UNITED STATES DISTRICT COURT
THE SOUTHERN DISTRICT OF FLORIDA
CASE NO. 2:17-CV-14302-ROSENBERG/MAYNARD

DENNIS MCWILLIAMS,
LORI MCWILLIAMS,

Plaintiffs,

v.

NOVARTIS AG, *a global healthcare company*,
NOVARTIS PHARMACEUTICALS CORPORATION,
a Delaware corporation,

Defendants.
_____/

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION FOR PARTIAL RECONSIDERATION OF THE COURT'S ORDER ON SUMMARY JUDGMENT

This Cause is before the Court on Plaintiffs' Motion for Partial Reconsideration of the Court's Order on Summary Judgment. DE 100. Defendant Novartis Pharmaceuticals Corporation responded, DE 105, and Plaintiffs replied, DE 107. The Court has considered all of the filings. For the reasons set forth below, the Motion is granted in part and denied in part. It is granted in that the Court considers Plaintiffs' argument that the New Jersey exception on the prohibition of punitive damages is applicable in this case, an argument the Court did not consider in its Order granting in part and denying in part Defendant's Motion for Summary Judgment, DE 92. But it is denied in that the Court concludes that the New Jersey exception is preempted. Accordingly, Plaintiffs cannot seek punitive damages.

I. LEGAL STANDARD

"[R]econsideration of a previous order is an extraordinary remedy to be employed sparingly." *Burger King Corp. v. Ashland Equities, Inc.*, 181 F. Supp. 2d 1366, 1370 (S.D. Fla.

2002) (citing *Mannings v. Sch. Bd. of Hillsborough Cnty.*, 149 F.R.D. 235, 235 (M.D. Fla. 1993)). "The 'purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence.'" *Id.* at 1369 (quoting *Z.K. Marine Inc. v. M/V Archigetis*, 808 F. Supp. 1561, 1563 (S.D. Fla. 1992)). Only three major grounds generally justify reconsideration: "(1) an intervening change in the controlling law; (2) the availability of new evidence; and (3) the need to correct clear error or prevent manifest injustice." *Id*. (citing *Offices Togolais Des Phosphates v. Mulberry Phosphates, Inc.*, 62 F. Supp. 2d 1316, 1331 (M.D. Fla. 1999)). On the other hand, "[a] 'motion for reconsideration should not be used as a vehicle to . . . reiterate arguments previously made.'" *Id.* (citing *Z.K. Marine Inc.*, 808 F. Supp. at 1563).

II. BACKGROUND

This case arises from a stroke that Plaintiff Denis McWilliams suffered while he was taking Defendant's drug, Tasigna, for his chronic myeloid leukemia. Mr. McWilliams alleges that his stroke was caused by Defendant's drug and that Defendant did not properly warn about the risks associated with its drug. Mr. McWilliams and his wife, Plaintiff Lori McWilliams, brought a three-count Amended Complaint alleging: (1) strict product liability under a failure to warn theory; (2) negligence under a failure to warn theory; and (3) loss of consortium for Mrs. McWilliams. DE 19. Defendant filed a Motion for Summary Judgment, DE 61, which the Court granted in part and denied in part, DE 92.

At issue in the instant Motion for Reconsideration is part of the Court's ruling on summary judgment with respect to punitive damages. In its Order on Defendant's Motion for Summary Judgment, the Court concluded that New Jersey, not Florida, law applied to the issue of whether Plaintiffs are entitled to punitive damages. DE 92 at 15–18. The Court noted that generally New Jersey law "prohibits an award of punitive damages in products liability actions

where the drug that caused the harm was subject to preapproval by the FDA." *Id.* at 15. The Court stated that "[t]here is one statutory exception to this prohibition on punitive damages 'where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question.' N.J. Stat. Ann. § 2A:58C-5. Courts, however, have found this exception to be preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001). *See McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 276 (N.J. Super. Ct. App. Div. 2008). Plaintiffs do not argue that this exception applies. Thus, the Court does not need to analyze whether the exception is preempted under *Buckman*." *Id.* at n.3.

In their Motion for Reconsideration, Plaintiffs state that they "*did* argue that the exception to New Jersey's prohibition on punitive damages applies and that such damages are not preempted." DE 100 at 1 (emphasis in original). Plaintiffs point to a footnote in their opposition to Novartis's Motion for Summary Judgment in which they state:

> For reasons already briefed (Doc. No. 28), even if New Jersey law applies, Plaintiffs have still created a triable issue of fact on punitive damages. Under New Jersey law, punitive damages are available "where the product manufacturer knowingly withheld or misrepresented [material and relevant] information required to be submitted under the agency's regulation." N.J.S.A. § 2A:58C-5c. Here, Plaintiffs have shown that Novartis both withheld material information related to atherosclerosis-related conditions associated with Tasigna, and further made material misrepresentations to the FDA about such information, intentionally misrepresenting to the FDA, among other things, the state of the medical literature on the association and Novartis's own internal analyses regarding the association. This is sufficient to create a triable issue of fact. Further, punitive damages under New Jersey law are not preempted. *Forman v. Novartis Pharms. Corp.*, 793 F. Supp. 2d 598, 607 (E.D.N.Y. 2011); *Chiles v. Novartis Pharms. Corp.*, No. 3:06-cv-96-J-25 JBT (M.D. Fla. Feb. 25, 2013) (Order, Doc. No. 214).

The Court recognizes that it did not consider Plaintiff's argument that the exception to New Jersey's prohibition on punitive damages applies and is not preempted. Accordingly, it grants

Plaintiff's motion for partial reconsideration in that it will consider now whether the exception applies.

III. ANALYSIS

N.J. Stat. Ann. § 2A:58C-5c prohibits an award of punitive damages in products liability actions where the drug that caused the harm was subject to preapproval by the FDA except "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question." There is a split of authority about whether the exception to the prohibition on punitive damages is preempted by the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Plaintiffs argue that the exception is not preempted under *Buckman* and that there is a triable issue of fact as to whether Defendant knowingly withheld or misrepresented material information required to be submitted to the FDA. Defendant argues that the exception is preempted under *Buckman*.

In *Buckman*, the plaintiffs brought claims against the manufacturer of orthopedic bone screws alleging that the manufacturer had "made fraudulent representations to the [FDA] in the course of obtaining approval to market the screws." 531 U.S. at 344. Plaintiffs claimed that these misrepresentations were the "but for" cause of their injuries. *Id.* The Supreme Court found that plaintiffs' "fraud-on-the-FDA" claims were impliedly preempted by the federal Food, Drug, and Cosmetic Act. *Id.* In reaching this conclusion, the Court found that "in contrast to situations implicating federalism concerns and the historic primacy of state regulation of matters of health and safety, [] no presumption against pre-emption obtains" in fraud-on-the-FDA claims. *Id.* at 348 (citations omitted). The Court noted the inherently federal nature between a federal agency and the entity it regulates and "that the federal statutory scheme amply empowers the FDA to

punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* The Court further explained that:

> State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA and the MDA.

Id. at 350.

A few courts to have considered the issue have found that the exception is not preempted. *See* Order, *Chiles v. Novartis Pharm. Corp.*, No. 3:06-cv-00096-HLA-JBT, (M.D. Fla. Feb. 25, 2013), ECF No. 214; *Forman v. Novartis Pharm. Corp.*, 793 F. Supp. 2d 598 (E.D.N.Y. 2011). For example, in *Forman*, the Court, relying on the binding Second Circuit precedent of *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2008) found that the New Jersey exception was not preempted. In *Desiano*, the Second Circuit interpreted a Michigan statute under *Buckman*. The statute immunized manufacturers of drugs that were approved by the FDA from all products liability actions unless the manufacturer withheld from or misrepresented material information from the FDA. *Id.* at 87–88. The Court held that *Buckman* did not preempt the statute stating that:

> Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. *Buckman* underscored this fact, finding implied preemption of a newly-fashioned state cause of action only where (1) no presumption against federal preemption obtained, and (2) the cause of action, by assigning liability *solely* on the basis of fraud against the FDA, imposed significant and distinctive burdens on the FDA and the entities it regulates.

Id. at 98 (emphasis in original). *Desiano* was summarily affirmed by an equally divided Supreme Court. *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008). Relying on *Desiano*, the *Forman*

Court found that the New Jersey exception was not preempted because "(1) it is properly classified under *Desiano* as a permitted state common-law tort claim premised on the obligations between a manufacturer and a consumer that require a prerequisite showing of fraud-on-the-FDA and (2) the presumption against preemption is equally applicable to claims for compensatory damages and punitive damages claims premised on state common-law torts." 793 F. Supp. 2d at 606. The Court noted that "to the extent the Plaintiff is seeking punitive damages based solely on NPC's alleged misrepresentations to the FDA, this is not permissible. However, the Plaintiff in the instant case is also seeking punitive damages that stem from NPC's misrepresentations to decedent Napolitano and the medical community." *Id.*

On the other hand, the majority of courts to have considered the issue have found that *Buckman* preempts the exception found in N.J. Stat. Ann. § 2A:58C-5c. *See, e.g., Guenther v. Novartis Pharm. Corp.*, 8:06-cv-1787-24-TBM, 2014 WL 2722483, at *3–4 (M.D. Fla. June 16, 2014); *Dopson-Troutt v. Novartis Pharm. Corp.*, No. 8:06-cv-1708-T-24-EAJ, 2013 WL 3808205, at *4–5 (M.D. Fla. July 22, 2013).; *Zimmerman v. Novartis Pharm. Corp.*, 889 F. Supp. 2d 757 (D. Md. 2012); *McDarby v. Merck & Co., Inc.*, 949 A.2d 223 (N.J. Super. App. Div. 2008). In *Zimmerman*, for example, the District Court found that the New Jersey exception was preempted because the "FDCA empowers the federal government, through the FDA, to regulate the safety and efficacy of pharmaceutical drugs via an extensive drug approval process" and that the New Jersey exception did "not enjoy a presumption of validity" "[b]ecause New Jersey's statutory immunity provision attempts to legislate in an area of significant federal concern." *Zimmerman*, 889 F. Supp. 2d at 768–71. The *Zimmerman* Court also noted that "[a]lthough the form of Plaintiff's claims differs from that of her counterparts in *Buckman*, both claims are identical in substance because they present the same conflict with the FDCA

regulatory scheme and the FDA's enforcement prerogatives." *Id.* at 773–77. Accordingly, the *Zimmerman* Court found the New Jersey exception to be preempted.

The Court agrees with these cases that have held that the New Jersey exception is preempted by *Buckman*. The Court in *Zimmerman* put it succinctly:

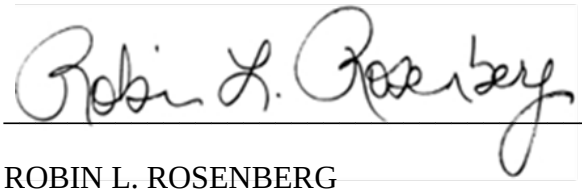
> Plaintiff's claim for punitive damages requires a state fact finder to determine what was required to be submitted to the FDA, whether it was submitted to the FDA and, whether the FDA would have made a different approval decision had it been provided with the correct or missing information. Plaintiff's claim thus requires a fact finder to make these types of determinations as a matter of state law even though federal law makes such determinations the exclusive province of the FDA. Accordingly, Plaintiff's claim for punitive damages poses an obstacle to the objectives and purpose of the FDCA, and is therefore preempted by the FDCA.

889 F. Supp. 2d at 776. Like the Court in *Zimmerman*, this Court finds the claims at issue here and those at issue in *Buckman* to be substantively the same. *See id.* Accordingly, the New Jersey exception is preempted under *Buckman* and Plaintiffs cannot seek punitive damages.

IV. CONCLUSION

For the foregoing reasons, it is hereby **ORDERED AND ADJUDGED** that that Plaintiffs' Motion for Partial Reconsideration of the Court's Order on Summary Judgment [DE 100] is **GRANTED IN PART AND DENIED IN PART**. Plaintiffs' cannot seek punitive damages.

DONE AND ORDERED in Chambers in West Palm Beach, Florida this 31st day of July, 2018.



ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE