.70. A supplemental application must satisfy all regulatory requirements that apply to original applications. *See id.* § 314.71(b). Although some label changes require prior FDA approval—obtained through a "prior approval supplement," *id.* § 314.70(b)—other changes are brought to FDA's

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Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims, David A. Kessler & David C. Vladeck, 96 Geo. L.J. 461, 485 (2008) (noting that "[r]esource constraints have been especially acute with the agency's post-marketing surveillance efforts" and that two-thirds of FDA doctors and scientists "worry that the FDA is not adequately monitoring the safety of drugs once they are on the market").

attention at the time the applicant makes the change through a "changes being effected" (CBE) supplement. *Id.* § 314.70(c). CBE supplements are authorized for, among other things, "[c]hanges in the labeling to reflect newly acquired information ... [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which" there is reasonable evidence of a causal association. *Id.* § 314.70(c)(6)(iii)(A).

The United States Supreme Court, deferring to the FDA's interpretation of the existing regulation, has held that the CBE process is not available to generic manufacturers. *PLIVA, Inc. v. Mensing* (2011) 131 S.Ct. 2567, 2575. Instead, in most cases, generic drug manufacturers can make safety updates only after approval of a CBE supplement submitted by the brand-name manufacturer for that product or when ordered to by the FDA.[13] This restriction follows from the general rule that the labeling of the generic product must generally be "the same as the labeling of" the corresponding brand-name drug. 21 C.F.R. § 314.94(a)(8)(iii); *see also id.* § 314.105(c). As a result, brand-name manufacturers—and only brand-name manufacturers—have the responsibility for updating labeling to provide adequate warnings, even after generic versions of the brand-name drug are on the market.

II. Brand-name manufacturers can easily foresee that physicians and patients will rely on the brand-name labeling, regardless of whether a patient's prescription is filled with a generic drug.

As explained above, current FDA regulations allow the brand-name company to make safety updates without prior FDA approval, but prohibit

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[13] *Guidance for Industry, Revising ANDA Labeling Following Revision of the RLD Labeling*, FDA, p. 5 (May 2000), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072891.pdf; *see also Draft Guidance, Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn*, FDA (July 2016), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510240.pdf.

the generic company from making safety updates except to mimic the brand-name labeling revision or as instructed by the FDA. *See* 78 Fed.Reg. 67985, 67988 (Nov. 13, 2013). As Novartis acknowledges, even after generics come on the market, the brand-name manufacturer has an "ongoing responsibility to monitor the drug safety and labeling," Novartis Reply Br. 33, while the generic manufacturer lacks control over the safety information in its product labeling. Amicus Public Citizen has advocated that this system should be changed to allow generic companies to initiate safety updates. However, as the regulatory scheme currently exists, the responsibility for safety labeling remains squarely with the brand-name manufacturer.

For this reason, a patient's (and physician's) reliance on the brand-name labeling is not only foreseeable—whether the patient takes the brand-name or the generic form of the drug—it is inevitable and expected. And in light of the brand-name manufacturer's responsibility for maintaining the adequacy of the drug's labeling, it is not surprising that patients who suffered injury after taking a generic drug that had inadequate safety warnings have sometimes sought to hold the brand-name manufacturer accountable. At least some such lawsuits do not seek to hold the brand-name company responsible under strict products liability theory; some cases, including this one, are premised on a negligent failure to warn or intentional misrepresentation. As explained in the Restatement (Second) of Torts, "one who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results ... *to such third persons* as the actor should expect to be put in peril by the action taken." Restatement (Second) of Torts (1965) § 311(1)(b), at 106. *See also id.* § 310 at 103 (imposes similar liability for knowing misrepresentations); Restatement (Third) of Torts (2016) § 18(a) (defendant may fail to exercise

reasonable care by failing to warn if "(1) the defendant knows or has reason to know: (a) of that risk; and (b) that those encountering the risk will be unaware of it; and (2) a warning might be effective in reducing the risk of harm"). This traditional understanding of a misrepresentation claim provides strong support for the plaintiffs' position here.

In *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, the Court of Appeal held that a negligent misrepresentation claim against a brand-name manufacturer for injury caused when the patient took the generic equivalent was proper in light of the relationship between branded and generic drug labeling. The United States Supreme Court's subsequent decision in *PLIVA* reinforces *Conte*'s strong foundation. And the Court of Appeal's decision in this case correctly adopted *Conte*'s reasoning. As the court acknowledged, whether or not the facts alleged "can be proven remains to be seen, but is not the issue before us. Accepting these facts as true ... they are sufficient to establish foreseeability and a connection between the alleged injuries and the harm." *T.H. v. Novartis Pharms. Corp.* (2016) 245 Cal.App.4th 589, 605-06.

As Novartis points out (at 32 n.11), several federal appellate courts, predicting how the issue would be resolved under state laws of states other than California, have held to the contrary. Only two *state* Supreme Courts have authoritatively addressed the issue under the laws of their states, however. In one, *Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, the state court held that such a claim was a products liability claim under Iowa law, not a negligent-misrepresentation claim, and under Iowa law a products liability claim can be brought only against the product seller or supplier. *Id.* at 369, 371. In the other, the Supreme Court of Alabama rejected the notion that a misrepresentation claim is a species of products liability claim. *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649, 675. That court held that the brand-name manufacturer *could* be held liable for

misrepresentation in an action brought by a patient who was injured by the generic version of its drug. *Id.* at 670.[14]

Here, the plaintiffs' misrepresentation claims are not properly deemed products liability claims under *California* law. *See Randi W. v. Muroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, 1077; *Garcia v. Superior Court* (1990) 50 Cal.3d 728, 735 (citing Restatement (Second) of Torts § 311, comment b, at 106). The reasoning of the Iowa court therefore is not pertinent here. As the Court of Appeal's decision in *Conte* indicates, California law is fully consistent with the statement in *Weeks* that "[a] brand-name manufacturer could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug." 159 So.3d at 670.

Moreover, courts that have rejected recognition of a state-law misrepresentation claim in this context have failed to appreciate the unique elements of drug regulation—such as the requirement that generics use the brand-name labeling, the bar against generic manufacturers updating except in response to a brand-name update or FDA order (and, on the flip side, the brand-name manufacturers' ability to update safety warnings promptly, without prior FDA approval), and state substitution laws requiring or, as in California pursuant to Cal. Bus. & Prof. Code § 4073, permitting pharmacists to fill prescriptions with generic versions where available. In addition, each of the federal court decisions looks to the tort law of the state in which the claim arose, not to California law. Only two cases—*Conte* and the decision below—address California law. Both offer strong support for the conclusion that, under California law, a misrepresentation claim can be

[14] After intense lobbying by the pharmaceutical industry, the State of Alabama later enacted a statute superseding that decision, *see* Ala. Code § 6-5-530 (2015).

brought against the brand-name manufacturer in the circumstances of this case, because a brand-name drug manufacturer can reasonably foresee that its labeling will be relied on by patients and physicians using both the brand-name and generic forms of the drug.

III. Novartis's position, if adopted, would put patients at risk.

If accepted, Novartis's plea to be exempt from accountability for labeling for which it is solely responsible would exacerbate a dangerous safety gap. "[M]ost critical safety-related label changes" are made years after the drug's initial approval, "underscoring the importance of persistent and vigilant postmarket drug safety surveillance." *Evaluation of FDA safety-related drug label changes in 2010*, *supra* note 10, at 304. And the majority of labeling changes are initiated by the brand-name manufacturers, not the FDA. *Id.* at 303. Because critical safety information may come to light after entry of the generic onto the market, and because the generic manufacturer is limited to mimicking the brand-name labeling, if the brand-name manufacturer does not continue actively to monitor and propose safety updates, patients are at risk.

Declaring that "[t]he federal regulatory scheme depends in part upon the continued presence of brand name drug manufacturers in the market after the end of the exclusivity period," Novartis argues that holding brand-name manufacturers accountable for misrepresentations to patients injured by generic forms of their drugs will encourage manufacturers to pull brand-name drugs from the marketplace after generic equivalents become available. Novartis Reply Br. 32. Novartis warns that this consequence would "leav[e] the public with no NDA [new drug application] holder with ongoing responsibility to monitor the drug safety and labeling." *Id.* at 33.

Novartis is correct that withdrawal of an NDA relieves the brand-name manufacturer of responsibility for labeling updates *going forward. Id.* at 3. The manufacturers' "ongoing responsibility" while the NDA is in

effect, however, does patients little good if those manufacturers have no accountability for failing to fulfill that responsibility.[15] *Looking backward*, though, the NDA withdrawal would not relieve the manufacturer of liability under California law, if (similar to the facts in this case) the labeling were inadequate at the time the brand-name company withdrew and the injured patient's reliance on that labeling were foreseeable.

In any event, no evidence supports the speculation that a rule allowing brand-name manufacturers to be held liable for injuries caused by generic versions of their products would cause brand-name manufacturers to change their behavior. Already, brand-name manufacturers sometimes withdraw their NDAs and stop selling their product when, because of the generic market share, the brand-name product is no longer profitable. In fact, the FDA recently issued a draft guidance addressing this specific situation. *See Updating ANDA Labeling after the Marketing Application for the Reference Listed Drug Has Been Withdrawn*, *supra* note 13 (discussing labeling changes after the brand-name product has withdrawn from the market). But the brand-name manufacturer keeps its product on the market as long as it is profitable to do so, because the manufacturer makes money only if it sells products. This common-sense point is true from the time the brand-name product first enters the market through an NDA: The brand-name manufacturer faces a potential for tort liability for injuries caused by failure to warn from the time it first places its product on the market, but that potential does not deter it from marketing its product, as long as the product remains profitable.

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[15] The brand-name manufacturer retains responsibility for "necessary revisions to update product labeling" even if it has stopped selling the product, until such time as the NDA has been withdrawn. *Draft Guidance, Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn*, *supra* note 13, at 3 n.6.