UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 12-1030

HERBERT FUSSMAN, individually and as Administrator of the Estate of Rita Fussman,

Plaintiff - Appellee,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant - Appellant.

Appeal from the United States District Court for the Middle District of North Carolina, at Greensboro. James A. Beaty, Jr., Chief District Judge. (1:06-cv-00149-JAB-PTS)

Argued: December 7, 2012 Decided: February 8, 2013

Before NIEMEYER, KING, and FLOYD, Circuit Judges.

Affirmed by unpublished per curiam opinion.

ARGUED: Bruce Jeffrey Berger, HOLLINGSWORTH, LLP, Washington, D.C., for Appellant. John J. Vecchione, VALAD & VECCHIONE, PLLC, Fairfax, Virginia, for Appellee. **ON BRIEF:** Peter G. Pappas, NEXSEN PRUET, PLLC, Greensboro, North Carolina; Joe G. Hollingsworth, Katharine R. Latimer, Robert E. Johnston, HOLLINGSWORTH, LLP, Washington, D.C., for Appellant. Jodi D. Hildebran, ALLMAN SPRY LEGGETT & CRUMPLER, P.A., Winston-Salem, North Carolina, for Appellee.

PER CURIAM:

In June 2001, upon learning that breast cancer had metastasized to her bones, Rita Fussman (Fussman) began receiving monthly infusions of Aredia, a pharmaceutical drug approved by the Food Drug Administration (FDA) and marketed by New Jersey-based Novartis Pharmaceuticals Corporation. Aredia is a bisphosphonate, a drug designed to prevent the loss of bone mass. Fussman began Aredia infusions at the behest of oncologist Dr. Heather Shaw and continued receiving the drug until November 2001 when Dr. Shaw changed her monthly regimen to infusions of Zometa, another Novartis-marketed, FDA-approved bisphosphonate. With the exception of a one month reprieve, Fussman remained on Zometa until June 2005. Fussman died in 2009.

This diversity action, which Fussman initiated in February 2006, involves a side effect of Aredia and Zometa known as "osteonecrosis of the jaw" (ONJ). ONJ occurs when the gums fail to cover part of the jaw bone and the bone starves and dies from lack of blood. Fussman developed ONJ in March 2003, shortly after having two teeth extracted. Herbert Fussman, individually and as the administrator of the Estate of Rita Fussman, alleges that Aredia and Zometa caused Fussman's ONJ and that Novartis failed to warn adequately either Fussman or Dr. Shaw of the ONJ risk associated with the drugs.

After coordinated Multidistrict Litigation proceedings in the Middle District of Tennessee, the Judicial Panel on Multidistrict Litigation remanded this case to the Middle District of North Carolina for trial. Following a fifteen-day trial, a jury awarded $287,000 in compensatory damages and $12,600,000 in punitive damages to Herbert Fussman as administrator. Additionally, it awarded $1 for loss of consortium to Herbert Fussman individually. Per North Carolina General Statute § 1D-25, the district court reduced the punitive damages award to $861,000. See N.C. Gen. Stat. § 1D-25 ("Punitive damages awarded against a defendant shall not exceed three times the amount of compensatory damages or two hundred fifty thousand dollars ($250,000), whichever is greater."). Thus, the total award, including pre-judgment interest, was $1,258,083.19.

Novartis filed three post-judgment motions: a motion for a new trial, a motion for judgment as a matter of law on all claims, and a motion for judgment as a matter of law on punitive damages. The district court denied all three motions, and Novartis now appeals the denial of its motion for judgment as a matter of law on punitive damages and the denial of its motion for a new trial. It does not appeal the court's denial of its motion for judgment as a matter of law on all claims. For the reasons that follow, we affirm.

I.

We first address Novartis's contention that the district court erred in denying its motion for a new trial. We review a district court's denial of a motion for a new trial for abuse of discretion, United States v. Perry, 335 F.3d 316, 320 (4th Cir. 2003), recognizing that "[u]nder the applicable legal principles, a trial court 'should exercise its discretion to award a new trial sparingly,' and a jury verdict is not to be overturned except in the rare circumstance when the evidence 'weighs heavily' against it," United States v. Smith, 451 F.3d 209, 216–17 (4th Cir. 2006) (quoting United States v. Perry, 335 F.3d 316, 320 (4th Cir. 2003)).

A.

Novartis challenges four of the district court's evidentiary rulings, which we also review under the deferential abuse of discretion standard, King v. McMillan, 594 F.3d 301, 310 (4th Cir. 2010), and overturn only when "arbitrary and irrational," United States v. Blake, 571 F.3d 331, 346 (4th Cir. 2009), and violative of a "party's substantial rights," Fed. R. Civ. P. 61 ("At every stage of the proceeding, the court must disregard all errors and defects that do not affect any party's substantial rights."). Thus, if we conclude that an alleged error would be harmless, we need not conduct additional analysis

to determine whether the district court actually erred. United States v. Banks, 482 F.3d 733, 741 (4th Cir. 2007).

In this case, our review of the evidentiary rulings Novartis cites indicates that none of them, even if erroneous, affected Novartis's "substantial rights." Accordingly, we affirm the district court's denial of Novartis's motion for a new trial on that basis.

E-mails Between Novartis and Drs. Schubert and Ruggiero

In 2004, Novartis published a "white paper" about ONJ. The paper indicated that although "[a] causal relationship between bisphosphonate therapy and osteonecrosis of the jaws ha[d] not been established," a panel of experts had convened "to discuss identification of risk factors" for ONJ, to "develop clinical guidelines for prevention, early diagnosis, management, and multidisciplinary treatment" of ONJ in cancer patients, and to "develop[] recommendations to reduce" ONJ in cancer patients receiving bisphosphonates.

At trial, the district court admitted e-mail conversations that occurred between Novartis and two experts—Dr. Mark Schubert and Dr. Salvatore Ruggiero—during the preparation and editing of the paper. In May 2004, during the final revisions of the paper, an e-mail exchange occurred between Dr. Schubert and Dr. Yong-jiang Hei, Global Medical Director of Novartis. Dr.

Schubert had requested that the following language be included in the paper's "Potential Risk Factors" section:

> While osteonecrosis of the jaws following bisphosphonate therapy has been associated with infection and/or dental surgery, cases of spontaneous osteonecrosis lesions without other apparent risk factors have been observed. Some cases of osteonecrosis of the jaws have been observed after as few as [two] administrations of a bisphosphonate.

Via e-mail, Dr. Hei responded that this language was excluded from the final draft for several reasons, one of which being that the language "implie[d] a degree of understanding of risk factors for osteonecrosis of the jaws that is not warranted in light of the general uncertainties regarding the causality of [the condition]." In a reply e-mail, Dr. Schubert commented at length regarding Novartis's decision not to include his proposed language, and relevant to Fussman's claims stated, "I encourage you to take a bold and honest approach to realistically warn people[,] an[d] this will, in the long run, be the best thing." In a different May 2004 e-mail exchange with Novartis, Dr. Schubert commented on Novartis's decision to include in the paper a long list of risk factors that were "possibly or possibly not related" to ONJ. Schubert stated, "The [inclusion of a] laundry list of factors leading to 'exposed bone' does have the appearance of 'blowing smoke.'" Similarly, in August 2004, Dr. Ruggiero referenced the paper via e-mail, stating that

it was misrepresenting the truth and that "bisphosphonates are the real culprits" behind ONJ.

Novartis contends that the district court erred in allowing Fussman to reference these e-mails because the statements therein were inadmissible hearsay. But we conclude that regardless of whether the district court erred in admitting the e-mails, such admission was harmless because the testimony included in the e-mails was also offered by Dr. Robert Marx, another member of the expert panel who testified at trial.

Dr. Marx testified that when he attended a meeting of the panel in 2004, he brought with him a "Notice of Importance" that he had developed and distributed to oral surgeons and oncologists regarding the relationship of ONJ to Aredia and Zometa. Dr. Marx also testified that his office faxed the Notice to Dr. Peter Tarasoff, a Novartis medical affairs employee. In part, the Notice stated, "The exposed bone in the jaws (either the maxilla or mandible) is directly related to Aredia/Zometa, but may be further contributed to by the primary disease itself, other chemotherapy agents, and steroids such as [D]ecadron." Regarding the white paper, Dr. Marx explained his problems with the paper, stating,

> It was denying any cause-and-effect relationship. . . . [I]t was actually attributing so many things to exposed bone, none of which really did that, that many of us, not just me, objected to the

> written form several times that it was not addressing what we had inputted into the meeting.

He further testified that he communicated his objections to the paper to the Novartis employee who was managing the project: "My recollection is I told him the paper danced around the issue; and that things such as smoking, alcohol drinking, periodontal disease, and a whole host of other possibilities don't cause exposed bone; and to throw it into that framework was misleading to the readership."

In sum, to the extent that the jury concluded that Novartis knew of the ONJ risks associated with bisphosphonates and that it failed to warn of those risks or intentionally concealed those risks, the e-mails from Drs. Schubert and Ruggerio were not the sole cause. Dr. Marx's testimony supported such a conclusion as well. Accordingly, the district court did not err in denying Novartis a new trial based on its admission of the e-mails.

Dr. Lynne McGrath's Testimony

Since October 2005, Dr. Lynne McGrath has been the Vice President of Regulatory Affairs at Novartis. At trial, Novartis elicited testimony from Dr. McGrath regarding the regulatory history of Aredia and Zometa. The court ruled that Dr. McGrath could testify only to information about which she had personal

knowledge, effectively limiting her testimony to post-October 2005 history. In contending that the district court erred in limiting Dr. McGrath's testimony, Novartis maintains that her position as Vice President "required her to have personal knowledge of the full regulatory history of the drug."

Novartis avers that the district court's ruling inhibited the jury from learning "information critical to [its] defense." Specifically, it notes that Dr. McGrath would have testified that (1) Novartis "worked closely with [the] FDA on all of the various label changes and that attention was paid to every word in the label," (2) Novartis "worked aggressively to obtain information from Dr. Marx and even hired a medical records company to assist in the process of collecting medical records," (3) Novartis's Emergency Management team "worked diligently to understand the new side effect, and, within a month of convening [in July 2003], decided to revise the label to reflect the cases of ONJ and began the process of revising the label," (4) "the risk factors listed in the September 2003 label were considered by [Novartis] to be well documented in the general medical literature for osteonecrosis generally, the only available literature at that time," (5) the "FDA simultaneously, looking at the same information, also recognized the propriety of listing the same risk factors," and (6) Novartis "considered label changes very serious matters and worked hard to ensure

that there was a strong basis for what it included in each label change." Additionally, Novartis contends that without the court-imposed limitation Dr. McGrath could have countered Fussman's presentation of the chronology of events, Fussman's implication that Novartis "simply 'chose' not to put necessary safety information into its label," and Fussman's disparagement of the Novartis Emergency Management team.

Once again, we need not determine whether the district court erred in limiting Dr. McGrath's testimony because any such error was harmless. Novartis's regulatory expert, Dr. Janet Arrowsmith, provided the testimony that Novartis maintains Dr. McGrath could have provided. Dr. Arrowsmith indicated that she reviewed "new drug applications for Aredia and Zometa," "notes of meetings between FDA and Novartis," and "notes of advisory boards [and] internal communications within Novartis." She testified, among other things, concerning the details of Novartis's interaction with the FDA; the timing and extent of Novartis's knowledge that bisphosphonates cause ONJ; whether Novartis would have modified the initial label on the drugs had potential cases of ONJ revealed during clinical trials been notated as such; the organization of the Novartis Emergency Management team; the team's decision to modify the drugs' labels in August 2003; and the actual modification of the labels in September 2003. Given the extent of Dr. Arrowsmith's testimony,

we cannot conclude that the district court's limitation of Dr. McGrath's testimony harmed Novartis in a manner that affected its "substantial rights."

Dr. Ruggiero's Testimony

At trial, Fussman repeatedly referenced Dr. Salvatore Ruggiero's research regarding occurrences of ONJ in patients that receive bisphosphonates. It presented an e-mail showing that in April 2002, Dr. Ruggiero queried Dr. Tarrassoff about whether bisphosphonates cause osteonecrosis. It also presented an e-mail indicating that in May 2003, when Dr. Ruggiero attempted to publish a case series regarding ONJ in bisphosphonate patients, Novartis sought to prevent such publication. Using this evidence, Fussman averred that Novartis knew bisphosphonates present ONJ risks and chose not to act on what it knew.

To rebut the implications of Fussman's evidence, Novartis attempted to admit deposition testimony that Dr. Ruggiero had provided in another Aredia and Zometa case. Novartis represented to the district court that in the prior case Dr. Ruggiero had testified that (1) in April 2002, he did not report a case of ONJ to Novartis, and (2) he had "no knowledge of anyone trying to stop him from publishing" his case series. Ultimately, the district court denied the admission of the

deposition, and Novartis now argues that such denial was prejudicial because the "excluded testimony tended to negate key allegations of wrongdoing that Fussman used to support liability and punitive damages." But such is not the case. The excluded deposition testimony would not have helped Novartis to any notable degree.

First, Novartis avows that Fussman repeatedly claimed that Dr. Ruggiero reported cases of ONJ to Novartis in April 2002. But our review of the record reveals that Fussman in fact did not make such a claim. Rather, Fussman merely repeated what the evidence demonstrated—that in April 2002, Dr. Ruggiero asked Dr. Tarasoff if bisphosphonates cause osteoneocrosis. Fussman did not present evidence that Dr. Ruggierio reported specific ONJ cases. Thus, although Novartis contends that Dr. Ruggerio's testimony from the prior case would have undermined Fussman's claims, his deposition would have simply contradicted an argument that Fussman never pressed—namely, that Dr. Ruggiero reported cases of ONJ to Novartis in April 2002.

Similarly, Dr. Ruggiero's testimony—that he did not know Novartis attempted to prevent publication of his case series—would have failed to contradict effectively Fussman's evidence that Novartis had indeed engaged in such conduct. Simply put, one would not expect that Novartis would notify Dr. Ruggiero of its own suppression attempts. It is unsurprising that Dr.

Ruggerio was unaware of Novartis's actions, and evidence supporting this fact would not have advanced Novartis's defense. Hence, given the harmlessness of any district court error, we again affirm the district court's denial of Novartis's motion for a new trial.

Evidence of 2007 Zometa Label Revision

In pertinent part, Zometa's 2003 label included the following paragraph:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies . . . , to patient's underlying disease, or to other comorbid risk factors . . . .

In 2007, Novartis revised this portion of the label so that it stated the following:

> Cases of osteonecrosis (primarily involving the jaws) have been reported predominantly in cancer patients treated with intravenous bisphosphonates including Zometa. Many of these patients were also receiving chemotherapy and corticosteroids which may be a risk factor for ONJ. Data suggests a greater frequency of reports of ONJ in certain cancers, such as advanced breast cancer and multiple myeloma. The majority of the reported cases are in cancer patients following invasive dental procedures, such as tooth extraction. It is therefore prudent to avoid invasive dental procedures as recovery may be prolonged . . . .

Prior to trial, Novartis moved to exclude evidence of the 2007 revision, maintaining that the revision constituted a

subsequent remedial measure. See Fed. R. Evid. 407 ("When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove: negligence[,] culpable conduct[,] a defect in a product or its design[,] or a need for a warning or instruction."). Although the district court granted Novartis's pre-trial motion, it reversed course at trial and allowed Fussman to cross-examine Dr. Arrowsmith regarding the label changes. Additionally, it allowed Fussman to reference the revision during closing argument.

To the extent that the district court erred in admitting evidence of the 2007 label revision, such error did not prejudice Novartis. Evidence of the revision was relevant to Novartis's awareness of the dangers of Zometa and to whether Zometa caused Fussman's ONJ. Given that Fussman presented extensive evidence apart from the 2007 label change that supported both of these claims, we cannot conclude that admission of the label change "substantially swayed" the jury's verdict. Thus, once again, we conclude that the district court did not err in denying Novartis a new trial on such a basis.

B.

Novartis also contends that the district court's denial of two of its requested punitive damages jury instructions merited

a new trial. We review jury instructions "holistically and through the prism of the abuse of discretion standard." Noel v. Artson, 641 F.3d 580, 586 (4th Cir. 2011). We must "simply determine 'whether the instructions construed as a whole, and in light of the whole record, adequately informed the jury of the controlling legal principles without misleading or confusing the jury to the prejudice of the objecting party.'" Id. (quoting Bailey v. Cnty. of Georgetown, 94 F.3d 152, 156 (4th Cir. 1996)). A party challenging a jury instruction "faces a heavy burden, for 'we accord the district court much discretion to fashion the charge.'" Id. (quoting Teague v. Bakker, 35 F.3d 978, 985 (4th Cir. 1994)). Indeed, we will reverse a district court for declining to give a requested instruction "only when the requested instruction '(1) was correct; (2) was not substantially covered by the court's charge to the jury; and (3) dealt with some point in the trial so important, that failure to give the requested instruction seriously impaired' that party's ability to make its case." Id. (quoting United States v. Lighty, 616 F.3d 321, 366 (4th Cir. 2010)).

Novartis challenges the district court's denial of Requested Jury Charge No. 37, which states:

> In making your determination of punitive damages in this case, you cannot consider any conduct occurring outside the state of North Carolina.

> In making your determinations of punitive damages, you may not consider any harm that may have been done to any other individual not in this case.
>
> Thus, in making your determinations of punitive damages in this case, you can only consider profits derived by [Novartis] from the state of North Carolina during the years of Mrs. Fussman's use.

It also challenges the denial of Requested Jury Charge No. 43, which states, "The law prohibits imposing punitive damages based on any corporate misconduct that did not specifically harm Mrs. Fussman."

Novartis avers that it requested these charges to guard against the risk that the jury would award damages to Fussman for harm that other individuals suffered. And Novartis maintains that such a risk was concrete because Fussman presented evidence that other individuals developed ONJ after they had been treated with Aredia and Zometa; questioned a Novartis expert about his diagnosis of a Tennessee woman who allegedly developed ONJ after using Aredia; and discussed total Zometa sales across the United States in 2005 and 2009. Citing Philip Morris USA v. Williams, 549 U.S. 346 (2007), Novartis urges that the "Due Process Clause precludes a jury from punishing for 'the harm caused to others,'" and that therefore, "when asked, the district court is required to provide a jury instruction that protects against the risk that punishment will be meted out for harm done to others." We conclude, however,

that the district court did not abuse its discretion in declining to give the charges Novartis requested.

First, Requested Jury Charge No. 37 is incorrect. Although Novartis accurately states that "the Constitution's Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties or those whom they directly represent, i.e., injury that it inflicts upon those who are, essentially, strangers to the litigation," id. at 353, Novartis fails to recognize that due process does allow reference to and consideration of nonparty injuries as evidence of reprehensibility, id. at 355 ("Evidence of actual harm to nonparties can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public, and so was particularly reprehensible . . . ."). Thus, Requested Jury Charge No. 37's counsel not to consider any harm inflicted on any nonparty or any conduct that occurred outside of North Carolina is improper, and the district court appropriately declined to instruct the jury in this manner.

Second, Requested Jury Charge No. 43 was "substantially covered" by the district court's actual charge. Instead of the language that Novartis requested, the court gave the following punitive damages instruction:

> In making [a] determination [as to punitive damages], you may consider only that evidence which relates to the following: the reprehensibility of the

> Defendant's motive and conduct, if you have so found; the likelihood at the relevant time of serious harm to Ms. Fussman; the degree of the Defendant's awareness of the probable consequences of its conduct; the duration of the Defendant's conduct; the actual damages suffered by Ms. Fussman; any concealment by the Defendant of the facts or consequence[s] of its conduct; the existence and frequency of any similar past conduct by the Defendant, if you so find; whether the Defendant profited by the conduct.

We believe that when the court admonished the jury to "consider only" evidence connected to reprehensibility and evidence of "actual damages suffered by Ms. Fussman," it sufficiently dealt with the risk that Requested Jury Charge No. 43 presumably sought to guard against—namely, that the jury would award damages for harm suffered by "strangers to the litigation." Id. at 353. Thus, we also affirm the district court's decision not to give Novartis's Requested Jury Charge No. 43.

In sum, as to the evidentiary rulings Novartis contests, we hold that any errors by the district court were harmless. And as to Requested Jury Charges Nos. 37 and 43, we hold that the district court did not abuse its discretion in declining to give these charges. Accordingly, we affirm the district court's denial of Novartis's motion for a new trial.

II.

We next address the district court's denial of Novartis's post-trial motion for judgment as a matter of law on punitive

damages. "We review de novo a district court's denial of a Rule 50 motion for judgment as a matter of law." Lack v. Wal-Mart Stores, Inc., 240 F.3d 255, 259 (4th Cir. 2001). "If, viewing the facts in the light most favorable to the non-moving party, there is sufficient evidence for a reasonable jury to have found in [Fussman's] favor, we are constrained to affirm the jury verdict." Id.

A.

In its motion, Novartis argued (1) that the evidence of its misconduct suggests negligence, not willful or wanton conduct as required under North Carolina law to support a punitive damages award and (2) that evidence of its suppression of medical information regarding ONJ cannot support a punitive damages award because Fussman failed to demonstrate a causal nexus between Novartis's acts and her harm. We disagree.

First, Fussman presented evidence showing that Novartis's high-ranking officials knew about the drugs' side effects and subverted medical inquiries into such effects. This evidence provided a sufficient foundation for the jury to determine that Novartis's actions were willful, not simply negligent. And second, Fussman presented evidence sufficient to support a determination that Novartis's acts proximately caused her ONJ. Fussman's deposition testimony, taken before her death and

presented at trial, indicated that she would not have taken Aredia and Zometa if she had known the drugs' risks. Indeed, evidence presented at trial indicated that Fussman stopped taking the drugs once she knew their hazards. Moreover, although Dr. Shaw testified that she would have continued Fussman's treatments even if she had known that ONJ was a possibility, the jury could have determined from other evidence that Dr. Shaw would have modified various aspects of Fussman's treatment had she been adequately warned of the drugs' perils.

We have simply sampled the record here. But the trial proceedings and the whole of the evidence that Fussman supplied to this Court bely a conclusion that insufficient evidence supported the jury's punitive damages award. Thus, we affirm the district court's denial of Novartis's motion for judgment as a matter of law on this basis.

B.

We also affirm the district court's denial of Novartis's motion for judgment as a matter of law on a preemption theory. Novartis contends that the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399, preempts the jury's award of punitive damages because the Aredia and Zometa labels complied with FDA regulations and the FDA has exclusive authority to

enforce the labeling requirements of the FDCA. Once again, we disagree.

In no uncertain terms, the Supreme Court has dictated that the FDCA does not preempt state law claims against a drug company whose drug label complies with FDA regulations. Wyeth v. Levine, 555 U.S. 555, 581 (2009). In Wyeth v. Levine, the Court examined the history of the FDCA and Congress's intent in enacting the statute. The Court noted that in spite of Congress's "certain awareness of the prevalence of state tort litigation," it declined to expressly preempt state law failure-to-warn claims for prescription drugs. Id. at 575 ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.") (alteration in original) (quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 166–67 (1989) (internal quotation marks omitted)). Congress's silence on the matter was notable, the Court reasoned, because in another context—i.e., medical devices—it had amended the FDCA to include an express preemption provision. See Pub. L. No. 94-295, § 521, 90 Stat. 574 (1976) (codified at 21 U.S.C. § 360k); Wyeth, 555 U.S. at 567.

Here, Novartis seeks to carve out a niche in existing precedent by arguing that Wyeth is inapplicable because it does not expressly reference punitive damages. But Novartis fails to put forth any logical reason why the basis for the Court's decision in Wyeth should not equally apply to claims involving punitive damages. Novartis argues that the FDCA preempts the recovery of punitive damages because (1) the purpose of punitive damages is to punish and deter, something the FDA has "ample power" to accomplish through enforcement of labeling requirements and (2) allowing the punishment of FDA-approved conduct is improper. 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. Thus, we affirm the district court's denial of Novartis's motion for judgment as a matter of law on this basis as well.

III.

For the foregoing reasons, we affirm the judgment of the district court.

AFFIRMED