UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

LYNN CROSS and CHARLES CROSS,
Plaintiffs,

v. CASE NO.: 8:06-cv-429-T-23AEP
WYETH PHARMACEUTICALS, INC.,
et al.,
Defendants.

ORDER

The plaintiffs move (Doc. 106) in limine to exclude evidence, and the defendants respond (Doc. 170) in opposition. The defendants also move (Docs. 112-123, 125, 128-131, 133-134, 185) in limine to exclude evidence, and the plaintiffs respond (Docs. 142, 143-146, 148-158, 166, 169) in opposition. Additionally, the defendants move (Docs. 111, 187) (1) to bifurcate the trial and to prohibit evidence of punitive damages until a determination as to compensatory liability and damages and (2) "for the application of [Section] 768.73(2)," Florida Statutes, to prohibit the award of punitive damages because punitive damages "have previously been awarded against [the] defendant for 'the same . . . failure to warn of the same hazards, with respect to similar units of a product." The plaintiffs move (Doc. 136) to compel the trial testimony of

¹ The defendants move (Doc. 77) for summary judgment and the motion remains pending. Additionally, the parties' motions (Docs. 78, 105, 110) under <u>Daubert v. Merrell Dow Pharm., Inc.</u>, 509 U.S. 579 (1993), remain pending. A May 4, 2011, order (Doc. 188) continues the trial in this action (following the death of Lynn Cross) upon request of the parties' counsel and in deference to the Cross family.

Jeannemarie Durocher and James Pickar (former employees of the defendant Wyeth Pharmaceuticals, Inc., ("Wyeth")) by "contemporaneous transmission".

1. The Plaintiffs' "Omnibus Motions in Limine"

The plaintiffs' "omnibus" motion (Doc. 106) comprises the following thirteen² requests for exclusion:

Motion one requests exclusion of "argument, suggestion[,] or implication" that the plaintiff Lynn Cross was pre-disposed to breast cancer because she suffered from skin cancer. The plaintiffs contend that the argument lacks a scientific basis and is speculative, prejudicial, and irrelevant. In response, the defendants argue that medical studies demonstrate both a link between breast cancer and certain skin cancers and an increased risk of internal cancer in people who suffer from cutaneous cancer. The defendants assert that the argument suggests an alternative theory of causation. The request for exclusion is **DENIED**, provided that the defendants proffer admissible evidence in support of the argument.

Motions two and sixteen request exclusion of evidence and argument that a family history of both breast cancer and other types of cancer contributed to Cross's developing breast cancer. The plaintiffs assert that no first-degree relative of Cross suffered from breast cancer, that the argument lacks a scientific basis, and that the evidence is prejudicial. The defendants assert (1) that medical literature demonstrates a link between a family history of cancer and breast cancer and (2) that Cross had a family history of breast and lung cancer. The request for exclusion is **DENIED**.

² The pre-trial order (Doc. 179) denies as moot motions number four, eight, nine, eleven, thirteen, eighteen, and twenty in the plaintiffs' "omnibus" motion. Accordingly, this order resolves the remaining requests.

Motions three and ten request exclusion of "irrelevant" evidence and argument pertaining to the risk associated with other drugs and "ordinary activities like driving a car". The defendants contend that the evidence creates a context helpful to the jury's understanding relative risk. Because the evidence appears cumulative, the request for exclusion is **GRANTED**, with the exception that the defendants may proffer one illustrative example of a risk unrelated to medicine.

Motion five requests exclusion of evidence of Cross's use of birth control, because the evidence qualifies as impermissible character evidence. The defendants assert that Cross's use of birth control is not evidence of character but support for the argument that Cross "would have accepted the risks of hormone therapy." Because the evidence is both highly speculative on the issue of risk acceptance and otherwise impermissible character evidence, the request for exclusion is **GRANTED**.

Motion six requests exclusion of evidence of (and "references to") Cross's cigarette smoking. The plaintiffs assert that the scientific evidence is both dubious and unreliable and that the evidence is inadmissible to the extent offered to show that Cross is a "risk taker." In response, the defendants assert (1) that medical literature establishes a link between smoking and an increased risk of breast cancer and (2) that the defendants will not use the evidence to show that Cross is a "risk taker".

Accordingly, the request for exclusion is **DENIED**, on the condition that the defendants refrain at any stage of the trial and in any manner from using the evidence to characterize Cross as a "risk taker".

Motion seven requests exclusion of argument and cross-examination on either the "initiation" of cancer or the "initiation" of bad cells. The plaintiffs argue that

"promotion" is the plaintiffs' only causation theory and that no expert supports the theory that hormone therapy "initiates" breast cancer. The defendants respond (1) that the "promotion" theory lacks merit and (2) that prohibiting argument on "initiation" usurps the role of the jury. Because causation is undoubtedly an issue for the trier of fact, the request for exclusion is **DENIED**.

Motion twelve requests exclusion of "references to irrelevant risk factors of breast cancer," i.e., risk factors inapplicable to Cross. The defendants claim the right to identify and compare other risks factors associated with hormone therapy. Because, in view of other evidence, the evidence is cumulative and otherwise inadmissible under Rule 403, the request for exclusion is **GRANTED**.

Motion fourteen requests exclusion of both anecdotal evidence and argument describing an attorney's or a witness's experience with either menopause, hormone therapy, or breast cancer. The plaintiffs object to this type of evidence and assert that the evidence is irrefutable and prejudicial hearsay. The defendants assert that the issue is more susceptible to resolution at trial. Upon review, the request for exclusion is **GRANTED IN PART** to the extent that the parties shall not adduce on direct examination anecdotal information about either an attorney's or a witness's experience with either menopause, hormone therapy, or breast cancer. However, the parties may adduce anecdotal evidence on re-direct examination (1) to the extent that the cross-examination includes questions or answers yielding testimony about the witness's personal experience, personal views, or the like, and (2) with the express permission of the court.

Motion fifteen requests exclusion of comments that hormone therapy drugs are the "most studied drugs" and that "3,000 published articles" prove the safety of hormone therapy drugs. The plaintiffs contend that the statements lack a foundation and confuse the issues, and the defendants argue that the statements are both true and relevant to the "failure to test" issue. The request for exclusion is **GRANTED**, and each statement is excluded unless offered to rebut its negative. (The evidence of x-thousand articles is a variant of misleading and inadmissible probability testimony.)

Motion seventeen requests exclusion of "reference[s] to" Cross's use of prescription drugs other than hormone therapy because Cross's use of other prescription drugs lacks probative value. The defendants contend that the issue is relevant to Cross's willingness to "accept the risks" associated with prescription medications. Because Cross's (purportedly) accepting a risk is unduly speculative, irrelevant, and inadmissible evidence of propensity (to predict conduct conforming to propensity), the request for exclusion is **GRANTED**.

Motion nineteen requests exclusion of claims that the defendants lacked the authority to change a product label without FDA approval. The plaintiffs assert that the defendants could have strengthened a warning label without FDA approval. However, the defendants claim that only in defined, limited circumstances may a manufacturer change a label without FDA approval. Additionally, the defendants argue that the motion is premature. The prospect of other and different labels and the respective discretion of the FDA and a manufacturer are tangential to the question of the adequacy of the label that appeared. Evidence on the issue seems undeserving of the resulting distraction to the jury. The request for exclusion is **GRANTED**.

2. The Defendants' Motion to Bifurcate

The defendants argue (Doc. 111) that bifurcation is necessary to avoid undue prejudice and inefficiency. Specifically, the defendants argue that evidence both of "dissimilar acts, independent from the acts upon which liability is premised" and of conduct that lacks a "nexus to the specific harm suffered by the plaintiff" bears (to the extent that the evidence is admissible) only on the defendants' liability for punitive damages. The plaintiffs respond (Doc. 141) (1) that the evidence supporting punitive damages is "inextricably intertwined" with the evidence of causation; (2) that evidence of allegedly malicious, wanton, and grossly negligent conduct is relevant to the issue of negligence; and (3) that bifurcation is appropriate only as to the amount of punitive damages.

Rule 42(b), Federal Rules of Civil Procedure, permits a separate trial of "one or more separate issues, claims, crossclaims, counterclaims, or third-party claims" for "convenience, to avoid prejudice, or to expedite and economize." The rule "confers broad discretion on the district court in this area" Harrington v. Cleburne County Bd. of Educ., 251 F.3d 935, 938 (11th Cir. 2001). In a products liability action, Campolongo v. Celotex Corp., 681 F. Supp. 261, 263-64 (D. N.J. 1988) (Wolin, J.), explains:

[O]ther policy reasons and concerns [exist] beyond those enumerated. Foremost, is the conduct of a trial free of the inflammatory influences that naturally flow from conduct-related proofs which possess the capacity to adversely affect a product-oriented proceeding through a disproportionate compensatory verdict. A balanced trial provides for a verdict reasonably related to the injury sustained and the resulting consequential damages. However, as soon as conduct-related proofs are intermingled with those that are purely product-related, a fiery element has been added that has the capacity to inject

punishment under the guise of a compensatory award. This is wrong and courts should not permit this to happen when they possess the authority to do otherwise.

In this instance, the plaintiffs assert negligence, strict liability, and negligent misrepresentation and request both compensatory and punitive damages. To prevail on a strict liability claim (for example), the plaintiffs must prove that the defendants' product contained a defect and that the defect proximately caused the plaintiffs' injury. If the plaintiffs successfully prove the strict liability claim, the defendant becomes liable for punitive damages "only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence." Fla. Stat. § 768.72 (providing that a corporation or other legal entity becomes liable based on the entity's knowledge of, active participation in, or consent or contribution to intentional or grossly negligent misconduct); Fla. Stat. § 768.71 (stating that "this part applies to any action for damages, whether in tort or contract"). Thus, the claims for compensatory and punitive damages involve an inquiry readily susceptible to severance from the question of a defect in the product. Furthermore, evidence of "intentional misconduct or gross negligence" is irrelevant and likely prejudicial to determination of the defendants' liability.

Accordingly, bifurcation appears convenient, expeditious, efficient, and just. The defendants' request (Doc. 187) for the application of Section 768.73(2), Florida Statutes, which applies to punitive damages, appears both premature and more appropriately decided after a determination as to the defendants' liability.

3. The Defendants' Motions in Limine

The defendants file the following eighteen³ motions, each of which requests exclusion of evidence that the plaintiffs may adduce at trial:

The defendants move (Docs. 112, 117) to exclude as irrelevant evidence of Premarin, Provera, and Premphase marketing material, because neither Cross nor her physician relied on the material. In response, the plaintiffs argue (1) that whether Cross or her physician relied on the material is irrelevant, (2) that the marketing material presents evidence relevant to the "reasonableness" of the defendants' conduct, and (3) that the evidence shows the defendants' promoting the benefits of hormone therapy before conducting a comprehensive study on the risk associated with hormone therapy. In this instance, the evidence appears impertinent and irrelevant to the plaintiffs' claim (i.e., the adequacy of the warning on each product) and neither the plaintiff nor her physician asserts reliance on the marketing material. Accordingly, the motions (Docs. 112, 117) are **GRANTED**.

Next, the defendants move (Docs. 113, 185) to exclude as irrelevant evidence of "ghostwritten" articles, in particular an article "ghostwritten" by James Fiorica, M.D. The defendants argue (1) that neither Cross nor her physician relied on a "ghostwritten" article, (2) that the evidence possesses no nexus to the plaintiffs' injury, and (3) that evidence of "ghostwriting" carries a substantial risk of misleading the jury. In response, the plaintiffs assert (Docs. 142, 193) (1) that the evidence is relevant to whether Wyeth acted reasonably and whether Wyeth could have communicated better information to

³ An additional motion, Doc. 130, relies on the defendants' <u>Daubert</u> motion (Doc. 105), which requests exclusion of the plaintiffs' expert witnesses. Accordingly, this order declines to address the motion (Doc. 130) until a decision on the defendants' Daubert motion.

doctors and (2) that the motion (Doc. 185) pertaining to Dr. Fiorica's article is untimely. The plaintiffs argue also that the evidence is relevant to punitive damages. Because the evidence appears irrelevant to the plaintiffs' claims and the defendants' liability, the motions (Docs. 113, 185) are **GRANTED**.

The defendants move (Doc. 114) to exclude evidence and argument about the history and events leading to Wyeth's amending the Premarin label to include an endometrial cancer warning. As a basis for exclusion, the defendants assert that the evidence (1) presents a danger of prejudice and confusion, (2) amounts to proof of prior "bad acts" suggesting conformity therewith, and (3) pertains to a disease that Cross never suffered. However, the defendants contend that the plaintiffs may properly present evidence (1) of the medical community's learning in 1975 that unopposed estrogen increases the risk of endometrial cancer in certain women and (2) of the basis (i.e., the risk of endometrial cancer) for physician's prescribing estrogen plus progestin. In response, the plaintiffs argue that the evidence is relevant (1) to the development of estrogen plus progestin therapy, (2) to the defendants' "notice" of the need to study hormone therapy products and discover the risk of hormone dependent cancers, and (3) to the theory that hormone therapy causes cancer by "promotion". Upon review, the motion (Doc. 114) is **GRANTED**, because the evidence most prominently conveys a sense of "bad acts" or corporate bad character and offends Rule 403.

The defendants move (Doc. 115) to exclude as irrelevant and prejudicial (1) notes of telephone calls by Wyeth sales representatives who never called Cross's physician and (2) notes of telephone calls to other physicians. The defendants assert (1) that no sales representative persuaded Cross's physician to prescribe hormone therapy and (2)

that, in fact, Cross's physician could not recall meeting with a Wyeth sales representative. In response, the plaintiffs assert that the evidence is relevant to Wyeth's state of mind and to Wyeth's liability for punitive damages. Because the evidence is irrelevant to the issue of the defendants' liability, the motion (Doc. 115) is **GRANTED**.

The defendants move (Doc. 116) to exclude evidence and argument about the defendants' correspondence with the FDA (1) because the dialogue between Upjohn and the FDA concerned advertising that (in the FDA's opinion) over-emphasized the use of Provera to protect against endometrial hyperplasia, (2) because Upjohn complied with the FDA's request to cancel the advertising, and (3) because the letters are irrelevant and present a risk of unfair prejudice that outweighs the letters' probative value. The plaintiffs respond (Doc. 151) (1) that the correspondence shows Upjohn's duty to study the safety of hormone therapy and (2) that the evidence is relevant to punitive damages. However, because the evidence is irrelevant to liability, the motion (Doc. 116) to exclude is **GRANTED**.

Additionally, the defendants move (Doc. 118) to exclude evidence and argument about the drug Provest, because Provest is not a hormone therapy product and because the evidence is irrelevant and prejudicial. The plaintiffs respond (Doc. 145) that the evidence is relevant to Upjohn's "duty to test" and to Upjohn's alleged notice (as early as 1970) of the risk of breast cancer. However, because Cross never used the product and because Provest is not a hormone therapy product, the evidence appears irrelevant. To the extent that the evidence is relevant, the risk of prejudice outweighs the probative value. Accordingly, the motion (Doc. 118) is **GRANTED**.

The defendants move (Doc. 119) to exclude as irrelevant a "material safety data sheet" (an "MSDS") submitted to the Occupational Safety and Health Administration ("OSHA"). The MSDS describes the risk presented by workplace exposure to hazardous chemicals, e.g., the chemical components of Provera. The defendants argue that the risk presented by uncontrolled exposure to the chemical components of Provera is irrelevant to the plaintiffs' claims. The plaintiffs respond (Doc. 144) that the MSDS shows notice to Upjohn of both the dangerous propensity of Provera and the need to study the risk presented by the drug. In this instance, the evidence appears irrelevant. To the extent that the evidence is relevant, the risk of prejudice and confusion greatly outweigh the minimal probative value. Accordingly, the motion (Doc. 119) is **GRANTED**.

Next, the defendants move (Doc. 120) to exclude as irrelevant letters exchanged in 2000 between the FDA and the defendants because neither letter discusses Provera. The plaintiffs respond (Doc. 148) that, because Provera is a progestin and a component of hormone therapy, the letters are relevant. Furthermore, the plaintiffs argue that the letters confirm the defendants' authority over the warning label on a drug (i.e., the evidence rebuts the defense that the FDA dictates the contents of the warning label). The motion (Doc. 120) is **GRANTED**, and the evidence is excluded as irrelevant, except to the extent that the plaintiffs offer the evidence to rebut a defense, including a claim about the FDA's responsibility for the warning label.

The defendants move (Doc. 121) to exclude "causality assessments," which the defendants describe as a report (prepared in accord with FDA regulations) of an adverse event experienced by a participant in a clinical study. The defendants argue

that the causality assessments are unscientific and unreliable. The plaintiffs argue (Doc. 143) that the causality assessments show both notice of the increased risk of breast cancer and the possibility of linking a cancer to a particular cause. However, the plaintiffs assert that they will not offer the evidence as proof of causation. Accordingly, the motion (Doc. 121) is **GRANTED** to the extent that the evidence is offered as proof of causation and risk.

In two separate motions (Docs. 122, 123) the defendants request exclusion of evidence describing the defendants' profit margins and the defendants' wealth. The issue, according to the defendants, is whether the defendants provided an adequate warning and not whether the defendants' profit motive or finances affected the ability to conduct a comprehensive study. The plaintiffs argue that the jury should receive evidence of the amount available to the defendants to study the risk associated with the defendants' products. As the defendants correctly argue, however, the evidence is irrelevant to the defendants' liability for a "failure to warn" and the plaintiffs' entitlement to compensatory damages. Accordingly, the motions (Docs. 122, 123) are **GRANTED**.

To the extent that the plaintiffs intend to present evidence of other hormone therapy claims, lawsuits, settlements, verdicts, and judgments, the defendants move (Doc. 125) to exclude the evidence as irrelevant, unfairly prejudicial, and inadmissible hearsay. The plaintiffs request (Doc. 149) denial of the motion as overbroad and assert that the evidence is proper for impeachment or rebuttal. The motion (Doc. 125) is **GRANTED**, and the evidence is excluded as irrelevant and inadmissible hearsay. However, a party may use the excluded evidence for either impeachment or rebuttal to the extent that the opposing party presents a predicate for either.

The defendants move (Doc. 128) to exclude evidence of the number of women whose breast cancer purportedly resulted from hormone therapy because the evidence is speculative, prejudicial, irrelevant, and likely to inflame the jury. Furthermore, the defendants assert that the evidence presents a risk of the jury's punishing the defendants for harm to others. The plaintiffs assert (Doc. 157) that the evidence is relevant (1) to "general causation," (2) to the reprehensibility of the defendants' conduct, and (3) to rebutting the claim that the risk of breast cancer is minimal and that hormone therapy is beneficial. Because the evidence is both irrelevant and prejudicial, the motion (Doc. 128) is **GRANTED**.

Additionally, the defendants move (Doc. 129) to exclude evidence of warnings that post-date Cross's last prescription for hormone therapy. The defendants assert that Rule 407, Federal Rules of Evidence, prohibits the evidence to the extent that the evidence shows a subsequent remedial measure. Furthermore, the defendants argue that the adequacy of the warning depends upon the information that a manufacturer knew or should have known at the time that a consumer read the warning. The plaintiffs argue (1) that the evidence supports causation by showing that an adequate study would have resulted in a stronger warning and (2) that Rule 407 permits evidence showing the feasibility of a precautionary measure to the extent that feasibility is controverted. Upon review, the motion (Doc. 129) is **GRANTED**, and the evidence is excluded absent a predicate defense of the unfeasibility of precautionary measures.

To the extent that the plaintiffs intend to offer evidence of "fraud on the FDA," the defendants move (Doc. 131) to exclude the evidence as irrelevant and assert that a claim for "fraud on the FDA" is pre-empted by federal law. The plaintiffs respond

(Doc. 166) and state that "the parties agree that the motion need not be ruled on prior to trial". Nonetheless, the motion (Doc. 131) is **GRANTED**, because the evidence of Upjohn's communications with the FDA in 1989 is irrelevant to the plaintiffs' claim for compensatory damages.

The defendants move (Doc. 133) to exclude as irrelevant and prejudicial a 2006 report from the Government Accountability Office (the "GAO"). The defendants argue that the GAO report pertains to medications other than hormone therapy. In response, the plaintiffs assert that GAO report establishes that the FDA lacked the authority to force a post-marketing study or other safety precaution. The motion (Doc. 133) is **GRANTED** because the evidence is irrelevant.

Lastly, the defendants move (Doc. 134) to exclude evidence of a proposed Provera "blister pack". According to the defendants, Upjohn submitted the "blister pack" to the FDA for approval, but the FDA declined to approve the packaging. Upjohn withdrew and never released the packaging onto the market. In support of the evidence, the plaintiffs assert that the evidence is relevant to the defendants' state of mind and intent to market Provera as a component of hormone therapy (an "off-label use") without testing the safety of the combination. Because the probative value of the evidence fails to outweigh the risk of prejudice, the motion (Doc. 134) is **GRANTED**, and the evidence is excluded.

4. The Plaintiffs' Motion to Compel Trial Testimony

In moving (Doc. 136) to compel the trial testimony of Jeannemarie Durocher and James Pickar by "contemporaneous transmissions," the plaintiffs assert (1) that Rule 43, Federal Rules of Civil Procedure, permits an order compelling a witness (who

resides beyond the subpoena power described in Rule 45(b)) to testify by "live videoconferencing"; (2) that the "underlying policies" of Rule 43 favor live testimony over the reading of a deposition or the playing of a deposition video recording; and (3) that neither the witnesses nor the defendants will sustain prejudice as a result of the live testimony because the plaintiffs intend to bear the cost of contemporaneous transmission of each witness's live testimony. In opposition, the defendants argue (1) that Rule 43 permits no expansion of the subpoena power in Rule 45; (2) that neither Rule 43 nor Rule 45 permits an order compelling the testimony of an out-of-state, non-party witness; (3) that Rule 43 expresses a preference for the use of deposition testimony at trial if a witness resides outside the reach of a subpoena; and (4) that the plaintiffs cannot otherwise satisfy the requirements of Rule 43.

Rule 43 states that "[f]or good cause in compelling circumstances and with appropriate safeguards, the court may permit testimony in open court by contemporaneous transmission from a different location." In addition to emphasizing the importance of live testimony, the advisory committee notes:

[t]he most persuasive showings of good cause and compelling circumstances are likely to arise when a witness is unable to attend trial for unexpected reasons, such as accident or illness, but remains able to testify from a different place. . . . Other possible justifications for remote transmission must be approached cautiously. Ordinarily depositions, including video depositions, provide a superior means of securing the testimony of a witness who is beyond the reach of a trial subpoena, or of resolving difficulties in scheduling a trial that can be attended by all witnesses.

Rule 45 permits service of a subpoena (1) "within the district of the issuing court";

(2) "outside the district but within 100 miles of the place specified for . . . trial"; (3) within

the state of the issuing court" as permitted by law; and (4) "on motion and for good cause" if "a federal statute so provides".

In this instance, each non-party witness resides outside the scope of Rule 45.

The plaintiffs identify neither "good cause" nor a federal statute permitting a subpoena.

Furthermore, the plaintiffs fail to show a sufficient basis for issuing a subpoena authorized neither by Rule 45 nor by compelling circumstances. Thus, to the extent that the plaintiffs deposed Durocher and Pickar, the plaintiffs may proffer the deposition testimony for admission at trial.

Conclusion

IN PART and DENIED IN PART in accord with part one of this order. The motion (Doc. 111) to bifurcate is GRANTED IN PART, and the issues of liability and damages are bifurcated. The motion (Doc. 187) for application of Section 768.73(2), Florida Statutes, is DENIED WITHOUT PREJUDICE. The defendants' motions (Docs. 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 125, 128, 129, 131, 133, 134, 185) to exclude are GRANTED in accord with parts two and three of this order. The motion to compel (Doc. 136) is DENIED. To the extent that this order excludes certain evidence but provides an exception to exclusion, a party must first secure the express permission of the court before adducing excepted evidence or argument.

This action came within days of trial before the May 4, 2011, continuance consequent upon the death of the plaintiff, Ms. Cross, and the parties' request in deference to the Cross family. Therefore, both the plaintiffs and the defendants have enjoyed ample opportunity for discovery, dispositive motions, and motions in limine.

Although creative legal minds will undoubtedly conceive additional arguments and theories pertaining to the opposition's proposed evidence, the parties shall file no further motion in limine absent leave of court.

ORDERED in Tampa, Florida, on June 23, 2011.

STEVEN D. MERRYDAY UNITED STATES DISTRICT JUDGE

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