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UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

BROOKLYN OFFICE

----- X  
KARLEEN HOGAN, surviving spouse and  
executor of the Estate of Timothy Hogan,  
deceased,

Plaintiff,

-against-

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Defendant.  
----- X

**MEMORANDUM**  
**DECISION AND ORDER**

06 Civ. 0260 (BMC) (RER)

COGAN, District Judge.

Before me is a motion in limine to exclude a new warning label as a subsequent remedial measure under Rule 407 of the Federal Rules of Evidence. Because I agree with defendant that the federal rule must apply in this diversity action, I grant the motion.

**BACKGROUND**

Karlene Hogan, surviving spouse of Timothy Hogan (hereinafter "Hogan"), brings this action based on products liability, negligence, and breach of implied warranty. The case was part of a multi-district litigation that was remanded to this Court from Judge Todd J. Campbell in the Middle District of Tennessee (the MDL Court).

Plaintiff alleges that her husband developed an "osteonecrosis of the jaw" ("ONJ") as a result of receiving Zometa, which is an intravenous bisphosphonate ("IV BP") drug produced by defendant, Novartis Pharmaceuticals Corporation ("NPC"). ONJ is a painful condition in which part of the individual's jaw bone has died. Dr. John Pryzgoda, Hogan's treating oncologist, prescribed Zometa to Hogan to ameliorate the bone-related complications caused by Hogan's

multiple myeloma. As plaintiff's counsel has aptly characterized it, the action distills down to NPC's failure to warn Hogan of the risk of developing a bisphosphonate-induced ONJ ("BONJ") from Zometa.

The parties agree that Rhode Island – Timothy Hogan's place of residence when he was treated for cancer – supplies the substantive law in this diversity action. They have filed motions in limine, most of which will be decided at the upcoming Final Pre-motion Conference. Plaintiff objects to some of the defendant's motions on the ground that Rule 407 of the Rhode Island Rules of Evidence, rather than the federal rule, governs the admissibility of the evidence in this case. This argument is plaintiff's sole objection to one of the defendant's motions, which seeks to exclude evidence that NPC removed the term "well-documented risk factors" from its 2007 Zometa label. Plaintiff's other oppositions to the motions cite the Rhode Island rule but contain other objections as well.

### **DISCUSSION**

Unlike the federal rule, Rhode Island's Rule 407 provides that "[w]hen, after an event, measures are taken which, if taken previously, would have made the event less likely to occur, evidence of the subsequent measures is admissible." As both parties acknowledge, this stands in direct contrast to the federal version that generally prohibits the admissibility of any remedial measures to show, *inter alia*, a defect in the product, its design, or a need for a warning, unless the evidence is offered for another purpose, such as the feasibility of the precautionary measures. See Fed. R. Evid. 407.

In support of her claim that the Rhode Island Rule should govern, plaintiff cites Moe v. Avions Marcel Dassault-Breguet Aviation, 727 F.2d 917, 932 (10th Cir. 1984), where the Court affirmed the application of a state's counterpart to Rule 407 in a products liability action.

Plaintiff argues that under Erie R.R. v. Tompkins, 304 U.S. 64 (1938), and its progeny, “Rhode Island Rule 407 is a substantive law” and should therefore be applied in this action as it is a “clear rejection of the policies behind Federal Rule 407.” Defendant disagrees, labeling Moe an outlier. The Second Circuit, although it has routinely affirmed the application of the federal rule in products liability actions, has never confronted the issue. See In re Joint E. Dist. & S. Dist. Asbestos Litig., 995 F.2d 343, 345 (2d Cir. 1993) (collecting cases).

Plaintiff applies the wrong standard and cites a case that is no longer good law for the proposition on which she relies. Most importantly, she overlooks Hanna v. Plumer, 380 U.S. 460, 473 (1965), which held that “Erie and its offspring cast no doubt on the long-recognized power of Congress to prescribe housekeeping rules for federal courts even though some of those rules differ from comparable state rules.” After Hanna, a federal procedural rule is not to be subjected to the naked Erie analysis that the plaintiff advocates:

When a situation is covered by one of the Federal Rules, the question facing the court is a far cry from the typical, relatively unguided Erie choice: the court has been instructed to apply the Federal Rule, and can refuse to do so only if the Advisory Committee, this Court, and Congress erred in their prima facie judgment that the Rule in question transgresses neither the terms of the Enabling Act nor constitutional restrictions.

Hanna, 380 U.S. at 471; see also Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co., 130 S. Ct. 1431, 1437 (2010) (“We do not wade into Erie’s murky waters unless the federal rule is inapplicable or invalid.”).

As the Court explained in Shady Grove, while in the context of Erie it did not matter whether the judge-made rule was one of substance or procedure (because the analysis turned on whether the rule affected the result of the litigation), the distinction is crucial when examining a federal procedural rule:

Congress has undoubted power to supplant state law, and undoubted power to prescribe rules for the courts it has created, so long as those rules regulate matters rationally capable of classification as procedure. In the Rules Enabling Act, Congress authorized this Court to promulgate rules of procedure subject to its review, but with the limitation that those rules shall not abridge, enlarge or modify any substantive rights.

130 S. Ct. at 1442 (citations and quotation marks omitted).

Of course both Hanna and Shady Grove involved the Federal Rules of Civil Procedure. But that does not make plaintiff's burden any lighter: "Because the Federal Rules of Evidence were enacted directly by Congress, their validity *vis-à-vis* state law and the principles of the Erie doctrine stands on ground even more firm than that of the Federal Rules of Civil Procedure." C. Wright, A. Miller & E. Cooper, 19 Federal Practice and Procedure 2d § 4512 (2010). That is because unlike the Federal Rules of Civil Procedure, the Federal Rules of Evidence were not enacted pursuant to the Rules of Enabling Act. Thus, "[t]heir validity is governed solely by the Constitution, but since all of the Rules of Evidence can be viewed rationally as rules of procedure (the constitutional standard announced in [Hanna]) they all clearly are constitutional." Id.

Rule 407, however, while passed directly by Congress, was amended in 1997 pursuant to the Rules of Enabling Act. This amendment was promulgated in part to adopt the prevailing view among circuit courts that applied the rule to products liability (rather than just negligence) actions. See, e.g., Cann v. Ford Motor Co., 658 F.2d 54, 59-60 (2d Cir. 1981). But regardless of whether plaintiff's challenge is to the original Rule or to its amendment, both roads lead to Hanna; for the federal rule not to apply, she must show that it cannot be rationally classified as procedural. See Hanna, 380 U.S. at 472.

Plaintiff's claim that the Rhode Island Rule must govern because it is substantive rather than procedural misses the mark. The inquiry begins and ends with the federal rule; Hanna

teaches that if the federal rule is valid, the Court will apply it. To determine the rule's validity, the Court must ask what it "*regulates*: If it governs only the manner and the means by which the litigants' rights are enforced, it is valid; if it alters the rules of decision by which the court will adjudicate those rights, it is not." Shady Grove, 130 S.Ct. at 1442 (emphasis in the original, quotation marks omitted). The Court in Shady Grove noted that it had rejected every challenge to a procedural rule even though each had "some practical effect on the parties' rights" because they all regulated the "process for enforcing those rights; none altered the rights themselves. . . ." Id. at 1443.

Regulating the process while potentially having some effect on the parties' rights is, respectively, the purpose and effect of Rule 407. See Flaminio v. Honda Motor Co., 733 F.2d 463, 472 (7th Cir. 1984) ("Although Rule 407 has substantive consequences by virtue of affecting incentives to take safety measures after an accident occurs, this just puts the rule in that borderland where procedure and substance are interwoven. The necessary-and-proper clause of Article I extends into the borderland, where are found 'matters which, though falling within the uncertain area between substance and procedure, are rationally capable of classification as either.'") (quoting Hanna, 380 U.S. at 472). Congress has determined, for example, that the jury may place too much weight on NPC's new label, which includes the type of warning that plaintiff claims should have been in place when her deceased husband began to receive Zometa infusions. Congress' judgment was therefore at least as much about the process as it was about the substance – it concerned "procedures designed to enhance accuracy or reduce expense in the adjudicative process." Id. at 471.

Plaintiff's reliance on Moe, 727 F.2d 917, is not persuasive. Moe represents the Tenth Circuit's ill-conceived excursion into pure Erie analysis for the Federal Rules of Evidence in

general and Rule 407 in particular. It was an excursion that was put in doubt by the 1997 amendment and put to rest by Sims v. Great Am. Life Ins. Co., 469 F.3d 870 (10th Cir. 2006) (“Although the Moe court’s reasoning is tempting, we are persuaded that Erie is inapplicable to the Federal Rules of Evidence.”).

Although plaintiff’s reliance on Moe is misplaced, her argument is not surprising given the confusion that still remains even among Circuit Courts. See, e.g., Hottle v. Beech Aircraft Corp., 47 F.3d 106, 110 (4th Cir. 1995) (collecting cases) (citing Hanna but observing that while the Federal Rules of Evidence generally govern in diversity cases, when the admissibility of evidence is so intertwined with a state substantive rule, then the state rule will be followed to “give full effect to the state’s substantive policy”) (citation and quotation marks omitted); Potts v. Benjamin, 882 F.2d 1320, 1324 (8th Cir. 1989) (citing Erie only, holding that although the Federal Rules of Evidence generally govern admissibility, the state rule at issue was “substantive law” and should therefore be applied). To the extent that this authority is inconsistent with the conclusion reached by this Court, I find it unpersuasive; the substantive/procedural dichotomy of a *state* rule is of no moment in this context. See Sims, 469 F.3d at 879.

Supreme Court jurisprudence allows for protection of state policy against the incursion of the Federal Rules of Evidence in other ways. The federal rules and sometimes even statutes protect it directly. See id. at 880; C. Wright et. al., supra § 4512 (“Properly construed, the Federal Rules of Evidence do not affect or alter . . . substantive rules of evidence.”); see also Holster v. Gatco, Inc., 618 F.3d 214, 217 (2d Cir. 2010) (on remand in light of Shady Grove, finding that even if state law could not override a federal procedural rule, it nonetheless applied because the federal statute delegated to the state the power to determine which causes of action

lie under the statute). Hanna does so indirectly – it instructs courts to void any federal substantive law masquerading as a procedural rule.

Accordingly, NPC's motion to exclude evidence of the 2007 Zometa label change, to which plaintiff objects solely on the basis of the Rhode Island rule, is granted. The Court will rule on the remaining motions, some of which rest in part on this argument, at the Pre-Trial Conference.

**SO ORDERED.**

Dated: Brooklyn, New York  
April 6, 2011

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U.S.D.J. |