No. 12-1339

In The Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,

Petitioner,

v.

HERBERT FUSSMAN, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF RITA FUSSMAN,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals For The Fourth Circuit

BRIEF OF RESPONDENT IN OPPOSITION TO CERTIORARI

JODI D. HILDEBRAN
ALLMAN SPRY LEGGETT & CRUMPLER, P.A.
380 Knollwood St., Ste. 700
Winston-Salem, NC 27103
Telephone: (336) 722-2300
jhildebran@allmanspry.com
Counsel for Respondent

JOHN J. VECCHIONE
Counsel of Record
JOHN J. VECCHIONE LAW PLLC
3863 Plaza Drive
Fairfax, VA 22030
Telephone: (703) 352-4800
Jvecchione@valadlaw.com
Counsel for Respondent

July 29, 2013

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

COUNTERSTATEMENT OF QUESTION PRESENTED

Whether the Court should grant the petition to consider whether a punitive damages award in connection with state-law claims for injury caused by a prescription drug is impliedly preempted by federal regulation, where there is no conflict among the circuits on the issue and no tension with any prior decision of this Court.

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INTRODUCTION

This case is the first federal case to be tried in MDL-1760, *In re Aredia and Zometa Products Liability Litigation*, No. 3:06-MD-1760 (M.D. Tenn.).[1] After a three-week trial, a jury found that Rita Fussman suffered a painful and disfiguring jaw injury called Bisphosphonate Induced Osteonecrosis of the Jaw ("BONJ" or "BIONJ"),[2] as a direct and proximate result of being infused with Novartis' bisphosphonate drugs Aredia and Zometa. It awarded $289,001 compensatory and $12.6 million dollars in punitive damages. The punitive damages award was reduced to $867,003 under North Carolina law which caps such damages at three times compensatory damages.

In its petition, Novartis Pharmaceuticals Corporation ("Novartis") argues that punitive damages cannot be assessed against pharmaceutical companies for wrongful conduct related to marketing of a prescription drug. Novartis does not argue that the courts of appeals are divided on the issue – they are not. Novartis does not argue that the punitive damages award was not in proportion to its misconduct

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[1] Certiorari was denied in the first state court case to go to trial but certiorari was sought on an issue of statute of limitations, not punitive damages which were not awarded in that 3.2 million dollar compensatory judgment. *Stevens v. Novartis Pharms. Corp.*, 358 Mont. 474, 247 P.3d 244 (2010), *cert. denied*, 2011 WL 1212227 (May 31, 2011).

[2] The condition is also known as Bisphosphonate Related Osteonecrosis of the Jaw ("BRONJ" or "BRON").

or was not supported by the evidence – the award was proportionate and well-supported by the evidence. Novartis does not argue that the punitive award was inconsistent with labeling that warned adequately of risks.

Moreover, no court has disagreed with the Fourth Circuit's analysis of Novartis' preemption arguments. The Fourth Circuit's decision follows from recent precedent of this Court, while Novartis' argument that regulation by a federal agency preempts state law awarding punitive damages in egregious cases seeks a broad expansion of preemption doctrine that this Court has never adopted, although pharmaceutical companies have made such argument for nearly a quarter of a century. *See, e.g., Pacific Mut'l Life Ins. Co. v. Haslip*, 499 U.S. 1, 8 n.4 (1991) (noting that the Brief submitted on behalf of Pharmaceutical Manufacturers Association *et al.* argues that "any award of punitive damages for lawful conduct approved in advance by the [Food and Drug Administration] must be deemed arbitrary and excessive"). The Fourth Circuit properly followed the logic of this Court in *Wyeth v. Levine*, 555 U.S. 555 (2009), by recognizing that, "[h]ad Congress intended to preempt punitive damages recovery, it could have clearly indicated as much – just as it did when it addressed medical devices." *Fussman v. Novartis Pharmaceuticals Corp.*, 509 F. App'x 215, 225 (4th Cir. 2013).

Novartis must comply with state law failure to warn standards as noted in *Wyeth v. Levine*, but contends it should not be subject to liability for any

willful and wanton failure to warn. The questions presented by petitioner not only misstate the law, but simply do not merit *certiorari* by this Court and, even if they did, this Case would be an extremely poor vehicle for addressing them.

STATEMENT OF THE CASE

A. Factual Background

Novartis has provided the Court very little in terms of the facts of this case. While Novartis would like this Court to think any conduct considered by the jury directly related to Novartis' dealings with FDA, that is not true, as the trial court noted. Pet. App. 29a n.6.

Rita and Herb Fussman, residents of North Carolina, were married for fifty years. Mrs. Fussman was diagnosed with metastatic cancer in May 2001 and began bisphosphonate therapy that same year. She began taking Aredia in June 2001. JA-834.[3] During a period when Novartis was aggressively marketing its new, more potent bisphosphonate Zometa to oncologists so that they would switch from its old drug Aredia (now under pressure from generic competition), Mrs. Fussman was switched to Zometa. *Id.*

[3] Citations to JA refer to the Joint Appendix filed in the Fourth Circuit.

Mrs. Fussman began experiencing jaw problems while taking Aredia and Zometa, but none of her physicians knew about BONJ (although Novartis did). She began to suffer dead bone and problems with her jaw after a tooth extraction, which Novartis knew or should have known was contraindicated for someone on long term bisphosphonates. In fact, Mrs. Fussman had pieces of her jaw bone die and extrude, multiple infections and reoccurrences that lasted throughout her fight against cancer, and went on for more than half a decade.

Mrs. Fussman stayed on Zometa until June of 2005. During that time, she required additional painful dental work and debridements. Today, oral care physicians know that these procedures are contraindicated in BONJ sufferers, but the campaign of misinformation and information suppression by Novartis sufficiently confused the medical profession when this disease started to appear in cancer patients. At the trial of this case in November of 2010, Novartis denied any causal link between Zometa and BONJ.

Novartis' petition extols purported benefits of Aredia and Zometa, but neither drug has been proven to either extend life expectancy or fight cancer. They are approved solely to delay the onset of, but not eliminate, bone-related injuries in cancer patients. JA-1097. Novartis' cancer expert conceded there was no evidence (which met the admissibility standards at trial) that they extend life. JA-1134.

Had Mrs. Fussman and her physicians been warned of the risks of BONJ, she either would not have taken the drugs or would have taken steps to minimize the complications of BONJ. JA-591. Nearly every treating physician, including the prescriber, stated they would have acted differently to lower the risk of BONJ to Mrs. Fussman if they had been adequately warned. *See*, *e.g.*, JA-777-79, JA-872-73, JA-841, JA-803-04 (also note Dr. James Hoke Trial Test. (Nov. 5, 2010), 37:5-38:1; 39:17-40:3; 55:4-14); Dr. Michael Schroer Dep. Test. (Feb. 15, 2008) as Shown at Trial (Nov. 9, 2010), 111:23-113:9, 126:23-127:4 (PX-248); JA-763 (also note Dr. Thomas McGraw Trial Test. (Nov. 4, 2010), 66:20-67:21). Moreover, the undisclosed risk was doubly harmful, as Zometa's side effects interfered with Mrs. Fussman's taking of her cancer drugs. JA-863; JA-866.

B. Proceedings Below

The Fussmans filed suit against Novartis on February 13, 2006, JA-4; JA-147, and their case was consolidated in a multidistrict litigation, JA-169. After years of discovery and motion practice (and Mrs. Fussman's death in August of 2009), the MDL court denied Novartis' various summary judgment motions and remanded the case for trial. JA-210-17. *See also In re Aredia and Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760 (*Fussman v. Novartis Pharms. Corp.*, No. 3:08-cv-0068), 2009 WL 2497536 (M.D. Tenn. Aug. 13, 2009) (denying Novartis' motion for summary judgment based on an alleged failure of causation

proof under *Daubert*); *In re Aredia and Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760 (*Fussman v. Novartis Pharms. Corp.*, No. 3:08-cv-0068), 2009 WL 2496843 (M.D. Tenn. Aug. 13, 2009) (denying Novartis' summary judgment motions on Fussman's failure to warn, breach of implied warranty, and loss of consortium claims).

After remand, Novartis again moved for summary judgment on the whole case and on punitive damages. Both were denied. JA-343-53; JA-354-66. *See also Fussman v. Novartis Pharms. Corp.*, No. 1:06-cv-00149-JAB, 2010 WL 4104707 (M.D.N.C. Oct. 18, 2010) (denying Novartis' additional motion for summary judgment sought for alleged lack of proximate cause); *Fussman v. Novartis Pharms. Corp.*, No. 1:06-cv-00149-JAB, 2010 WL 4273195 (M.D.N.C. Oct. 25, 2010) (denying Novartis' motion to preclude punitive damages). The testimony at trial presented overwhelming evidence that Novartis' failure to warn caused Mrs. Fussman's injury and that Novartis' intentionally concealed and misrepresented risks known to it.

Mrs. Fussman's oncologist, Dr. Shaw began providing treatment to Rita Fussman in 2001 and stopped in 2008. JA-827. She testified through deposition that she did not know about bisphosphonate related osteonecrosis of the jaw and had never heard of BRONJ or BRON. JA-858. Had she known that the clinical trials (not reported by Novartis) showed a risk of BRONJ, that information would have been helpful to her. *Id.* There was no difference between Aredia

and Zometa but infusion time as far as she knew. JA-828. In fact, Aredia causes BONJ at a lower rate than Zometa. She gave Mrs. Fussman Novartis' Aredia product information which had no BONJ information in it. JA-861. She testified that Zometa side effects interfered with Mrs. Fussman's taking her real cancer drugs. JA-863; JA-866. She stopped prescribing Zometa to Mrs. Fussman because of ONJ. JA-854. She was unaware of the long half-life of bisphosphonates in the bones. *Id*. She had not a whisper of a hint of ONJ and bisphosphonates as of September 12, 2003. JA-868. Mrs. Fussman even rejected low dose oral bisphosphonates after being warned of their ONJ effects. JA-856; JA-871. Finally, Dr. Shaw read the "warnings" section with more care than other parts of the package inserts. JA-873.

At no time when Mrs. Fussman took Aredia was there any mention of ONJ of any kind on the label or package insert.

Dr. Shaw also testified that where a warning appeared in a label, *i.e.*, in the warning or precaution sections, made a difference. JA-873. It is clear that Mrs. Fussman directly asked Dr. Shaw about her gums which would not heal in 2003, but Dr. Shaw did not know about the relationship between bisphosphonates and ONJ at that time. JA-868-69. After later being told by Rita Fussman about the side effects she was experiencing and the bone coming out of her mouth, Dr. Shaw wrote, then coupled with knowledge of Zometa, "Glad you have some jaw left." JA-868-69.

The Fussmans presented a host of evidence showing Novartis' reckless indifference to the risk of BONJ. A number of oral maxillofacial surgeons had been tasked with drafting and commenting on a "White Paper" that Novartis hoped to use to show that its drugs did not cause BONJ. Dr. Robert Marx, chosen by Novartis to advise it on BONJ, testified for plaintiffs that he told Novartis that the "risk factors" promoted by Novartis were false and would be misleading. JA-716. Other oral maxillofacial surgeons on the panel chosen by Novartis to comment on the draft White Paper sent the same unequivocal message to Novartis. JA-220-21; (email thread with comment of Dr. Mark Schubert stating that "THE LAUNDRY LIST OF FACTORS LEADING TO 'EXPOSED BONE' DOES HAVE THE APPEARANCE OF 'BLOWING SMOKE'"); JA-1728-29 (email thread from Dr. Ana Hoff in response to Dr. Schubert, stating she agreed with all his points). Novartis' Global Medical Director, Yong Hei, claimed that these comments, and those of the other oral maxillofacial surgeons like Dr. Marx, had been incorporated into the White Paper with few exceptions, JA-225, but Yong Hei's response to Dr. Schubert demonstrates that the claim is not true. *Id.* The White Paper went to the medical community and was not a requirement of FDA regulation. This White Paper was part of Novartis' "plan" to obfuscate and confuse the issues in the medical community so sales would not be affected – this action had *nothing* to do with FDA regulations.

The evidence supporting punitive damages is vast and encompassed, *inter alia*, the testimony of Drs. Marx, Parisian, and Tarassoff, and Mr. Fratarcangeli and emails produced by Novartis. The evidence showed that Novartis specifically prevented a label change until 2007 in an effort to ensure that its benign (non-cancer) indications with the same active ingredient as Zometa would sail through FDA, and its label approval and sales would not be impacted by the BONJ, which it believed could be blamed on cancer and other cancer treatments, rather than bisphosphonates. *See, e.g.,* JA-1085-86. Novartis' own documents and its behavior with regard to the White Paper also supported punitive damages. *See*, *e.g.*, JA-1576-80 (email from Dr. Ruggiero stating that the manuscript sounded like Novartis was trying to find "other" reasons for why osteonecrosis of the jaw was occurring in patients on bisphosphonates, and that the comparisons being used were invalid because "bisphosphonates are the real culprits"), JA-1622-26 (email from Mr. Fratarcangeli, Executive Director for Zometa for Novartis, setting out "agreed actions" to be implemented by May 16, 2003, including attempts to suppress publication of a paper by a prominent oral surgeon, Dr. Salvatore Ruggiero, regarding the link between bisphosphonates and ONJ and preparing for release a publication to immediately refute Dr. Ruggiero's report, if published, but stating that "we'll try to avoid that the paper is ever published"; the email also discussed the fact that if Novartis cannot make a compelling case that there is no connection between Zometa and ONJ, a label change might be

requested) JA-889-92 (Fratarcangeli's testimony on the email); *cf.* JA-1734-35 ("White Paper"). Novartis' CEO, David Epstein, officially approved the strategy of stating that other risk factors for ONJ were "well documented." David Epstein Dep. Test. (Feb. 9, 2010) as Shown at Trial (Nov. 9, 2010), 126:10-16; 126:23-127:22 (PX-248). He also appointed Mr. Fratarcangeli, who developed the plan to stop Dr. Ruggerio from publishing his findings, to lead the company's entire response to BONJ.

Dr. Marx was on the advisory board of Novartis regarding BONJ and presented powerful factual testimony to the jury. He testified that he and others warned Novartis that the approach it was taking was disingenuous and contrary to the medical facts, and he authenticated email messages concerning his complaints in this regard. JA-707-08; JA-713-14; JA-716; JA-743-44.

The documents demonstrated that Novartis did all it could to avoid acknowledging the jaw problem and that when others brought it to Novartis' attention, the company ignored them or, in the case of Dr. Marx, counteracted the warning sent out. JA-971-76.

Dr. Peter Tarassoff noted that an Oral Maxillofacial Surgeon had been asking him about ONJ and Aredia since early 2002. JA-1551. Dr. Marx sent a draft alert to the medical community he wanted to publish to Novartis in June of 2003. JA-1556-65. Novartis sought to discredit that medical alert by a

letter urging physicians to continue their prescribing habits without change and called ONJ "not unexpected" in the patient population. JA-971-76. *See also* Peter Tarassoff Dep. Test. (Apr. 10 and Apr. 18, 2010) as Shown at Trial (Nov. 10, 2010), 274:8-275:10 (PX-248).

A May 12, 2004 email message placed in evidence discussing the real risk factors showed notice to a high level Novartis employee. Dr. Tarassoff indicated he got the message but ignored it. JA-1576-80 (Dr. Ruggiero states bisphosphonates were "the real culprit. . . ." *and Dr. Tarassoff of Novartis underlined those words*).

Dr. Katarzyna Sablinska, Novartis' only epidemiologist explained the evidence did not support any "well documented" alternate risk factors for ONJ. Dr. Sablinska, told Novartis its "well documented" risk factors were nothing of the kind. JA-765-66.

Probative of NPC's complicity at the highest levels was the testimony of Novartis' CEO Mr. David Epstein. His email of January 29, 2003 and his testimony concerning it and the failure to test lower doses could support a willful and wanton disregard of patient safety. JA-1647-85. In fact, his explanation of why Japanese studies cannot be trusted is they are too safety conscious. JA-926-28. *See also* David Epstein Dep. Test. (Feb. 9, 2010) as Shown at Trial (Nov. 9, 2010), 256:17-24 (PX-248). His testimony about Mr. Fratarcangeli's email that was sent to him and other NPC higher ups (JA-1686-96) easily

demonstrated to the jury NPC's cavalier attitude to truthful science reporting. In fact, Mr. Epstein's testimony alone could support a jury's finding of punitive damages because it's clear, as CEO, he is dismissive of safety concerns and wants to sell the drug regardless of effects on patients or health. One of the key messages NPC adopted was to direct attention to other supposed causes of ONJ which Mr. Epstein thought was a "good strategy." *Id.* at 126:10-127:22.

Almost all of the evidence that demonstrates Novartis' wanton and willful effort to ignore and divert attention from BIONJ comes from the mouths, or records of NPC's own agents or chosen advisors.

The Fratarcangeli email (JA-1622-26), where he lays out a plan to minimize Dr. Ruggiero's article and prevent its publication, if possible, was cited in support of punitive damages, and NPC did not produce one piece of paper disapproving that plan. Dr. Parisian's testimony concerning the FDA approval process is but a tiny portion of this case.

C. The Decisions Below

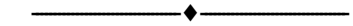
At the close of Plaintiff's case and of all evidence, the Court denied Novartis' Fed. R. Civ. P. Rule 50 motions. JA-1009; JA-1276-77. The Jury returned a verdict for Mrs. Fussman's estate of $287,000.00 in compensatory damages and for $1.00 on Mr. Fussman's loss of consortium claim. The jury also awarded $12,600,000.00 in punitive damages. JA-495-97.

Consistent with North Carolina law, the district court reduced the punitive award to $867,003, three times compensatory damages for a total award of $1,258,083.19 (including prejudgment interest).

Novartis filed post-trial motions again seeking judgment as a matter of law on all counts or in the alternative for a new trial. JA-504. The district court denied the motions. As pertinent here, the trial court "conclude[d] that sufficient evidence was presented to support a finding by the jury, by clear and convincing evidence, that Novartis managers intentionally concealed the risk of ONJ and attempted to subvert the medical inquiry regarding the risks of ONJ, all with the knowledge and approval of high-ranking officials within the company." Pet. App. 31a. The trial court further found that the evidence "support[ed] the conclusion that Novartis managers took this course of action for purely financial reasons, in order to protect its marketing of bisphosphonate drugs." *Id*. In addition, the trial court found that the deception was related to Ms. Fussman's injury because the evidence supported the jury's conclusion that this intentional deception and suppression of medical evidence by Novartis was related to Mrs. Fussman's jaw injuries, and the evidence was sufficient to support the finding that "the actions by Novartis were undertaken as part of an effort to keep doctors and other medical professionals from learning of the ONJ risks, and it was this lack of adequate warning and information that the jury had already determined was the proximate cause of Mrs. Fussman's injuries." Pet. App.

32a. The trial court also rejected the argument that an award of punitive damages is preempted and noted particularly that this case was not analogous to *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Pet. App. 29a-30a (Note 6).

Novartis appealed the verdict (along with various other rulings made at the trial court level) and the Fourth Circuit affirmed. On the issue of whether the punitive damages award is preempted, the Fourth Circuit summarily rejected Novartis' effort "to carve out a niche in existing precedent by arguing that *Wyeth* is inapplicable." Pet. App. 19a. The Court rejected the twin arguments that the FDA had "ample power" to punish and that allowing punishment of FDA-approved conduct is improper. *Id.* It stated, "Neither of these arguments is efficacious. Had Congress intended to preempt punitive damages recovery, it could have clearly indicated as much – just as it did when it addressed medical devices." *Id.* The Fourth Circuit's reasoning is consistent with existing precedent from this Court, and therefore, no good reason exists for this Court to revisit an issue it settled less than four years ago.



REASONS FOR DENYING THE PETITION

Plaintiff pled and proved that Novartis created a new disease (BONJ) that the medical community has named after the class of drugs of which Aredia and Zometa are the strongest and most potent. JA-728. Plaintiff pled and proved both that Novartis knew

and should have known of this devastating side effect and failed to warn the medical community about it. In addition Novartis warranted that Aredia and Zometa were bone strengtheners, while failing to warn that they actually killed jaw bones in significant numbers, particularly after invasive dental surgery. Novartis' advisors told the company in 2003 to warn the dental community because if unwarned, they could make the situation worse, but Novartis did the opposite by trying to suppress information that could have eliminated or made Mrs. Fussman's situation less severe.

The Circuit Courts are in agreement that punitive damages awards are not preempted. Indeed, Novartis does not claim a circuit split. Although Novartis does not identify the type of preemption that it seeks, its theory is essentially that punitive damages under state law conflict with the FDA's enforcement authority. The punitive damages here, however, were not awarded to punish Novartis for violating FDA requirements. They were awarded to punish Novartis for deception and disregard that caused significant pain and injury to Mrs. Fussman and to deter such conduct in the future. An award in these circumstances is fully consistent with the FDA's goal of protecting patients from harmful drugs and its objective that a drug's labeling disclose adverse effects associated with it.

I. There Is No Conflict Within The Circuits On The Availability Of Punitive Damages.

As Novartis admits, no court of appeals has agreed with Novartis' preemption theory. In fact, Novartis' theory has not drawn even a dissent. *See In re Levaquin Products Liability Litig.,* 700 F.3d 1161 (8th Cir. 2012) (finding evidence lacking for punitive damages, but did not address lower court's holding that punitive damages not preempted under *Buckman v. Plaintiffs' Legal Committee,* 531 U.S. 341, 348 (2001)); *Schedin v. Ortho-McNeil-Janssen Pharms., Inc.*, 776 F. Supp. 2d 907, 915-16 (D. Minn. 2011)); *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 563, 572 (8th Cir. 2009) (allowing punitive damages on proper evidence); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1389 (4th Cir. 1995) (where FDA regulations played a role in labeling, court upheld an award of compensatory and punitive damages); *O'Gilvie v. Int'l Playtex, Inc*., 821 F.2d 1438, 1446 (10th Cir. 1987) ("compliance with the FDA regulations does not preclude punitive damages when there is evidence sufficient to support a finding of reckless indifference to consumer safety."); *Forman v. Novartis Pharms. Corp.*, 793 F. Supp. 2d 598, 599 (E.D.N.Y. 2011) (no preemption *citing Silkwood v. Kerr McGee Corp.*, 464 U.S. 238 (1984)); *Mahaney v. Novartis Pharms. Corp.*, No. 1:06-cv-00035-R, 2011 WL 4103669 (W.D. Ky. Sept. 14, 2011) (punitives allowed); *and see Wooderson v. Ortho Pharm. Corp.,* 235 Kan. 387, 418-19, 681 P.2d 1038, 1063 (Kan. 1984) (drug company's efforts to downplay emerging reports of complications

and continuing "to urge sale of its higher estrogen product until Ortho itself could be entirely satisfied that the product was causing damage" preserved punitive damages).

II. The Decision Below Is Consistent With Prior Decisions Of This Court.

"[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth,* 555 U.S. at 565. In a field like pharmaceutical legislation, traditionally the preserve of the States, the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* (*citing Medtronic v. Lohr*, 518 U.S. 470, 485 (1996)) (further citation omitted).

These principles support the decision below, as this Court's prior cases illustrate. Most notably, as identified by the Court below, in *Wyeth v. Levine*, "the Court examined the history of the FDCA [Food, Drug, and Cosmetic Act] and Congress's intent in enacting the statute." Pet. App. 18a. Yet the Court found that Congress did not intend to preempt state-law claims: "If Congress thought that state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history." *Wyeth*, 555 U.S. at 575. Novartis' nebulous preemption theory is irreconcilable with the decision in *Wyeth*.

The decision below is also consistent with other cases of this Court rejecting arguments that federal regulation preempts punitive damages awards. For example, in *Silkwood v. Kerr McGee Corp.*, the defendant, a producer of nuclear power, argued that federal regulation preempted a punitive damages award against it. In contrast to the pharmaceutical industry, the nuclear industry and nuclear safety is wholly regulated by the federal government, except for the "limited powers expressly ceded to the states." *Silkwood*, 464 U.S. 238, 249 (1984) (*citing Pacific Gas & Electric Co. v. State Energy Resources Conservation,* 461 U.S. 190 (1983)). Nonetheless, the Court held that punitive damages were not preempted. There, federal control through ownership and regulation was far stronger than the federal regulation that overlays traditional state regulation of pharmaceuticals.[4]

In *English v. General Electric Co.,* 469 U.S. 72 (1990), this Court reinstated a claim (which allowed punitive damages) of intentional infliction of emotional distress against nuclear power plant operators who retaliated against whistleblowers, rejecting preemption arguments similar to those made here. In so doing, the Court noted that if state tort law based on "outrageous conduct" were preempted, state *criminal*

[4] Indeed, it bears noting that the federal government created the first successful nuclear program. The power to split the atom, unlike the ability to make and market pharmaceuticals, did not exist until the federal government did so.

law would also be preempted – a result the Court found plainly incorrect. *Id.* at 83. The Court stated:

> We recognize that the claim for intentional infliction of emotional distress at issue here may have some effect on these decisions [regarding nuclear safety], because liability for claims like petitioner's will attach additional consequences to retaliatory conduct by employers. As employers find retaliation more costly, they will be forced to deal with complaints by whistle-blowers by other means, including altering radiological safety policies. **Nevertheless, we believe that this effect is neither direct nor substantial enough to place petitioner's claim in the preempted field.**

Id. at 85 (emphasis added).

Within three years of the Court's decision in *Silkwood*, Congress amended the Price Anderson Act to prohibit punitive damages. *See Nieman v. NLO, Inc. et al.,* 108 F.3d 1546, 1550-51 n.5 (6th Cir. 1997) (discussion of 1988 Amendments noting they prohibit punitive damages and create a federal tort remedy). Four years after *Wyeth*, Congress has taken no action to preempt private tort remedies against the pharmaceutical industry. If Congress wished to preempt state law, it knows how to do it and it is to that body that Novartis should direct its arguments.

The *Silkwood* decision is not the only instance in which this Court has rejected the argument that punitive damages for extreme misconduct are

preempted by federal regulation. In *International Union, United Automobile, Aircraft and Agricultural Implement Workers of America (UAW-CIO) v. Russell*, 356 U.S. 634 (1958), a plaintiff prevented from working by the actions, including violence, of strikers sued under Alabama law for compensatory and punitive damages, *id*. at 638, and obtained both. The question presented to the Court was whether the state court's jurisdiction was "pre-empted by Congress and vested exclusively in the National Labor Relations Board." *Id*. at 640. The Court held that the availability of punitive damages under state law did not "alter[ ] rights and duties affirmatively established by Congress." *Id.* at 645. The Court noted that "[p]unitive damages constitute a well-settled form of relief under the law of Alabama when there is a willful and malicious wrong." *Id.* at 646. It noted that the "power to impose punitive sanctions is within the jurisdiction of the state courts but not within that of the Board." *Id.* Justice Warren's dissent stated a parade of horribles that would result from allowing punitive damages, but his concerns were not shared by the Court and have not come to pass. *Id*. at 657-58.

Similarly, in *Exxon Shipping Co. v. Baker*, 554 U.S. 471 (2008), this Court held that punitive damages were not preempted by the Clean Water Act's penalties for water pollution. The Court approved a punitive damages award of over half a billion dollars. *Id*. at 515. The Court stated:

> This concession [that compensatory damages for water pollution were not preempted],

> however, leaves Exxon with the equally untenable claim that the CWA somehow preempts punitive damages, but not compensatory damages, for economic loss. But nothing in the statutory text points to fragmenting the recovery scheme this way, and we have rejected similar attempts to sever remedies from their causes of action.

Id. at 489 (*citing Silkwood*).

Novartis relies on *Heckler v. Chaney*, 470 U.S. 323 (1985), and *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but neither provide support for its argument. In those cases, the plaintiffs sought to create a private right of action under the FDCA or to force a federal agency to perform a discretionary act. Neither case involved a traditional state tort claim, such as presented in this case.

Moreover, Novartis reads *Buckman* far too broadly. There, the cause of action was for "fraud on the FDA." Here, the duty to warn was owed directly to Mrs. Fussman, her oncologists, and dental treaters. The FDA process was explained to the jury – by both parties – to show the ways in which Novartis could have and should have warned, to show what a reasonable company would have done and to show the extent of Novartis' effort to deceive, but the regulatory process was not the basis of a claim. Thus, lower courts in other cases to be remanded from the MDL have explicitly noted that *Buckman* is inapposite. Pet. App. 29a-30a; *see, e.g., Forman v. Novartis Pharmaceuticals Corp.*, 793 F. Supp. 2d 609

(analyzing *Buckman* and concluding that "the Supreme Court has recognized that a punitive damages claim based on traditional state tort law principles does not raise the same concerns as a dispositive fraud-on-the-FDA claim").

Gertz v. Welch, 418 U.S. 323 (1974), another case cited by Novartis, is even less apposite and its citation in this context borders on the bizarre. Libel law touches on core constitutional rights – primarily the right to freedom of the press and of speech. *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964). The specter of punitive damages would chill first amendment rights. Here, no constitutional rights are at issue. Petitioner's assertion (Pet. 24), without citation, that the right to sell pharmaceuticals is a right akin to the right to publish a newspaper or speak on issues of the day is unsupported by case law.

III. The Decision Below Is Fully Consistent With This Court's Precedents. For This Additional Reason, The Petition Should Be Denied.

Petitioner attempts to combine two different lines of cases that neither blend well, nor bear the weight it wishes to put on them. It attempts to use the Court's due process constitutionalization of punitive damages law to note such damages are penal in nature, and then use the regulatory and preemption cases to state that all penal actions against drug companies are encompassed in the FDA statutes and regulations. This conflates two separate

constitutional arguments that no Court has placed together, and in fact, this Court rejected in *English v. General Electric,* 469 U.S. at 83, because to preempt punitive damages on these grounds would also preempt state criminal law. Moreover, as Congress has not preempted the field, the position taken here would risk raising challenges to the "dual sovereignty" approach to double jeopardy not applying to prosecutions by different sovereigns. *U.S. v. Lara,* 541 U.S. 193, 210 (2004) (holding successive prosecution by Federal Government and Indian Tribes was not prohibited as they were separate sovereigns); *Heath v. Alabama*, 474 U.S. 82, 90-91 (1985) (successive prosecution by two different states, like between the Federal Government and a State are not prohibited as they are punishments by different sovereigns for different wrongs) (and cases cited therein).

As noted in *Exxon,* 554 U.S. at 489 this Court has never severed a cause of action and its remedies. There is no need to do so here. North Carolina limited punitive damages so they cannot far exceed compensatory damages – and thus cannot affect the analysis of *Wyeth v. Levine*. *See Rhyne v. K-Mart Corp.*, 149 N.C. App. 672, 690, 562 S.E.2d 82, 95 (2002), *aff'd*, 358 N.C. 160, 594 S.E.2d 1 (2004) (holding that the punitive damages cap under N.C. Gen. Stat. § 1D-25 is constitutional).

Even if North Carolina had not done so, this Court's tests, which place some upper limit on the amount of punitive damages that may be constitutionally acceptable and the circumstances in which

they can be awarded, allow courts to reduce punitive awards for constitutional reasons. The authority vested in lower courts to remit punitive awards, even in the absence of punitive damage caps like the one in effect in North Carolina, significantly reduces any concern such awards would interfere with the FDA's regulatory structure. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 582 (1996) (recognizing that while there is no set formula, a sliding scale may be appropriate when considering the ratio of punitive damages to compensatory damages); *see also State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 425 (2003) (suggesting a single-digit ratio of compensatory to punitive damages is constitutionally reasonable).

Indeed, the award in this case reinforces the federal regulatory scheme, as the deception that caused Mrs. Fussman's injury also violated various federal requirements. *See Riegel v. Medtronic, Inc*., 552 U.S. 312, 330 (2008) (no preemption of claims that parallel federal requirements concerning medical devices); *Bates v. Dow AgroSciences*, 544 U.S. 431 (2005) (state-law duties that parallel federal duties imposed on pesticide manufacturers not preempted); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (same, concerning medical devices).

Novartis made the judgment that because most of the people taking its drug were elderly cancer patients it could cover up the drug's side effects and withstand the compensatory claims of such people, with limited life spans who were usually not working. Punitive damages in this context serve to deter a

company from deciding it can simply do what it likes to vulnerable victims as their compensatory claims will be sustainable. Our system reduces physical injury to monetary numbers. That does not mean that *in reality* to the person affected money can ever be equal to physical injury. Punitive damages serve as pain to a corporate defendant who cannot actually feel real pain.

The Petitioner fails to address the reasons this case is such a poor vehicle for certiorari even if it were otherwise cert-worthy, which it is not. The punitive damages here are less than one million dollars and statutorily bound at three times compensatory damages.

Wyeth v. Levine gave no indication that the size of a compensatory award would change the outcome of the preemption argument. (And indeed, the $7.7 million award in that case was far higher than the award here. *See Wyeth*, 555 U.S. at 562). That being the case, the make up of a judgment including compensatory and punitive elements should make no difference to the outcome.

While Novartis (Pet. at 14-21) makes numerous policy arguments why punitive damages should be forbidden for a federally regulated company, it cites no decision in which that policy issue was resolved based on implied preemption. Novartis makes a policy argument that federal marketing approval immunizes it from a punitive damages award because only the FDA should be able to penalize it for misconduct.

In support of this contention, Novartis cites 21 U.S.C. § 337, but does not explain why that single statute preempts state tort claims, including punitive damage claims. The statute states, in relevant part, "(a) Except as provided in subsection (b) of this section [regarding state enforcement agencies], all such proceedings for the *enforcement*, or to *restrain violations*, of this chapter shall be by and in the name of the United States" (emphasis added). Novartis does not explain why a civil action including a state law punitive damage claim which attempts to punish it for egregious conduct, unrelated to Novartis' interactions with FDA, somehow constitutes an "enforcement" action or is an attempt to "restrain violations" of the FDCA. Moreover, the punitive damage award in the case below is not an attempt to punish Novartis for "its exercise of a right granted under federal law to market a brand name prescription medication," (Pet. at 2), because the suit does not punish Novartis for marketing its drug or prevent Novartis from marketing its drug. This suit is about serious injury sustained by the Fussmans.

Novartis' policy argument is even less convincing than the argument this Court rejected in *Wyeth*, 555 U.S. at 563-64. In *Wyeth*, the drug manufacturer argued (unsuccessfully) that an *affirmative* act by FDA, *i.e.*, the *approval* of a label's contents, foreclosed state tort law claims related to that label. Here, Novartis argues that the *absence of action* by FDA, *i.e.*, the *failure* to seek civil and criminal penalties

against Novartis for its misconduct, forecloses any state tort law actions related to that misconduct. By this logic, any time a federal entity with authority to do so does not seek civil and/or criminal penalties against a company for its misconduct, then states cannot allow a person injured by that company's conduct to assert a claim for punitive damages. Novartis takes a step further by implying that any time a federal agency has the power to enforce its own rules and regulations, any attempt to punish any conduct by an entity regulated by that federal agency through the use of the civil system (even when not related to its dealings with that federal agency) is an impermissible encroachment on federal sovereignty. This proposition lacks merit, would effect a significant policy change, and is properly addressed to Congress. This case is not the appropriate avenue for considering such a rule.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

JOHN J. VECCHIONE