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- Plaintiff Sinks Manufacturer of Defective Boat at Trial
- Louisiana Failure to Warn Claim Against Generic Drug Maker Allowed to Proceed

### PLAINTIFF SINKS MANUFACTURER OF DEFECTIVE BOAT AT TRIAL

***Rousse v. Triton Boat Co.*, No. 08-0396 (La. App. 1 Cir. Oct. 31, 2008), 2008 WL 4763734**

Joey Rousse was driving a boat manufactured by Triton Boat Company (“Triton”) when he attempted to pull himself up from a seated position using the steering wheel in order to get a better view. Unexpectedly, the steering wheel and center console broke free from the boat and collapsed into his lap. A collision ensued, and Rousse sustained injuries.

Claiming that the boat was “unreasonably dangerous,” Rousse sued Triton under the Louisiana Products Liability Act (“LPLA”). Specifically, Rousse pointed out that while the console should have been mounted with both rivets and screws, this particular one was mounted only by rivets. In its defense, Triton argued that Rousse was comparatively negligent at the time of the accident by attempting to pull himself up with the steering wheel.

The jury found Triton to be only 50% liable for Rousse’s injuries, finding that Rousse was also at fault for the accident. But the trial court overturned this finding and assigned Triton full liability. In doing this, the trial court held that there was no evidence presented at trial to show any fault whatsoever on the part of Rousse.

On appeal, the Louisiana First Circuit upheld the trial court’s ruling, reasoning that a reasonable jury could not have found that pulling oneself up from a seated position with the help of a steering wheel was negligence. Rousse was awarded \$22,450 for medical expenses and \$125,000 in general damages.

– *Tarak Anada*

### LOUISIANA FAILURE TO WARN CLAIM AGAINST GENERIC DRUG MAKER ALLOWED TO PROCEED

***Demahy v. Wyeth, Inc.*, No. 08-3616, 2008 WL 4758615 (E.D. La. Oct. 28, 2008)**

Actavis, Inc. (“Actavis”) is the manufacturer of Metoclopramide, the generic version of the name brand drug Reglan. Metoclopramide is prescribed for treatment of acid reflux. Julie Demahy took Metoclopramide beginning in 2002 through April 2006. In October 2007, Demahy was diagnosed with tardive dyskinesia, a neurological disorder, which her doctors linked to her long term use of Metoclopramide.

Demahy sued Actavis under the Louisiana Products Liability Act (“LPLA”) asserting a failure to warn claim and fraud on the Food and Drug Administration

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("FDA"). Actavis moved to dismiss based upon federal conflict preemption, arguing that the Food, Drug, and Cosmetic Act ("FDCA"), including the 1984 Hatch Waxman Amendments, prohibited Actavis from changing the approved language of the label and package insert for its generic product and, thus, Actavis could not add the warning plaintiffs sought regarding neurological risk. According to Actavis, under Hatch-Waxman, the generic manufacturer is not subject to the same initial and continuing testing and reporting requirements and the name brand drugs and the generic drug must *always* have the same labels that have been approved for the pioneer name brand drug. Actavis cited several statements issued by the FDA, in the formal rulemaking process and in informal statements such as amicus briefs, that reject the ability of the generic manufacturer to make post approval changes to the label or package insert under the regulatory mechanism available to brand name manufacturers.

Plaintiff opposed the Motion, asserting that Hatch Waxman applies only to the initial approval labeling requirements under the Abbreviated New Drug Application ("ANDA") and that after a generic drug is approved the generic manufacturer has a continuing duty under both the LPLA and the FDCA to include warnings regarding newly discovered risks and to, at least, notify the FDA of possible side effects.

Judge Carl Barbier denied the Motion, finding that while Demahy's fraud on the FDA claims were preempted, the "failure to warn claims under the LPLA were not preempted as a matter of conflict preemption under the FDCA's applicable regulations and relevant FDA position statements." Significantly, Judge Barbier did not afford the FDA's interpretive statements any deference. Judge Barbier addressed each of the FDA's interpretive statements offered by Actavis in support of preemption, and after a lengthy analysis of the relevant statutes, regulations, and rule-making guidance, found that the FDA's interpretation that a generic manufacturer was prohibited from unilaterally making label changes under the FDCA was internally inconsistent and contradictory to the regulations and the FDA's own statements on the issue.

Judge Barbier confirmed that there is a general presumption against preemption of state law by federal statute. In cases where the federal agency administering the statute (here, the FDA), has issued interpretive statements, certain deference is afforded to the agency based upon congressional intent. "[I]f the statute is silent or ambiguous with respect to the specific issue, the court must determine whether the agency's construction is based on a permissible construction of the statute." Such agency constructions will be controlling unless they are "arbitrary, capricious or manifestly contrary to the statute." The U.S. Supreme Court has developed three different standards of deference to agency constructions, depending on their context:

- *Chevron* Deference – A high level of deference afforded to actions that are the result of a "relatively formal administrative procedure," such as notice and comment rulemaking, formal adjudications or other procedures for promulgating the interpretation that evidences congressional intent for such to be binding.

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- *Auer* Deference – A second level of deference applies to an agency’s interpretation of a regulation that is ambiguous as to the specific question considered unless the interpretation is plainly erroneous or inconsistent with the regulation.
- *Skidmore* Deference – The least deferential standard applies to an agency’s informal interpretations or actions but only if the interpretation has the “power to persuade,” meaning it is grounded in thoroughness of consideration, validity of reasoning and consistency with earlier and later pronouncements.

Judge Barbier first addressed the statements made by the FDA in the rule making process, specifically in connection with the application process for generic products. Actavis argued that both the FDA’s 1989 Proposed Rule and the 1992 Final Rule require generic manufacturers to have at all times the same label “verbatim” as the brand name drug. Judge Barbier rejected this interpretation. Although a generic manufacturer applicant must confirm that the proposed labeling for its drug product is the *same as* that of the referenced listed drug, Judge Barbier stated that the FDA’s guidance “only concerns whether the generic label must be the same as the name brand *at the time of the initial ANDA application.*” In contrast, the issue in Demahy’s case was the duty to update the label after approval. Judge Barbier noted that the FDA has authority to withdraw the approval of a generic drug if the “label for the generic is no longer *consistent with* that for the listed drug” or if the FDA finds that the product’s labeling is false or misleading. Judge Barbier also found that the “same as” requirement was contradicted by the mandatory requirement that a generic manufacturer “shall comply” with labeling change requirements. Judge Barbier concluded that these provisions support the finding that the generic manufacturer has the right to make label changes.

Judge Barbier further discounted the FDA’s statements in the 1992 Final Rule that a generic manufacturer cannot make changes to labeling post-approval without the permission of the FDA. According to Judge Barbier, this statement was not entitled to deference because it was “non-responsive, merely permissive, extraneous, and inconsistent” with the mandatory obligations imposed upon generic manufacturers. Judge Barbier also found the statement inconsistent with another FDA statement in 1992 Final Rule that supports a generic manufacturer’s authority to initiate and unilaterally make labeling changes. The FDA explained a change that requires generic applicants, like brand name applicants, to submit periodic reports of adverse drug experiences even if the ANDA applicant has not *initiated any labeling changes*. The FDA explained that this is intended to “*help FDA determine whether [generic] products have appropriate labeling* and ensure that no adverse drug experiences go unreported.” In Judge Barbier’s view, this statement “clearly contemplates that a generic manufacturer may initiate labeling changes.”

According to Judge Barbier, because the specific issue of preemption was not addressed in either the Proposed Rule or the Final Rule, the issue of deference was irrelevant. However, to the extent the FDA’s statements were relevant, they were entitled to high deference under the *Chevron* standard, but “the only relevant portions of the 1989 Proposed Rule and the 1992 Final Rule that are subject to *Chevron* deference actu-

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ally suggest that the FDA *historically confirmed* the right of generic manufacturers to unilaterally alter their labels.”

Applying the same analysis, Judge Barbier found that the FDA’s recent statements in its 2008 Proposed Rule were inconsistent with and contradictory to the regulations and its prior statements on the issue. The 2008 Proposed Rule, which concerns Supplemental Applications Proposing Labeling Changes, was published to update and codify the FDA’s “longstanding view” regarding labeling changes without prior FDA approval but, according to Judge Barbier, has “*nothing whatsoever to do with* the existence or availability of those procedures to [generic] holders.” In this Proposed Rule, the FDA, in a footnote, expressly indicates that the procedure to make label changes is not available to generic drug manufacturers. Judge Barbier found this footnoted statement was irrelevant and beyond the scope of the proposed rule, but also was insufficient to support preemption. “The FDA essentially took the opportunity to make a significant statement on preemption of generic drug labeling claims in the relative obscurity of a footnote in the introductory statement of a document that has nothing at all to do with rules pertaining to generic drugs or to the ANDA process. The Fifth Circuit has suggested that a footnote to a finalized regulation, even though it may have been made the product of notice-and-comment rulemaking may not be entitled to *Chevron* or *Auer* deference...As such, a footnote in a proposed rule should not be afforded any significant level of deference.” Like the FDA’s prior statements, Judge Barbier found that the FDA’s footnoted interpretation contradicts the FDA’s own mandatory requirement that a generic applicant must comply with the CBE mechanism for initiating label changes. “Therefore, not only is the statement that generic manufacturers cannot make CBE labeling changes irrelevant in its own context and contradictory to the FDA’s own regulations, [the footnote in a proposed rule] is not entitled to any deference at all under Fifth Circuit law.”

Judge Barbier also addressed the import of statements made by the FDA in two amicus briefs submitted in other cases – statements that were obviously made outside of the formal rule-making process. Judge Barbier refused to give *Auer* deference to the FDA’s interpretation in its amicus briefs, finding that *Auer* only applies if the regulation is ambiguous and the regulation at issue is “simple, concise, and patently unambiguous.” Further, under *Skidmore*, the FDA’s amicus briefs did not have the power to persuade, and were afforded no deference, because the FDA did not address its internal inconsistencies and contradictions with other regulatory requirements. Judge Barbier specifically disagreed with the Third Circuit’s decision in *Colacicco v. Apotex, Inc.*, 521 F. 3d 253 (3d Cir. 2008) to defer to the FDA’s interpretation in its amicus brief because the position was inconsistent with its regulations.

Judge Barbier concluded that Actavis had not provided any evidence dispositive of preemption issue and denied its Motion to dismiss the LPLA failure to warn claims under federal conflict preemption. Actavis will take an interlocutory appeal of this ruling to the Fifth Circuit.

– *Amy W. Truett*

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*Remember that these legal principles may change and vary widely in their application to specific factual circumstances. You should consult with counsel about your individual circumstances. For further information regarding these issues, contact:*

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