UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Gladys Mensing,

Plaintiff,

v.

WYETH, INC. (d/b/a WYETH); SCHWARZ PHARMA, INC.; PLIVA, Inc.; TEVA PHARMACEUTICALS, USA, INC.; ALPHARMA, INC., d/b/a ALPHARMA PHARMACEUTICALS; UDL LABORATORIES, INC.; ACTAVIS ELIZABETH, LLC, and PUREPAC PHARMACEUTICAL CO.; and the following fictitious party defendants (whether singular or plural, individual or corporate): No. 1, that entity which originally obtained permission from the U.S. Food and Drug Administration to market the drug branded Reglan; No. 2, that entity which obtained permission from the FDA to market the Reglan, metoclopramide and/or metoclopramide HCI ingested by Gladys Mensing; No. 3, that entity which originally manufactured and sold any Reglan which was ultimately ingested by Gladys Mensing: No. 4, that entity which originally manufactured and sold any Reglan, metoclopramide and/or metoclopramide HCI which was ultimately ingested by Gladys Mensing: No. 5, that entity which marketed Reglan or generic metoclopramide and/or metoclopramide HCI, jointly and individually,

Defendants.

Civil No. 07-3919 (DWF/SRN)

MEMORANDUM OPINION AND ORDER

Daniel J. McGlynn, Esq., and Patty F. Trantham, Esq., McGlynn, Glisson & Koch, APLC; and Lucia J. W. McLaren, Esq., and Michael K. Johnson, Esq., Goldenberg & Johnson, PLLC, counsel for Plaintiffs.

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Andrew J. Calica, Esq., and Henninger S. Bullock, Esq., Mayer Brown, LLP; and Erin M. Verneris, Esq., and Bridget M. Ahmann, Esq., Faegre & Benson LLP, counsel for Defendant Schwartz Pharma, Inc.

Joseph P. Thomas, Esq., Matthew V. Brammer, Esq., Rex A. Littrell, Esq., and Tiffany Reece Clark, Esq., Ulmer & Berne LLP; and Jan R. McLean, Esq., Tracy J. Van Steenburgh, Esq., and Dana M. Lenahan, Esq., Halleland Lewis Nilan & Johnson PA, counsel for Defendants PLIVA, Inc.

David L. Hashmall, Esq., Fellhaber Larson Fenlon & Vogt, PA, counsel for Defendants Teva Pharmaceuticals USA, Inc. and UDL Laboratories, Inc.

Bradley J. Linderman, Esq., and Michael D. Hutchens, Esq., Meagher & Geer, PLLP; and Richard A. Dean, Esq., Tucker Ellis & West, counsel for Defendants Alpharma Inc., Actavis Elizabeth, LLC, and Purepac Pharmaceutical Co.

INTRODUCTION

This matter is before the Court on a Motion to Dismiss brought by Actavis Elizabeth, LLC ("Actavis"); a Motion to Dismiss or for Summary Judgment brought by Pliva, Inc. ("Pliva"); and a Motion for Relief Under Fed. R. Civ. P. 56(f) brought by Plaintiff Gladys Mensing. For the reasons stated below, the Court grants Actavis's and Pliva's motions and denies Plaintiff's motion.[1]

BACKGROUND

In her Amended Complaint, Plaintiff alleges that on or about March 23, 2001, her physician prescribed the drug Reglan to her to treat diabetic gastroparesis. (Am. Compl.

[1] The question presented by both Actavis's and Pliva's motions to dismiss is purely legal in nature. Accordingly, further factual discovery is unnecessary and Plaintiff's motion under Fed. R. Civ. P. 56(f) is denied.

¶ 27). The active ingredient in Reglan is metoclopramide ("MCP"). MCO, which is available in brand (Reglan) or generic form, is used to treat certain gastrointestinal disorders. Plaintiff alleges that she ingested Reglan/MCP from March 23, 2001, until March 2005, and that her long-term ingestion of Reglan/MCP caused her to develop tardive dyskinesia, a neurological movement disorder. (*Id*. ¶¶ 27, 32, 34, 37, 38.)

Both Actavis and Pliva manufacture MCP, a generic version bioequivalent of Reglan.[2] Reglan, the reference listed drug for MCP, was approved by the FDA in 1980. In March 1985, the FDA required that Reglan's label be updated to include a warning regarding the risk of developing tardive dyskinesia. Actavis and Pliva revised their insert labeling to comport to approved changes to the Reglan label. There is no dispute that the labels for both Actavis's and Pliva's MCP were at all relevant times the same as Wyeth's Reglan label.

Plaintiff asserts state-law tort claims against both Wyeth and the manufacturers of generic MCP. Although Plaintiff has asserted a variety of claims against Actavis and Pliva, at the core of all of Plaintiff's claims is the basic assertion that Actavis and Pliva failed to adequately warn about the association between long-term ingestion of MCP and movement disorders. For example, Plaintiff alleges that Actavis and Pliva ignored scientific and medical literature establishing a higher risk of developing tardive dyskinesia, failed to request a labeling revision to the FDA, and failed to report safety information directly to the medical community.

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[2] Defendant Wyeth, Inc., is the name brand manufacturer of Reglan.

Actavis and Pliva move separately to dismiss Plaintiff's claims against them, arguing that Plaintiff's claims are preempted by federal law.

DISCUSSION

I. Motions to Dismiss

A. Standard of Review

In deciding a motion to dismiss, a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged. *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id.* at 1964–65. This standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Id.* at 1965. The Court

evaluates a motion brought under Rule 12(c) under the same standard as a motion brought under Rule 12(b)(6). Fed. R. Civ. P. 12(c) and (h)(2).

B. Federal Preemption

A state law that conflicts with a federal law is preempted under the Supremacy Clause of the Constitution, U.S. Const. art. VI, cl. 2. *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-13 (1985). Congressional intent to preempt state law can either be expressed in statutory language or implied in the structure and purpose of federal law. *Id*. Implied preemption has two types—field and conflict preemption. Field preemption is inferred where Congress legislates so pervasively in a particular field that no room remains for supplementary state legislation. *Id*. Even if Congress has not completely displaced state regulation, preemption may occur when state law actually conflicts with federal law. *Id*. Conflict preemption arises when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Id*. (citing *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) and *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). State laws can be pre-empted by both federal statutes and federal regulations. *Id*. at 713.

Both Actavis and Pliva assert that Plaintiff's claims are conflict preempted. First, they argue that as generic drug manufacturers, they cannot comply with both federal law that requires their generic drug labels to be the "same as" the Reglan® label and with a state-imposed duty to heighten warning labels. In particular, Actavis and Pliva contend that it would be impossible for it to comply with both the Abbreviated New Drug

Application ("ANDA") provisions of the Food, Drug & Cosmetic Act ("FDCA") and the labeling requirements Plaintiff seeks to impose pursuant to state law. In addition, both Actavis and Pliva maintain that Plaintiff's claims are conflict preempted because the state laws pose an obstacle to Congressional objectives in enacting federal law applicable to generic drug manufacturers and vesting exclusive authority to regulate prescription drug labeling with the Food and Drug Administration ("FDA").

In support of their preemption arguments, both Actavis and Pliva point to the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or the "Act") (codified at 21 U.S.A. § 355(j)). The Hatch-Waxman Act codified the ANDA procedures being used by the FDA. Actavis and Pliva assert that under the ANDA procedures, a generic manufacturer is required to put exactly the same language on its warning labels as the listed drug.[3]

1. Regulatory Framework

To determine whether or not Plaintiff's claims are preempted, the Court must first understand the relevant regulatory framework. The FDA is the federal agency charged by Congress in the FDCA with regulating the manufacture, sale, and labeling of new prescription drug products that are marketed for human consumption and, in particular, to ensure the safety and efficacy of new drugs. 21 U.S.C. § 393. In this capacity, the FDA regulates the introduction of all new drugs. 21 U.S.C. § 355(b). Under 21 U.S.C. § 355(a), "[n]o person shall introduce or deliver for introduction into interstate commerce

[3] Despite the fact that the bases for Actavis's and Pliva's preemption arguments vary to some degree, the Court analyzes their motions to dismiss together.

any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." Section 355(b) applies to "pioneer" or "innovator" drugs. A manufacturer seeking approval to market a pioneer drug must submit a New Drug Application ("NDA"). 21 U.S.C. § 355(b). As part of the NDA, the manufacturer must submit, among other things, "full reports of investigations" on the drug's safety and effectiveness and "specimens of the labeling proposed to be used" for the new drug. 21 U.S.C. § 355(b)(1)(A)-(F). The FDA may refuse an application if it finds that the investigations "do not include adequate tests . . . to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(1).

In 1984, Congress amended the FDCA by passing the Hatch-Waxman Act. The legislative history of the Hatch-Waxman Act reveals that the primary purpose of amending the FDCA to implement the ANDA procedure was to increase the availability of low cost generic drugs by establishing a generic drug approval procedure. (*See* Aff. of Tiffany Reece Clark ("Clark Aff.") ¶¶ 2 & 3, Exs. A & B.) The FDCA, as amended, provides for an ANDA procedure that allows for the expedited FDA approval of a generic version of a drug previously approved under the FDA (a "listed drug").[4] *See* 21 U.S.C. § 355(j); *see also Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241 (Fed.

[4] A "listed drug" refers to a drug previously approved that serves as the basis for a generic drug. 21 C.F.R. § 314.3.

Cir. 2000) (explaining the ANDA process).[5] 21 U.S.C. § 355(j) applies to generic drugs, or drugs that are based on another previously FDA approved or "listed" drug. When a drug for which approval is sought is the "same as a listed drug," then an applicant may submit an abbreviated application complying with the ANDA provisions of 21 C.F.R. § 314.94. 21 U.S.C. § 355(j)(1); 21 C.F.R. § 314.92(a). The manufacturer of a generic drug must show that the generic drug has the same active ingredients and is the "bioequivalent" of the listed drug. 21 U.S.C. § 355(j)(2)(A)(ii) and (iv). In addition, an applicant filing an ANDA must submit:

> information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug . . . except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers.

21 U.S.C. § 355(j)(2)(A)(v) (emphasis added). To this effect, an ANDA applicant must submit a side-by-side comparison of the applicant's proposed labeling. 21 C.F.R. § 314.94(a)(8)(iv). The labeling for the proposed drug "must be the same as the labeling approved for the reference listed drug," with the exception of certain allowable changes. *Id*. These allowable changes may include:

> . . . differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.

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[5] Prior to the Hatch-Waxman Act, the FDA created an ANDA procedure for the approval of "duplicate" drug products. Those procedures were codified by the Hatch-Waxman Act. *See* 57 Fed. Reg. at 17951 (Apr. 28, 1992) (explaining that the Act adopted, with few modifications, the FDA's ANDA procedure for pre-1962 drugs).

Id.

The FDA will not approve an ANDA if information submitted by the applicant is "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug." 21 C.F.R. § 314.127(a)(7). Moreover, the FDA may withdraw approval of a generic drug if the labeling for the generic product varies from that of the listed drug. 21 C.F.R. § 314.150(b)(10).

2. Plaintiff's Claims

With this framework in mind, the Court must determine whether Plaintiff's claims against Actavis and Pliva conflict with the FDCA or the FDA regulations, so as to be preempted by the federal law. As a threshold matter, Plaintiff argues that there is a strong presumption against preemption. The Supreme Court has stated:

> In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (quotations omitted). Although commonly acknowledged, the presumption against preemption is not always appropriate. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 347-48 (2001). In the context of conflict preemption, which analyzes preemption in the absence of explicit Congressional intent, "the lack of a Congressional directive expressly approving or rejecting preemption in the context of drug labeling regulations is not determinative." *See Colacicco v. Apotex Inc.*, 521 F.3d 253, 265 & n.11 (3d Cir. 2008). Thus, the Court

must analyze the propriety of preemption where Congress has not explicitly expressed its intent.

Plaintiff alleges that Actavis and Pliva's MCP labels failed to adequately warn of the risk or prevalence of tardive dyskinesia. In particular, Plaintiff claims that the risk ratio of developing tardive dyskinesia was significantly higher than the ratio listed on the Reglan and MCP labels. [6] Actavis and Pliva argue that these failure to warn claims are preempted because they, as generic manufacturers, could not unilaterally alter their labels to include a warning that varied from that of the listed drug, Reglan. In addition, Actavis and Pliva argue that Plaintiff's failure to warn claims are preempted because they stand as an obstacle to the accomplishment of the full purposes and objectives of the FDCA, the Hatch-Waxman Act, and the corresponding regulatory scheme.

Plaintiff asserts that her state law claims do not present a conflict because compliance with both state and federal regulations is possible and that Actavis and Pliva could have provided stronger warnings about the risks posed by prolonged exposure to MCP without conflicting with FDA regulations. In particular, Plaintiff argues that Actavis and Pliva could have altered their labeling to strengthen warnings without prior approval of the FDA; sought FDA approval for such a change; or provided health care professionals with stronger warnings by other means, such as a "Dear Doctor" letter. The Court addresses each argument in turn.

[6] This allegation is at the heart of all of Plaintiff's claims against Actavis and Pliva. Thus, all of Plaintiff's claims are essentially "failure to warn" claims and are encompassed by the Court's preemption analysis.

The Court first turns to Plaintiff's argument that Actavis and Pliva can, and are required to, strengthen their product warnings without prior FDA approval. After reviewing the statutory provisions of the Act, the legislative history of the Act, the Act's governing regulations, and comments made by the FDA[7], the Court concludes that a generic drug manufacturer may not unilaterally strengthen a label without prior approval of the FDA.

Under the statutory provisions of the Act, there is no dispute that Actavis's and Pliva's MCP labels were required to be "the same as the labeling approved" for Reglan when the initial ANDA applications were submitted. 21 U.S.C. § 355(j)(2)(A)(v). Plaintiff argues, however, that 21 U.S.C. § 355 (j)(2)(A)(v) does *not* apply to post-approval labeling. Instead, Plaintiff argues that the FDA regulations require both name brand and generic manufacturers to strengthen warning labels post-approval. The Court disagrees.

The FDA's own comments in implementing the Hatch-Waxman Act support the conclusion that a generic manufacturer is not free to unilaterally alter the labeling from that of the name brand drug. In particular, in a proposed rule implementing the Act, the FDA described various types of labeling differences that the FDA might consider

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[7] When Congress has not unambiguously expressed its intent as to a particular question of statutory interpretation, the Court will defer to the agency's answer on the issue if it is based on a permissible construction of the statute. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). Here, the FDA's position on the ability of a generic manufacturer to unilaterally alter its label is based on a permissible construction of the relevant federal statutes and promulgating regulations. Accordingly, that position is entitled to deference.

acceptable under the statute's permitted exceptions. *See* 54 Fed. Reg. 28872 at 28884 (July 10, 1989). Notably, the FDA emphasized limited exceptions to the requirement that a generic drug label be the "same as" that of the listed drug. *Id*. The FDA stated that "[t]he 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." *Id.*

In addition, under the statutory scheme, the FDA may withdraw an ANDA if the ANDA drug labeling "is no longer consistent with that for the listed drug." 21 C.F.R. § 314.150(b)(10). In this regard, the FDA has explained:

> Because an ANDA must have labeling that is the same as the reference listed drug . . . , FDA believes that a generic drug product approved on the basis of studies conducted on the listed drug and whose labeling is inconsistent with the listed drug's labeling might not be considered safe and effective for use under the conditions prescribed, suggested, or recommended in the listed drug's labeling. FDA, therefore, has revised § 314.150 to permit the agency to withdraw approval of an ANDA if the applicant fails to maintain labeling in compliance with the requirements of the act.

57 Fed. Reg. 17950 at 17961 (Apr. 28, 1992) (emphasis added).

Several FDA responses to comments submitted in connection with proposed ANDA regulations underscore the notion that the ANDA drug's label must remain the same as that of the listed drug. For example, in response to a comment proposing that ANDA labeling provisions be "revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions and other safety-related information," the FDA stated:

> FDA disagrees with the comment[]. Except for labeling differences due to exclusivity of a patent and differences under section 505(j)(2)(v) of the act, the ANDA's product labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval. Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart. (See 54 FR 28872 at 28884.) <u>If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After 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.</u>

Id. at 17961 (emphasis added). In addition, in response to a comment recommending that the "FDA accept ANDAs with warning**s** or precautions in addition to those on the reference listed drug's label, provided that such information was not indicative of diminished safety or effectiveness of the generic product," the FDA stated:

> As for accepting ANDA's with additional warnings or precautions, section 505(j)(2)(A)(v) and (j)(3)(G) of the act requires that the applicant's proposed labeling be the same as that of the reference listed drug unless: (1) The labeling differences are due to an approved petition under section 505(j)(2)(C) of the act (otherwise referred to as a "suitability petition"); or (2) the drug product and the reference listed drug are produced or distributed by different manufacturers. Thus, the exceptions in section 505(j)(2)(A)(v) of the act are limited. In addition, under the patent and exclusivity provisions of the act, the ANDA labeling may be required to carry fewer indications than the reference listed product's labeling or to have other labeling differences. In the preamble to the proposed rule, the agency described various types of labeling differences that might fall within the permitted exceptions.

Id. at 17953 (citations omitted).

Further, in industry guidance documents, the FDA reiterates the ANDA labeling requirements. For example, in its Guidance for Industry regarding Changes to an Approved NDA or ANDA, the FDA states:

> A drug product labeling change includes changes in the package insert, package labeling, or container label. An applicant should promptly revise all promotional labeling and drug advertising to make it consistent with any labeling change implemented in accordance with the regulations. All labeling changes for ANDA products must be consistent with section 505(j) of the Act [codified at 21 U.S.C. § 355(j)].

(Clark Aff. ¶ 15, Ex. N. at 20 (emphasis added).) Again, section 505(j) (codified at 21 U.S.C. § 355(j)) requires that the labeling be the "same as" the listed drug.

That a generic drug manufacturer cannot unilaterally change the label is also supported by the positions of the FDA provided in recent *amicus briefs*. For example, in an *amicus brief* filed in *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), the FDA asserted the following:

> For a generic drug manufacturer, there is no statutory or regulatory provision permitting a labeling change to be made without prior FDA approval. To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug. If a generic drug manufacturer believes that new safety information should be added to the label for its drug, it is directed to contact FDA with "adequate supporting information." 57 Fed. Reg. at 17,961. The agency will consider this information and determine whether the labeling for both the generic drug and the innovator drug should be revised. *Id*.

(Clark Aff. ¶ 19, Ex. Q at 7-8.)[8]

[8] The Third Circuit recognized that the "FDA states that generic drug manufacturers may not add new warnings to the approved labeling for the listed drug." *Colacicco*, 521 F.3d at 260 n.5.

Plaintiff relies primarily on 21 C.F.R. § 314.70(c), the "Changes Being Effected" ("CBE") regulation, for the proposition that generic drug manufacturers can change their product labels without waiting for FDA approval.[9] Section 314.70(c) allows NDA manufacturers, under certain limited circumstances, to strengthen warnings prior to FDA approval. The FDA has explained, however, that the CBE provision does *not* permit ANDA manufacturers to make unilateral changes. In particular, the FDA explained:

> The plaintiff asserts that 21 C.F.R. § 314.70(c) empowers a generic drug manufacturer to add a new warning to the label for its drug without prior FDA approval. That regulatory provision, however—like the other provisions of Title 21, Part 314, Subpart B of the Code of Federal Regulations—applies to applications involving drug products for which a full application has been submitted, *i.e.*, innovator drug products. Drug manufacturers that submit abbreviated applications to market generic drugs are subject to the requirements set forth in Title 21, Part 314, Subpart C. Although Subpart C contains a provision requiring applicants to "comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application," 21 C.F.R. § 317.97, that provision does not modify the requirement that the drug label for a generic drug must be the same as the label for the approved innovator drug (with limited exceptions not relevant here). Any ambiguity in the regulatory text has been clarified by FDA, which explained at the time of promulgation that the regulations do not authorize drug manufacturers to add new warnings to the approved labeling for the innovator drug. *See* 57 Fed. Reg. at 17,961, 17,953, 17,955.

(Clark Aff. ¶ 18, Ex. Q at 8 n.4 (emphasis added).) In addition, in a rule proposed on January 2008, the FDA confirmed that § 314.70 does not permit unilateral label changes

[9] With the Court's permission, Pliva submitted a copy of an *amicus brief* filed by the United States in a case currently before the United States Supreme Court. Pliva contends that portions of the argument therein would be helpful to the Court, particularly with respect to the interpretation of § 314.70(c). Plaintiff has moved to strike Pliva's submission. The Court denies Plaintiff's motion. While the Court reviewed Pliva's submission and the attached *amicus brief*, this review did not alter the Court's analysis or the outcome of the dispositive motions before the Court.

by ANDA manufacturers. *See* 73 Fed. Reg. 2848 at 2848-49 (Jan. 16, 2008). In particular, the FDA stated: "FDA is proposing to amend its regulations regarding changes to an approved NDA, BLA, or PMA to codify the agency's longstanding view on when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency's review." *Id*. at 2849. In the Supplementary Information section of the proposed rule, the FDA explains: "CBE changes are not available for generic drugs approved under an [ANDA] 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." *Id*. at 2849 n.1 (citations omitted).

The Court concludes that under the federal statutory scheme, the labeling for generic drugs must always remain the "same as" that of the name brand drug and that a generic drug manufacturer cannot unilaterally change its label without prior FDA approval. Here, it is undisputed that at all relevant times, Actavis's and Pliva's MCP drug labels were the same as that of the listed drug Reglan. Plaintiff's failure to warn claims against Actavis and Pliva rely on state law imposing a duty on the generic drug manufacturers to provide adequate warnings that Actavis and Pliva allegedly did not provide. Any such duty to unilaterally heighten their warning labels, however, would directly conflict with the federal law requiring that their labels be the "same as" those of the listed drug, Reglan. Indeed, under these circumstances, it would be impossible for Actavis and Pliva to abide by both state and federal laws. If Plaintiff's claims were not preempted, Actavis and Pliva would be forced to choose between complying with the federal law while being exposed to state tort liability, or unilaterally adding a heightened

warning to their labels at the risk of exposing themselves to federal liability. This conflict would stand as an obstacle to the accomplishment and full purposes and objectives of the Hatch-Waxman Act, a key purpose of which is to increase the availability of low-cost generic drugs and to relax the generic approval and labeling process.

The Court turns next to Plaintiff's argument that Actavis and Pliva could have sought to strengthen their warnings through the prior approval supplemental process under 21 C.F.R. § 314.70. Based on the statutory scheme discussed above, the Court discerns no legal duty requiring a generic drug manufacturer to propose revised labeling. While the manufacturer of a generic drug may seek to add safety information to a drug label, in order to do so, it must first provide certain information to the FDA; the FDA then in turn determines whether the labeling for both the generic and listed drug should be revised. *See* 57 Fed. Reg. 17950 at 17961 cmt. 40. The outcome of any such request to make a revision is uncertain and would require speculation as to what the FDA might have done. In light of the statutory scheme discussed in detail above, the Court determines that Plaintiff's failure to warn claims, insofar as they assert that Actavis and Pliva had an independent duty to seek to add safety information to MCP's label, again would directly conflict with the statutory scheme of the Hatch-Waxman Act and would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of the Act.

Finally, the Court turns to Plaintiff's argument that Actavis and Pliva were free to employ other means to warn health care professionals, such as submitting a "Dear Doctor" letter. The regulatory scheme, however, does not allow for ANDA manufacturers to send "Dear Doctor" letters. Instead, for drugs approved through the ANDA procedures, "the Secretary shall undertake any communication plan to health care providers required under [the risk evaluation and mitigation strategies][10] for the applicable drug." 21 U.S.C. § 355-1(i)(2)(A). The imposition of an independent duty on the part of the generic manufacture to send "Dear Doctor" letters would directly conflict with the statutory scheme of the Hatch-Waxman Act. In addition, this Court's speculation over what the FDA might have done if Actavis or Pliva had requested such a letter would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of the Act.

CONCLUSION

Accordingly, **IT IS HEREBY ORDERED** that:

1. Actavis's Motion to Dismiss (Doc. No. 39) is **GRANTED**.
2. Pliva's Motion to Dismiss (Doc. No. 64) is **GRANTED**.
3. Plaintiff's Rule 56(f) Motion is **DENIED**.
4. Plaintiff's Motion to Strike (Doc. No. 85) is **DENIED**.
5. This action is dismissed as to Defendants Actavis and Pliva.

Dated: June 17, 2008

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court

[10] This includes sending letters to health care providers. 21 U.S.C. § 355-1(e)(3)(A).