

California Dreamin'?? Generic Drug Users Can Sue Brand Name Drug Manufacturers

By Anthony L. Martin, Jr.

DRUG MANUFACTURERS BEWARE! The rules governing the liability exposure of brand name drug manufacturers are changing, at least in California. Whether the rule announced in *Conte v. Wyeth, Inc.*,¹ is an anomaly or will become the majority rule is a question which should be considered by all innovator drug companies, their law departments, and their outside counsel. Before *Conte*, the universal rule was that generic drug users could not sue brand name drug manufacturers. The California Court of Appeals adopted a contrary rule in *Conte v. Wyeth, Inc.* Thus far, no court outside California has adopted *Conte*, but it is far too early for innovator drug manufacturers to declare victory. California courts are innovative and influential. If brand name drug manufacturers want the *Conte* rule to be isolated to a few courtrooms in California, they need to take immediate steps to properly exert their considerable influence to achieve that goal.

Brand name or innovator drug manufacturers are just that. They have massive research and development departments to develop new drugs to help solve more and more medical problems. Once a new drug shows sufficient promise, these manufacturers undertake a time-consuming, challenging, and costly regulatory process. That process includes preparing and submitting for approval



Anthony L. Martin is a shareholder with more than 25 years of litigation experience in the law firm of Sandberg Phoenix & von Gontard P.C. He concentrates his practice in the areas of product liability, insurance law (primarily coverage and bad faith cases) and class action litigation. Mr. Martin has successfully tried cases throughout central and southern Illinois, particularly Madison and St. Clair Counties; throughout Missouri; and in the federal courts in southern Illinois and eastern Missouri. Mr. Martin is a member of the American Bar Association, The Missouri Bar, the Illinois State Bar Association, the Illinois Association of Defense Trial Counsels, the Missouri Organization of Defense Lawyers, and the Defense Research Institute. Mr. Martin earned his B.S. degree with honors, from Illinois State University and his J.D. degree from Southern Illinois University School of Law – Carbondale. The author acknowledges the significant assistance provided by Casey Wong. Mr. Wong is an associate at Sandberg Phoenix & von Gontard P.C.

appropriate labeling package inserts and warnings. The brand name manufacturer also prepares its proposed monograph entry for use in the Physician's Desk Reference (PDR).

Manufacturers of generic drugs obtain approval for their products in a

¹ 168 Cal. App. 4th 89 (Cal. App. Ct. 2008).

much more streamlined fashion. As a general rule, they copy verbatim the drug labeling information of the brand name drug. In practice, physicians become familiar with the brand name drug because it precedes any generic equivalent and because of the marketing efforts of the brand name manufacturer. Once a generic equivalent becomes available, it is often preferred by patients and health insurers because of the cost savings. Thus, it is frequently substituted by the pharmacist filling the prescription, if not prescribed by the physician directly. In fact, unless a physician affirmatively indicates that a prescription is to be dispensed as written, in most states a pharmacist may substitute the lower priced generic equivalent for the brand name drug actually prescribed. When it comes to lawsuits involving these generic products, plaintiffs often contend that brand name manufacturers can also be held liable under a theory of negligent misrepresentation because of insufficient warnings read by plaintiff's physician.

Since 1994, the majority rule has been that a brand name manufacturer does not owe a duty to users of the generic equivalent drug, noting that the injury alleged was caused by a different company's product. The leading case supporting the majority rule is *Foster v. American Home Products Corporation*.² *Foster* remained virtually unquestioned until 2008, when the California Court of Appeals decided *Conte v. Wyeth*.³ The court in *Conte* held that the brand name manufacturer owes a duty of care to generic drug users whose doctors

foreseeably relied on the brand name manufacturer's product information.

California has long been recognized as one of the nation's leaders when it comes to judicial and legal innovation. *Crisci v. Security Insurance Company*⁴ and *Gruenberg v. Aetna Insurance Company*⁵ are preeminent cases regarding insurance bad faith. Similarly, *Greenman v. Yuba Power Products*⁶ is a renowned strict product liability case. The question now is whether *Conte* will become the leading case on brand name manufacturers' liability to users of generic drugs using a negligent misrepresentation theory, or whether it remains an isolated anomaly. Though *Foster* continues to be the prevailing rule, it should be remembered that most jurisdictions have not decided the issue. *Conte* has given hope to generic drug users and their attorneys that *Conte* will supplant *Foster*. Familiarizing oneself with the issues and arguments found in *Conte* and *Foster* is vitally important.

I. The Majority Rule: *Foster v. American Home Products Corporation*⁷

A. Facts and Procedural History

The defendant in *Foster*, American Home Products Corporation/Wyeth-Ayerst ("Wyeth") was the brand name manufacturer of Phenergan. In 1988, infant twins Brandy and Bradley Foster had colic for which their doctor

⁴ 426 P.2d 173 (Cal. 1967).

⁵ 510 P.2d 1032 (Cal. 1973).

⁶ 377 P.2d 897 (Cal. 1963).

⁷ 29 F.3d 165 (4th Cir. 1994).

² 29 F.3d 165 (4th Cir. 1994).

³ 168 Cal. App. 4th at 105.

prescribed Phenergan. As permitted by statute, the pharmacy substituted a generic equivalent of Phenergan, called Promethazine Syrup Plain, manufactured by My-K Laboratories, Inc. The brand name and generic medications contained the same active ingredient. After the twins took the generic drug over several days, Brandy died.

The Fosters filed suit against Wyeth (the brand name manufacturer) and the entity they incorrectly believed manufactured the generic drug. After substituting the correct generic manufacturer, the Fosters agreed to dismiss the generic manufacturer with prejudice, for reasons not stated in the record.⁸ The Fosters alleged two counts of negligence against Wyeth, one in strict liability, and one for breach of warranty. In its initial motion for summary judgment, Wyeth argued that it could not be liable for Brandy's death because it did not manufacture the drug Brandy ingested. However, the U.S. District Court agreed with the Fosters that the negligence counts could be read to include a claim for negligent misrepresentation against Wyeth. Manufacturing the drug actually used was not an element of the negligent misrepresentation claim.

Notably, the district court considered the negligent misrepresentation claim to be separate and distinct from the product liability claim. The district court granted summary judgment in favor of Wyeth on all claims except for negligent misrepresentation. The Fourth Circuit in *Foster* described the district court's

reasoning as follows: if Wyeth "made a false representation concerning the safety of [its drug] for use in infants and [Brandy's doctor] relied on the representation in prescribing [the drug] for Brandy Foster, then Wyeth may be liable for any harm caused to Brandy as a result."⁹

Wyeth thereafter filed its second motion for summary judgment, attacking the negligent misrepresentation claim. The second motion was granted after the prescribing doctor signed an affidavit stating that he had prescribed the brand name drug "based only on his own experience with the drug and did not rely on any representations made by Wyeth."¹⁰ Both the Fosters and Wyeth appealed the ruling. Wyeth appealed the initial determination that Wyeth could be held liable on a negligent misrepresentation theory for injuries caused by another manufacturer's product.

Essential to Plaintiffs' argument in *Foster* were the practices of the generic drug industry and the federal regulatory scheme governing the manufacture and sale of generic drugs. Generic drug manufacturers gain approval of their drugs by using an Abbreviated New Drug Application, which is a streamlined and less expensive procedure than what brand name manufacturers must complete.¹¹ Basically, a generic manufacturer seeks

⁹ *Foster*, 29 F.3d at 167.

¹⁰ *Id.* at 168.

¹¹ A description of the Abbreviated New Drug Application process is available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm>.

⁸ It is likely that the correct generic manufacturer elected to settle with the Fosters.

FDA approval by establishing that its drug is the bio-equivalent of the previously approved brand name drug, and it uses the same labeling as that previously approved for the brand name drug. Based on these factors, Plaintiffs contended that if a doctor prescribes a brand name drug based upon representations made by the brand name manufacturer, the substitution and the resulting injury were entirely foreseeable to the brand name manufacturer because of the known practice of substituting bio-equivalent generics for brand name drugs. Therefore, any representations Wyeth made regarding Phenergan were applicable to the generic substitutes because for all intents and purposes the generic drug user would receive Wyeth's warnings, and Wyeth knew that.

B. The Fourth Circuit's Legal Analysis in *Foster*

1. Threshold Concept: Claimants cannot change the result by changing the label on their legal theory.

The Fourth Circuit began its analysis by discussing the propriety of the district court's distinction between claims of negligent misrepresentation and product liability. The Fourth Circuit rejected this distinction, emphasizing that Maryland law requires a plaintiff seeking to recover for injury by a product to demonstrate that the defendant manufactured the product at issue. The Fourth Circuit rejected the *Fosters'* negligent misrepresentation theory, calling it an "effort to circumvent the necessity that a defendant be shown to have manufactured

the product that caused an injury prior to being held liable for such injury."¹²

The Fourth Circuit rejected Plaintiffs' reasoning on several grounds. First, the court discussed how a generic manufacturer can be liable for its labeling representations even though initially it did not create the labeling. FDA regulations allow generic drug manufacturers to alter a drug's labeling to add or strengthen warning information regarding adverse reactions and to delete false, misleading or unsupported indications for use or claims for effectiveness without prior FDA approval. The court further noted that a generic drug manufacturer is held to the status of an expert, which meant that, at a minimum, it must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby. Accordingly, if a generic manufacturer simply adopted the brand name manufacturer's warnings and representations without any independent investigation, it did so at its own risk. Under the proper circumstances, even the generic manufacturer would have an obligation to modify the labeling. Thus, generic drug manufacturers are responsible for their warning representations even if they copy the labeling information from the brand name manufacturer. In addition, the Fourth Circuit declared there was "no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control."¹³

¹² *Foster*, 29 F.3d at 168.

¹³ *Id.* at 170.

2. Prioritizing Policy

The court in *Foster* also discussed the practical, economic reasons why generic manufacturers typically accept the studies of the brand name manufacturers without question and essentially copy the brand name drugs' package inserts while addressing fairness considerations of liability against brand name manufacturers versus generic manufacturers. The court noted that public policy principles strongly supported its holding. Brand name manufacturers undertake the expense of developing primary drugs, perform the studies to obtain premarket approval, and formulate labeling information, whereas generic manufacturers avoid those expenses by "duplicating successful pioneer drugs and labels."¹⁴ Generic manufacturers also benefit from the costly advertising of the brand name drugs. It would be unfair for the generic manufacturer to reap all the benefits of the name brand manufacturer's investments in research and development, by copying its labels, and riding on the coattails of its advertising, without also running the risk of liability for any harm done by its products.

3. Duty Analysis

The Fourth Circuit also held that the negligent misrepresentation claim against Wyeth must fail because Wyeth owed no duty of care to the Fosters. Under Maryland law, the first element of a negligent misrepresentation claim is that a defendant must owe a duty of care to the

plaintiff. The Fosters contended that Wyeth owed them a duty because it was foreseeable to Wyeth that representations regarding its brand name drug could result in personal injury to users of the generic equivalent. The court in *Foster* rejected that contention, stating that "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far."¹⁵ Quite simply, a duty arises "when there is such a relation that one party has the right to rely for information upon the other, and the other giving the information owes a duty to give it with care."¹⁶ No such relationship existed between the parties in *Foster*, as Brandy Foster was injured by a product that Wyeth did not manufacture.

C. After *Foster*

Until *Conte*, the ruling in *Foster* had gained increasingly wider acceptance. In fact, it was recognized as a majority rule which had not been challenged or questioned by any appellate court in the nation. In *Colacicco v. Apotex, Inc.*,¹⁷ the Eastern District of Pennsylvania confronted a similar issue. Lacking controlling precedent, the court in *Colacicco* conducted a nationwide review of the law, stating that *Foster* was the single case which had confronted this issue most directly and in most detail. Though not bound by the ruling in *Foster*, the court in *Colacicco*—like many courts before it—found it persuasive and adopted the holding in *Foster*. The court in *Colacicco* concluded that "an innovator

¹⁵ *Id.* at 171.

¹⁶ *Id.* (internal citations omitted).

¹⁷ 432 F. Supp.2d 514 (E.D. Penn. 2006).

¹⁴ *Id.* at 170.

drug manufacturer does not owe a legal duty to a consumer of a generic drug.”¹⁸

II. Winds of Change from California: *Conte v. Wyeth, Inc.*¹⁹

As a brand name manufacturer of many prescription drugs, Wyeth had fought the war against negligent misrepresentation claims against it for many years and in many venues by the time the *Conte* case was filed. Wyeth’s attorneys knew the issues and arguments well, allowing Wyeth to prevail in the cases decided after *Foster*. With a growing body of precedent supporting Wyeth, it was no surprise when the trial court in *Conte* granted summary judgment in its favor. However, in a radical departure from the reasoning in *Foster*, the California Court of Appeals held that “the common law duty to use due care owed by a name brand prescription drug manufacturer in providing product warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name brand manufacturer’s product information when prescribing a medication, even if the prescription is filled with a generic version of the prescribed drug.”²⁰ The court of appeals reversed the summary judgment the trial court entered in favor of Wyeth and remanded the case.²¹

¹⁸ *Colacicco*, at 539. For a series of other cases adopting *Foster*, see *id.* at 541.

¹⁹ 168 Cal. App. 4th 89 (Cal. App. Ct. 2008).

²⁰ *Id.* at 304-305.

²¹ The Supreme Court of California denied review in January 2009. That denial of review, however, does not address the merits

A. Facts and Procedural History of *Conte*

Wyeth manufactured Reglan, the brand name version of the drug prescribed to Elizabeth Conte. Conte’s prescription was subsequently filled with Reglan’s generic equivalent, manufactured by three companies: Purepac Pharmaceutical Company, TEVA Pharmaceutical USA, Inc., and Pliva, Inc. After taking the drug for almost four years, Conte developed tardive dyskinesia, a debilitating and incurable neurological disorder, allegedly caused by long-term use of the drug.²²

Plaintiffs brought suit against Wyeth and the generic manufacturers. Against Wyeth, Plaintiffs claimed fraud, fraud by concealment, and negligent misrepresentation. The thrust of Plaintiffs’ claims against Wyeth was that it “knew or should have known of a widespread tendency among physicians to misprescribe Reglan and [its generic equivalent] for periods of twelve months or longer, even though the medication was only approved for 12 weeks of use, because the drugs labeling substantially understates the risks of serious side effects from extended use.”²³

Plaintiffs’ claims against Wyeth were premised on “misrepresentation in Wyeth’s labeling of Reglan and in a monograph on Reglan it provided for the Physician’s Desk Reference (PDR).”²⁴ As in *Foster*, Wyeth produced an

of any issues raised and has no precedent value.

²² *Conte*, 168 Cal. App. 4th at 305.

²³ *Conte*, 168 Cal. App. 4th at 305.

²⁴ *Id.* at 307.

affidavit from the prescribing physician stating he did not rely upon the Wyeth labeling materials or the PDR monograph in making his prescribing decisions. However, Plaintiffs created an issue of fact by producing deposition testimony from the same prescribing physician where he stated he “probably did look at the PDR” during his residency regarding Reglan. From this the Court of Appeals concluded that there was a reasonable inference that Wyeth’s PDR product information was a causal factor in the prescribing doctor’s decision to treat Conte with the drug, which created a sufficient question of fact to defeat summary judgment.²⁵

B. California Court of Appeals’ Analysis in *Conte*

1. Threshold Concepts

If Conte had alleged that Wyeth was strictly liable because inadequate warnings rendered the Wyeth product unreasonably dangerous, she would have lost, because Wyeth did not manufacture or sell the product. Instead, Conte contended that a brand name manufacturer which provides information about the product owes a duty of care to ensure the information’s accuracy given to any doctor who prescribes the generic drug in reasonable reliance on that information. As in *Foster*, Wyeth argued that brand name manufacturers have no duty to users of drugs manufactured by

²⁵ The strength of this reasonable inference seems questionable. Even so, the court in *Conte* did not seem to be concerned in the least regarding the tenuous nature of this link in causation.

others, including the users of Reglan’s generic equivalent.

After stating this was an issue of first impression in California, the court rejected Wyeth’s contention, reasoning the negligent misrepresentation claim was a fault-based theory rather than a strict product liability claim. Like the district court in *Foster*, the court in *Conte* found that negligence and strict product liability theories are separate and distinct grounds for liability which “do not automatically collapse into each other because the plaintiff might allege both when a product warning contributes to her injury.”²⁶ Accordingly, the court stated that Wyeth’s reliance upon product liability case law was useless in its defense against this negligent misrepresentation claim.

The court in *Conte* reviewed the federal regulatory scheme leading to the approval of brand name and generic drugs. However, unlike the court in *Foster*, the court in *Conte* did not address the regulations allowing generic manufacturers to revise the labeling to issue stronger warnings if warranted.²⁷

2. Prioritizing Policy

Noting that its decision was rooted in common sense and California common law, the court in *Conte* squarely rejected the ruling in *Foster*. The California Court of Appeals perceived “no logical or legal

²⁶ *Conte*, 168 Cal. App. 4th at 310.

²⁷ Plaintiff Conte conceded that she could not show her doctor relied on representations by any of the generic manufacturers, so discussion regarding issues relating to federal regulations about warnings was deemed inappropriate as such issues were not necessary for the court’s holding.

inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability.”²⁸ The court reasoned that even though the defendant would not be liable in strict product liability because it did not manufacture or sell the product, it could be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on the information disseminated even though another manufacturer’s product caused the injury. The court in *Conte* also stated that the policy reasons proffered by the Fourth Circuit in *Foster* were unpersuasive and problematic. Instead, the court in *Conte* agreed with plaintiff asking what was unfair about requiring the brand name manufacturer to “shoulder its share of responsibility for injuries caused, at least in part, by its negligent or intentional dissemination of inaccurate information?”²⁹

3. Duty Analysis

The California Court of Appeals in *Conte* then undertook a different duty analysis from the Fourth Circuit’s analysis in *Foster*, noting that a duty analysis must look primarily to the foreseeability of physical harm.³⁰ The court stated that in California, the general rule is that all persons have a duty to use ordinary care to prevent others from being injured as a result of their conduct. Since under California law, as in Maryland, pharmacists have the statutory authority to substitute generic drugs for

brand name drugs unless the doctor forbids it, there was a substantial likelihood of a generic substitution for the brand name drug prescribed.³¹ Accordingly, Wyeth should have reasonably perceived there could be an injurious reliance on its product information by the doctors of generic drug users.³²

The court in *Conte* acknowledged that the Supreme Court of California had set forth additional policy factors to consider when determining whether a duty of care exists in a novel situation. The court proceeded to consider several of these “Rowland Factors,” acknowledging that the summary judgment record would not allow a complete consideration. Nevertheless, the court concluded that the application of the Rowland Factors to the case did not support a departure from the general rule that all persons have a duty to use ordinary care to prevent harming others. Because there were no overriding contrary policy considerations and foreseeability of risk was of primary importance in establishing a duty, the court held that Wyeth owed a duty of care to Conte. Specifically, the California Court of Appeals stated: “We hold Wyeth’s duty of care in disseminating product information extends to those patients who are injured by [the generic drug] as a result of prescriptions written in reliance on Wyeth’s product information for Reglan.”³³

In declining to follow the *Foster* decision, the court of appeals in *Conte*

²⁸ *Conte*, 168 Cal. App. 4th at 311.

²⁹ *Id.* at 317.

³⁰ *Id.* at 312.

³¹ CAL. BUS. & PROF. CODE § 4073 (2007).

³² *Conte*, 168 Cal. App. 4th at 313.

³³ *Id.* at 315.

acknowledged it was departing from the majority of courts which had “wrestled” with this issue. Regarding the foreseeability analysis in *Foster*, the court in *Conte* described its reasoning as circular, and thus rejected it. To paraphrase *Conte*: *Foster* concludes – without further discussion – that no duty lies because Plaintiff was injured by a product the brand name manufacturer did not make, but that is the question posed—not the answer.³⁴ The court in *Conte* stated that the Fourth Circuit’s foreseeability analysis faltered because the court in *Foster* failed to address the point that “the foreseeability of harm to consumers of the generic drug in reliance on information disseminated about the name brand version should have some significance in considering whether a duty of care arises in these circumstances.”³⁵

Of course, the Fourth Circuit’s point in *Foster* was that Brandy Foster and her family had no relationship with Wyeth which would give rise to a duty of care. The required relationship did not exist because the injury to Brandy Foster was not caused by a Wyeth product. The court in *Foster* accordingly found that the foreseeability analysis broke down because of the lack of such a relationship. In contrast, the court in *Conte* reasoned that the injury was foreseeable notwithstanding the lack of any such relationship. The California Court of Appeals concluded: “California law supports Conte’s position that Wyeth owes a duty of due care to those people it should reasonably foresee are likely to

ingest [the drug] in either the name brand or generic version when it is prescribed by their physicians in reliance on Wyeth’s representations.”³⁶

III. Life After *Conte*

A. California District Court Follows, But Others Reject *Conte*

A year after *Conte* was decided, it was recognized by a federal court as the law in California,³⁷ but it also appears that for the foreseeable future, *Foster* will continue as the leading case supporting the majority rule outside of California. Wyeth’s attempt to have the Supreme Court of California review the *Conte* opinion failed, and the federal court in *Dorsett* noted that *Conte* had changed the law in California. Despite support for *Conte* in California, subsequent opinions in Alabama, Florida, Nevada, Oklahoma, South Carolina, and Texas expressly or implicitly rejected its holding. For example, in *Cousins v. Wyeth*,³⁸ the court held there was no duty owed because

³⁶ *Id.* at 318.

³⁷ *Dorsett v. Sandoz, Inc.*, No. CV 06-7821, 2009 WL 3633874, at 3 (C.D. Cal., Oct. 28, 2009). In denying a motion for judgment on the pleadings the U.S. District Court stated that before “*Conte*, every single court to address the issue of brand name manufacturer’s liability for conduct leading to or arising out of the generic version of a drug had concluded that the brand name manufacturer was not liable. [Citing *Foster* and *Colacicco*.] ... The *Conte* court was the first to allow brand name manufacturers liability for a generic drug.”

³⁸ No. 3:08-CV-0310, 2009 WL 648703 (N.D. Tex., March 10, 2009).

³⁴ *Id.* at 316.

³⁵ *Id.* at 316.

defendant did not manufacture the injurious product. In *Schrock v. Wyeth*,³⁹ the court implicitly rejected the reasoning of the court in *Conte* and noted that 24 courts in 14 different states had rejected the plaintiff's arguments. In *Moretti v. Wyeth*,⁴⁰ the court explicitly rejected *Conte*, stating that "*Conte* stands alone and is contrary to Nevada law and public policy." Similarly, in *Fisher v. Pelstring*,⁴¹ the district court stated that while *Conte* has at least some persuasive effect, that decision "is in conflict with the law of [South Carolina] and of [the Fourth Circuit]." The court then noted that in *Mensing v. Wyeth, Inc.*, the "Eighth Circuit specifically rejected *Conte* and endorsed the Fourth Circuit's analysis in *Foster*."⁴²

B. *Mensing v. Wyeth, Inc.* – Eighth Circuit Rejects *Conte*

In *Mensing v. Wyeth, Inc.*,⁴³ the Eighth Circuit became the first U.S. Circuit Court of Appeals to examine the holding in *Conte*. The facts in *Conte* were almost exactly the same as in *Mensing* along with the same issue: whether under Minnesota law a brand name manufacturer owes a duty to

generic drug users for fraud or negligent misrepresentation.

The court in *Mensing* cited with approval the Fourth Circuit's decision in *Foster*. The Eighth Circuit also briefly discussed *Flynn v. American Home Products Corp.*,⁴⁴ a pre-*Conte* decision from the Minnesota Court of Appeals which undertook a duty analysis very similar to that by the court in *Foster*. The plaintiff in *Mensing* relied upon the *Conte* decision, but the Eighth Circuit rejected the notion that a plaintiff may prevail against a brand name manufacturer by alleging (and later demonstrating) that plaintiff's doctor relied upon the labeling of a brand name drug. The court noted that *Conte* stood alone. The court also stated: "Whatever the merits of *Conte* under California law," Minnesota common law requires a "stronger relationship and a direct communication" before recognizing a duty.⁴⁵ The Eighth Circuit reasoned that reliance upon brand name labeling by the plaintiff's physician was insufficient to create a duty by a name brand manufacturer: "Regardless of whether [plaintiff's] doctor relied upon the [name brand] label, [plaintiff] must show that the name brand manufacturers owed *her* a duty of care."⁴⁶ Relying on *Flynn*, the Eighth Circuit held that no such duty of care existed where a plaintiff did not purchase or use the brand name drug.⁴⁷

Addressing plaintiff's foreseeability argument, the Eighth Circuit adopted the *Foster* rationale that to hold name brand manufacturers liable for harm caused to

³⁹ 601 F. Supp.2d 1262, 1267 (W.D. Okl. 2009).

⁴⁰ No. 2:08-cv-00396, 2009 WL 749532 (D. Nev., March 20, 2009).

⁴¹ No. 4:09-cv-00252, 2010 WL 2998474 at 7 (D. S.C., July 28, 2010) (Collecting pre- and post-*Conte* decisions noting the weight of authority has followed *Foster*.)

⁴² *Id.*

⁴³ 588 F.3d 603 (8th Cir. 2009) (applying Minnesota law).

⁴⁴ 627 N.W.2d 342 (Minn. Ct. App. 2001).

⁴⁵ *Mensing*, 588 F.3d at 613.

⁴⁶ *Id.* (emphasis in original)

⁴⁷ *Id.*

generic users “stretch[es] the concept of foreseeability too far.”⁴⁸ The Eighth Circuit in *Mensing* essentially limited *Conte* to California while adopting *Foster* and pre-*Conte* Minnesota law.

IV. Conclusion

Conte will likely continue to be recognized as an anomaly for the foreseeable future outside of California. However, counsel should be aware of this case and its rationale. *Conte* was decided by an intermediate level court of appeals, but that court is in California and *Conte* was recently recognized as stating the law in California by a federal district court. The influence of California common law is well known. Although the court in the very recent *Mensing* decision noted that thirty-two courts in at least seventeen states have followed *Foster*, it appears that the issue has not been addressed at all in more than thirty states.

Although the holding in *Conte* represents only persuasive authority outside of California, the logic and reasoning of the court will appeal to many readers. This is an issue bound to arise again and again, many times as an issue of first impression for a particular jurisdiction. For instance, since *Conte* was decided, plaintiffs in at least six jurisdictions raised the prevailing arguments in *Conte*.⁴⁹ As noted above,

cases of first impression decided in California often become the cutting edge for the next majority rule. Very likely its holding will be adopted outside California in the next decade, unless of course, the Supreme Court of California takes up the issue in another case and specifically rejects *Conte*. In the meantime, counsel for brand name manufacturers need to emphasize the superior reasoning of *Foster*, note the limited applicability of *Conte*, and contend that it is much more likely that *Conte* is an aberration and the vast majority of courts have followed *Foster*. Only time will tell if *Conte* dethrones *Foster* and becomes the majority rule or whether it remains in the distinct minority.

⁴⁸ *Id.*

⁴⁹ In addition, one commentator has advocated rejection of *Foster* and suggested that *Conte*'s reasoning is superior. Beatrice Skye Resendes, Note, *The Extinct Distinction of Privity: When a Generic Drug Label Fails to Warn, the Drug's Pioneer Should be Liable as Component Part Supplier of the Warning*

Label, 32 T. JEFFERSON L. REV. 95, 116-17, 131-36 (2009).