UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation

Case No. 6:06-md-1769-Orl-22DAB

This document relates to:

TERRY BARNES v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16752-ACC-DAB

TAMMY COLMAN v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16751-ACC-DAB

AMBER DONALDSON v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16742-ACC-DAB

DARLEEN DUNCAN v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16736-ACC-DAB

SHELIA GORDON v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16738-ACC-DAB

OCTAVIA JACKSON v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-522-ACC-DAB

SHELLY JENSEN v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16743-ACC-DAB

JAMES MAKINSON v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16757-ACC-DAB

LEONARD SAUVAGEAU v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16754-ACC-DAB

SANDRA THOMAS v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP
MDL Case No. 6:07-cv-16748-ACC-DAB

JACQUELINE WILSON v. ASTRAZENECA PHARMS. LP and ASTRAZENECA LP

MDL Case No. 6:07-cv-16740-ACC-DAB

ORDER

I. INTRODUCTION

This cause comes before the Court for consideration of AstraZeneca's Motion For Partial Judgment on the Pleadings on the Basis of Federal Preemption (Doc. 329), filed on July 31, 2007, to which Plaintiffs responded (Doc. 365) on August 10, 2007. Oral argument was held on the motion on September 27, 2007, and supplemental briefs were submitted by both parties thereafter. Upon careful consideration of the arguments presented by the parties, the Court determines that AstraZeneca's motion is due to be **DENIED** at this time.

In July, 2006, the Judicial Panel on Multidistrict Litigation transferred ninety-two actions involving alleged injuries resulting from the use of Seroquel, an atypical antipsychotic drug manufactured by AstraZeneca Pharmaceuticals and AstraZeneca LP, to this Court for consolidated and coordinated pretrial proceedings. *See In re Seroquel Prods. Liab. Litig.*, 447 F. Supp. 2d 1376 (J.P.M.L. 2006). Since that time, this consolidated action has grown to include the personal injury claims of close to 6,300 people from across the nation. The plaintiffs primarily allege that they contracted diabetes, and other related hyperglycemic conditions, as a result of their use of Seroquel. The legal claims set forth by the plaintiffs in this regard encompass strict liability design defect and failure to warn claims, negligence, misrepresentation, breach of express and implied warranty, and, in some cases, consumer fraud, deceptive trade practices and civil conspiracy. The instant motion seeks to dismiss the "failure to warn" claims

asserted by eleven plaintiffs because they seek to enforce state duties that are preempted by the U.S. Food and Drug Administration's drug labeling regulations.

II. LEGAL STANDARD

Pursuant to Fed. R. Civ. P. 12 (c), "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." Judgment on the pleadings is proper where there are no material facts in dispute, and the moving party is entitled to judgment as a matter of law. *Cannon v. City of W. Palm Beach*, 250 F.3d 1299, 1301 (11th Cir. 2001). Therefore, a court must accept the facts alleged in the complaint as true and must view those facts in the light most favorable to the non-moving party. *Hawthorne v. Mac Adjustment, Inc.*, 140 F.3d 1367, 1370 (11th Cir. 1998).

The Eleventh Circuit routinely considers the standard for reviewing a Rule 12 (c) motion akin to the standard for reviewing a motion to dismiss under Fed. R. Civ. P. 12 (b)(6). *See Id.*; *Slagle v. ITT Hartford*, 102 F.3d 494, 497 (11th Cir. 1996); *Horsley v. Rivera*, 292 F.3d 695, 700 (11th Cir. 2002). The long-accepted standard for dismissal of a complaint, derived from *Conley v. Gibson*, 355 U.S. 41, 47 (1957), instructs that, "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Recently, the Supreme Court discarded this oft-quoted language, labeling it "an incomplete, negative gloss on an accepted pleading standard" that "has been questioned, criticized, and explained away long enough." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1969 (2007). In its stead, the Supreme Court articulated a somewhat heightened standard, which requires a plaintiff to supply more than just any conceivable set of facts tending to support a claim, but "enough facts to state a claim to relief that

is plausible on its face." *Id*. at 1974. In other words, a plaintiff must "nudge [a] claim[] across the line from conceivable to plausible" in order to survive a motion to dismiss. *Id*.

III. ANALYSIS

In this instance, AstraZeneca seeks partial judgment on the pleadings with respect to Plaintiffs' claim that AstraZeneca failed to warn consumers and the medical community of the risks associated with the use of Seroquel. The failure to warn claim is set forth in the Amended Complaint[1] as follows:

> **B. Inadequate and Improper Warnings.**
>
> 124. AstraZeneca was the manufacturer, developer and/or supplier of SEROQUEL®. SEROQUEL®, as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper warnings regarding the serious risks of ingesting the drug. Further, AstraZeneca failed to warn of these serious risks after it had knowledge of same. The information provided to consumers failed to reflect AstraZeneca's knowledge that SEROQUEL® was not safe and effective as indicated in its aggressive marketing campaign. Nor were consumers made aware that ingesting the drug could result in serious injury, pain, discomfort and/or death. Full and proper warnings that accurately and fully reflected the risks of serious injury and/or death due to the ingestion of SEROQUEL® should have been disclosed with respect [to] this drug.

Terry Barnes v. AstraZeneca Pharms. LP and AstraZeneca LP, Case No. 6:07-cv-16752-ACC-DAB, Doc. 2 at 19-20.

[1] All plaintiffs to which this motion applies were once parties to a single action, *Jackson et al. v. AstraZeneca Pharms. LP, et al.*, Case No. 6:07-cv-522-ACC-DAB. Shortly after transfer to this Court, all plaintiffs in the action were severed and given individual case numbers. As such, all plaintiffs to which this motion applies are deemed to have filed identical complaints, i.e., the Amended Complaint originally filed in Case No. 6:07-cv-522-ACC-DAB.

As asserted by defense counsel at oral argument,[2] AstraZeneca interprets Plaintiffs' failure to warn claim to relate only to allegations that Seroquel's labeling was deficient. Plaintiffs have argued, both in their response to the motion[3] and at oral argument,[4] however, that the failure to warn claim is not so limited. The Court agrees. The plain language of the complaint does not limit Plaintiffs' claim to AstraZeneca's failure to include appropriate warnings in the drug labeling. Instead, Plaintiffs allege a more general failure to communicate the risks of using Seroquel that also encompasses promotional materials used by AstraZeneca's sales representatives during meetings with members of the medical community, as well as "Dear Doctor" letters disseminated by the company. In this regard, the Court is aware of a November 2006 letter sent to AstraZeneca by the FDA, in which the FDA declared that certain promotional

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[2] In response to Plaintiffs' contention that a November 2006 letter from the FDA regarding the misbranding of certain promotional materials was pertinent to the instant motion, counsel for AstraZeneca stated, "[t]hose are really apples and oranges, given the way this motion is presented to this Court … Now, if plaintiffs have separate claims that they think they can make about promotional activity that's inconsistent with that, we will deal with those types of claims at another day on another record." Mot. Hr'g Tr. 13-14, Sept. 27, 2007.

[3] In a footnote, Plaintiffs maintain that "[AstraZeneca] ignores the subsequent reprimand it received in November 2006 for undermining the same label warnings and misinforming prescribers regarding Seroquel's safety … not to mention representations made by [AstraZeneca's] salespeople regarding the drug's purported safety, all of which should be considered in determining the adequacy of warnings regarding Seroquel's side effects." Doc. 365 at 3 n.4.

[4] At oral argument, counsel for Plaintiffs asserted:

> …but there are other ways that he can warn patients. The defendant can warn patients by having its sales reps advise doctors of new information that comes to light. It can warn patients by sending dear doctor letters. There are - - the warning is far more dynamic than the labeling is and includes far more than the labeling.

Mot. Hr'g Tr. 26, Sept. 27, 2007.

materials distributed by company sales representatives were misleading and omitted material facts with respect to the risks associated with Seroquel. *See* Doc. 329, Ex. 8; Doc. 365, Ex. B.

In light of this evidence, and given the fact that AstraZeneca has not addressed the failure to warn claim with respect to the promotional activities of company sales representatives, it appears that even if the Court were to grant AstraZeneca's motion as currently framed, a substantial portion of Plaintiffs' failure to warn claim is likely to survive. The Court is hesitant to expend valuable judicial resources on breaking the already lengthy complaints into pieces smaller than the individual claims they present. Still, the Court recognizes the important issues presented by the instant motion, and therefore grants AstraZeneca an opportunity to reassert the motion at a later stage in this litigation, after the parties have conducted further relevant discovery.

IV. CONCLUSION

Based on the foregoing, it is **ORDERED** that AstraZeneca's Motion For Partial Judgment on the Pleadings on the Basis of Federal Preemption (Doc. 329) is **DENIED** without prejudice to AstraZeneca's refiling the motion at the summary judgment stage of this proceeding, should AstraZeneca deem such a motion appropriate at that time.

DONE and **ORDERED** in Chambers, in Orlando, Florida on November 6, 2007.

Copies furnished to:

Counsel of Record

ANNE C. CONWAY
United States District Judge