Morris v. Wyeth, Inc. et al Doc. 110

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION
CASE NO. 1:07-CV-176-R

DENNIS MORRIS PLAINTIFF

v.

WYETH, INC., et al. DEFENDANTS

MEMORANDUM OPINION

This matter comes before the Court on Plaintiff Dennis Morris's Motion for Reconsideration (Docket #96). Defendant PLIVA, Inc. has responded (Docket #101). Defendant Morton Grove Pharmaceuticals, Inc. has joined Defendant PLIVA Inc.'s response (Docket #102). Defendants Teva Pharmaceuticals USA, Inc. and UDL Laboratories, Inc. have joined Defendant PLIVA, Inc.'s response (Docket #103). Plaintiff has filed a reply (Docket #104). This matter is now ripe for adjudication. For the reasons that follow, Plaintiff's Motion for Reconsideration is **DENIED**.

BACKGROUND

Metoclopramide is a prescription drug used to treat gastric reflux symptoms. It is the generic equivalent of Reglan, the listed drug for metoclopramide.[1] Plaintiff Dennis Morris ("Morris") took metoclopramide from March 1993 to October 2005. Morris alleges that his use of metoclopramide caused him to develop severe and persistent Tardive Dyskinesia. Tardive Dyskinesia is a drug-induced neurological disease affecting a patient's brain chemistry that loosely resembles Parkinson's Disease.

[1]A listed drug, or reference listed drug, is the new drug already approved by the FDA that serves as the basis for the generic drug manufacturer's abbreviated application. *See* 21 U.S.C. §355(j); 21 C.F.R. § 314.3.

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Morris filed a complaint in federal court asserting various products liability, negligence, and breach of implied warranty claims under Kentucky law against both the brand manufacturers of Reglan and the generic manufacturers of metoclopramide. Central to all of Morris's claims is the assertion that Defendants failed to adequately warn him of the long-term negative effects of ingesting metoclopramide.

In its June 30, 2008 Order, the Court dismissed all of Morris's claims against Defendant Schwarz Pharma, Inc., a brand manufacturer of Reglan, because Morris did not allege that he consumed a product manufactured by Schwarz as required under Kentucky's Products Liability Act. The Court also dismissed any claims against Defendant Wyeth Inc., the original successor in interest to Reglan, for the injures caused by a generic drug manufacturer's product. Because Morris alleges in his complaint that he consumed a product manufactured by Wyeth, those claims still remain against Wyeth.

Defendants PLIVA, Inc. ("Pliva"), Teva Pharmaceuticals USA, Inc. ("Teva"), UDL Laboratories, Inc. ("UDL"), and Morton Grove Pharmaceuticals, Inc. ("Morton Grove") are all generic drug manufacturers that manufactured and distributed metoclopramide. In its October 24, 2008 Order, the Court dismissed Morris's strict liability and negligence failure-to-warn claims against Defendants based on federal preemption. Morris's design defect and breach of implied warranty claims remain.[2] Morris now moves the Court to reconsider its October 24,

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[2] Defendants contend that Morris's complaint does not allege a design defect claim. However, the Court understands Count I of Morris's complaint to allege, albeit tersely, a design defect claim. Count I reads, in pertinent part:

> At the time metoclopramide left the control of the DRUG COMPANY DEFENDANTS it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, *or, in the alternative, because it was designed in a defective manner*, or, in the alternative, because the drug breached

2008 Order dismissing his failure-to-warn claims.

STANDARD

Morris filed his motion to reconsider pursuant to Federal Rule of Civil Procedure 59(e). Rule 59(e) allows a party to file a motion to reconsider a final order or judgment within ten days of entry. Fed. R. Civ. P. 59(e); *Inge v. Rock Financial Corp.*, 281 F.3d 613, 617 (6th Cir. 2002). Because the Court has yet to enter a final order or judgment in this case, the Court alternatively construes Morris's motion as one for reconsideration pursuant to Federal Rule of Civil Procedure 60(b).

Motions to reconsider under Rule 60(b) provide an "opportunity for the court to correct manifest errors of law or fact and to review newly discovered evidence or to review a prior decision when there has been a change in the law." *United States v. Davis*, 939 F. Supp. 810, 812 (D. Kan. 1996). Rule 60(b) motions fall within the sound discretion of the district court. *FHC Equities, L.L.C. v. MBL Life Assurance Corp.*, 188 F.3d 678, 683 (6th Cir. 1999). Such motions seek extraordinary judicial relief and can be granted only upon a showing of exceptional circumstances. *McAlpin v. Lexington 76 Auto Truck Stop, Inc.*, 229 F.3d 491, 502-03 (6th Cir. 2000) (citing *Dickerson v. Bd. of Educ. of Ford Heights*, 32 F.3d 1114, 1116 (7th Cir. 1994)).

ANALYSIS

Morris offers three reasons why the Court should reconsider its finding that federal law

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> an express warranty or failed to conform to other expressed factual representations upon which DENNIS MORRIS's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiffs seek recovery herein.

(Compl. ¶ 176) (emphasis added). In his reply brief, Morris maintains that his complaint alleges a design defect claim. The Court declines to consider this issue further until it is properly briefed by both parties in a separate motion before the Court.

preempts state failure-to-warn claims involving generic drugs approved under the Food and Drug Administration's ("FDA") Abbreviated New Drug Approval ("ANDA") procedure. First, Morris argues that the weight of legal authority supports a finding that conflict preemption does not apply to state failure-to-warn claims against generic drug manufacturers. Second, Morris argues that the Court should take into consideration the views of Representative Henry A. Waxman, co-sponsor of the Hatch-Waxman Amendments, and the Attorney General of the Commonwealth of Kentucky, both of whom oppose conflict preemption for generic drug manufacturers. Finally, Morris argues that public policy favors the reinstatement of his state failure-to-warn claims. The Court will address each of these arguments in turn.

I. Conflict Preemption

Conflict preemption occurs "when compliance with both state and federal law is impossible, or when the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objective of Congress.'" *United States v. Locke*, 529 U.S. 89, 109 (2000) (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100-101 (1989) (citations omitted)). "Pre-emption fundamentally is a question of congressional intent." *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990). However, conflict preemption "turns on the identification of 'actual conflict,' and not on an express statement of pre-emptive intent." *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 885 (2000). A federal agency need not formally find that an actual conflict exists for there to be conflict preemption. *Id.* Evidence of an actual conflict can include statutory language, regulatory history, and agency commentary. *Id.*

The basic question to be reconsidered by this Court is whether state failure-to-warn claims actually conflict with federal regulation of generic drug labeling. Morris cites four recent

court opinions, all of which he argues demonstrate that there is no conflict between state and federal generic drug labeling requirements. None of these four cases have any binding authority on this Court. However, they do evidence an emerging split of authority among lower courts over whether FDA regulation of generic drug labeling preempts state failure-to-warn claims. The Court now takes these cases into consideration.

A. *McKenney*

As in this case, the court in *McKenney v. Purepac Pharmaceutical Company*, 83 Cal. Rptr. 3d 810 (Cal. Ct. App. 2008), considered whether federal labeling requirements of generic manufacturers of metoclopramide actually conflict with state failure-to-warn tort liability. The court concluded that an actual conflict arises only where the generic manufacturer sought some form of heightened warning that the FDA then expressly precluded. *Id.* at 819-20. The court reached its conclusion by making two significant findings.

First, the court found that there was no reason to distinguish between brand drugs and generic drugs under current federal law because the FDA's "mechanism for compelling labeling revisions 'applies to both ANDA and NDA drug products' and that '[a]fter approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.'" *Id.* at 818 (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950, 17961 (proposed April 28, 1992)). The *McKenney* court found that federal regulation of brand and generic drug labeling is indistinguishable for federal preemption purposes because (1) the FDA can withdraw both brand and generic drugs from the market if their labels make unsubstantiated claims, and (2) an ANDA holder (generic

drug manufacturer) should notify the FDA of new safety information if it believes a drug's labeling should be changed. The fact that the FDA has never explicitly taken the position that its regulation of generic drug labeling preempts state tort law further reinforced the *McKenney*'s court finding. *Id.*

Second, the *McKenney* court found *Carlin v. Superior Court*, 920 P.2d 1347 (Cal. 1996), dispositive of the issue. *Id.* at 819-20. In *Carlin*, the California Supreme Court held that California law recognizes a strict liability cause of action against brand manufacturers who fail to warn the public of a drug's known or reasonably known dangerous propensities. 920 P.2d at 1348. The *Carlin* court rejected the argument that such a cause of action was inconsistent with federal regulation of brand drugs, *id.* at 1352, nonetheless concluding that a brand drug manufacturer could not be held liable where its proposed labeling had been expressly precluded by the FDA, *id.* at 1353 n.4. Relying primarily on its interpretation of federal law and the *Carlin* case, the *McKenney* court reached its conclusion that a demurrer based on federal preemption should be granted only where the plaintiff pleads that a generic manufacturer should have given warnings that the FDA expressly precluded the manufacturer from giving. *McKenney*, 83 Cal. Rptr. at 820.

The Court finds the reasoning of the *McKenney* court unpersuasive. As the Court explained in its October 24, 2008 Order, federal regulation of brand and generic drug labeling differs significantly. The *McKenney* court reached the opposite conclusion based on a limited review of the applicable federal law. For example, the *McKenney* court found that the FDA's ability to withdraw both brand and generic drugs bearing labels with unsubstantiated claims from the market as evidence that regulation of brand and generic drug labeling is indistinguishable for

preemption purposes. 83 Cal. Rptr. 3d at 818 (citing 57 Fed. Reg. 17950, 17961 (codified at 21 U.S.C. §355(e))). However, the fact that the FDA can withdraw both types of drugs from the marketplace does not necessitate that brand and generic drug manufacturers are unilaterally able to change their labels to conform to state imposed duties. Nor does it necessitate that federal regulation of brand drug labeling should be viewed in the same way as federal regulation of generic drug labeling. Federal regulation simply provides that if a drug manufacturer's label is unsubstantiated, then the FDA can remove the drug from the market. In other words, the FDA's ability to withdraw a drug from the market says nothing about whether state tort law can effectuate a greater duty on a drug manufacturer, brand or generic, to maintain heightened label warnings.

The federal notification requirements imposed on brand versus generic manufacturers are distinguishable. The relevant regulation states that an ANDA holder "should" notify the FDA if and when it believes that new safety information should be added to a product's label. *See* 57 Fed. Reg. 17950, 17961. Then, "FDA will determine whether the labeling for the generic and listed drugs should be revised;" the ANDA holder does not make the determination. *Id.* In contrast, a NDA holder "must" notify FDA about a change in safety information established in an approved application. *See* 21 C.F.R. § 314.70(a). Whether or not a NDA holder is then able to unilaterally change its label is an open-ended question currently pending before the Supreme Court. *See Wyeth, Inc. v. Levine*, No. 06-1249 (2008).

The *McKenney* court believed its analysis of federal law was reinforced by the fact that the FDA has never taken the position that its labeling requirements for generic drugs preempt state failure-to-warn tort liability. However, this fact has little bearing on conflict preemption

analysis. Conflict preemption "turns on the identification of 'actual conflict,' and not on an express statement of pre-emptive intent." *Geier*, 529 U.S. at 885. A federal agency need not formally find that an actual conflict exists for there to be conflict preemption. *Id.* *See also Colacicco v. Apotex Inc.*, 521 F.3d 253, 262-65 (3d Cir. 2008).

In short, the federal regulations that the *McKenney* court relied on to conclude that regulation of brand and generic drugs are indistinguishable for federal preemption purposes either do not pertain to federal preemption analysis or, in fact, demonstrate that brand and generic drug labeling requirements are distinguishable concerning federal preemption. The *McKenney* court could only apply the *Carlin* case to its analysis of generic drug preemption because it found that federal regulation of brand and generic drug manufacturers is indistinguishable for preemption purposes. Had the *McKenney* court found otherwise, then it would not have been able to apply the *Carlin* case because *Carlin* only discussed federal preemption of brand drugs. Because the Court declines to adopt the *McKenney* court's finding that federal regulation of brand and generic drugs is indistinguishable for federal preemption purposes, it likewise cannot extend the court's reasoning to the California Supreme Court's federal preemption analysis of brand drugs in *Carlin*. For these reasons, the Court finds that *McKenney* does not change its understanding of federal preemption as applied to generic manufacturers.

B. *Demahy*

Next, Morris points to the federal district court's reasoning in *Demahy v. Wyeth, Inc. et al.*, No. 08-3616, 2008 WL 4758615 (E.D. La. 2008), as evidence that state failure-to-warn claims are not preempted by federal law. The *Demahy* court concluded that federal regulation of

generic drug labeling does not conflict with state failure-to-warn liability primarily based on its understanding of 21 C.F.R. § 314.70. Section 314.70(c)(6)(iii), commonly referred to as the CBE regulation, states that post-approval, an "approved applicant" may submit a supplement to its labeling "to reflect newly acquired information" to add or strengthen, among other things, a drug label's warning.

The *Demahy* court determined that the CBE regulation applies to both NDA and ANDA holders. The court reached its determination based on its analysis of the FDA's 1989 Proposed Rule in conjunction with 21 C.F.R. § 314.150, and based on its understanding of 21 C.F.R. § 314.97. The *Demahy* court reasoned that because the CBE regulation applies to ANDA holders, generic drug manufacturers have the ability to unilaterally change their labels to conform to heightened state warnings. The court further reasoned that because generic drug manufacturers can unilaterally change their labels, federal law does not conflict with state tort imposed duties to warn. Thus, the *Demahy* court concluded that there can be no federal preemption where there is no actual conflict between state and federal law.

The Court declines to adopt the *Demahy* court's reasoning for several reasons. First, the Court does not agree with the *Demahy* court's reading of the FDA's 1989 Proposed Rule. In relevant part, the 1989 Proposed Rule states:

> FDA emphasizes that the exceptions to the requirement that a generic drug's labeling be the same as that of the listed drug are limited. The agency will not accept ANDA's for products with significant changes in labeling (such as new warnings or precautions) intended to address newly introduced safety or effectiveness problems not presented by the listed drug. . . . FDA does not believe that it would be consistent

> with the purpose of section 505(j) of the act, which is to assure the marketing of generic drugs that are safe and effective as their brand-name counterparts, to interpret section 505(j)(2)(A)(v) of the act as permitting the marketing of generic drugs with diminished safety and effectiveness and concomitantly heightened labeled warnings.

Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28884 (proposed July 10, 1989). The *Demahy* court read the 1989 Proposed Rule as applicable to only initial ANDA applicants, not ANDA holders. 2008 WL47581615 at *6. Thus, the court understood the FDA's longstanding policy that a generic drug's label be "the same as" the brand drug's label to be limited to the pre-ANDA approval process and does not address "whether a generic drug *that has already been approved* via the ANDA process can change its label to include new or different warnings without FDA approval." *Id.* (emphasis in the original). The *Demahy* court then read the 1989 Proposed Rule to contemplate the approval of post-ANDA unilateral label changes because the 1989 Proposed Rule allows the FDA to withdraw a generic drug from the market and not the corresponding brand drug under 505(e) of the Act. *Id.* at *7 (citing 54 Fed. Reg. at 28904). Section 505(e) is codified today at 21 U.S.C. § 355(e). It provides a variety of bases upon which the FDA can withdraw a drug from the market, including "on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of . . ." 21 U.S.C. § 355(e).

The Court agrees with the *Demahy* court that the relevant language of the 1989 Proposed

Rule pertains only to the initial ANDA applicants and does not necessitate that, post-ANDA approval, a generic drug manufacturer cannot unilaterally change its label. However, the Court disagrees with the *Demahy* court's consequent analysis that the 1989 Proposed Rule also contemplates that an ANDA holder can unilaterally change its label. As the Court explained above, the fact that the FDA can withdraw a drug from the market says nothing about the ability of a drug manufacturer to unilaterally change its label. All that section 355(e) contemplates is that if a generic manufacturer provides new information to the FDA, and consequently, the FDA tells the manufacturer to change its drug's label but the manufacturer fails to do so, then the FDA can withdraw the generic drug from the market. In other words, the basis for a label change and consequent withdrawal of the drug from the market is a determination FDA makes, not the generic manufacturer.

The Court also disagrees with the *Demahy* court's reading of 21 U.S.C. § 314.97. Section 314.97 provides that "the applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application." The *Demahy* court understood this regulation to mean that an ANDA holder can unilaterally change its label consistent with the CBE regulation, § 314.70. The Court, however, finds two possible interpretations of § 314.97. Either the *Demahy* court is correct that § 314.97 requires ANDA holders to utilize § 314.70, in which case whether or not an ANDA holder can unilaterally change its label is an issue currently pending before the United States Supreme Court,[3] or the *Demahy* court is incorrect and § 314.97 merely states that when a brand

[3]In *Wyeth, Inc.v. Levine*, the Supreme Court will consider the issue of whether or not § 314.70 allows brand manufacturers to unilaterally change their drug labels. *See Wyeth, Inc. v. Levine*, No. 06-1249 (2008). Should the Supreme Court determine that brand manufacturers

manufacturer utilizes § 314.70, then so too must the generic manufacturer make that same change to its corresponding drug's label.[4] The Court notes that the latter of these two interpretations is consistent with the FDA's assertion that an ANDA applicant's drug label be "the same as" the labeling of the listed drug. 21 C.F.R. § 314.94(a)(8)(iii).

The Court's understanding of the 1989 Proposed Rule and § 314.94 is reinforced by a footnote in the FDA's 2008 Proposed Rule. The footnote states, "CBE changes are not available for generic drugs approved under an abbreviated new drug application under 21 U.S.C. 355(j). To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug." Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 (proposed January 16, 2008) (internal citations omitted). Because this clear statement of intent was "regulated to a mere footnote," the *Demahy* court determined that it was not entitled to deference. This Court does not reach the same conclusion and finds the footnote persuasive evidence of conflict preemption. *See Kentucky Waterways Alliance v. Johnson*, 540 F.3d 466, 474-75 (6th Cir. 2008) ("When interpreting an agency regulation, a court should also defer to the agency's interpretation of the regulation unless it is plainly erroneous or inconsistent with the regulation.") (internal citation

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cannot unilaterally change their labels under § 314.70 based on conflict preemption, then neither can generic manufacturers unilaterally change their labels under the *Demahy* court's reasoning.

[4] The Court need not determine at this time which of these two interpretations is, in fact, correct. This is because, under the *Demahy* court's interpretation, the Supreme Court will decide whether or not generic manufacturers can unilaterally change their labels to conform with state imposed heightened warnings, and under the Court's proposed interpretation, there is no question that generic manufacturers cannot unilaterally change their labels to conform with state imposed heightened warnings. Thus, neither interpretation leads to the absolute conclusion that generic manufacturers can unilaterally change their labels to conform with state imposed duties.

omitted).

For the above reasons, the Court is unpersuaded by the *Demahy* court's reasoning.

C. *Swicegood*

Morris cites *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351 (N.D. Ga. 2008), as further support that the CBE regulation applies to generic manufacturers. *Swicegood* involved brand manufacturers of Reglan who moved to dismiss the case against them because, under Georgia law, plaintiffs had failed to state claims for strict liability, negligence, and fraudulent and negligent misrepresentation. In its discussion of fraudulent and negligent misrepresentation, the *Swicegood* court noted that brand manufacturers cannot be held liable for the misrepresentation of generic drug labels because generic manufacturers are not bound by a brand manufacturer's labeling. *Id.* at 1358. The court explained that generic manufacturers have "the ability - albeit with approval by the FDA - to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' or 'delete false, misleading, or unsupported indications for use.'" *Id.* (citing *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 523 (E.D. Pa. 2006) (explaining the FDA's interpretation of 21 C.F.R. § 314.70(c)(6)(iii)(A)). In response, Defendants argue that the *Swicegood* case is irrelevant because the case only discusses generic manufacturers in passing and does not discuss federal preemption at all.

The *Swicegood* court determined that the CBE regulation applies to generic manufacturers with little discussion of the specific regulations and was meant to resolve the question of whether a brand manufacturer could be held liable for the labeling of its generic competitor, not whether a generic manufacturer could unilaterally change its label post-FDA

approval. *Id.* at 1358. The conclusion reached by the *Swicegood* court that generic manufacturers are not bound to completely follow the labels of their listed drugs is correct. However, the basis for the labeling difference is not the CBE regulation, but rather other federal regulations pertaining to ANDA applicants, such as § 314.93. *See* 21 C.F.R. § 314.93 (allowing ANDA applicants to submit an abbreviated new drug application for a drug product not identical to the listed drug "in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients" upon the permission and approval of the FDA). Furthermore, the district court case cited by the *Swicegood* court in support of its determination, *Colacicco v. Apotex, Inc.*, held that federal regulation of generic manufacturers impliedly preempts state tort law. 432 F. Supp. 2d 514, 537-38 (E.D. Pa. 2006) ("state tort law which would hold a generic drug manufacturer liable for failing to modify a label when, pursuant to the Hatch-Waxman Amendments to the FDCA [Food, Drug, and Cosmetic Act], the ANDA approval process required that the labeling be the same as that approved for the innovator drug, and when the FDA would have deemed any post-approval enhancements 'false or misleading,' would actually conflict with the FDCA"). In short, the *Swicegood* court reached the conclusion that brand manufacturers cannot be held liable for the labels of generic drugs based, in part, on erroneous reasoning. The Court declines to now adopt that court's erroneous reasoning, as Morris suggests it should.

D. *Sharp*

Like *Swicegood*, *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. 2006), involved brand manufacturers of Reglan who moved to dismiss the case against them because the plaintiff had never ingested Reglan, only generic metoclopramide. Ultimately, the

Sharp court declined to extend state tort liability to brand manufacturers when the evidence was clear that the plaintiff never ingested drugs produced by them. *Id.* at *3. In reaching this conclusion, *Sharp* referenced the Fourth Circuit's decision in *Foster v. American Home Products Corporation*, 29 F.3d 165 (4th Cir. 1994). *Id.* at *4. In *Foster*, the Court of Appeals held that brand manufacturers cannot be held liable for the labeling of their generic competitors because to do so would "stretch the concept of foreseeability too far." 29 F.3d at 171. The *Foster* court explained,

> When a generic manufacturer adopts a name brand manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed. . . . Although generic manufacturers must include the same labeling information as the equivalent name brand drug, they are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval. 21 C.F.R.§ 314.70 (1993). The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law. Manufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products.

Id. at 169-70. It is the language of *Foster*, not *Sharp*, upon which Morris bases his argument that generic manufacturers can unilaterally change their labels in conformance with state tort liability. Like *Swicegood*, the holding in *Sharp* is unconcerned with federal preemption of state tort claims against generic manufacturers.

The Court declines to address the *Foster* case in detail, since it is apparent that the difference between the *Foster* court's dicta about generic manufacturer liability and this Court's opinion is based upon the applicability of the CBE regulation to generic manufacturers; a difference upon which this Court and the Fourth Circuit disagree, and the Court has already explained earlier in this opinion. For the reasons stated above, the Court declines to adopt the reasoning of the Florida Circuit Court's decision in *Sharp*, and by logical extension, the reasoning of the Fourth Circuit in *Foster*.

II. Representative Waxman and Kentucky Attorney General Comments

Next, Morris argues that the Court should consider the views of Representative Henry A. Waxman and the Attorney General of the State of Kentucky in its assessment of federal preemption of state failure-to-warn claims against generic manufacturers. Both oppose federal preemption. In response, Defendants argue that these views are irrelevant, do not reflect congressional intent, and have no binding authority on the Court.

Representative Henry A. Waxman was the co-sponsor of the Hatch-Waxman Amendments. He has since joined an amicus brief for the federal preemption case, *Wyeth, Inc. v. Levine*, currently pending before the Supreme Court. *See* Brief for Members of Congress as Amici Curiae Supporting Respondent, Wyeth, Inc. v. Levine, No. 06-1249 (2008). The brief argues that when Congress enacted the FDCA, "it deliberately preserved state law damages claims," and the FDA's current position in support of federal preemption does not reflect congressional intent. *Id.* at 3-4. While the brief discusses the CBE regulation, it does not discuss how it relates to generic manufacturers.

In *Chickasaw Nation v. United States*, the Supreme Court considered whether a

subsection of the Indian Gaming Regulatory Act exempted tribes from paying gambling-related taxes. 534 U.S. 84, 122 S.Ct. 528 (2001). The tribes argued that the explicit language of the subsection exempted them from taxation, but they also argued that a letter written by the author of the Gaming Act demonstrated that Congress intended for the taxes not to apply to them. *Id.* at 533-34. The Supreme Court stated that the letter could not demonstrate congressional intent. *Id.* at 534.

> This letter, however, was written after the event. It expresses the views of only one member of the committee. And it makes no effort to explain the critical legislative circumstance, namely, the elimination of the word "taxation" from the bill. The letter may express the Senator's interpretive preference, but that preference cannot overcome the language of the statute and the related considerations we have discussed. *See Heintz v. Jenkins*, 514 U.S. 291, 298, 115 S.Ct. 1489 (1995) (A "statement [made] not during the legislative process, but after the statute became law ... is not a statement upon which other legislators might have relied in voting for or against the Act, but it simply represents the views of one informed person on an issue about which others may (or may not) have thought differently"). *Cf. New York Telephone Co. v. New York State Dept. of Labor*, 440 U.S. 519, 564, n. 18, 99 S.Ct. 1328 (1979) (Powell, J., dissenting) ("The comments ... of a single Congressman, delivered long after the original passage of the [act at issue], are of no aid in determining congressional intent ...").

Id.

Similarly, the comments of Representative Waxman as expressed in the amici brief do

not represent the intent of Congress in enacting the Hatch-Waxman Amendments. As the brief itself states at the outset, "amici submit this brief in their individual capacities, not on behalf of Congress itself . . . ." *Id.* at 2. Furthermore, the brief does not even discuss federal preemption or the CBE regulation as applied to generic manufacturers, which further diminishes Morris's reliance on it. The Court finds no reason to view Representative Waxman's views as indicative of congressional intent.

The same can be said for the views of the Attorney General of the Commonwealth of Kentucky. The Kentucky Attorney General, along with the attorneys general of forty-six other states, has joined an amici brief opposing federal conflict preemption in the *Wyeth, Inc. v. Levine* case. *See* Brief of Vermont, Alabama, Alaska, et al. as Amici Curiae Supporting Respondents, Wyeth, Inc. v. Levine, No. 06-1249 (2008). The brief argues that state tort liability does not conflict with federal labeling regulations, nor does it frustrate the objectives of the FDCA.

The Court greatly respects the Commonwealth of Kentucky's role in safeguarding the public health, safety, and welfare of its citizens, many of whom consumer generic drugs. But the views of the Kentucky Attorney General, and by extension, the Commonwealth of Kentucky, do not express Congress' intent. Accordingly, the Court finds the views of Representative Waxman and the Attorney General of the Commonwealth of Kentucky unpersuasive in reevaluating its earlier opinion.

III. Public Policy

Finally, Morris argues that the economic burden placed on generic manufacturers to comply with heightened state failure-to-warn liability does not outweigh the life-saving benefit of clearly informing consumers about the risks associated with taking metoclopramide. He states

that, "[s]ince generic drug manufacturers have captured the largest share of the market for metoclopramide sales, public policy requires the retention of a basic duty to warn consumers." Otherwise, Morris argues that Defendants, who were aware of the safety concerns associated with metoclopramide, will continue to shirk their responsibility to strengthen existing drug labeling.

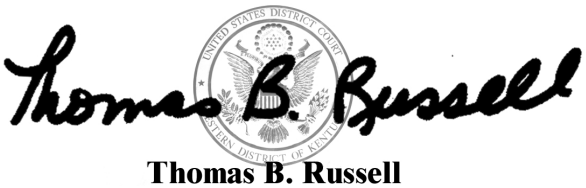
In response, Defendants argue that Congress made a public policy decision in enacting the Hatch-Waxman Amendments. That public policy decision favored the availability of lower costing generic drugs at the risk that not all drugs would be safe for every consumer. Most often, a drug's safety profile is already established by the time a listed drug becomes eligible for generic production. Based on that knowledge, Congress exempted generic manufacturers from conducting "the onerous, expensive, and unethical testing" required to obtain approval of a new drug.

The competing public policy arguments presented by Morris and Defendants demonstrate the delicate balance of considerations concerning the manufacture and safety of generic pharmaceuticals. However, these public policy arguments were presented to the Court at the time it rendered its October 24, 2008 Order. Having been presented with no new public policy arguments, the Court finds that these arguments offer no compelling reason for the Court to reconsider its previous decision.

CONCLUSION

For the reasons stated above, the Court finds that Plaintiff has failed to establish the exceptional circumstances necessary for the Court to reconsider its October 24, 2008 Order. According, Plaintiff's Motion for Reconsideration is DENIED.

An appropriate order shall issue.



Thomas B. Russell
Chief Judge, U.S. District Court

February 20, 2009