IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

STACY ZIMMERMAN, ***personal representative of Phyllis Newman***	*	
Plaintiff	*	
v.	*	Case No.: RWT 08cv2089
NOVARTIS PHARMACEUTICALS CORPORATION	*	
Defendant.	*	

MEMORANDUM OPINION

This pharmaceutical products liability lawsuit involves the drugs Aredia and Zometa, both of which were approved by the United States Food and Drug Administration ("FDA") and are sold by defendant Novartis Pharmaceuticals Corporation. This matter is before the Court on Defendant's Motion to Preclude Punitive Damages. As explained below the Defendant's motion will be granted.

BACKGROUND

On December 5, 2007, Plaintiff, Stacy Zimmerman, as personal representative of the estate of her deceased mother Phyllis Newman, filed a products liability suit against Defendant, Novartis Pharmaceutical Corporation, in the United States District Court for the Middle District of Tennessee. Novartis is a Delaware corporation with its principal place of business in New Jersey. Ms. Newman was a resident of Maryland, as is her personal representative.

In the amended complaint, Plaintiff asserted strict liability and negligence claims against Novartis in connection with the manufacturing, distribution, promotion, testing, labeling and

selling of Aredia and Zometa, two FDA approved bisphosphonate drugs which were approved for the treatment of patients with hypercalcemia of malignancy (a potentially fatal elevation of calcium in the blood), multiple myeloma, and breast cancer that has metastasized to bone. Ms. Newman, who was diagnosed with metastatic breast cancer to bone, was prescribed and received Aredia and Zometa in Maryland. As a result of her use of these drugs, she allegedly developed a jaw condition known as osteonecrosis of the jaw.

On August 14, 2008, the United States District Court for the Middle District of Tennessee transferred the case under 28 U.S.C. § 1404 to this Court. On September 22, 2008, the Judicial Panel on Multidistrict Litigation issued a conditional transfer order transferring the case from this Court back to the Middle District of Tennessee for coordinated pretrial proceedings. On July 27, 2011, the Middle District of Tennessee advised the panel that coordinated pretrial proceedings have been completed and that the case should be remanded back to this Court.

Defendant filed a Motion to Preclude Punitive Damages on December 9, 2011. On December 20, 2011, Plaintiff filed her Response and on January 3, 2012, Defendant filed its Reply. On May 30, 2012, this Court heard arguments on this motion.

DISCUSSION

I. CHOICE OF LAW

New Jersey and Maryland laws differ with respect to punitive damages. Because this case was filed in Tennessee, the choice of law rules of that state apply. In determining the substantive law to apply in tort cases, Tennessee applies the Restatement (Second) of Conflict of Laws "significant relationship" approach. Under the "significant relationship" approach, this Court can theoretically apply Maryland law to the issues of liability and compensatory damages

and New Jersey law to the issue of punitive damages. In the present case, the threshold issue is whether New Jersey has a more significant relationship to Plaintiff's punitive damages claim than Maryland. Here, the Court finds that New Jersey has a more significant relationship to the issue of punitive damages than Maryland in light of Novartis' contacts with New Jersey and the Restatement's § 6 principles.

A. New Jersey and Maryland laws differ with respect to punitive damages.

The issue before the court is whether New Jersey or Maryland law governs the issue of punitive damages. But before embarking on a choice of law analysis, courts generally analyze whether there is in fact a difference.

Under Maryland law, a plaintiff must show more than mere negligence to recover punitive damages in connection with a products liability action. *See ACandS, Inc. v. Godwin*, 340 Md. 334, 360, 667 A.2d 116, 128 (1995). More specifically, to recover punitive damages a plaintiff must establish "actual malice" through clear and convincing evidence. *See Owens–Illinois, Inc. v. Zenobia*, 325 Md. 420, 601 A.2d 633, 653 (1992).[1] In contrast to Maryland law, New Jersey law, has enacted legislation that immunizes drug and device manufacturers like Novartis from punitive damages if the drug at issue was approved by the FDA, "or is generally recognized as safe and effective pursuant to conditions established by the [FDA] and applicable regulations, including packaging and labeling regulations." *See* N.J.S.A. § 2A:58C–5(c). The only way for a plaintiff to circumvent New Jersey's statutory restrictions on punitive damages awards against drug manufacturers is by a particularized showing that "the manufacturer

[1] In a products liability case, actual malice requires proof of "(1) actual knowledge of the defect on the part of the defendant, and (2) the defendant's conscious or deliberate disregard of the foreseeable harm resulting from the defect." *Owens–Illinois*, 325 Md. at 462. 601 A.2d at 653 (1992).

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." *Id.* Even if a plaintiff could make such a showing under New Jersey law, any award would be capped at $350,000 or five times the compensatory damages award, whichever is greater. *Id*. § 2A:15-5.14b.[2]

Because Maryland allows for the recovery of non-capped punitive damages upon clear and convincing evidence of actual malice, and New Jersey generally immunizes drug and device manufacturers from punitive damages and limits recovery to $350,000 or five times the compensatory damages award, the laws of New Jersey and Maryland are different, thus necessitating a decision on which law is to be applied.

B. Because this case was filed in Tennessee, the choice of law rules of that state apply.

A federal district court sitting in diversity applies the substantive law of the state in which it sits. *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78–79 (1938). As part of that principle, the federal court must also apply that state's choice of law principles. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941). However, when cases are transferred from another district, the transferee court applies the law of the state in which the transferor court is located. *See Van Dusen v. Barrack*, 376 U.S. 612, 639 (1964) ("[W]here the defendants seek transfer, the transferee district court must be obligated to apply the state law that would have applied if there had been no change of venue. A change of venue under § 1404(a) generally should be, with respect to state law, but a change of courtrooms."). The present case was filed in a Federal District Court in Tennessee and transferred here twice; thus, as the transferee court, this Court must apply Tennessee's choice of law principles.

[2] There is no such cap on punitive damages under Maryland law.

C. Under Tennessee's "significant relationship" choice of law rule, New Jersey law governs the issue of punitive damages.

In determining which state's substantive law to apply in a tort case, Tennessee's choice of law rules adopt the "significant relationship" approach contained in the Restatement (Second) of Conflict of Laws. *See Hataway v. McKinley*, 830 S.W.2d 53, 59 (Tenn. 1992) (holding that the "most significant relationship" approach of Restatement (Second) of Conflict of Laws is the best-reasoned rule for resolving conflicts questions in tort cases and will be adopted and applied to all cases applying Tennessee choice of law principles).

1. Under the "significant relationship" approach, this Court can theoretically apply Maryland law to the issues of liability and compensatory damages and New Jersey law to the issue of punitive damages.

The parties agree that under the Restatement (Second) of Conflict of Laws "significant relationship" approach, Maryland law governs the issues of liability and compensatory damages. Yet Plaintiff asserts that under the "significant relationship" approach, once this Court finds Maryland law governs compensatory damages and liability, this Court must also find that Maryland law governs punitive damages. This Court disagrees.

The "significant relationship" approach allows for "depecage," such that a court can apply different state laws to different issues in a single case— *i.e.* liability, compensatory damages, and punitive damages. *See* Restatement (Second) of Conflicts of Law § 146 (1971) ("the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, *with respect to the particular issue*, some other state has a more significant relationship") (emphasis added); *id.* § 145 cmt. d ("courts have long recognized that they are not bound to decide all issues under the local law of a single state."); *Brown v. Novartis*

Pharmaceuticals Corp., No. 08-cv-00130-FL, 2011 WL 6318987 at * 2 (E.D.N.C. Dec. 16, 2011) ("The Restatement and Tennessee choice of law jurisprudence allow for depecage, the application of different state's laws to different issues in a case"); *see also Aguirre Cruz v. Ford Motor Co.*, 435 F. Supp.2d 701, 706 (W.D. Tenn. 2006) (applying Tennessee choice of law principles to hold that although Tennessee residents purchased the vehicle in Tennessee and the crash occurred in Mexico, Michigan law on punitive damages applies because "[d]efendants' principal place of business and the place where the alleged misconduct occurred has the most significant relationship to the issue of punitive damages"); *Talley v. Novartis Pharmaceuticals Corp*., No. 08-cv-361-GCM, 2011 WL 2559974 (W.D.N.C. June 28, 2011) (holding that under Tennessee choice of law principles North Carolina law applied to the case generally, but New Jersey punitive damages law applied because "the corporate decisions at issue regarding labeling and packaging occurred in New Jersey"); *Meng v. Novartis Pharmaceuticals Corp*., Nos. L-7670-07MT, L-6072-08MT, 2009 WL 4623715 (N.J. Super. Law Div. November 23, 2009) (noting that under the most significant relationship test, the law governing the right to punitive damages need not necessarily be the same as the law governing the measure of compensatory damages) (alteration and quotations omitted)

2. New Jersey has a more significant relationship to the issue of punitive damages than Maryland in light of Novartis' contacts with New Jersey and the Restatement's § 6 principles.

Under the Restatement (Second) of Conflict of Laws "significant relationship" approach, Tennessee courts will apply "the law of the state where the injury occurred, … unless some other state has a more significant relationship to the litigation." *Id*.; *see also MacDonald v. General Motors Corp*., 110 F.3d 337, 342 (6th Cir. 1997). To clarify, although the law of the place where the injury occurred provides the default rule, "the Restatement approach allows a court to apply

the law of a state that legitimately has a stronger interest in the controversy. . . .” *Hataway*, 830 S.W.2d at 59; *Aguirre Cruz*, 435 F. Supp.2d at 704.

In this case, there is no dispute that the harm to Ms. Newman occurred in Maryland and that under Tennessee choice of law principles, Maryland law, as the law of the place of injury, governs liability and compensatory damages. Thus, having determined that New Jersey and Maryland laws on punitive damages differ, the issue before this Court is whether Defendant Novartis can overcome the “default” rule and show that New Jersey has a more significant relationship to the issue of punitive damages than Maryland. *Hataway*, 830 S.W.2d at 59.

a. Contacts

In determining whether a particular jurisdiction—i.e. New Jersey—has a more significant relationship or stronger interest in the controversy than this state—Maryland— courts generally consider the following contacts: (1) the place where the injury occurred; (2) the place where the conduct causing the injury occurred; (3) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (4) the place where the relationship, if any, between the parties is centered. *Hataway*, 830 S.W.2d at 59; Restatement (Second) of Conflicts of Law § 145(2)(a)-2(d) (1971).

Novartis’ contacts weigh in favor of applying New Jersey law. The place where the injury occurred, Maryland, is “simply fortuitous” with respect to punitive damages as “it bears little relation to the occurrence and the parties with respect to the particular issue.” Restatement (Second) of Conflicts of Law § 145 cmt. e (1971); *Meng*, 2009 WL 4623715, at *2 (finding in an Aredia and Zometa products liability litigation that the place where the injury occurred is “simply fortuitous” with respect to the punitive damages issue); *Talley*, 2011 WL 2559974, at *3 (same).

The next two factors—i.e. the place where the conduct causing injury occurred and the place of business/incorporation—also weigh in favor of applying New Jersey law. Novartis' primary place of business is in New Jersey and the corporate decisions with respect to labeling and packaging of Aredia and Zometa took place in New Jersey. To the extent that Plaintiff contends New Jersey law should not apply because these decisions occurred in Switzerland, such an argument is unavailing since Plaintiff does not ask this court to apply Swiss law. *See Talley*, 2011 WL 2559974, at *4 (holding in a similar Aredia and Zometa litigation that "Plaintiff's contention that the relevant decisions were made in Switzerland is unpersuasive based on the record; additionally, Plaintiff does not request that Swiss law be applied"); *Deutsch v. Novartis Pharmaceuticals Corp.*, 723 F. Supp. 2d 521, 525 (E.D.N.Y. 2010) (holding in a similar Aredia and Zometa litigation that the "testimony does not establish the broad proposition that all corporate decisions are made in Basel [Switzerland] [and] [e]ven if it did, under the proper choice of law analysis, this would simply mean that Swiss law governing punitive damages would apply in this case … [and] punitive damages are not permitted under Swiss law").

The final factor— the place where the relationship, if any, between the parties is centered—also supports application of New Jersey law because Novartis' New Jersey business activities, including its interactions with the FDA, form the foundation of Plaintiff's claim for any punitive damage award. *See Meng*, 2009 WL 4623715, at *4 (holding that the relationship between Novartis and the Aredia and Zometa plaintiffs was centered in New Jersey with respect to any claims for punitive damages); *Talley*, 2011 WL 2559974, at *4 (finding that the relationship between the Novartis and the Aredia and Zometa plaintiffs was centered in New Jersey with respect to punitive damages because "the relevant contacts are those that relate to the alleged conduct giving rise to their claims for punitive damages" and the corporate decisions at

issue regarding labeling and packaging, occurred in New Jersey); *Brown*, 2011 WL 6318987, at *3 (same).

b. Restatement § 6 Principles

The "significant relationship" test does not merely focus on the number of contacts with a particular state, but also the nature of those contacts in light of the Restatement's § 6 principles: (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied. *See* Restatement (Second) of Conflicts of Law § 6 (1971).

These principles fully support the application of New Jersey law to the issue of punitive damages. At their core, the § 6 principles ask courts to consider the policy reasons for applying the law of a particular state. In this regard, the reasoning in *Talley* is particularly instructive for three reasons. First, in *Talley*, as in the instant case, the plaintiff filed an Aredia and Zometa products liability suit against Novartis in Tennessee and the case was transferred to North Carolina. Thus, as in the present case, the *Talley* court sitting in diversity applied Tennessee choice of law principles. Second, as here, both parties agreed that under Tennessee choice of law principles the law of the transferee court—North Carolina—governed compensatory damages and liability, but disagreed as to what law governed punitive damages. The *Talley* plaintiff asserted that North Carolina law governs punitive damages while Novartis asserted that New Jersey law governs punitive damages. Third, in considering the Restatement § 6 principles, the *Talley* court, just like this Court, confronted competing policy concerns such as the purpose of

punitive damages generally, the policy underlying New Jersey punitive damages provisions, Tennessee's interests as the original forum state, Novartis' expectations as to what law would govern punitive damages, plaintiff's expectations as to what law would govern punitive damages, the reasonableness of both parties' expectations, and the need for predictability and uniformity across jurisdictions. In analyzing the Restatement § 6 principles, the *Talley* court reasoned:

> The additional factors listed in the Restatement § 6 also support application of New Jersey law. New Jersey has made a policy decision on how to impose punitive damages, and has an interest in its citizens being governed by those provisions. Tennessee, as the original forum state, has an interest in having its choice of law analysis applied here. The Defendant, having its principal place of business in New Jersey, has a justified expectation of being subject to New Jersey law for punitive damages. The justified expectations of the Plaintiff are met as she will be compensated under North Carolina law. The basic policy underlying punitive damages is to punish and deter the Defendant, whose conduct occurred in New Jersey, thus the interests of the tort field are enhanced through consistent application of New Jersey law. Certainty, predictability and uniformity of result are furthered because this Court has followed the analysis of the *Deutsch* and *Meng* courts, which considered an almost identical issue and reached the same conclusion.

Talley, 2011 WL 2559974, at *4. Here, the Court agrees with the reasoning in *Talley* and finds that the Restatement § 6 principles weigh in favor of applying New Jersey law to the issue of punitive damages.

II. PREEMPTION

The Supremacy Clause, Article VI, Clause 2 of the United States Constitution states: "This Constitution, and the Laws of the United States shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any

State to the Contrary notwithstanding." The Supremacy Clause "invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough County v. Automated Med. Labs., Inc*., 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824)). State laws can be preempted by federal regulations as well as by federal statutes. *See City of Charleston v. A Fisherman's Best, Inc.*, 310 F.3d 155, 169 (4th Cir. 2002), *cert. denied*, 539 U.S. 926 (2003) ("Regulations duly promulgated by a federal agency pursuant to a Congressional delegation have the same preemptive effect as a legislative enactment"). The imposition of damages is a form of state law that may be subject to preemption. *See Geier v. Am. Honda Motor Co*., 529 U.S. 861, 881 (2000).

Over a century ago, Congress passed the precursor to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, which empowers the federal government, through the Food and Drug Administration (FDA), to regulate the safety and efficacy of pharmaceutical drugs through an extensive new drug approval process. *See infra* Part.II.A. Before the FDA will approve a new drug, drug companies must make extensive disclosures to the FDA in accordance with the agency's regulations. *Id.* The FDA has the exclusive authority to initiate enforcement proceedings against those drug companies that fail to comply with the FDCA and applicable regulations. *See* 21 U.S.C. § 337(a).

The present case implicates a type of implied conflict preemption known as obstacle preemption.[3] New Jersey, like many states engaging in tort reform, recently enacted a statutory

[3] There are three ways a federal law can preempt a state law: express preemption, field preemption, and implied preemption. *See Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373–374 (2000).

Express preemption arises when Congress includes explicit language displacing or nullifying state law in certain circumstances. *See, e.g., Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008) (holding that the express preemption provision of the Medical Device Amendments (MDA) to

immunity provision that generally prevents a plaintiff from recovering punitive damages in a pharmaceutical products liability case if that drug manufacturer complied with FDA regulations. *See* N.J. Stat. Ann. § 2A:58C–5(c) (West 2012). A plaintiff can recover punitive damages at common law only if a fact finder determines that the drug manufacturer defendant "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." *Id.* The relevant portion of the statute provides:

> (c) Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and

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the FDCA bars common-law state causes of action relating to a premarket approved device's safety or effectiveness because the statute states that "no state . . . may establish . . . with respect to any device . . . any requirement…which is different from, or in addition to . . . [the premarket approval process established for devices], and …which [is] related to the safety or effectiveness of the device.").

In a field preemption case, Congress preempts state law in a particular area because federal legislation can "occupy the field" by "regulating so pervasively that there is no room left for the states to supplement federal law." *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

Under the doctrine of implied preemption, Congress implicitly expresses its intent to supersede state law because the federal law or regulatory scheme conflicts with state law. Implied conflict preemption generally occurs in two situations. One such situation is when "compliance with both federal and state regulations is a physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963); *See, e.g.*, *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2577 -2578 (2011) (finding implied conflict preemption under the impossibility doctrine because "[s]tate tort law places a duty directly on all drug manufacturers to adequately and safely label their products" and "[f]ederal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels."). The other type of implied conflict preemption occurs where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This Court will explain the application of the obstacle preemption doctrine in Part II.C.

> effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, 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, punitive damages may be awarded. For purposes of this subsection, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

Id.

At issue is whether New Jersey's statutory immunity provision for punitive damages is preempted by federal law because it requires a jury to speculate as to whether Novartis misrepresented material information that was required to be submitted under the FDCA and applicable regulations. This speculation raises a preemption concern because the FDA is charged with determining whether a new drug is safe and effective enough to be sold in the United States, and with ensuring compliance with FDCA-mandated disclosure obligations in connection with new drugs. Here, the FDA approved Aredia and Zometa and has not made any finding that Novartis did not comply with its FDCA-mandated disclosure obligations. Thus, because the New Jersey statute predicates punitive damages on whether a jury finds Novartis violated the FDCA and applicable regulations, the New Jersey statute creates an obstacle to the FDA's ability to effectively police compliance.

The resolution of the preemption issue depends largely on how one interprets the Supreme Court's decision in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). There, the Supreme Court held that plaintiffs' state tort fraud on the FDA claim—i.e. a claim that the manufacturer of orthopedic bone screws made fraudulent representations to the FDA and but for these fraudulent representations the FDA would not have approved the bone screws that injured plaintiff—was preempted by the FDCA. In reaching this conclusion, the Court reasoned

that the plaintiffs' state tort fraud on the FDA claim enjoys no presumption of validity because "policing fraud against Federal agencies is hardly a field the states have traditionally occupied." *Id.* at 347. This is especially true because plaintiffs' fraud on the FDA claim exists "solely by virtue of the FDCA disclosure requirements" and the alleged failure of a manufacturer to comply with those requirements. *Id.* at 353. Consequently, a new tort remedy based entirely on the concept of fraud on the FDA would inevitably create an obstacle to the FDA's ability to effectively police fraud because it includes compliance or non-compliance with FDA regulations as a "critical element" of the claim and leaves open the possibility that the tort regimes of the 50 States could reach a different conclusion than the FDA with respect to this critical element. *Id.* at 351-53.

Lower courts analyzing New Jersey's immunity provision have reached opposite conclusions as to whether this immunity provision is preempted under *Buckman*. This is because, as one commentator has noted, "[w]hile there is near consensus on the view that *Buckman* forecloses a claim predicated solely upon the failure to disclose material information to the FDA in violation of FDCA regulations, the extent of its further reach is fraught with controversy." *See* Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841, 856 (2008). For example, in *Forman v. Novartis Pharmaceuticals Corporation*, a federal district court in a similar Aredia and Zometa case, interpreted *Buckman* narrowly. It held that the FDCA did not preempt New Jersey's punitive damages exception because the consumer's claim was not premised principally, let alone exclusively, on a drug manufacturer's failure to comply with federal disclosure requirement. 793 F.Supp.2d 598, 608 (E.D.N.Y. 2011). The *Forman* court viewed the exception as merely a prerequisite to the imposition of punitive damages at common law. *Id.* In *McDarby v. Merck & Co.*, a New Jersey intermediate appellate

court interpreted *Buckman* in a less restrictive manner. 949 A.2d 223, 275 (N.J. Super. Ct. App. Div. 2008), *appeal dismissed as improvidently granted*, 200 N.J. 267 (2009). There, the court found *Buckman* to be controlling and New Jersey's punitive damages provision to be preempted because the purpose of punitive damages is to deter a manufacturer's knowingly inadequate response to FDA informational requirements under *Buckman*. *Id*. The plaintiff's claim for punitive damages in the case before that court closely resembled the fraud on the FDA claim in *Buckman* because both claims require a showing that "the FDA would have responded differently to an application if the manufacturer had fully and accurately provided all the information that federal law required." *Id.* at 276.

The divide amongst courts analyzing New Jersey's statutory immunity provision is not surprising because federal courts of appeals considering this issue in the context of similar state statutory schemes[4] are also in disagreement. *See generally*, Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841 (2008). For example, the Sixth and Fifth circuits have held that the FDCA preempts the Michigan and Texas statutory immunity provisions for drug manufacturers. *See Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961, 966 (6th Cir.

[4] Arizona, Colorado, North Dakota, Ohio, Oregon, and Utah—like New Jersey—eliminate punitive damages against drug manufacturers who have complied with FDA guidelines. *See* Ariz. Rev. Stat. Ann. § 12-701(a)(1); Colo. Rev. Stat. § 13-64-302.5(5)(a); N.D. Cent. Code § 32-03.2-11(6); Ohio Rev. Code Ann. § 2307.80(c)(1); Or. Rev. Stat. § 30.927(1)(a) (2005); Utah Code Ann. § 78-18-2(1).

One state, Michigan, adopted a complete, blanket immunity based upon compliance with FDA regulations. *See* Mich. Comp. Laws Ann. § 600.2946(5).

Other states—Colorado, Indiana, Kansas, Kentucky, New Jersey, Tennessee, Texas, and Utah—establish a rebuttable presumption that FDA-approved warnings are adequate in the face of failure-to-warn claims. *See* Colo. Rev. Stat. § 13-21-403(1)(b); Ind. Code Ann. § 34-20-5-1(2); Kan. Stat. Ann. § 60-3304(a) (2005); Ky. Rev. Stat Ann. § 411.310(2); N.J. Stat. Ann. § 2A:58C-4; Tenn. Code Ann. § 29-28-104; Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a); Utah Code Ann. § 78-15-6(3).

2004) (holding that the FDCA impliedly preempts a Michigan statute which eliminated immunity for the manufacturer of a FDA approved drug if that manufacturer misrepresented or withheld material information that would have altered FDA's approval decision, because "*Buckman* prohibits a plaintiff from invoking that exception on basis of *state court* findings of fraud on the FDA"); *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012) (holding that the FDCA preempted a Texas statute requiring plaintiffs to assert, in failure to warn cases, that a drug manufacturer withheld or misrepresented material information to the FDA because under *Buckman*, "where the FDA has not found fraud, the threat of imposing state liability on [a] drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities"). On the other hand, the Second Circuit held that the FDCA does not preempt Michigan's statutory immunity provision. *See Desiano v. Warner-Lambert & Co*., 467 F.3d 85, 96 (2d Cir. 2006) (holding that the FDCA did not preempt a Michigan statute, which eliminated immunity for manufacturer of a FDA approved drug if that manufacturer misrepresented or withheld material information that would have altered FDA's approval decision, because such suits depended primarily on traditional and preexisting tort sources, not at all on a "fraud-on-the-FDA" cause of action created by state law, and forbidden under *Buckman*). The Supreme Court is also divided. When asked to address the issue of whether the FDCA preempted Michigan's immunity statute for drug manufacturers, the Court affirmed the Second Circuit's ruling in an equally divided (4-4) *per curiam* decision with no precedential value. *See Warner–Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008).

With this lack of consensus, the Court enters the debate reluctantly and only after confirming on the record that Plaintiff intends to seek punitive damages even if the Court decides

that New Jersey law applies. For the reasons that follow, the Court concludes that Plaintiff's claim for punitive damages is preempted.

A. The FDCA empowers the federal government, through the FDA, to regulate the safety and efficacy of pharmaceutical drugs via an extensive drug approval process

There are "two cornerstones of . . . preemption jurisprudence." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). The first and "ultimate touchstone of preemption analysis is the intent of Congress." *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Because preemption claims turn on Congress's intent, this Court will begin its analysis by examining the text and structure of the FDCA, as well as its legislative history and the accompanying regulations. *See Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 516 (1992) (conducting a similar analysis of the Federal Cigarette Labeling and Advertising Act in the preemption context).

Over a century ago, Congress passed the precursor statute to the FDCA.[5] The FDCA empowers the federal government, through the FDA, to regulate the safety and efficacy of pharmaceutical drugs via an extensive new drug approval process.[6] Before a drug can be put on

[5] In 1902, Congress passed the False Branding or Marking Act, which prohibited the marketing of "any dairy or food products which shall be falsely labeled or branded as to the State or Territory in which they are made, produced, or grown." *See* Act of July 1, 1902, 57 Pub. L. No. 223, ch. 1357 § 2, 32 Stat. 632; *see also In re Vioxx Products Liab. Litig*., 501 F. Supp.2d 776, 782 (E.D. La. 2007) (discussing FDA regulatory history). Congress broadened the authority of the FDA and its predecessor agencies when it passed the Pure Food and Drug Act of 1906, banning the manufacture and shipment of adulterated or misbranded food and drugs. *See* Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938). In 1938, Congress significantly augmented the authority of the FDA when it passed Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified and amended at 21 U.S.C. § 301, *et seq*.).

[6] Under the FDCA, "no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application [is] filed." *See* 52 Stat 1052. The 1962 Amendments to the FDCA also authorized the FDA to evaluate drugs not only for safety but for effectiveness as well. *See* Pub. L. No. 87-781, 76 Stat 780 (1962); *see also* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (stating that the FDA is responsible for reviewing and approving

the market, a manufacturer must first submit a "new drug application" ("NDA") for the FDA's review and approval. 21 U.S.C. § 355(a)-(b). A drug manufacturer's NDA application must include information about the clinical trials, which demonstrate the safety and effectiveness of the product, and a proposed drug label. 21 U.S.C. § 355(b),(d); 21 C.F.R. §314.50 (detailing the form and content of the NDA). The drug manufacturer's NDA must include submissions regarding the drug's components and composition, as well as the methods and controls used in manufacturing, processing, and packing the drug. 21 U.S.C. §355(b)(1)(A)-(F).

After reviewing the NDA and providing the drug manufacturer with notice and an opportunity to respond, the FDA may refuse to approve a drug if the FDA determines that the application itself does "not include adequate tests," testing reveals that the "drug is unsafe for use," there is a lack of substantial evidence that the "drug product will have the effect it purports," or the drug label "is false or misleading." *See* 21 C.F.R. § 314.125(b). The FDA may also deny approval if it determines that the NDA "contains an untrue statement of a material fact." *See id.* § 314.125(b)(7). The FDA will approve a new drug only after "it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." *Id.* § 314.105(c); *see id.* §§ 201.56(d), 201.57.

Even after approval, the FDA continues to monitor the safety of drugs. The drug manufacturer is required to maintain records on the drug after approval, report on any additional testing or clinical evidence as directed, and report on any significant adverse drug experiences. *See* 21 U.S.C. § 355(k)(1); 21 C.F.R. §§ 314.80 and 314.81. If scientific data indicates that the drug is not safe or if new information reveals that the labeling of the drug "is false or misleading in any particular," the FDA can withdraw approval of a drug. 21 U.S.C. § 355(e).

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all prescription drugs that are marketed in the United States to ensure "that drugs are safe and effective and that their labeling . . . is truthful and not misleading.").

The FDA enforces violations of the drug approval process, not private litigants. *Id*. § 337 ("all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). And, the FDA is specifically authorized to investigate suspected fraud or misrepresentations by the manufacturer. *Id*. § 372. Indeed, the FDCA provides the FDA with a number of enforcement options. These options include in rem forfeiture, injunction, and even criminal prosecutions. *See id*. § 332(a) (injunctions); *id*. § 333 (criminal penalties); *id*. § 334(a) (seizure); and *id*. § 337(a) (enforcement proceedings). In fact, the FDA is vested with considerable discretion in how it chooses to deploy these enforcement tools. The FDCA provides that "[n]othing in [FDCA] shall be construed as requiring [FDA] to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever [FDA] believes that the public interest will be adequately served by a suitable written notice or warning." *Id.* § 336. Finally, courts have found the FDA's decision not to undertake certain enforcement actions to be non-reviewable. *See Heckler v. Chaney*, 470 U.S. 821, 837-38 (1985).

B. Because New Jersey's statutory immunity provision attempts to legislate in an area of significant federal concern, it does not enjoy the presumption of validity.

The second cornerstone of preemption analysis is that state statutes enjoy a presumption of validity "in a field which the States have traditionally occupied." *Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009) (citations omitted). A threshold question then is whether New Jersey's statutory immunity provision stands in an area of traditional state regulation, entitled to a presumption of validity, or instead receives no benefit from the presumption because it attempts to legislate in an area of significant federal concern. Commentators and courts are not in agreement as to this issue. *See generally*, Mary J. Davis, *The "New" Presumption Against. Preemption*, 61 HASTINGS L.J. 1217, 1220 (2010) ("In the one hundred plus years that the

Supreme Court has addressed preemption issues, it has been inconsistent about the role that the presumption against preemption plays").

As a general matter, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). The presumption against preemption "is strongest when Congress legislates 'in a field which the States have traditionally occupied.'" *Southern Blasting Services, Inc. v. Wilkes County*, 288 F.3d 584, 590 (4th Cir. 2002) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). And states have traditionally occupied the field as it relates to the protection of their citizens' health and safety. *Abbot v. American Cyanamid Co.*, 844 F. 2d 1108, 1112 (4th Cir. 1988) (citing *Lohr*, 518 U.S. at 485); *see also Hillsborough County v. Automated Med. Labs., Inc*., 471 U.S. 707, 719 (1985) ("the regulation of health and safety matters is primarily, and historically, a matter of local concern"). For this reason, the Court in *Wyeth v. Levine* applied the presumption against preemption where a plaintiff brought a products liability suit against a drug manufacturer even though the Federal Government has regulated drug labeling for more than a century. 555 U.S. at 565 n.3. The Court reasoned that the "presumption . . . accounts for the historic presence of state law but does not rely on the absence of federal regulation." *Id.* [7]

[7] In *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), the Court did not make any reference to the presumption against preemption, even though the Court held that Plaintiff's common law tort claims against a generic drug manufacturer were impliedly preempted under the impossibility doctrine. The FDCA's generic drug provisions concern health and safety and states have traditionally regulated the health and safety of their citizens through tort law. The presumption against preemption was omitted because only a plurality of the Justices could agree to a new theoretical framework that would virtually eliminate the presumption against preemption. Writing for the plurality, Justice Thomas reasoned that the portion of the Supremacy Clause, which provides that federal law shall be supreme, "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding" is a *non obsante* clause, as understood by the framers. *Id.* at 2579. At the time of this nation's founding, a *non obstante* clause "in a new statute acknowledged that the statute might contradict prior law." *Id.* If a new statute contained a *non obstante* clause, courts would follow the new statute and "not to apply the general presumption

A presumption against preemption "is not triggered when the State regulates in an area where there has been a history of significant federal presence." *United States v. Locke*, 529 U.S. 89, 108 (2000). For example, in *Buckman*, the Court held that there is no presumption against preemption where a jury is asked to decide whether there has been a material fraud on the FDA during the regulatory process. 531 U.S. at 347. This is because federal law dictated the Defendant's interactions with and representations to the FDA. *Id.* at 347-48. Thus, unlike circumstances that implicate "federalism concerns and the historic primacy of state regulation of matters of health and safety," the relationship between a regulated entity and the FDA is "inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* For this reason, the Court found that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id.* (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)).

In analyzing whether the presumption against preemption applies in the context of state statutory immunity provisions, two out of three federal appeals courts have applied the presumption and began with the "assumption that a state law is valid." *Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961, 965 (6th Cir. 2004) (applying presumption against preemption in the context of Michigan's immunity provision); *Desiano v. Warner-Lambert & Co*., 467 F.3d 85, 94-95 (2d Cir. 2006) (same). *But see Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d

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against implied repeals." *Id.* Applying these principles to the Supremacy Clause, the *non obstante* provision suggests that "federal law should be understood to impliedly repeal conflicting state law." *Id.* at 2580. Although Justice Thomas' plurality opinion may serve as a mechanism for dismantling the presumption against preemption in the future, the Court has yet to disclaim directly the presumption against preemption. Indeed, Justice Alito, a member of the *PLIVA* plurality, seemed unwilling to completely dispense with the presumption, bemoaning in a recent post-*PLIVA* dissent that the "[C]ourt gives short shrift to our presumption *against* pre-emption." *See Arizona v. United States*, No. 11-182, 2012 WL 2368661, at * 39-50 (June 25, 2012).

372, 378 (5th Cir. 2012) (expressing doubt as to whether a presumption against preemption exists in the context of a Texas immunity provision for drug manufacturers). For example, in *Desiano,* Judge Calabrasi applied the presumption against preemption in his analysis of the Michigan statutory immunity provision—a provision that closely resembles the New Jersey provision at issue in this case. 467 F.3d at 94-95. Judge Calabrasi reasoned that presumption should apply because this provision, unlike the fraud on the FDA claim in *Buckman,* "cannot reasonably be characterized as a state's attempt to police fraud against the FDA." *Id.* at 94. Rather, the immunity provision just "regulate[s] and restrict[s] when victims could continue to recover under preexisting state products liability law." *Id.* at 94. Because the immunity provision is a reflection of the state legislature's "desire to rein in state-based tort liability," the provision falls into "a sphere in which the presumption against preemption applies" and "stands at its strongest." *Id.* at 93 -94; *See also Forman v. Novartis Pharmaceuticals Corporation,* 93 F. Supp.2d 598, 609 (E.D.N.Y. 2011) (following *Desiano* and applying the presumption against preemption to claims brought under New Jersey's statutory immunity provision for punitive damages); *Yocham v. Novartis Pharmaceuticals Corp.*, 736 F. Supp.2d 875, 889 (D.N.J. 2010) (holding that the presumption against preemption applies to a Texas statutory immunity provision because, unlike a tort for fraud-on-the-agency, the Texas statute involves regulation of traditional state interests).

Although this Court agrees that the presumption against preemption applies to state tort claims implicating health and safety generally, the Court concludes that such a presumption does not apply to that part of Plaintiff's claim, which by virtue of New Jersey law, conditions any recovery of punitive damages on a showing that a defendant-drug manufacturer "knowingly withheld or misrepresented information required to be submitted under the [FDA's] regulations,

which information was material and relevant to the harm in question." N.J. Stat. Ann. § 2A:58C–5(c) (West 2012). This conclusion is confirmed by the Court's analysis in *Buckman*. There, the Court found that the presumption against preemption did not apply to a specific type of tort claim—a fraud on the FDA claim—even though the presumption against preemption applies to traditional tort claims implicating health and safety matters. 531 U.S. at 347-48. *See also Boyle v. United Technologies Corp*., 487 U.S. 500, 504-05 (1988) (applying no presumption against preemption to the question of under what circumstances government contractors have a "defense" to state tort suits even though state tort law as a whole related to health and safety); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1205 (9th Cir. 2002) (applying no presumption against preemption to a specific type of tort claim—a claim based on pesticide manufacturer's allegedly purposeful submission of false information to Environmental Protection Agency (EPA)—even though the presumption applies to state traditional tort claims generally); *McDarby v. Merck & Co*, 949 A.2d 223, 275 (N.J. Super. Ct. App. Div. 2008) (finding that a presumption against preemption does not apply in the context of New Jersey's statutory immunity provision for punitive damages even if the presumption against preemption applies to compensatory damages generally). Accordingly, this Court declines to apply the presumption against preemption in this case. However, as explained below, even if it were to be applied, any presumption against preemption is overcome in this case.

C. Even if the presumption against preemption were to apply, the FDCA preempts Plaintiff's claim for punitive damages under New Jersey's statutory immunity provision.

Even if the presumption against preemption were applied to New Jersey's immunity provision, this presumption is hardly outcome-determinative and courts have found preemption even where the presumption against preemption did apply. *See, e.g., Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961, 965-66 (6th Cir. 2004) (finding preemption despite agreeing with the notion

that "a court must begin with the assumption that a state law is valid"). In this case, any presumption against preemption is rebutted because Plaintiff's claim for punitive damages under New Jersey's statutory immunity provision poses an obstacle to the FDCA regulatory scheme and FDA enforcement prerogatives. Although the form of Plaintiff's punitive damages claim differs from that of her counterparts in *Buckman*, both claims are identical in substance because they present the same conflict with the FDA's regulatory scheme and enforcement prerogatives.

1. Plaintiff's claim for punitive damages under New Jersey's statutory immunity provision poses an obstacle to the FDCA regulatory scheme and FDA enforcement prerogatives.

Implied conflict preemption occurs when "under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat. Foreign Trade Council*, 530 U.S. 363, 372–73 (2000). In evaluating whether a state claim serves as an obstacle to the purposes and objectives of a federal statute, courts primarily consider whether the state claim requires a fact finder to make a determination that a federal law leaves exclusively to the agency.

If a state claim requires a fact finder to make a determination exclusively committed by federal law to the agency, courts are likely to find this claim to be an obstacle to the purposes and objectives of a federal statute. *Arizona v. United States*, No. 11-182, 2012 WL 2368661, at * 9 (June 25, 2012) (finding obstacle preemption because "[p]ermitting the State to impose its own penalties for the federal offenses would conflict with the careful framework Congress adopted.").

For example, in *Buckman*, plaintiffs filed a state tort fraud on the FDA claim against the consulting company[8] that helped the device maker obtain FDA approval for orthopedic bone

[8] The fact that the *Buckman* plaintiffs sued the consultant rather than the manufacturer is irrelevant. Plaintiff brought identical fraud on the FDA claims against the medical device manufacturers, which the district court also found to be preempted. *In re Orthopedic Bone*

screws which allegedly caused their injuries. 531 U.S. at 343. The Court stressed that plaintiffs could only prevail on their state tort fraud on the FDA claim if a jury finds: (1) the FDA would not have approved the orthopedic bone screws "but for" the consultant's pre-approval misrepresentations to the FDA, (2) the plaintiffs would not have been injured if the FDA did not approve the orthopedic bone screws for sale in the United States. *Id.* at 343. But when analyzing specific FDCA provisions, the Court noted the ways in which these jury determinations under state law create an obstacle to the enforcement of federal law.

First, the FDCA imposed a duty on medical device manufacturers to make specific disclosures to the FDA during the device approval process. *Id.* at 346 (citing 21 U.S.C. § 360(e)). Second, the FDCA vests the FDA, not private litigants, with the exclusive authority to investigate and prosecute any suspected fraud or misrepresentation in connection with FDCA-created disclosure requirements. *Id.* at 349 n.4 (citing 21 U.S.C. § 337). Third, the FDCA accords the FDA considerable flexibility in how it chooses to address any fraud or misrepresentation in connection with the disclosure requirements: the FDA has authority to seek civil penalties, injunctive relief, seizure of the device, and criminal convictions or the authority not to pursue any remedy. *Id.* at 349 (citing 21 U.S.C. §§ 372, 333, 334, 18 U.S.C. § 1001). Thus, unlike an ordinary tort claim that requires a jury to consider whether a manufacturer breached a common law duty of care *owed to the public*, the "critical element" of the *Buckman* plaintiffs' claim required a jury to consider whether the device maker breached a FDCA-created disclosure duty *owed to the FDA*. *Id.* at 353 (emphasis added). Stated differently, the *Buckman*

Screw Products Liability Litigation, MDL-1064, 1997 WL 305257, at *3 (E.D. Pa. March 28, 1997), *rev'd*, 159 F.3d 817 (3d Cir. 1998), *rev'd*, 531 U.S. 341 (2001). Because plaintiffs asserted no other cause of action against the consultant, they obtained an order under Fed. R. Civ. P. 54(b) permitting an interlocutory appeal against the consultant, but not against the manufacturers.

plaintiffs' state tort fraud on the FDA claim arose "solely from the violation of FDCA requirements." *Id.*

Because plaintiffs' state tort fraud on the FDA claim requires a fact finder to make a determination under state law that a federal law leaves exclusively to the FDA—i.e. that the device manufacturer made a material misrepresentation to the FDA in violation of FDCA-created disclosure requirements—the *Buckman* Court found plaintiffs' claim to be an obstacle to the purposes and objectives of the FDCA.[9] *Id.*; *see also Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 881 (2000) (finding obstacle preemption because state tort claim would require a jury to make a determination regarding passive restraint systems—i.e. all car manufacturers have a duty to install air bags—that federal law left to the Department of Transportation, which created a regulation rejecting the all-air bag standard in favor of a variety and mix of passive restraint systems).

If a state claim requires a fact finder to make a separate determination that federal law contemplates may be made in parallel by both a state fact finder and a federal agency, courts are unlikely to find any obstacle to the enforcement of a federal statute. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (holding that the FDA's approval of a new medical device based on the finding that this device is substantially similar to devices already on market did not "den [y] Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.").

[9] The obstacles in *Buckman* included increased administrative burdens, which result from device-maker applicants who fear "that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id*. at 351. As a result these applicants may submit a "deluge of information that [FDA] neither wants nor needs." *Id*. at 351. Consequently, the approval process for a new device might "encounter delays" and these delays could "impede competition" in the medical device market. *Id.*

For example, in *Wyeth v. Levine*, the Court rejected a drug company's argument that a plaintiff's state tort failure to warn claim regarding the drug Phenergan posed an obstacle to the purposes and objectives of the FDCA "because [plaintiff's state tort claims] interfere with Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." 555 U.S. at 573. In its reasoning, the Court emphasized that neither it nor the defendant-drug company could identify a specific federal statute, federal regulation, or collection of federal statutes and regulations, which precludes the possibility of two seperate but parallel determinations—i.e. the possibility that the FDA could find a particular label to be adequate in terms of safety for purposes of the FDCA and a jury could find that same label to be inadequate in terms of safety and efficacy for the purposes of state tort duties. *Id.* at 578-80. This understanding is reinforced by the fact that Congress chose to expressly preempt common law state tort claims in the medical device context but retain common law tort claims in the pharmaceuticals context.[10] *Id.* at 574-75. The *Wyeth* Court noted the ways in which the FDCA's legislative history demonstrates Congress' desire for the federal regulatory scheme and state common law duties to operate separately, but in parallel. *Id.* at 579 (citing H.R. 6110, 73d Cong., 1st Sess., § 25 (1933) (First version of precursor to the FDCA provided a federal cause of action for damages to injured consumers); Hearings on S.1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 400 (1933) (statement of W.A. Hines) (testifying that federal cause of action for damages to injured consumers was unnecessary

[10] One may argue that *Buckman* is inapplicable in this context because it concerned a medical device— orthopedic bone screws—and Congress chose to expressly preempt common-law tort claims with respect to medical devices. However, this argument is entirely without force. In *Buckman*, the Court explicitly stated that although plaintiff's state tort fraud on the FDA claim posed an obstacle to the purposes and objectives of the FDCA, the Court "express[ed] no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k." *See* 531 U.S. at 348 n.2.

because common law claims were already available under state law.); Hearings on S.1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 403 (1933) (statement of J.A. Ladds) ("This act should not attempt to modify or restate the common law with respect to personal injuries")). Because the FDCA contemplates that the FDA could make a determination as to the safety and efficacy of a drug label under the FDCA and a state fact finder could reach the opposite conclusion under entirely separate but parallel state tort law principles, the *Wyeth* Court did not find obstacle preemption. *Id.* *See also Buckman*, 531 U.S. at 353 ("*Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements.")

In contrast, Plaintiff's claim for punitive damages under New Jersey's statutory immunity provision poses an obstacle to the FDCA regulatory scheme because it requires a fact finder to make a determination that a federal law leaves exclusively to the agency. Here, as in *Buckman*, the FDA has exclusive authority to decide whether a drug is safe and effective enough to be approved for sale in the United States and the flexibility to decide whether and what type of enforcement claim to bring against a drug manufacturer that breaches the FDCA-mandated disclosure duty owed to it during the NDA and post-approval processes. *See supra* Part.II.A. But the FDA has never found that Novartis knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which was material to Ms. Newman's osteonecrosis of the jaw. Yet, under New Jersey law, Plaintiff can *only* recover punitive damages in connection with Aredia and Zometa—both of which are FDA approved drugs—if a jury first finds that (1) Novartis "knowingly withheld or misrepresented information" to the FDA (2) this information was "required to be submitted under the [FDA's] regulations" and (3) "information

was material and relevant to the harm in question," specifically, Ms. Newman's osteonecrosis of the jaw. *See* N.J. Stat. Ann. § 2A:58C–5(c) (West 2012).[11]

Simply put, 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.

> *2. Although the form of Plaintiff's claim 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.*

In finding Plaintiff's claim for punitive damages to be preempted, this Court recognizes that its decision conflicts with that of its counterpart in the Eastern District of New York, which reached the opposite conclusion in the Aredia and Zometa products liability context. *See*

[11] The proposition that a jury must find these elements before awarding punitive damages under New Jersey law is confirmed by the proposed jury instructions in an Aredia and Zometa litigation where the court found no preemption. *See Forman v. Novartis Pharmaceuticals Corp*., No. 09–CV–4678 (ADS)(WDW), Novartis Jury Instructions, ECF No. 491-1 at 28 ("Punitive damages cannot be awarded for harm caused by a drug such as Zometa® that was approved by the FDA as safe and effective unless you find by clear and convincing evidence that the product manufacturer knowingly withheld or misrepresented information required to be submitted to the FDA under FDA regulations, and that such information was material and relevant to the harm caused to Mr. Napolitano"); *Forman v. Novartis Pharmaceuticals Corp*., No. 09–CV–4678 (ADS)(WDW), Plaintiff Jury Instructions, ECF No. 494-1 at 15 ("If you find that Novartis has knowingly withheld or misrepresented information required to be submitted under the Food and Drug Administration's regulations, which information was material and relevant to the harm in question, you must consider whether or not to award punitive damages to Plaintiff.").

Forman v. Novartis Pharmaceuticals Corporation, 93 F. Supp. 2d 598 (E.D.N.Y. 2011).[12] The court in *Forman* did not find preemption because it distinguished the plaintiff's claim for punitive damages under the New Jersey law with the fraud on the FDA claim in *Buckman*. These distinctions are unpersuasive because they elevate the form of a claim over its substance.

The Eastern District of New York declined to find preemption because Forman's claim for punitive damages under New Jersey law was "not premised principally (let alone exclusively) on a drug maker's failure to comply with federal disclosure requirements" whereas the fraud on the FDA claim in *Buckman* was based exclusively on a device maker's failure to comply with federal disclosure requirements. *Id.* at 605. It concluded that "the fact that fraud in FDA disclosures is necessary for the pre-existing common law punitive damages claim to survive [under New Jersey law], is not equivalent to a [fraud on the FDA] claim 'based *solely* on the wrong of defrauding the FDA.'" *Id.* (citing *Desiano*, 467 F.3 at 95 (emphasis in original)). This distinction is meaningless because it is simply not entirely accurate. In *Buckman*, the plaintiffs not only had to prove the device maker's non-compliance with FDCA disclosure requirements, which served as the predicate false representation in a common law fraudulent misrepresentation action, but also other common law elements of a fraudulent misrepresentation action such as injury and proximate cause. *See In re Orthopedic Bone Screw Liab. Litig*., 159 F.3d 817, 822 (3d Cir. 1998) (stating that plaintiffs' claim of fraud on the FDA "track[s] the elements of a common law cause of action for fraudulent misrepresentation"). Put another way, the preemption analysis

[12] The difference in opinion likely stems from the fact that the *Forman* court was bound by the Second Circuit's decision in *Desiano v. Warner-Lambert & Co*., 467 F.3d 85 (2d Cir. 2006) *aff'd by an equally divided court sub nom. Warner–Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008), while this Court is free to take an alternate approach because the Fourth Circuit has not addressed this issue

does not change simply because, under New Jersey law, this Plaintiff must prove something in addition to non-compliance with a FDCA disclosure requirement to recover punitive damages.

The *Forman* court also declined to apply *Buckman* to New Jersey's statutory immunity provision because the claim in *Buckman* was based on a "newly concocted duty between manufacturer and a federal agency," whereas the plaintiff's New Jersey punitive damages claim is based on traditional tort duties. 93 F. Supp.2d at 606. Such a distinction might make sense if one were comparing a traditional tort claim with the claim in *Buckman* before New Jersey passed its punitive damages immunity statute. In the pre-statutory immunity world, a jury would consider whether a drug manufacturer's communications with the plaintiffs, their doctors, or the public violates a common law duty to the plaintiff and whether those communications were motivated by actual malice or accompanied by a wanton and willful disregard of potential harm whereas the FDA considers whether a drug manufacturer's submission supports a finding that the drug is safe enough to be approved or violates a FDCA-created disclosure obligation. *Wyeth v. Levine*, 555 U.S. 555, 578-80 (2009) (finding no preemption because federal law does not preclude the FDA from finding a particular label to be adequate in terms of safety and efficacy under FDCA and a jury from finding the same label to be inadequate in terms of safety and efficacy under common law state tort duties.) Once New Jersey passed the statutory immunity provision for punitive damages, the traditional cause of action is no more rooted in common law doctrine than the stand-alone claim in *Buckman*. This is because, in the post-statutory immunity world, a plaintiff's punitive damages claim hinges on whether the defendant-drug maker made adequate disclosures to the agency and whether, in the face of these inadequate disclosures, the agency would have approved the drug. *See Buckman*, 531 U.S. at 353 (finding obstacle preemption because the "critical element" of plaintiffs' claim requires a jury to consider whether

the device maker breached a FDCA-created disclosure duty owed to the FDA). In this way, New Jersey's statutory immunity provision makes fraud on the FDA a "critical element" of every punitive damages claim.

For these reasons, this Court is convinced that the formalistic differences between Plaintiff's punitive damages claim and the *Buckman* plaintiffs' fraud on the FDA claim are immaterial. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (finding formalistic differences between the claim in *Buckman* and a claim brought under Michigan's statutory immunity provision to be "immaterial"); *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 380 (5th Cir. 2012) (same). The Plaintiff's punitive damage claim in this case is preempted because it requires a fact finder to make a determination under state law that federal law leaves exclusively to the FDA. Allowing state fact finders to second-guess the very decisions that federal law leaves entirely to the agency presents "the same inter-branch-meddling concerns that animated *Buckman*." *Garcia*, 385 F.3d at 966. As in *Buckman*, allowing punitive damages liability here would require applicants to submit a "deluge" of unnecessary information during the approval process, which in turn, delays the approval of new drugs. 531 U.S. at 351. In seeking to comply with various statutory immunity provisions, drug manufacturers would "exert an extraneous pull on the scheme established by Congress." *Id.* at 353.

III. CONCLUSION

While the legal journey leading to this conclusion has encountered many twists and turns, the destination is clear: Plaintiff's punitive damages claim cannot be pursued and, accordingly,

the Defendant's motion will be granted.

A separate order follows.

Date: September 5, 2012

/s/
ROGER W. TITUS
UNITED STATES DISTRICT JUDGE