Hamilton County Law Library

HCLL NEWS

Professional legal information, resources, and services

A Monthly Newsletter from the Hamilton County Law Library June 2010

Alice In Pharmaland: The "Curiouser And Curiouser" Case Of Conte v. Wyeth

By Z. Ileana Martinez and Leslie J. Suson, reprinted with permission.

"It would be so nice if something made sense for a change."

– Alice from Alice's Adventures in Wonderland – Lewis Carroll.

"The time has come," the Plaintiff said, "to talk of many Torts, of disregarded precedents and medicines -- all sorts."

So begins our trip down the rabbit hole of juris(im)prudence. The one prerequisite for pursuit of a claim in any product liability case – that a defendant's product must have caused a plaintiff 's injury – has gone by the wayside, at least in California. Recently, a California appellate court recognized a cause of action based on negligent misrepresentation against one manufacturer for injuries stemming from the use of another manufacturer's product. Thus, a name-brand manufacturer of a prescription drug may be held liable to a plaintiff who never consumed its product, for alleged negligent misrepresentations contained in its product labeling. Conte v. Wyeth, Inc., et al., 85 Cal.Rptr.3d 299 (Cal. Ct. App. 2008), review denied, Case No. S169116, Sup. Ct. Cal. (Jan. 21, 2009). The facts in Conte are similar to a long line of cases preceding it. For a period of almost four years, Conte's physician prescribed metoclopramide to treat her gastroesophageal reflux disease. Wyeth marketed and manufactured metoclopramide under the name brand Reglan®. Metoclopramide was also available in its generic form and was manufactured by Purepac Pharmaceutical Company, Teva Pharmaceutical USA, Inc. and Pliva, Inc. During the time Conte took metoclopramide, she purchased and ingested only the generic form of the drug. Conte claimed that her long-term use of metoclopramide caused her to develop tardive dyskinesia, a debilitating and incurable neurological disorder. She sued Purepac, Teva, and

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Annual Meeting of the Membership of the Cincinnati Law Library Association

Thursday, July 1, 2010 at 12:00 noon
Hon. Robert S. Kraft Boardroom, 6th fl.,
Hamilton County Courthouse

The Board of Trustees has scheduled the annual membership meeting for July 1 at 12:00. Please mark your calendar.

The Association's regulations identify members as those people who have paid dues as set by the Trustees. For the purposes of notification and voting at the 2010 annual meeting, the membership consists of those people who were members as of December 31, 2009. If you were a law library member in 2009, you are a voting member for purposes of the 2010 meeting, whether or not you are currently a member.

RSVP to Mary Ann Sweeney at 513.946.5300 or masweeney@cms.hamilton-co.org. Lunch will be provided so we'd appreciate knowing if you plan to attend.

The agenda will include the following items:

- Approval of the minutes of the 2009 meeting
- Librarian's annual report
- Treasurer's report
- Election of trustees
- Discussion of CLLA's purpose and bylaws
- Other business before the membership

Clearly, the governance change that went into effect on January 1, 2010 has an impact on the Association, its membership, and, potentially, its support of the law library.

At the 2010 annual meeting, it will be necessary for the membership to consider changes to the Association's regulations related to membership and privileges. The meeting will also provide an opportunity to provide input to the trustees regarding the mission and purpose of the Association.

For more information, please contact a member of the Board of Trustees or Mary Jenkins, Law Librarian & Director.

Cathy R. Cook, Board President
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Mary Ann Jacobs, Treasurer

A Brief Overview of Wills, Trusts and Probate Administration

Speaker: Michael Mann, Attorney at Law
Friday, June 18, 2010 at 12:00 noon
Hamilton County Law Library
A program for the general public
To register, call 513.946.5300

Mr. Mann, of Mann & Mann, LLC in Cincinnati, will address these questions:

What is a Will?
Why do I need a Will?
What is a Trust?
Why chose a Trust versus a Will?
What if I don't have a Will or Trust?
When is probate administration necessary?
How does probate administration work?

Please note that this is not a CLE event; it is intended for the general public. However, please do pass along the program announcement to clients, staff, and community organizations. For more information or if you would like some flyers to distribute, please call 513.946.5300.

This program is offered as a public service by the HCLL and the Lawyer Referral Service of the Cincinnati Bar Association.

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Pliva, the manufacturers of the generic metoclopramide she ingested. Although Conte never ingested Wyeth's Reglan®, she also named Wyeth as a defendant in her lawsuit. Conte alleged that the product labeling for metoclopramide and Reglan® provided by the defendants did not adequately warn of the risks associated with long-term use of metoclopramide. Id. at 305.

Conte sought to hold Wyeth liable for fraud, fraud by concealment and negligent misrepresentation, based on the alleged inadequacy of the warnings accompanying Reglan®. Id. At 305. Conte asserted that Wyeth could be liable because "a name-brand manufacturer that disseminates information about its product owes a duty of care to ensure the information's accuracy to any doctor who prescribes the drug in reasonable reliance on that information, even if the patient ends up taking the name-brand product's generic equivalent." Id. at 309.

Although the Plaintiff in Conte is not the first generic-consuming plaintiff to have raised the negligent misrepresentation argument against a name-brand manufacturer, no court – until now – has ever allowed the claim to proceed. In a departure from every jurisdiction to have considered the issue, the California Court of Appeals in Conte reversed the trial court's findings in favor of Wyeth and concluded that Wyeth did owe a duty of care to Conte, even if her alleged injuries were caused by another manufacturer's product. According to the California Court of Appeals, Wyeth should reasonably have perceived that there could be injurious reliance on its product information by a patient taking generic metoclopramide. The Conte court did not view this conclusion as a departure from California law. Rather, in the court's view, it simply applied the general rule in California that "all persons have a duty to use ordinary care to prevent others from being injured as a result of their conduct." Id. at 311. The court relied on the Restatement Second of Torts, sections 310 and 311, focusing on the foreseeability of physical harm, and emphasized that the case was not one involving product liability principles, but rather, one involving common law principles of negligent misrepresentation. According to the court's holding, liability could be based on Wyeth's statements regarding Reglan®, and not on a claim regarding the product it manufactured: "[w]e are not marking out new territory by recognizing that a defendant who authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product. . . . We perceive no logical or legal inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability." Id.

The Conte court criticized the reasoning of Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994), the seminal case holding that a name-brand drug manufacturer cannot be held liable on a negligent misrepresentation theory for injuries resulting from the use of another manufacturer's product. In Foster, the Fourth Circuit Court of Appeals rejected the plaintiff 's contention that Wyeth, the manufacturer of Phenergan®, owed a duty to the plaintiffs

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because it was foreseeable that misrepresentations regarding Wyeth's Phenergan® could result in personal injury to users of generic equivalents. The Foster court stated, "we think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." Id. at 171. In rejecting the Foster court's analysis (and by implication every opinion addressing the issue after Foster), the Conte court dismissed the notion that the plaintiff 's negligent misrepresentation claim was an attempted end-run around the long-standing requirement of product liability law that a plaintiff must, as a threshold requirement, establish that the defendant made the product she ingested, and which allegedly caused her harm.

The Conte court also addressed, but refused to be swayed by, the various policy considerations that have repeatedly been raised by name-brand manufacturers faced with a claim for liability related to a plaintiff 's use of a generic drug that it did not manufacture. One of the most compelling policy considerations is the extraordinary impact that the Conte court's imposition of the duty to warn has on name-brand pharmaceutical manufacturers. A name-brand manufacturer of a prescription drug may be held liable to a plaintiff who never consumed its product, for alleged negligent misrepresentations contained in its product labeling. In effect, the holding in Conte means that name-brand manufacturers may be held responsible for ***any injuries, to any plaintiffs, caused by any generic drug made by other manufacturers,*** if the prescribing physician relied on the name-brand manufacturers' product labeling.

For obvious reasons, this result has been described by other courts faced with the same issue as an "exotic" theory of liability, "new and uncharted territory," and an "unprecedented departure" from traditional tort law. The Conte court's response: "these dire consequences are neither self-evident nor substantiated by the record." Conte, 85 Cal.Rptr.3d at 317. Another important policy consideration is the time and expense invested by pioneer manufacturers in the development and marketing of new drugs. To market a new drug, a name-brand manufacturer must file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA"), which must include, among other things, full reports of investigations made of the drug's safety and effectiveness, a full list of the drug's components, a full statement of the drug's composition, a full description of the methods, facilities and controls used for the drug's manufacturing, processing and packing, and "specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1). Estimates for the time and cost invested by a name-brand manufacturer for bringing a new prescription drug to

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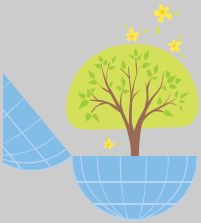
Save a Tree!



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market are upwards of 10 years and $800 million dollars (in year 2000 dollars). Given the explosion in R&D and other costs since then, estimates of the current costs borne by a name-brand manufacturer to bring a new drug to market are in excess of $970 million. Pursuant to The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"), generic drug manufacturers can file an Abbreviated New Drug Application ("ANDA") and must merely show that its generic version is bioequivalent to an already approved drug, 21 U.S.C. 355(j)(2)(A)(iv), and that "the labeling proposed for the generic drug is the same as the labeling approved for the listed drug." 21 U.S.C. 355(j)(2)(A)(v). A generic manufacturer's ANDA need not contain independent reports or investigations of the drug's safety and effectiveness, and the generic manufacturer is allowed to rely upon the safety and effectiveness evidence presented by the original manufacturer in its NDA. Courts repeatedly have recognized the intent behind the Hatch-Waxman Amendments: to motivate name-brand drug manufacturers to devote resources toward new drugs, and, concurrently, to allow their competitors to provide more economical generic options to consumers. Thus, name-brand manufacturers undertake the time and expense to develop new drugs, yet once patent protection has expired, manufacturers of generics can immediately begin to sell their drugs by simply replicating the name-brand drugs, bypassing the enormous development expense, and benefiting from the association with, and advertising about, the name-brand drug.

Given the undertaking by pioneer manufacturers, and the benefit to generic competitors, the holding in Conte imposing liability on the name-brand manufacturer for the warnings used by the generic manufacturer is manifestly unfair and inconsistent with apparent Congressional intent. Neither the Hatch-Waxman Amendments nor the statutory drug application process include any indication that name-brand manufacturers are to be liable for injuries caused by the generic form of a drug manufactured by another company. Even the court in Conte recognized that the generic manufacturer is responsible for the information it disseminates to consumers of its products, and the copycat manufacturer is not bound by the name-brand label. Generic manufacturers have the ability to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or "delete false, misleading or unsupported indication for use." Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514,

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523 (E.D. Pa. 2006); see 21 C.F.R. §§ 314.70, 314.80. As the Foster court stated: "[w]e do not accept the assertion that a generic manufacturer is not responsible for negligent misrepresentation on its product labels if it did not initially formulate the warnings and representations itself. When a generic manufacturer adopts a namebrand manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed." Foster, 29 F.3d at 169-70. In Conte, there was no evidence that the prescribing physician ever read any warnings or product information disseminated by the generic manufacturers.

However, if the generic manufacturers disseminated the exact same labeling information as Wyeth and chose not to strengthen or change the labeling used to sell their generic products (assuming Conte is correct that such changes were necessary), and Conte took only the generic form of the drug, where is the fairness in keeping Wyeth in the case, yet dismissing the generic manufacturers?

Faced with these policy considerations, and the unfairness of allowing misrepresentation actions against namebrand manufacturers, the Conte court pointed to "countervailing factors," such as the "unique advantages" enjoyed by the new drug innovator, including "the initial period of patent-protection from competition, the fiscal rewards of namebrand recognition, and the commensurate ability to charge a higher price for its product, even after its exclusive marketing position expires." Conte, 85 Cal. Rptr.3d at 317.

The impact of Conte on the pharmaceutical industry is yet to be seen, but it is a given that some impact is predictable, notwithstanding the Conte court's position that it was "unpersuaded by Wyeth's assertion that imposing liability would undermine the goal of preventing future harm because it would chill innovation in the pharmaceutical industry." Conte, 85 Cal.Rptr.3d at 314. It cannot seriously be disputed that the potential cost of liability to innovator drug manufacturers for every alleged injury by every equivalent generic drug would be enormous.

As explained in one opinion addressing the issue, courts "have recognized the societal importance of new and effective prescription drugs... . [and] the need not to unduly burden the pharmaceutical industry with unfettered liability." Colacicco, 432 F. Supp. at 542. The cost, ultimately, will be placed at the feet of the consumer who will have to pay higher prices for the new drug during that "initial period of patent-protection." Conte, 85 Cal. Rptr.3d at 317.

Conte's expansion of the "general duty to use due care in disseminating product information to those [whom the manufacturer] . . . knows or should know are likely to be harmed as a result of the consumer's reliance on that information" poses a serious and threatening departure from product liability law as it currently exists. And arguably, the threat is not limited to the pharmaceutical industry, as plaintiffs suing other product manufacturer's will likely cite the Conte opinion in support of their negligent misrepresentation claims. Conte's vast interpretation of a manufacturer's "duty" and "foreseeability" means, in effect, that in California (and soon coming to a court near you), any consumer may rely on and sue a manufacturer who is the first to dispense

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product information and warnings in any given industry, regardless of whether that manufacturer's product was used by the plaintiff consumer.

The Mock Turtle in Alice's Adventures in Wonderland must certainly have been reading the Conte v. Wyeth decision when he said, "I never heard it before, but it sounds uncommon nonsense." Moreover, since the California Supreme Court has declined to review the Conte decision, it appears that Wyeth's and other name-brand manufacturer's only relief from this "uncommon nonsense" might lie in the hands of the United States Supreme Court.

Ileana Martinez is a partner at Thompson Hine LLP. She focuses her practice on product liability litigation, including litigation for pharmaceutical and medical device companies and many other consumer and commercial product manufacturers.

Leslie Suson is a senior attorney at Thompson Hine LLP. She focuses her practice on product liability, commercial and business matters, insurance coverage and defense, and tort litigation. Contact the authors for full text, including footnotes.

What are we missing?

Offering library users appropriate, current, and reliable information is our goal. Therefore, we value your input! Please share with us with us any suggestions you have regarding our print and electronic resources. Contact library director Mary Jenkins at mjenkins@cms.hamilton-co.org or 513.946.5300 with your ideas. We look forward to hearing from you.

Using the AND versus the W/n Connector in LEXIS

From Lexis-Nexis

Because AND can connect terms that are far apart from one another or in different segments, searches using AND usually find more documents than searches using the W/n connector. As a general rule, use AND when it doesn't matter where your search terms appear in a document. Use the W/n connector when there is a connection between your search terms and you need to find the terms near each other.

EXAMPLE: If your search terms are fairly unique, the AND connector can find documents that are related to your research. Using the AND connector can also help you get started on your research, until you begin to find more specific concepts and terms for your search. For example, if you want information about how land can be preserved in Ohio using a land trust, you could use this search: **land trust AND Ohio**

However, to find documents that are relevant when your search terms are less specific, you may need to use the W/n connector. For example, the following search will find more relevant documents than if the AND connector were used: **business loss w/10 tax deduction**

If you're looking for a document in which the same term occurs twice, such as a court case with Marvin v. Marvin as respondents, do not use the AND connector. The following search would find many unrelated documents: **marvin AND marvin**

Instead, use the W/n or W/seg connector, such as
marvin W/5 marvin
marvin W/SEG marvin

Free! 1 Hour of CLE credit

Shannon Kemen, Reference Librarian at the Robert S. Marx Library, University of Cincinnati College of Law, will offer pointers on using social media to locate witnesses, vet experts, and research jury members.

What: Mining Social Media: How to Locate Witnesses, Vet Experts & Learn More about Jurors

Why: To earn **free CLE credit** while learning how to use and locate information on social media sites

When: Thursday, June 24 @ 12:30 p.m.

Where: Hamilton County Law Library Honorable Robert S. Kraft Board Room

How: To register call 513.946.5300, or email gherald@cms.hamilton-co.org

Nonsubscribers welcome! $35 fee

June 2010 Law Library Newsletter

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