IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

DOUGLAS M. RAY, JR.,

Plaintiff,

v. Civil Action No. 3:10CV136

ALLERGAN, INC., et al.,

Defendants.

MEMORANDUM OPINION

This matter is before the Court on DEFENDANT'S RULE 59 MOTION FOR A NEW TRIAL (Docket No. 227), filed by Defendant Allergan, Inc. ("Defendant" or "Allergan").[1] For the reasons set forth below, DEFENDANT'S RULE 59 MOTION FOR A NEW TRIAL (Docket No. 227) will be granted.

BACKGROUND

1. Factual Background

Plaintiff, Douglas M. Ray, Jr. ("Plaintiff" or "Ray"), filed this action against Allergan after he received three BOTOX® injections between January through July 2007 to treat a dystonic movement disorder of his right hand. Am. Compl. ¶ 2. Allergan manufactured, tested, marketed, and sold BOTOX®, a drug first approved by the United States Food and Drug Administration ("FDA") in 1989. Amended Final Pretrial Order, Stipulated Facts

[1] The other Defendant, Allergan USA, Inc., was dismissed with prejudice on the Plaintiff's oral motion to dismiss on April 26, 2011.

¶ 3 (Docket No. 164); Am. Compl. at ¶ 6. Ray received BOTOX® injections on three dates: January 10, 2007, April 3, 2007, and July 17, 2007. Amended Final Pretrial Order, Stipulated Facts ¶¶ 5, 6 & 7; Am. Compl. at ¶ 18. Ray alleges that he sustained a severe reaction to the BOTOX® that required hospitalization and left him totally disabled. Id. at ¶ 2. Allergan contends that Ray's injuries are due to a pre-existing neurodegenerative condition. Amended Final Pretrial Order, Stipulated Facts ¶ 9.

2. Procedural Background

This action initially was filed in the Circuit Court of the City of Richmond and thereafter removed to federal court on March 3, 2010. The Amended Complaint was filed on December 9, 2010 (Docket No. 52), and a jury trial was scheduled to begin on April 18, 2011. The Amended Complaint included six claims: product liability/failure to warn; product liability/manufacturing defect; negligence; breach of implied warranty; breach of express warranty; and negligent misrepresentation. The jury was selected on April 18, 2011, trial began on April 21, 2011, and, on that date, pursuant to the representations of Ray's counsel, the Court dismissed with prejudice all claims in the Amended Complaint with the exception of the negligent failure to warn claim. See Order, April 21, 2011 (Docket No. 173).

At the end of the Plaintiff's case, Allergan moved for judgment as a matter of law (Docket Nos. 189 & 190), and, for the reasons stated on the record, the motion was denied. The jury

returned a verdict in favor of Ray, awarding compensatory damages in the sum of $12,000,000 and punitive damages in the sum of $200,000,000. Jury Verdict, April 28, 2011 (Docket No. 203). The punitive damage award was reduced to $350,000, the maximum punitive award allowed by Virginia law. Order, April 29, 2011 (Docket No. 207).

On May 27, 2011, Allergan filed DEFENDANT'S RULE 59 MOTION FOR A NEW TRIAL (Docket No. 227). Responses and replies were filed. Thereafter, the Court ordered supplemental briefing (Docket No. 240) on the motion for a new trial. The supplemental briefs have been filed, and the motion is ripe for decision.

LEGAL STANDARDS

A motion for new trial may be granted, "after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). A new trial is to be granted under Rule 59(a) if: "(1) the verdict is against the clear weight of the evidence, or (2) is based upon evidence which is false, or (3) will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict." Cline v. Wal-Mart Stores, Inc., 144 F.3d 294, 301 (4th Cir. 1998) (citing Poynter v. Ratcliff, 874 F.2d 219, 223 (4th Cir. 1989)) (quoting Atlas Food Sys. & Servs., Inc. v. Crane Nat'l Vendors, Inc., 99 F.3d 587, 594 (4th Cir. 1996)).

> Although a comprehensive list of the grounds for granting a new trial is elusive, the Supreme Court has held that a motion for a new trial may rest on the fact that "the verdict is against the weight of the evidence, that damages are excessive, or that, for other reasons, the trial was not fair to the party moving; and may raise questions of law arising out of alleged substantial errors in admission or rejection of evidence or instructions to the jury."

Alphamed Pharmaceuticals Corp. v. Arriva Pharmaceuticals, Inc., 432 F. Supp. 2d 1319, 1334 (S.D. Fla. 2006) (quoting Montgomery Ward & Co. v. Duncan, 311 U.S. 243, 251 (1940)). The granting or denial of a motion for a new trial under Rule 59(a) "is a matter resting in the sound discretion of the trial judge." Wadsworth v. Clindon, 846 F.2d 265, 266 (4th Cir. 1988) (citing Old Dominion Stevedoring Corp. v. Polskie Linie Oceaniczne, 386 F.2d 193 (4th Cir. 1967)). "In reviewing a grant or denial of a new trial, the crucial inquiry is 'whether an error occurred in the conduct of the trial that was so grievous as to have rendered the trial unfair.'" Bristol Steel & Iron Works v. Bethlehem Steel Corp., 41 F.3d 182, 186 (4th Cir. 1994)(citing DMI, Inc. v. Deere & Co., 802 F.2d 421, 427 (Fed. Cir. 1986)).

DISCUSSION

Allergan argues that a new trial is warranted because: (1) the verdict is against the clear weight of the evidence; (2) Allergan was substantially prejudiced by errors related to the admission of evidence, the questioning of witnesses, and instructions given to the jury, as well as improper argument by

Ray's counsel; and (3) enforcement of the judgment would otherwise result in a miscarriage of justice.

As it is wont to do, Allergan advances many grounds for a new trial, and, as is so often the case, most of them lack merit. But, the plea for a new trial is really focused on the core of any failure to warn claim: the nature and extent of the warning itself, and that ground is a serious one.

At the heart of Allergan's argument is the assertion that, on that core issue, the trial was unfair. In particular, Allergan argues that it was prejudiced by "improper questioning and [closing] argument concerning the unilateral addition of a boxed warning or other bold, prominent warning at the top of the label, and the Court's erroneous jury instructions emphasizing the same." Def.'s Mem. Supp. at 2 (Docket No. 228).

Allergan also contends that other aspects of the Plaintiff's closing argument warrant a new trial. Specifically, Allergan takes the view that Ray's counsel: (1) violated the prohibition against invoking the so-called "Golden Rule principle, thereby running afoul of the decision in Leathers v. General Motors Corp., 546 F.2d 1083 (4th Cir. 1996); and (2) erroneously asked the jury to impose punitive damages because the conduct that injured Ray also injured third-parties, thereby offending the principle made clear in Phillip Morris USA v. Williams, 549 U.S. 346 (2007).

1. THE SO-CALLED "BLACK BOX WARNING" ISSUE

From the outset of the case, Ray took the view that Allergan should have used what is often referred to as a "black box warning" to alert physicians to the risk that BOTOX® could migrate to the central nervous system, including the brain, and cause damage there. The term "black box warning" often is used to describe a warning in bold type that is circumscribed, and thus emphasized, by a bold black rectangle which houses the warning. The applicable regulations and some decisions also call this a "boxed warning." This opinion will use both terms interchangeably.

At the urging of Allergan, the Court, at trial, concluded that, under the applicable FDA regulations, Allergan could not have used a black box warning without prior approval of the FDA. However, the Court also concluded, over Allergan's objection, that Allergan was free to approach the FDA to request permission to use a black box warning. Thus, Ray's counsel was allowed to question some Allergan witnesses respecting whether Allergan could have approached the FDA about placing a black box warning on the BOTOX® package inserts, i.e. the BOTOX® warnings that accompany the product.

As will be explained in further detail later, one of those witnesses, Dr. Mitchell Brin, Allergan's Senior Vice President and Chief Scientific Officer, testified that Allergan could not "go to the FDA and say we'd like to add this [information about

BOTOX®] as a black box warning." Trial Tr. 615:5-7. There followed more examination about "black box warnings." Outside the presence of the jury, the issue was debated by counsel, and the Court concluded that Dr. Brin was in error on the point and so instructed the jury with the caveat that further instruction would follow later.[2]

At the jury charge conference, the Court held that, if Ray was to argue that Allergan should have approached the FDA about adding a black box warning, the jury had to be informed as well that Allergan could not have added such a warning without the FDA's prior approval. Ray's counsel decided not to make that argument, and advised that he would argue only that Allergan should have issued a prominently situated, adequately informative warning. See Trial Tr. 1521-1523.

In making his closing argument, Ray's counsel said, inter alia:[3]

- "It should have been very **prominently displayed right up front in the label**, where no one could miss it." (Trial Tr. at 1559:24-1560:1)

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[2] Allergan contends that this instruction was in error. As explained elsewhere, that argument is rejected because no FDA regulation would have kept Allergan from approaching the FDA and asking to use a black box warning respecting the spread of BOTOX® to the central nervous system.
Nor is there merit to Allergan's contention that, in giving the instruction, the Court branded Dr. Brin as not credible. The Court merely corrected an erroneous legal assertion made by Dr. Brin.

[3] The emphasis is added.

- "Well, the United States label is a local label and guess what's in section 6 through 15, spread of toxin warning with a **big, bold heading**, but it wasn't in the United States label." (Id. at 1560:12-15);

- "Now, let's talk about the issue of **prominence**. . . . If you've got something serious to warn them about, don't bury it in the fine print on page 3. **Put it right up front in big, bold letters. That's the law and they didn't do it.**" (Id. at 1560:18-1561:4);

- "If there's a serious risk, you need to **put it somewhere prominent** and they didn't do that here, by design." (Id. at 1561:23:25);

- "We know that billions of dollars are at stake, and we heard the vice president of sales tell us what our common sense already knew and that is having a **prominent warning about serious adverse events and deaths right up at the beginning of your label** where everybody could see it, . . . that's not good for sales." (Id. at 1565:24:1566:6).

At the same time, Ray's counsel made gestures with his hands that Allergan says were representative of a box. The arguments, alone, and the gesture and the arguments combined, lie at the core of Allergan's new trial motion.

However, Allergan's argument is not confined to the position that Ray erroneously argued for a black box warning. Allergan also contends that Ray could not even argue for a prominently displayed warning of any type.

Those arguments and the issue about what warnings - whether a black box or otherwise prominent - must be resolved in perspective of what the applicable FDA regulations say about

warnings because Ray cannot be heard to advance a theory of adequate warnings that contravenes what the FDA has said on the matter. That necessitates an objective examination of the applicable regulations (which are quite cumbersome). Regrettably, neither party has been either careful or objective in undertaking that task.

A. The Labeling Regulations

BOTOX® is a biological product, also referred to as a biologic, pursuant to 42 U.S.C. § 262(i).[4] "The term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein . . . , or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i)(1)(2012).[5] The distribution and sale of both prescription drugs and biologics is regulated by the FDA under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, et seq. and related regulations. The FDA regulates the content of the label, the order in which the label is formatted, and the mechanisms by which label changes can be made. See 21 C.F.R. §§ 201.56 & 201.57 (effective June 30, 2006) (dealing with drugs and biologics), § 601.12 (effective June 30,

[4] The term "biologic" is used to differentiate biological products from prescription drugs.

[5] The definition in effect in 2006 and 2007 was almost identical. See 42 U.S.C. § 262(i)(effective Dec. 3, 2003 to Sept. 27, 2007 and dates thereafter).

2006 to December 27, 2007)[6](dealing with changes regarding biologics), and § 314.70 (effective June 30, 2006 to December 27, 2007)[7] (dealing with changes regarding drugs).

Boxed warnings were created in 1979 by the FDA as a way to address special problems of the most serious nature - those that may lead to death or serious injury. "Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. . . . If a boxed warning is required, its location shall be specified by the Food and Drug Administration." 21 C.F.R. § 201.80(e)(effective June 30, 2006); see also § 201.57(c)(1)("Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box.") (effective June 30, 2006).

During the comment period in 1979, the FDA was asked whether a manufacturer could include a boxed warning without first securing approval of the FDA and whether the FDA would consider the manufacturer's desires when specifying the location of boxed warnings. 44 Fed. Reg. 37,434, 37,448 (June 26, 1979). The FDA responded that "to ensure the significance of boxed warnings in drug labeling, they are permitted in labeling only when

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[6] The current version of this regulation went into effect on November 18, 2008.

[7] The current version of this regulation went into effect on September 22, 2008.

specifically required by the FDA. The labeler's desires about location and wording of boxed warnings, however, will be considered." Id.; see also Lars Noah, *The Imperative to Warn: Disentangling the 'Right to Know' from the 'Need to Know' about Consumer Product Hazards*, 11 Yale J. Reg. 293, 328 (1994)(quoting 44 Fed. Reg. 37,434, 37,448 (1979)). However, the Final Rule and the regulations state that: "[i]f a boxed warning is required, its location will be specified by the Food and Drug Administration." 44 Fed. Reg. at 37,463. See also 21 C.F.R. § 201.80(e)(effective June 30, 2006).

In 2006, the FDA revised the requirements for the content and format of labeling, and the new regulations became effective on June 30, 2006. The most significant of these revisions created a "Highlights of Prescribing Information" section ("Highlights") at the top of the label where key information was to be displayed. 21 C.F.R. § 201.57(a) (effective June 30, 2006). However, the regulations applied the new labeling requirements only to new and recently approved drugs and biologics according to a staggered implementation schedule. 71 Fed. Reg. 3922, 3961 (Jan. 24, 2006); 21 C.F.R. § 201.56(c) (effective June 30, 2006). Thus, for certain products,[8] the pre-June 2006 labeling requirements continued to apply. However,

[8] The old requirements continued to apply to products with a new drug application (NDA), a biologics license application (BLA), or an efficacy supplement (a new indication of a previously approved drug) that was approved before June 30, 2001.

even for those products, conforming labeling could be submitted to the FDA for approval at any time after June 2006. 71 Fed. Reg. at 3962 ("[M]anufacturers of older products not covered by the implementation plan may voluntarily revise, and submit for review, labeling for their products in the new format *at any time.*") (emphasis added). For other products, the new (June 2006) requirements applied but were not effective immediately.[9] Instead, implementation of the new requirements was phased in over time.[10]

The staggered implementation schedule notwithstanding, there is nothing in the statute or the regulations that prevents a manufacturer from submitting proposed labeling before the date by which it must be submitted. Moreover, the Federal Register that accompanied issuance of the 2006 regulations says the following about the manufacturers' responsibility:

> While the [FDA] will not require a systematic evaluation of all existing labeling to identify unsubstantiated claims within 1 year of the effective date of the final rule, the [FDA] wishes to make it clear that

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[9] This delayed effectiveness applied to products with NDAs, BLAs, or efficacy supplements that were approved on or after June 30, 2001 but before June 30, 2006.

[10] For example, for applications approved one to two years before June 30, 2006, the date by which conforming labeling must be submitted to the FDA for approval was June 30, 2010. 71 Fed. Reg. at 3928 (Table 5). For applications approved two to three years before June 30, 2006, the date by which conforming labeling must be submitted to the FDA for approval was June 30, 2011. Id. For products with NDAs, BLAs, or efficacy supplements submitted for approval on or after June 30, 2006, the new labeling requirements applied immediately.

> manufacturers have an ongoing obligation to ensure that claims in labeling have adequate substantiation and are not false or misleading. When new information comes to light that causes information in labeling to become inaccurate, manufacturers must act to change the content of their labeling, in accordance with §§ 314.70 and 601.12 . . . . To clarify this obligation, the agency has revised § 201.56 to specify that manufacturers must act to correct labeling that, in light of new information, has become inaccurate (see § 201.56(a)(2)).

71 Fed. Reg. at 3962 (emphasis added).

B. The Allergan Labeling And The Regulations

According to Allergan, the FDA approved an efficacy supplement for BOTOX® on July 19, 2004. See Def.'s Supplemental Mem. Supp., Exhibit 4, at 19. Thus, says Allergan, BOTOX® was subject to the labeling requirements in § 201.56(d) and § 201.57 (the Highlights requirements) according to the schedule in § 201.56(c), which required, under (c)(3), that Allergan submit proposed labeling that conformed to the new requirements no later than June 30, 2010. Until that date, Allergan argues in its supplemental brief, the BOTOX® label was subject to the old labeling requirements, which now appear in § 201.80. [11] The best view of the record and the regulations is that the BOTOX® label remained subject to the pre-2006 labeling requirements during the period that is relevant in this case (before July 2007 when Ray received the last of three BOTOX® injections).

[11] In its previous briefs and during the charge conference, Allergan cited the new regulations and argued that they, not the old regulations, applied.

The pre-2006 regulations specified, in broad terms, the topics that were to be included in the product labels and the order in which the information about those topics must appear. 21 C.F.R. § 201.57 (effective to June 29, 2006) ("Each section heading [topic] listed in § 201.56(d) . . . shall contain the following information in the following order.")[12] The specified topics and the specified order of appearance were:

Description
Clinical Pharmacology
Indications and Usage
Contraindications
Warnings
Precautions
Adverse Reactions
Drug Abuse and Dependence
Overdosage
Dosage and Administration
How Supplied
Animal Pharmacology and/or Animal Toxicology
"Clinical Studies" and "References"

Thus, the FDA regulations that governed Allergan's obligations respecting labeling for BOTOX® would not allow Allergan unilaterally to have placed a boxed warning at the top of the page without the FDA's approval. However, nothing in the regulations prohibited Allergan from approaching the FDA to suggest use of a boxed warning. Nor did the regulations prohibit the placement of an adequate and informative warning in the "Warnings" section, in the "Adverse Reactions" section, or in both sections. Indeed, the regulations specifically contemplate changing the labeling if, and as, information comes to light that

[12] The June 2006 regulation contained the identical requirement. 21 C.F.R. § 201.80 (effective June 30, 2006).

make an existing label misleading. And, certainly, information about a newly-known, extremely serious adverse reaction would fit that description. Nor would anything in the applicable FDA regulations have prohibited Allergan from using bold type or spacing to give the new warning prominence.[13]

The regulations governing Allergan's obligation respecting changes in warnings did not require Allergan to obtain the FDA's approval to "add [to] or strengthen a contraindication, warning, precaution or adverse reaction." Changes of that sort could be made under what are known as FDA's "changes being effected" ("CBE") regulations. To make such a change, Allergan simply had to notify the FDA of a change by submitting a supplemental application that the change was being made (or "effected"). 21 C.F.R. § 601.12(f)(2).[14] Although Allergan is correct in contending that the CBE process could not be used to add a black box warning, that does not mean that the CBE process could not have been used to change other sections of the labeling.

Indeed, a principal purpose of the labeling regulations is to get warnings and adverse reaction information into the hands of prescribing physicians promptly. For example, the FDA

[13] The regulations that went into effect in June 2006 contained "format" provisions (including some related to bold type, spacing, bullet points, and type size). 21 C.F.R. § 201.57(d)(effective June 30, 2006). But, of course, Allergan no longer considers the post-June 2006 version of the regulations to be controlling.

[14] Of course, if after having been notified of the change, the FDA had decided it should not have been made, the FDA could require corrective action.

regulations (before and after June 2006) make clear that "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not be established." 21 C.F.R. §§ 201.57(e) (pre-June 30, 2006) and 201.80(e) (June 30, 2006) (emphasis added).

Contrary to Allergan's position, the pre-2006 regulations did not require FDA approval to issue a so-called "Dear Doctor letter" informing the medical profession of possibly harmful adverse effects associated with the use of a drug. For example, the rules published in 1979 contain the following prefatory text:

> [The FDA regulations] do not prohibit a manufacturer . . . from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered. The addition to labeling and advertising of additional warnings, as well as contraindications, adverse reactions, and precautions regarding the drug, or the issuance of letters directed to health care professionals (e.g., "Dear Doctor" letters containing such information) is not prohibited by these regulations.

44 Fed. Reg. at 37,447 (emphasis added). As will be explained elsewhere, the decision in PLIVA, Inc. v. Mensing, __ U.S. __, 131 S. Ct. 2567 (2011), does not alter that precept.

C. The Questioning, The Closing Arguments, and The Instructions

The problem that led to the present state of affairs came into sharp focus during the questioning of Allergan's Dr. Mitchell Brin. When called in Plaintiff's case-in-chief, Dr.

Brin was questioned about a Dear Doctor letter that Allergan had sent in Europe in June 2007, warning about the possible spread of BOTOX® in the central nervous system. Dr. Brin then was asked: "Would it have been feasible to add this [referring to the warning in the confidential core data sheet] as a black box warning to the United States label in the first half of 2007?" After an objection was overruled, Dr. Brin answered: "Not as a unilateral activity, no." The Court asked: "What does that mean?" Dr. Brin answered: "In other words, we can't just go to the FDA and say we'd like to add this as a box warning. Box warnings are heavily regulated by the agencies, so the answer is no." The Court then asked: "You can't go to the FDA and say we want to add this as a label, black box label? You can't do that?" Dr. Brin answered: "I'd have to check, I'm not a regulatory expert on this. I guess it's possible, but I've never heard of it." The Court then asked: "Well, the question is could you do it? Not whether it's possible or not, but his question is could you do it? Could you have done it in 2007?" Dr. Brin responded: "Well, again, not being an expert in it." The Court directed: "Just give us your view as opposed to being an expert. That's what he wants, I think." Dr. Brin: "I think it's feasible."

After discussing this matter with counsel outside the presence of the jury, but still during Dr. Brin's testimony, the Court instructed the jury:

> Just to clear one thing up, Dr. Brin made a statement about what he thought the company could have done about getting a label changed and said he didn't think that the FDA [sic] could do it without the FDA's approval. I will tell you that that isn't correct and give you some more definition and instruction on that at a later, a fuller instruction at a later time.

Trial Tr. 654:21-655:3.

The topic of approaching the FDA about adding a black box warning came up again in the jury charge conference. Ray's counsel was informed that, if he argued that before Ray was injected Allergan could have asked the FDA to allow a black box warning about the risk of the spread of BOTOX® to the central nervous system (similar to the European Dear Doctor letter), the jury would be instructed that the black box warning could not be used without prior FDA approval. Whereupon, Ray's counsel advised that he would not argue that Allergan should have suggested to the FDA a black box warning be approved. He would instead argue that Allergan should have issued a prominently presented warning about the risk that BOTOX® could spread from an injection in a muscle to the central nervous system.

In the closing argument, Ray's counsel made several points about the warning that Allergan could have, and should have, made. He said:

- "It should have been very **prominently displayed right up front in the label**, where no one could miss it." (Trial Tr. at 1559:24-1560:1)

- "Well, the United States label is a local label and guess what's in section 6 through 15, spread of toxin warning with a **big, bold heading**, but it wasn't in the United States label." (Id. at 1560:12-15);

- "Now, let's talk about the issue of **prominence**. . . . If you've got something serious to warn them about, don't bury it in the fine print on page 3. **Put it right up front in big, bold letters. That's the law and they didn't do it.**" (Id. at 1560:18-1561:4);

- "If there's a serious risk, you need to **put it somewhere prominent** and they didn't do that here, by design." (Id. at 1561:23:25);

- "We know that billions of dollars are at stake, and we heard the vice president of sales tell us what our common sense already knew and that is having a **prominent warning about serious adverse events and deaths right up at the beginning of your label** where everybody could see it, . . . that's not good for sales." (Id. at 1565:24:1566:6).

While these points were being made, Ray's counsel repeatedly made hand gestures that, according to Allergan, described a box. Allergan objected at the time, but not having seen the gestures, the Court overruled the objection and gave the jury no instruction limiting the text of the argument to the prominence of the warning or dispelling any suggestion that a black box warning could have been issued unilaterally by Allergan. A review of the courtroom security videotape, although not definitive on the point, teaches that such an instruction should have been given because, in the context of the words used by Ray's counsel, the jury could have concluded that counsel was

arguing that a black box warning should have been given without having the jury also informed that such a warning would have required prior FDA approval.

An instruction that was given in the final charge to the jury then exacerbated the confusion over the propriety of a black box warning. Instruction No. 26 told the jury:

> A drug manufacturer, I tell you, may change its label to add or strengthen a warning without waiting for the approval of the change by the Food and Drug Administration. That is because it is the obligation of the manufacturer to publish an adequate warning and to ensure that its warnings remain adequate as long as the drug is on the market.

Trial Tr. 1653:3-10.

Taken as a whole, the way evidence came in about the black box warning,[15] the closing argument of Ray's counsel, and the instruction allowed the jury to assess the failure to warn claim in an incorrect way, influenced by improper argument. Given the text of Ray's closing argument and the nature of the accompanying hand gestures, and in perspective of the questioning of Dr. Brin about a black box warning and the verbal instruction given to the jury during that testimony, the jury should also have been told in the final charge that Allergan could not have added a black

[15] It is not necessary now to decide the extent which Ray was entitled to inquire about whether Allergan could have approached the FDA about a black-box warning. For now, it will be assumed that such inquiry was appropriate, at least for purposes of assessing Allergan's liability for punitive damages.

box warning without the approval of the FDA. No such instruction was given.[16]

The result was prejudice to Allergan's right to have the warning issue decided within the confines of the applicable FDA regulations. Under the law and on the evidence, Ray's counsel was entitled to argue that a warning should have been given, and should have been prominently presented, but he was not entitled to say that it should have been a black box warning or that its place should have been at the top of the label, absent an instruction that the FDA would first have had to approve those changes.

This was prejudice on a core issue respecting Allergan's liability, and the only remedy for it is a new trial.

2. THE PLAINTIFF'S CLOSING ARGUMENT

Allergan first argues that Ray's closing argument violated the prohibition against "Golden Rule" arguments as explained in Leathers v. General Motors Corp., 546 F.2d 1083 (4th Cir. 1976), and other decisions. The closing argument made by Ray included this comment:

> This [picture] was taken just a few months before he got BOTOX. This is him and Peggy in their shop, Fancy Hats. Do you think he would have taken $12 million to give up the last 15, 20 years of his life and to have this massive brain damage? Do you think he would have made that trade? I'll give you

[16] Allergan asked for such an instruction (Docket No. 181 at 8-9). However, it became moot when Ray's counsel agreed not to argue that a black box warning should have been issued. Trial Tr. 1507-24.

> $12 million, you can forget the rest of your life. You're just going to be in bed with brain damage. Do you think he would have made that trade? Do you think any reasonable person would? I don't.

Trial Tr. 1587:13-1588:23. Allergan argues that this part of the argument, as did the argument in Leathers, invited jurors to put themselves in Ray's shoes and consider whether $12 million was a fair price for their lives. In Leathers, the Fourth Circuit found the following argument to be improper:

> I don't know how much you - how much you put a dollar value on it, but how much dollars would it be worth to you, $30 a day, $20, $300 a month?

526 F.2d at 1085. The Fourth Circuit awarded a new trial to the defendant based on this argument and the "thin" evidentiary record in the case, rejecting the dissenting judge's suggestion that the offending argument was "at least arguably a use of the word 'you' in an impersonal sense." Id. at 1087.

Ray's counsel contends that his use of "you" referred to Ray himself, not to members of the jury. It is arguable that this part of the closing referred to Ray. However, viewed in context, it came across as a suggestion for the displacement and substitution of the sort that Leathers forbids.

Allergan also argues that the following passage offended the Golden Rule:

> Can you imagine the horror when he first realized that something was terribly wrong? He couldn't walk right. He couldn't think right. Couldn't speak right. He's not going to be able to take care of his mother and his

> wife. His mother is going to have to go live somewhere else. Can you imagine?

Trial Tr. 1586:20-1587:1.

Some courts have held that arguments using "can you imagine" language are improper "Golden Rule" arguments. See Whitehead v. Food Max, 163 F.3d 265, 278 (5th Cir. 1998)("This court has forbidden plaintiff's counsel to explicitly request a jury to place themselves in the plaintiff's position and do unto him as they would have him do unto them," finding that counsel's "can you imagine how it would feel to have a knife in your side . . ." argument was an improper Golden Rule argument because the can you imagine text "was clearly inviting the members of the jury to put themselves in the place of the plaintiffs when deciding damages.") (citing Stokes v. Delcambre, 710 F.2d 1120, 1128 (5th Cir. 1983)); see also Delaware Olds, Inc. v. Dixon, 367 A.2d 178 (Del. 1976) (holding that asking the jury to "[t]ry to imagine" plaintiff's situation was an improper "Golden Rule" argument).

The Fourth Circuit, however, has not addressed this language. But, viewed in context of the part of the argument discussed above, use of the "can you imagine" language shortly

thereafter is yet another appeal for displacement and substitution and hence it too runs afoul of Leathers.[17]

Allergan also argues that Ray's closing argument violated the rule in Phillip Morris USA v. Williams, 549 U.S. 346 (2007). In closing, Ray's counsel invited jurors to "think of all the Douglas Rays in the United States that were being injected with BOTOX® in 2007 for mild to moderate non-life-threatening conditions." Trial Tr. 1567:23-1568:4. In Williams, the Supreme Court held 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." 549 U.S. at 353.

Ray contends that his statement was made "in the context of whether the conduct was sufficiently reprehensible" to support an award of punitive damages. The Supreme Court recognized that "[e]vidence 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," but it also cautioned that "a jury may not go further than this and use a punitive damages verdict to punish a

[17] Allergan has not argued that the punitive award is so disproportionate to the compensatory award as to be unconstitutional, e.g. State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003); BMW of No. Am. Inc. v. Gore, 517 U.S. 559 (1996) or that it offends the principles laid out in Exxon Shipping Co. v. Baker, 128 S. Ct. 2605 (2008). Hence, there is no need to address either rubric of the law of punitive damages.

defendant directly on account of harms it is alleged to have visited on nonparties." Id. at 355.

The argument here runs afoul of Williams, and thus the argument was improper for that reason. It also was improper because there was no evidence in the record about how many people were injected with BOTOX® who thereafter sustained injury upon migration of the toxin to the central nervous system, much less to the brain. In other words, the contention was sheer speculation.

However, Allergan did not object to the closing argument on either the Golden Rule or the Williams ground. So this issue devolves to whether the failure to object to the argument precludes granting a new trial.

In general, failure to object to a closing argument waives the right to attack the verdict on a motion for a new trial based on a prejudicial closing argument. Doe by and through G.S. v. Johnson, 52 F.3d 1448, 1465 (7th Cir. 1995)("[N]either trial tactics nor mere temerity will excuse counsel's failure to object to a remark made in closing argument.")(internal citations omitted). "Any potentially improper statements should have been called to the attention of the trial judge, in order that she might be given a timely opportunity to correct any prejudice that might result from such remarks." Id. "[F]ailure to do so waives this issue on appeal." Id.

The Fourth Circuit endorsed that rationale in Dennis v. Gen. Elec. Corp., 762 F.2d 365 (4th Cir. 1985). In Dennis, the Fourth Circuit held that: "It is the universal rule that during closing argument counsel 'cannot as a rule remain silent, interpose no objections, and after a verdict has been returned seize for the first time on the point that the comments to the jury were improper and prejudicial.'" Id., 762 F.2d at 366-67 (quoting United States v. Elmore, 423 F.2d 775, 781 (4th Cir.), cert. denied, 400 U.S. 825 (1970)(quoting United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 238-39 (1940))). "A motion for a new trial should not be granted, therefore, where the moving party has failed to timely object to the alleged impropriety giving rise to the motion." Id. at 367 (citing Uhl v. Echols Transfer Co., 238 F.2d 760, 765 (5th Cir. 1956)). "The failure to object at the proper time will be overlooked on appeal only if exceptional circumstances exist such as when the error is so obvious or so serious that the public reputation and integrity of the judicial proceeding is impaired." Id. (citing Socony-Vacuum Oil. Co. at 239). See also Carmel v. Clapp & Eisenberg, P.C., 960 F.2d 698, 704 (7th Cir. 1992) (quoting United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 238-39 (1940)).

However, five years earlier, the Fourth Circuit decided Werner v. The Upjohn Company, Inc., 628 F.2d 848 (1980). In Werner, the plaintiff's closing argument offended Federal Rule of Evidence 407 by using a post-injury change in a drug company's

warning label as evidence of antecedent negligence. The defendant failed to object to the closing argument in which that contention was advanced. Citing Leathers, the Fourth Circuit, in Werner, held that "such an objection [to closing argument] is not required in this circuit." Werner v. The Upjohn Company, Inc., 628 F.2d at 854. The Court of Appeals went on to explain that "[d]espite lack of objection to the [Golden Rule] argument [in Leathers] we reversed and remanded for a new trial stating that the defendant was not required to make a contemporaneous objection because to do so might only have emphasized the impermissible point and have antagonized the jury." Id. Finding that the argument in Werner that violated Rule 407 "was at least as damaging as the argument in Leathers," the Court of Appeals vacated the verdict and ordered a new trial.

Obviously, there is at least facially, a conflict between Dennis, which seems always to require objection to an inappropriate closing argument, and Werner, which suggests a contrary rule. The decision in Dennis came after the decision in Werner but did not discuss the case at all. And, to further complicate the analysis, in Dennis, the Court of Appeals relied upon United States v. Elmore[18] and its citation to United States v. Soconoy-Vaccuum Oil Company.[19] Elmore was decided by the Fourth Circuit in 1969. Soconoy-Vaccuum was decided in 1940, but

[18] 423 F.2d 775 (4th Cir.), cert. denied, 400 U.S. 825 (1970).

[19] 310 U.S. 150, 239 (1940).

the decision in Werner does not mention Elmore or Soconoy-Vaccuum.

Thus, on the surface, there appear to be two conflicting Fourth Circuit opinions addressing the need to make contemporaneous objections during closing arguments. The first decision was a panel decision issued in 1980, and the second one was a panel decision issued in 1985. It is the general rule in the Fourth Circuit that one panel cannot overrule the decision of another panel. But, it does not appear that, in Dennis, the panel intended to overrule Werner because Dennis does not cite Werner.

Under the circumstances, it is obligatory on a district court to determine whether the two decisions can be harmonized. Each decision gives some suggestion how that might be accomplished. For example, in Werner, the Court of Appeals looked at the nature and the severity of the offending argument, finding that it was damaging and suggesting that an argument that "is sufficiently out of bounds" is excused from the contemporaneous objection requirement. Werner v. The Upjohn Company, Inc., 628 F.2d at 854 ("if the Golden Rule [in Leathers] argument is sufficiently out of bounds to excuse the contemporaneous objection requirement then this clear violation of Rule 407 [in Werner] is no less so."). An examination of Dennis suggests that whether a contemporaneous objection is required (notwithstanding the absolute language requiring a

contemporaneous objection) will depend upon the obviousness or the severity of the offending conduct. Dennis v. Gen. Elec. Corp., 762 F.2d at 367 ("[m]anifestly, the district court's alleged error in permitting Jose to refer to the cartoon in his closing argument without later giving what amounts to an unsolicited cautionary instruction was not sufficiently obvious or severe to render an objection by the plaintiff unnecessary."

That language harkens back to the citation in Dennis to the decision in Soconoy-Vaccuum which the Court of Appeals held to have stood for the following proposition:

> The failure to object at the proper time will be overlooked on appeal only if exceptional circumstances exist such as when the error is so obvious or so serious that the public reputation and integrity of the judicial proceeding is impaired.

Dennis v. Gen. Elec. Corp., 762 F.2d at 367 (citing Soconoy-Vaccuum Oil Co., 310 U.S. at 239, 60 S. Ct. at 851).

Considering that, in Leathers, the Fourth Circuit vacated the verdict and reversed the judgment of the district court because of the Golden Rule closing argument, it is reasonable to conclude that the Court of Appeals considers that such arguments meet the limited exception in Soconoy-Vaccuum (i.e., that "the error is so obvious or so serious that the public reputation and integrity of the judicial proceeding is impaired"). Moreover, given the constitutional principle which animated the decision in Williams, the Court is confident that the Fourth Circuit would

find that a closing argument of that sort prohibited by Williams to fit within the Soconoy-Vaccuum exception.

Accordingly, it is possible to harmonize the decisions in Dennis and Werner in the foregoing fashion and, in applying the resulting precept, it is appropriate to conclude that, under the law of the circuit, an argument that offends Leathers and/or Williams is excused from the contemporaneous objection requirement.[20] Accordingly, because Ray's counsel made arguments that offended the rules in Leathers and Williams, a new trial is appropriate on that basis as well.

3. PREEMPTION

Allergan argues that Ray's theory of recovery is preempted under the Supremacy Clause, citing PLIVA, Inc. v. Mensing, and other decisions. The Supremacy Clause provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . ." U.S. Const. art. VI, cl. 2. Preemption is the application of the Supremacy Clause, resulting in the rule that "any state law that conflicts with federal law is without

[20] That approach, of course, serves the salutary purpose of motivating lawyers to refrain from making such arguments upon pain of losing a verdict. However, in most instances, the mischief of such arguments can be cured by an appropriate instruction (which could be made at a bench conference, thereby avoiding the consequences which animated the decision in Werner); and thus the approach can be, indeed almost always will be, wasteful of judicial resources. Left to its own devices, the Court would insist on the general rule requiring contemporaneous objection to an argument that invoked the Golden Rule or that offended Williams. But, here, the Court is not writing on a clean slate and has sought to discharge its obligation to harmonize Werner and Dennis.

effect." Cippolone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (internal citations omitted). "Preemption is disfavored in areas of historic importance to the states' police powers - areas such as public health and safety." Schedin, 808 F. Supp. 2d at 1130 (quoting In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig., No. 01-MDL-1396, 2004 WL 45503, at *5 (D. Minn. Jan. 5, 2004) (citing Kemp v. Medtronic, Inc., 231 F.3d 216, 222 (6th Cir. 2000))). See also Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 347 (2001)(contrasting "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety.'") (cited in In re St. Jude, at *5 and quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

Express preemption occurs when Congress preempts state law by so stating in express terms. Id. (internal citations omitted). That concept is not at issue here.

Implied preemption occurs upon an inference that the state law is preempted. A court will find implied preemption "where it is impossible for a private party to comply with both state and federal law, and where 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 objections of Congress." Crosby v. Nat. Foreign Trade Council, 530 U.S. 363, 372-73 (2000) (cited in Schedin, 808 F. Supp. 2d at 1131).

It is Allergan's theory that it is so situated and is thus protected by the rule of implied preemption.

Allergan relies on the decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) as the basis for its contention that, under Mensing, Ray's failure to warn claim is impliedly preempted. However, if Allergan is correct, the Plaintiff's claim would fail entirely and, in that event a new trial would not be appropriate. Thus, the issue of preemption is not one to be resolved in Allergan's motion for a new trial under Rule 59.

CONCLUSION

For the foregoing reasons, DEFENDANT'S RULE 59 MOTION FOR A NEW TRIAL (Docket NO. 227) will be granted.

It is so ORDERED.

/s/ REP
Robert E. Payne
Senior United States District Judge

Richmond, Virginia
Date: May 31, 2012