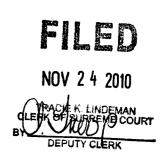
126 Nev., Advance Opinion 44

IN THE SUPREME COURT OF THE STATE OF NEVADA

WYETH, A DELAWARE CORPORATION, AND ITS DIVISIONS AND SUBSIDIARIES: AND WYETH PHARMACEUTICALS, INC., A DELAWARE CORPORATION, AND ITS DIVISIONS AND SUBSIDIARIES. Appellants, vs.

ARLENE ROWATT; WENDELL FORRESTER, DULY APPOINTED SPECIAL ADMINISTRATOR FOR THE ESTATE OF PAMELA FORRESTER; AND JERALDINE SCOFIELD, Respondents.



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No. 51234

Appeal from a district court judgment, certified as final under NRCP 54(b), in a tort action. Second Judicial District Court, Washoe County; Robert H. Perry, Judge.

Affirmed.

Lewis & Roca LLP and Daniel F. Polsenberg and Joel D. Henriod, Las Vegas; Williams & Connolly LLP and F. Lane Heard III and Heidi Hubbard, Washington, D.C.; Winston & Strawn LLP and Dan K. Webb, Chicago, Illinois, for Appellants.

Peter Chase Neumann, Reno; White & Wetherall, LLP, and Geoffrey P. White and Peter C. Wetherall, Reno; Littlepage Booth and Zoe Littlepage and Rainey Booth. Houston, Texas. for Respondents.

Robert S. Peek, Washington, D.C., Law Office of Matthew L. Sharp and Matthew L. Sharp, Renof

; Center for Constitutional Litigation, P.C., and

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1/21/11: Corrected per letter to publishers. OF

for Amicus Curiae Nevada Justice Association.

BEFORE THE COURT EN BANC.¹

<u>OPINION</u>

By the Court, CHERRY, J.:

This case arises from personal injury and strict products liability actions filed by respondents against appellants after respondents took appellants' drugs for years and were subsequently diagnosed with breast cancer. The matter was presented to a jury, with the assessment of damages being bifurcated, as respondents also sought punitive damages against appellants. A verdict was rendered in respondents' favor, awarding compensatory and punitive damages. On appellants' motion, the district court decreased the amount of damages but denied appellants' motion for a new trial and judgment as a matter of law.²

In this appeal, we are asked to decide three main issues. First, we must determine whether the district court erred in finding that Nevada law applied to the underlying action because respondents were diagnosed with cancer in Nevada. We agree with the district court's conclusion, and we adopt the "last event

²The district court certified the judgment as final under NRCP 54(b), as respondents' claims against appellants have been fully resolved and respondents have no claims pending against another party. Thus, the resolution of respondents' claims below removed them as parties from the underlying action. Additionally, other plaintiffs' claims remain pending against appellants. <u>See Mallin v.</u> Farmers Insurance Exchange, 106 Nev. 606, 797 P.2d 978 (1990).

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¹The Honorable Kristina Pickering, Justice, voluntarily recused herself from participation in the decision of this matter.

necessary" analysis to determine choice of law when an injury involves a slow-developing disease, such as cancer, and under that analysis the last event necessary for a claim against a tortfeasor is the place where the plaintiff becomes ill.

Second, we are asked to decide whether the district court abused its discretion when it gave a substantial-factor causation instruction, rather than a but-for causation instruction, and when it subsequently modified the instruction. We agree with appellants that the district court abused its discretion when it gave a substantial-factor causation instruction because each party argued its own theory of causation, mutually exclusive of the other, and respondents' injuries were purportedly only caused by one act. Nevertheless, the error was harmless, as appellants failed to demonstrate that their substantial rights were affected so that, but for the error, a different result may have been reached. The district court's modification of the instruction was not an abuse of discretion as it tailored the instruction to comply with existing scientific consensus, consistent with the evidence presented at trial.

Third, we address whether the compensatory and punitive damages awards are supported by substantial evidence and are excessive, even after the district court reduced the amount of the awards. Both awards are supported by substantial evidence. As to the compensatory damages, the awards do not shock our conscience and, thus, are not excessive. Regarding the punitive damages awards, the amounts awarded do not violate appellants' due process rights, as the awards are reasonable and proportionate to appellants' actions, or lack thereof. Finally, although the jury improperly and

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prematurely deliberated punitive damages, the error was cured by the jury's redeliberation and the district court's subsequent granting of the remittitur. Because we perceive no reversible errors in the issues raised on appeal, we affirm the district court's judgment.

FACTUAL AND PROCEDURAL HISTORY

Respondents Arlene Rowatt, Pamela Forrester, and Jeraldine Scofield all took hormone replacement therapy drugs for a number of years and later developed breast cancer.³ The specific hormone replacement drugs prescribed to respondents were in one of two forms: two pills—one estrogen pill and one progestin pill, or a single pill that combined both hormones. Appellants Wyeth and Wyeth Pharmaceutical, Inc., manufactured and sold the estrogen pill known as Premarin, which was combined with a progestin pill manufactured by a different pharmaceutical company. Wyeth also manufactured the combination hormone pill known as Prempro.

Respondents Rowatt and Scofield were prescribed the two-pill hormone medication when they lived in other states. Rowatt was later prescribed Prempro. After moving to Nevada, and while still on the medication, both women were diagnosed with breast cancer. Respondent Forrester, a Nevada resident, was originally prescribed the two-pill regimen before switching to a Prempro prescription. Before being diagnosed with cancer, respondent

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³Subsequent to the conclusion of the underlying trial, respondent Forrester passed away from causes unrelated to the injuries claimed in the district court action. Forrester is represented on appeal by her husband, Wendell Forrester, as the special administrator for her estate.

Forrester switched to another manufacturer's estrogen-based hormone product.

In 2004, each woman filed a personal injury and strict products liability suit against Wyeth in the district court.⁴ The three cases were subsequently consolidated and set for trial. Because respondents also alleged punitive damages claims against Wyeth, the trial was bifurcated into two phases. In the first phase, the jury was to determine whether Wyeth was liable for respondents' injuries and the amount of any compensatory damages. The jury was also asked to consider whether Wyeth acted with malice or committed fraud, and if the jury made either finding, a second trial would be conducted to determine the amount of punitive damages, if any, to award respondents.

Respondents had three main theories of liability that they presented to the jury. First, they contended that Wyeth's failure to study the estrogen-progestin combination was a legal cause of their cancer because Wyeth had knowledge that hormonereceptive organs, such as breast tissue, responded to the introduction of additional hormones in the body, and Wyeth allegedly failed to reasonably test the estrogen-progestin combination based on that Second, respondents argued that Wyeth failed to knowledge. adequately warn them and their physicians about the breast cancer risk associated with the estrogen-progestin combination. Third, respondents alleged that Wyeth's drugs were unreasonably

⁴Respondents Forrester and Scofield also filed claims against the progestin manufacturer. Those claims were resolved before trial.

dangerous because they could cause breast cancer and respondents purportedly developed breast cancer as a result of taking the estrogen-progestin combination. Based on these same theories, respondents asserted that Wyeth acted with malice, so as to warrant the award of punitive damages.

At trial, respondents offered evidence of Wyeth's development of Premarin and Prempro and various independent studies of the drugs. The evidence was presented to the jury to establish that Wyeth's knowledge that there was a potential increased risk of breast cancer, combined with its failure to conduct its own studies to determine the precise risk, was a legal cause of respondents' cancers. We begin by examining Premarin's and Prempro's history in conjunction with independent studies. The development of hormone replacement therapy

In 1942, Wyeth introduced Premarin, an estrogen hormone used to treat menopausal symptoms. By the 1970s, the medical community had recognized a potential link between the use of estrogen and endometrial cancer. Wyeth's Premarin sales dropped. In 1976, Wyeth's internal documents show that its researchers knew that the presence of both estrogen and progestin in a tumor indicates that the tumor had responded to hormones. In the late 1970s, a published scientific article recommended adding progestin to an estrogen regimen to avoid the risk of developing endometrial cancer. Consequently, physicians began prescribing estrogen and progestin. Respondents' physicians prescribed them Wyeth's Premarin with another manufacturer's progestin.

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In 1983, Wyeth sought approval from the FDA to study and market the combination of estrogen and progestin. The FDA allowed Wyeth to study the drugs' combination, but rejected its application to market the drugs together. The FDA specifically told Wyeth that a large, long-term study was first needed to evaluate the drug combination's safety. An internal Wyeth document shows, however, that the company viewed such studies as costly and lengthy, with unpredictable results. In 1988, Wyeth was approached for funding to conduct a study that consisted of reviewing data of women who had already been taking estrogen and progestin for a number of years. Wyeth declined to fund the study. In fact, Wyeth's documents showed that it had a company policy of not supporting breast cancer studies.

Starting in the late 1980s and early 1990s, independent studies were published that linked an increase in breast cancer risk to the estrogen-progestin hormone therapy regimen. For example, in 1989, a study was published in the New England Journal of Medicine that showed a 4.4 relative risk⁵ of breast cancer in premenopausal women. The study characterized the risk as a "slightly increased risk of breast cancer" among women who took estrogen plus progestin for a long time. The 1989 study was followed by another study shortly thereafter confirming those results. In 1990, another independent study showed an increased risk of developing breast

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⁵The record indicates that a relative risk of 4.4 means that the risk when using hormone therapy drugs is more than 4 times the normal risk.

cancer when the hormone therapy regimen was estrogen plus progestin. Internal Wyeth documents show that it responded to studies suggesting a possible breast cancer risk by downplaying the risk through public relations campaigns and its sales representatives' interactions with physicians. Wyeth also created an internal task force to counteract such findings.

In 1992, the FDA's advisory committee noted that there was insufficient data to determine whether adding progestin to estrogen increased the breast cancer risk. Wyeth's internal documents revealed that it was pleased that its efforts resulted in the FDA's conclusion that the risk was uncertain. That same year, Wyeth provided its drug to the National Institutes of Health, which was conducting a study called the Women's Health Initiative (WHI). The WHI consisted of 27,000 postmenopausal women grouped into two substudies to assess the risks and benefits of taking estrogen plus progestin or estrogen alone as compared to a group taking only placebos. This long-term study was halted in 2002 because a significant number of women on the estrogen-progestin combination had developed cancer.

In 1994, Wyeth sought approval from the FDA to market Prempro. Along with its request, Wyeth submitted at least 14 different breast cancer studies, including a quantitative statistical analysis of 31 breast cancer studies performed at Wyeth's request. The FDA, relying on the studies, approved Prempro as safe and effective. Its approval, however, was conditioned on Wyeth conducting a large-scale clinical trial on bone mineral density and the breast cancer risk to obtain comprehensive answers about breast

cancer. The breast cancer issue was highlighted as the most important issue concerning hormone therapy drugs. The FDA also recognized that it would take many years of studying the drug before the relationship between estrogen, progestin, and breast cancer could be definitively determined.

Prempro's approval was also conditioned on precise warning-label language. The FDA modified Wyeth's proposed warning label. The modified warning informed readers that "[s]ome studies have reported a moderately increased risk of breast cancer." The label noted that "[t]he effect of added progestins on the risk of breast cancer is unknown, although a moderately increased risk in those taking combination estrogen/progestin therapy has been reported." The label also stated that the rate of breast cancer that showed up in Wyeth's own human study did "not exceed that expected in the general population." Wyeth, however, never conducted its own human study.

With the launch of Prempro, Wyeth became the first pharmaceutical company to combine estrogen and progestin into one pill. Although Wyeth knew there were no long-term studies on the safety of estrogen plus progestin, it recommended Prempro's use for "all women for life."

A 1996 published European study showed that the estrogen-progestin combination increased the breast cancer risk for thin or lean women. Following that study, Wyeth updated its European label warning, but did not update its warning label in the United States. Wyeth specifically cautioned its "Breast Cancer Working Group" to keep the article "confidential, [and] not discuss

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[it] with anyone outside of Wyeth." Testimony indicated that Wyeth developed a plan to minimize the study and divert attention from it. Wyeth contended, however, that the marketing strategy to counter this European study was never utilized.

By 1997, Wyeth had not begun a comprehensive clinical trial, as required by the FDA. Even so, Wyeth requested and the FDA agreed that Wyeth could rely on the WHI study to fulfill its commitment.

By 2000, a number of published scientific articles linked hormone replacement drugs to an increased risk for breast cancer. Evidence showed that Wyeth responded to these articles by creating a task force and adding \$40.4 million to its large yearly marketing budget to counter rising consumer awareness about the relationship between breast cancer risk and hormone replacement therapy. Wyeth also began promoting Prempro's unproven, and later debunked, heart and mental health benefits in television advertisements and informational pamphlets, guides, and textbooks. The promotional materials failed to mention any breast cancer risk. The FDA admonished Wyeth for recommending its drugs for unapproved benefits as a violation of FDA regulations. As it pertained to those promotional materials, Wyeth disregarded the admonition, and the FDA never sanctioned Wyeth for the improper practices. In another situation involving different promotional materials that Wyeth intended to send to its hormone therapy consumers, Wyeth complied with the FDA's warnings to omit information about unapproved benefits.

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Over the years, Wyeth sponsored 51 medical articles by selecting different physicians to author the articles, when in fact Wyeth personnel wrote the articles or provided the substance for the articles. Wyeth's involvement with those articles was never identified. Published under independent doctors' names, the 51 ghostwritten medical articles touted the benefits of hormone replacement therapy while minimizing the breast cancer risk.

In July 2002, the Prempro arm of the large-scale WHI study was terminated because the data showed an increased risk of invasive breast cancer, coronary heart disease, and stroke. The WHI study also concluded that estrogen plus progestin did not provide any cognitive benefit for women 65 and older, but actually caused a decline in cognitive functioning. Respondents' epidemiological expert testified that the use of estrogen plus progestin caused approximately 8,000 to 15,000 extra breast cancers each year for women between 50 to 69 years of age.

After the WHI study results were released, prescriptions for the standard dose of estrogen plus progestin dropped by 80 percent. Similarly, the number of diagnosed hormone-receptorpositive breast cancers—cancers in which tumors show an active hormone receptor—also fell.

Following the WHI study, Wyeth introduced a new, lower dose estrogen-progestin pill called Prempro Low. This lower-dose treatment is recommended only as a second-line treatment and for the shortest duration necessary. It also carries the strongest warning possible—a "black box" warning—and informs the consumer that the risk of breast cancer increases with prolonged use.

With this background in mind, we discuss the procedural posture of the underlying district court case.

Trial testimony

The parties' causation theories

Expert testimony was presented from both sides regarding the cause of respondents' breast cancer. Respondents argued and presented evidence that, but for ingesting estrogen plus progestin, they would not have developed cancer. Wyeth countered that the cause of respondents' cancer is unknown, that the prescribed hormone therapy drugs did not cause their cancer, and that respondents had other risk factors for breast cancer.

Respondents' epidemiologist and oncologist testified that breast cancer can be caused either by initiation, where an agent damages a cell's DNA and causes the first abnormality, or by promotion, when a substance, such as Wyeth's hormone-therapy drugs, causes an already existing abnormal cell to grow from a benign lesion into cancer. The oncologist testified that hormonedeficient women, such as respondents, have a lower risk of developing hormone-receptor-positive breast cancer after menopause. The expert testified that the risk is low because hormone-deficient women's bodies lack sufficient hormones to cause abnormal cells to grow into cancer. The oncologist stated that once the stimulus, <u>i.e.</u>, hormone replacement drugs, are removed, the hormone-positive tumors shrink. On cross-examination, respondents' epidemiologist testified, however, that after menopause, a women's chance of developing cancer increases even while the woman's hormone levels are naturally decreasing. Thus, according to the epidemiologist, the

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presence of an estrogen receptor does not consistently determine that a tumor's growth was caused by the estrogen receptor.

Respondents argued that the WHI study demonstrated that the rate of breast cancer with the use of hormone replacement therapy had a quadrupling of the relative risk; consistent with earlier studies, the WHI study initially indicated a relative risk of 1.24, but further analysis of the WHI study showed a 4.61 relative risk for women who took estrogen plus progestin for more than five years. Respondents' experts explained that this discrepancy occurred because not every woman who enrolled in the study abided by its terms. In other words, the 1.24 relative risk took into account the total number of women who enrolled in the study, but the 4.61 relative risk included only those women who stayed in the study and took the medication as directed. Wyeth acknowledged the risk, but insisted that the relative risk was only 1.24, which was less than the 1.3 to 2.0 risk that it provided in Prempro's warning label.

Respondents' oncologist also testified that respondents' tumors were studied and showed the presence of estrogen and progestin receptors. Thus, the oncologist testified that respondents' breast cancer was caused by hormones, as they had developed estrogen and progestin receptor-positive breast cancer. Respondents argued that because they introduced hormones into their bodies, through the prescribed hormone therapy drugs, they were put at a greater risk for developing hormone-positive breast cancer. According to respondents' oncologist, but for taking the hormone therapy drugs, respondents would not have developed cancer.

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Wyeth solicited evidence from respondents' oncologist and epidemiologist that science does not know exactly what causes breast cancer and that respondents had other risk factors for developing breast cancer. The specific risk factors included respondents' gender, their age, the denseness of their breasts, that each woman was a long-time smoker, that they all had previous biopsies to remove benign lesions, and the overall number of years that the women had menstrual cycles. Respondents' experts also testified on cross-examination that all three women had abnormal cells before taking the hormone replacement therapy. Respondents Rowatt and Forrester had an additional risk factor: they were both overweight. Testimony also showed, however, that respondents' physicians did not believe that respondents were at risk for cancer because they had no family history of breast cancer and none of them had ever taken birth control.

Respondents' oncologist, on direct examination, discounted the majority of respondents' existing risk factors. The expert testified, for instance, that respondents' dense breast tissue would not be a significant risk factor, as during menopause women tend to lose density in their breasts. On cross-examination, the oncologist conceded, however, that the same is not true for every woman. Respondents' oncologist and Wyeth's radiology expert disagreed as to whether respondents' breast density had changed while on hormone replacement therapy.

Respondents' epidemiologist and cancer biologist physician testified that it could be anywhere from a few to 40 years for a benign lesion to turn into cancer. The oncologist explained that

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respondents' cancers were not detectable for years because the women did not have preexisting cancer cells. Thus, in respondents' case, it took years for the estrogen-progestin drug combination to fertilize respondents' abnormal cells and develop the cells into cancer. Further expert testimony was presented that recent medical literature confirmed that estrogen-progestin-receptor-positive cancers have an even higher statistical chance of recurrence than other breast cancers. At the time of trial, none of respondents' breast cancer had spread, and respondents were in remission.

<u>Respondents' hormone replacement therapy history</u>

Each respondent testified at trial as to how long she had been taking hormone therapy drugs. Respondent Rowatt testified that she had taken the drugs for a total of 7 years while living in Oregon and approximately 5 months after moving to Nevada; respondent Forrester, a Nevada resident, took the drugs for 9 years; and respondent Scofield took the drugs for 14 years while living outside Nevada, then for approximately 1 year after she moved to Nevada. Respondents were all diagnosed with breast cancer while living in Nevada.

Respondents testified regarding the affects their diagnoses had on them and their families; how, following their diagnoses, they underwent various surgeries to remove the cancer; and the resulting effects, both physical and mental, that they experienced from the surgeries. Evidence was also presented about respondents' various post-surgery treatments, such as chemotherapy or radiation and projected years of medication necessary to prevent the recurrence of cancer. Respondent Forrester testified that she

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was unable to take any post-surgery medication due to the severe side effects.

As to the drug labels, respondent Rowatt testified that she knew there was a risk of breast cancer, but after discussing the risk with her doctor, she did not think that she was in the risk category because she did not take birth control pills and there was no family history of breast cancer. Respondent Forrester testified that she was unaware of any risks because her doctor failed to have that discussion with her; she never asked about any risks. Respondent Scofield testified that she never saw the drug's warning label, as she received her prescriptions at military bases, and she testified that the warning inserts were not provided. All three women testified that if they had known of the risk of breast cancer, they would not have taken the medication. Each of their health care providers testified that when they prescribed the hormone therapy drugs, they believed that the benefits outweighed the risks. Following the WHI study, their opinions changed.

Respondents further testified about their post-cancer lives. They all testified as to how they try to lead normal lives, but are always fearful that the cancer will return. Respondents' oncologist expert testified that there is always a possibility that the cancer could return.

The jury's verdict

At the close of evidence, the parties and the district court settled the jury instructions. Due to respondents' objection to the bifurcation instruction, the district court did not inform the jury that a second trial would be held if the jury found that Wyeth acted with malice or fraud. Wyeth did not object. The parties agreed to a but-

for causation instruction, yet, the district court gave a substantialfactor causation instruction. Wyeth objected, but the court responded by modifying its proposed substantial-factor causation instruction.

After the jury was instructed and the parties made closing arguments, the case was submitted to the jury. The jury returned verdicts in favor of respondents totaling \$134.6 million in compensatory damages. The jury also found that Wyeth had acted with malice or fraud. Because the jury made this last finding, the court ordered the jury to return for a trial on punitive damages.

Before the punitive damages phase began, the district court learned and confirmed that the jury had awarded punitive damages along with the compensatory damages. Wyeth moved for a mistrial, which was denied. The district court reinstructed the jury on the law of compensatory damages, and the jury was directed to deliberate again, but solely on compensatory damages. It returned three compensatory damages awards totaling \$35.1 million.

For the punitive damages phase, the jury was instructed on assessing punitive damages. Evidence was presented regarding Wyeth's financial condition and following deliberations the jury returned three punitive damages awards totaling \$99 million.

Wyeth moved for a renewed judgment as a matter of law and a new trial or, in the alternative, remittitur. Respondents opposed the motions. The district court denied the renewed motion for judgment as a matter of law and the new trial motion, but granted the remittitur. It reduced the compensatory damages to \$23 million and the punitive damages to \$57,778,909; respondents

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accepted the remittitur. This appeal followed. The Nevada Justice Association was granted leave to file an amicus brief in support of affirmance.

DISCUSSION

We begin our analysis by determining the threshold issue of whether the district court properly decided choice of law. We take this opportunity to provide Nevada courts with guidance for a choice-of-law analysis when a slow-developing disease is involved. This discussion is followed by Wyeth's challenges to the jury instructions. And finally, we address the compensatory and punitive damages awards.

Standard of review

This court reviews de novo a district court's denial of a motion for judgment as a matter of law. <u>Winchell v. Schiff</u>, 124 Nev. 938, 946-47, 193 P.3d 946, 952 (2008). We review a district court's decision to deny a new trial motion for an abuse of discretion. <u>Nelson v. Heer</u>, 123 Nev. 217, 223, 163 P.3d 420, 424-25 (2007). Appellate issues involving a purely legal question are reviewed de novo. <u>Settelmeyer & Sons v. Smith & Harmer</u>, 124 Nev. 1206, 1215, 197 P.3d 1051, 1057 (2008).

The district court properly concluded that Nevada law applied

Wyeth contends that the district court erred when it determined that Nevada law applied to respondents Rowatt's and Scofield's claims because they lived in other states while taking Wyeth's hormone replacement therapy, and thus, the laws of the states where they lived when the disease process began should have been applied to their claims. Respondents counter that Nevada constitutes the "legal" place of injury because the final event

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necessary to assert a claim against Wyeth did not exist until the women were diagnosed in Nevada with breast cancer. We agree with respondents.

This court has adopted the Restatement (Second) of Conflict of Laws, section 146, for determining the choice of law for personal injury cases. General Motors Corp. v. Dist. Ct., 122 Nev. 466, 474, 134 P.3d 111, 117 (2006). Section 146's general rule provides that the state's law where the injury occurred governs the rights and liabilities of the parties. Restatement (Second) of Conflict of Laws § 146 (1971). To make a proper choice of law under section 146, the court must apply the section's general place-of-injury rule, unless a party presents evidence that another state has a more significant relationship with the alleged tortious conduct and the parties. <u>General Motors Corp.</u>, 122 Nev. at 474, 134 P.3d at 117. Section 146 has defined "personal injury" as "either physical harm or mental disturbance, such as fright and shock, resulting from physical harm or from threatened physical harm or other injury to oneself or to another." Restatement (Second) of Conflict of Laws § 146 cmt. b. More than one type of personal injury can arise from a single event. Id.

We have not yet defined what constitutes the place of injury for a slow-developing disease such as cancer, and we take the opportunity to do so now. Wyeth argues that courts have held that the place of injury for a slow-developing disease is the state where the disease process begins. <u>See Rice v. Dow Chemical Co.</u>, 875 P.2d 1213, 1218-19 (Wash. 1994); <u>Clayton v. Eli Lilly and Co.</u>, 421 F. Supp. 2d 77, 79-80 (D. D.C. 2006); <u>Smith v. Walter C. Best, Inc.</u>, 756

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F. Supp. 878, 880-81 (W.D. Pa. 1990); <u>Harding v. Proko Industries</u>, <u>Inc.</u>, 765 F. Supp. 1053, 1056-2657 (D. Kan. 1991). Other courts, however, have determined that the place of injury for slowdeveloping diseases is the place where the disease, or injury, was first ascertainable. <u>See generally Renfroe v. Eli Lilly & Co.</u>, 686 F.2d 642, 645-47 (8th Cir. 1982) (holding that there is no legally compensable injury to sue upon until a slow-developing disease is detected); <u>In re Joint Eastern & Southern Dist. Asbestos Lit.</u>, 721 F. Supp. 433, 435 (E.D. and S.D.N.Y. 1988) (concluding that the last act necessary for a claim against a tortfeasor refers to the place where the plaintiff became ill); <u>Trahan v. E.R. Squibb & Sons, Inc.</u>, 567 F. Supp. 505, 507 (M.D. Tenn. 1983) (recognizing that the "law of the state where injury was <u>suffered</u> controls," rather than the state's law where the tortious conduct occurred).

We reject the cases cited by Wyeth and adopt the analysis of the cases that recognize that the place of injury is the state where the slow-developing disease is first ascertainable, which is the last event necessary for a claim against a tortfeasor. Designating the place of injury as the state where the last element necessary for a claim against the tortfeasor occurs conforms to our definition of injury. <u>See Massey v. Litton</u>, 99 Nev. 723, 725-26, 669 P.2d 248, 250-51 (1983) (defining "injury," in the context of medical malpractice, as a legal injury in which the plaintiff has suffered damages and knows or has reason to know of the health care provider's negligence). This analysis will also guide district courts in making a choice-of-law decision when a slow-developing disease is involved. The rule adopted in this opinion is preferable to Wyeth's

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approach because until a slow-developing disease is detected, there is no legally compensable injury to sue upon.⁶

For example, in Renfroe v. Eli Lilly & Co., 686 F.2d 642, 645 (8th Cir. 1982), the Eighth Circuit Court of Appeals affirmed the lower court's determination that the plaintiffs' injuries occurred in the state where their injuries were ascertainable. The lower court specifically recognized that a cause of action does not accrue until the "final element of the cause of action occurs." Id. at 645. The Renfroe plaintiffs were exposed to the defendants' anti-miscarriage drug while in utero. Id. at 644. Both plaintiffs' exposure occurred in Missouri and both plaintiffs eventually moved to California, where their cervical cancers were diagnosed. Id. The plaintiffs filed suit against the defendants, who moved for summary judgment on the basis that the plaintiffs' claims were barred by the relevant statute of limitations. <u>Id.</u> at 644-45. The lower court ultimately found that the plaintiffs' claims did not originate in Missouri, where the exposure to the harmful drug occurred, but where the plaintiffs' damages were sustained and capable of determination. Id. at 646. In affirming the lower court, the <u>Renfroe</u> court noted that the plaintiffs' damages claims were not based on the physiological or genetic injuries sustained in utero, but rather on the development of cancer and resulting surgeries. Id. at 647. Thus, the Renfroe court held that the

⁶Our adoption of the "last event necessary" test for the placeof-injury rule is not to be confused with the plaintiff's discovery of his or her illness, which implicates the beginning of the limitation period. <u>Asbestos Lit.</u>, 721 F. Supp. at 435.

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plaintiffs' injuries originated in the state where their cancer had developed and was ascertainable. <u>Id.</u>

Turning to the present case, the record shows that respondents Rowatt and Scofield were both exposed to estrogen plus progestin for a number of years while living in other states, however, the last event necessary to give rise to their claims against Wyeth occurred in Nevada, when the women were diagnosed with cancer. Their cancer was not detected while they lived in other states, even though the cancerous tumors may have been developing while they lived in those states.

This does not conclude the choice-of-law inquiry. Under Restatement section 146, if a party submits sufficient evidence that another state's law applies based on the parties' relationship and the tortious conduct, we move past the general place-of-injury rule. <u>See General Motors Corp. v. Dist. Ct.</u>, 122 Nev. 466, 474, 134 P.3d 111, 117 (2006). Here, Wyeth argues that Nevada does not have a significant relationship to the alleged tortious conduct, as respondents Rowatt and Scofield ingested the hormone therapy drugs for 7 and 14 years, respectively, while living in other states. We conclude, however, that these facts are not sufficient to demonstrate that states other than Nevada have a more significant relationship.

Specifically, after moving to Nevada, the women continued taking the hormone therapy drugs. Respondents Rowatt and Scofield were diagnosed with breast cancer in Nevada, and they were Nevada residents at that time. They underwent the physical and emotional pain and suffering of their breast cancer surgeries and

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post-surgery medical treatments in Nevada. Since their surgeries, both women have had follow-up medical care, in Nevada, to detect if their breast cancers had returned. No evidence was presented that either respondent has moved from Nevada. Thus, even under the most-significant-relationship test, we conclude that Nevada law applies, as Wyeth failed to demonstrate that another state has a more significant relationship to the women's injuries or the parties' relationship.

Because we conclude that the place of injury for respondents Rowatt and Scofield was in Nevada and that Nevada has the most significant relationship to the injuries and parties' relationship, we thus conclude that the district court did not err or abuse its discretion in denying Wyeth's motion for judgment as a matter of law or a new trial based on choice of law.⁷

⁷We also conclude that the district court did not abuse its discretion in submitting the statute of limitations questions to the jury, as the district court properly found that material questions of fact existed. <u>Allstate Insurance Co. v. Miller</u>, 125 Nev. ____, ___, 212 P.3d 318, 322 (2009) (recognizing that when questions of fact exist concerning a triable issue, the district court does not abuse its discretion when it submits the questions to the trier of fact for resolution); <u>Siragusa v. Brown</u>, 114 Nev. 1384, 1391, 971 P.2d 801, 806 (1998) (providing that when a claimant discovered or should have discovered the facts constituting a cause of action is a question of fact for the jury).

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The district court did not abuse its discretion when it modified the causation instruction, but the evidence supported a but-for causation instruction

Wyeth raises two challenges to the causation instruction given by the district court to support its contention that a new trial is warranted. First, it argues that the district court abused its discretion in giving a substantial-factor causation instruction instead of a but-for causation instruction. Second, Wyeth contends that the abuse of discretion was compounded when the district court amended the substantial-factor instruction to adopt respondents' theory of causation, which rendered the instruction partial and prejudicial.

At the close of testimony, both parties requested that the jury be instructed that Wyeth could be held liable for respondents' injuries if the jury determined that, but for taking Wyeth's drugs, respondents would not have developed breast cancer. Despite the parties' request, the district court concluded that a substantial-factor causation instruction was warranted because sufficient evidence was presented to the jury to suggest that there were multiple causes of respondents' breast cancer. Wyeth objected to the court's proposed instruction, which the district court overruled. The district court modified the "substantial-factor" pattern jury instruction by tailoring it to the evidence presented. The pattern instruction states that "[a] legal cause of injury, damage, loss, or harm is a cause which is a substantial factor in <u>bringing about</u> the injury, damage, loss, or harm." Nev. J.I. 4.04A (emphasis added). The district court replaced "bringing about" with "producing or promoting."

The district court's decision to give or refuse a particular instruction will not be overturned absent an abuse of the district

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court's discretion or judicial error. Countrywide Home Loans v. <u>Thitchener</u>, 124 Nev. 725, 735-36, 192 P.3d 243, 250 (2008). "A party is entitled to an instruction on every theory that is supported by the evidence, and it is error to refuse such an instruction when the law applies to the facts of the case." Woosley v. State Farm Ins. Co., 117 Nev. 182, 188, 18 P.3d 317, 321 (2001); accord Posas v. Horton, 126 Nev. ___, 228 P.3d 457 (2010). A district court is not bound by the suggested language of the standard instructions and is free to adapt them to fit the circumstances of the case. In re Prempro Products Liability Litigation, 586 F.3d 547, 567-68 (8th Cir. 2009); Cedars-Sinai Medical Center v. Superior Court, 954 P.2d 511, 517 (Cal. 1998). A but-for causation instruction applies when each party argued its own theory of causation, the two theories were presented as mutually exclusive, and the cause of the plaintiff's injuries could only be the result of one of those theories, but not both. Johnson v. Egtedar, 112 Nev. 428, 436, 915 P.2d 271, 276 (1996). A substantialfactor causation instruction is appropriate when "an injury may have had two causes, either of which, operating alone, would have been sufficient to cause the injury."⁸ Id. at 435, 915 P.2d at 275-76.

The causation theories advanced by the parties were mutually exclusive. Respondents presented evidence that Wyeth's drugs were the sole cause of their injuries. Wyeth countered by

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⁸We leave open the issue of whether the substantial-factor instruction applies in negligence cases. <u>See Mitchell v. Gonzales</u>, 819 P.2d 872, 878 (Cal. 1991) (holding that the "substantial factor" jury instruction subsumes the "but for" instruction in negligence cases).

presenting evidence refuting that claim on the basis that science has not yet determined what causes cancer and that respondents had numerous risk factors that increased their chances of developing cancer without taking the hormone replacement medication. Although Wyeth elicited testimony from respondents' experts that respondents had other risk factors for developing breast cancer, respondents' experts gave little significance to those factors. Thus, contrary to the district court's conclusion, the evidence supported a but-for causation instruction. We conclude, however, that the error was harmless.

An error is harmless when it does not affect a party's substantial rights. NRCP 61. When an error is harmless, reversal is not warranted. <u>Id.</u>; <u>see also Countrywide Home Loans</u>, 124 Nev. at 747, 192 P.3d at 257. But if the moving party shows that the error is prejudicial, reversal may be appropriate. <u>Cook v. Sunrise Hospital & Medical Center</u>, 124 Nev. 997, 1006-07, 194 P.3d 1214, 1219-20 (2008). To establish that an error is prejudicial, the movant must show that the error affects the party's substantial rights so that, but for the alleged error, a different result might reasonably have been reached. <u>Id.</u> at 1007, 194 P.3d at 1220; <u>El Cortez Hotel, Inc. v. Coburn</u>, 87 Nev. 209, 213, 484 P.2d 1089, 1091 (1971). The inquiry is fact-dependent and requires us to evaluate the error in light of the entire record. <u>Carver v. El-Sabawi</u>, 121 Nev. 11, 14, 107 P.3d 1283, 1285 (2005); <u>Boyd v. Pernicano</u>, 79 Nev. 356, 359, 385 P.2d 342, 343 (1963).

Here, the appellate record shows that during trial, evidence was presented that respondents were hormone-deficient

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women; however, respondents were diagnosed with estrogenprogestin-receptor-positive breast cancer only after taking Wyeth's Premarin and a progestin pill or Wyeth's Prempro for many years. In other words, the cells in respondents' breast tissue responded to the presence of hormones in respondents' bodies. The hormones present in their bodies, however, were the result of ingesting Premarin and progestin or Prempro. Thus, the jury concluded that Wyeth's drugs caused respondents' cancer tumors.

Scientific evidence supported the jury's conclusion. The WHI study showed an increased risk of invasive breast cancer with the use of estrogen and progestin and a 4.61 relative risk for women who took estrogen plus progestin longer than 5 years, meaning that respondents, who took the drugs for more than 5 years, had more than 4 times the normal risk of developing breast cancer. Even Wyeth classified this as a substantial risk. The post-WHI label now warns that "[t]he excess risk [of breast cancer] increased with duration of use." After the WHI study was published, those breast cancer cases commonly associated with hormone therapy dropped significantly. Thus, the district court's instructional error was harmless, as it did not substantially affect Wyeth's rights, and reversal is not supported based on this contention.

Finally, Wyeth argues that the district court abused its discretion by amending the substantial-factor instruction to adopt the language of respondents' experts by substituting "promotion" into the instruction's language, which represented respondents' theory of causation. Wyeth contends that in doing so, the district court diluted the concept of causation and rendered the instruction both partial

and prejudicial. Respondents support the district court's modification, as they assert that it was within the district court's broad discretionary authority to tailor the instruction to fit the evidence presented.

At trial, respondents' epidemiologist expert testified that the concept of "promotion" is recognized in epidemiological textbooks as a mechanism for causation. Experts for both parties recognized the scientific theory that breast cancer can be caused either by initiation, whereby an agent damages the DNA of a cell and causes the first abnormality, or by promotion, which occurs when a substance causes an abnormal cell to grow from a benign lesion into cancer. Because neither respondents nor Wyeth alleged initiation, the district court limited the instruction to promotion. Wveth's experts may have contested whether its drugs caused breast cancer through promotion, but its experts nonetheless recognized the scientific principle of promotion. Accordingly, the district court's decision to give the modified causation instruction was not an abuse of discretion, as it was tailored to comply with existing scientific consensus and was consistent with the evidence presented at trial.⁹

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⁹We do not consider Wyeth's argument that the district court improperly gave a life-expectancy jury instruction when neither party requested it because Wyeth failed to provide authority to support its argument. <u>Mainor v. Nault</u>, 120 Nev. 750, 777, 101 P.3d 308, 326 (2004). As to Wyeth's argument that the given instruction misled the jury because it was not aware that respondent Forrester had terminal lung cancer, we conclude that reversal is not warranted on this issue because the district court reduced the compensatory damages awards.

<u>Compensatory and punitive damages awards</u>

Wyeth primarily raises two arguments concerning the district court's compensatory and punitive damages awards. First, Wyeth argues that its compliance with federal regulations negates the imposition of punitive damages. Second, Wyeth argues that the awards are not supported by substantial evidence and that, even after remittitur, they are excessive.

<u>Compliance with applicable regulatory standards does not</u> <u>automatically insulate a defendant from punitive damages</u>

Wyeth argues that because it complied with all FDA requirements for labeling and testing its drugs, the imposition of punitive damages is negated. Wyeth points out that its position on the breast cancer risk reflected the available scientific evidence, which at the time, provided sufficient warning about the breast cancer risk, and at any rate, its drug remains FDA approved and continues to be prescribed. Wyeth urges this court to follow a line of cases that hold that compliance with FDA regulations negates malice such that punitive damages should not be awarded. We decline to do so.

While the cases cited by Wyeth allowed the defendants to avoid punitive damages by complying with federal standards, those cases' holdings are inapplicable to the facts presented in this case. <u>See, e.g., Richards v. Michelin Tire Corp.</u>, 21 F.3d 1048, 1059 (11th Cir. 1994) (holding that compliance with federal and industry standards is "some evidence of due care" and that insufficient evidence was presented to demonstrate that the tire manufacturer failed to warn, as the manufacturer complied with both standards); <u>Nader v. Allegheny Airlines, Inc.</u>, 626 F.2d 1031, 1035 (D.C. Cir.

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1980) (concluding that punitive damages were not warranted when the airline complied with federal standards and such standards were in the public's interest); Boyette v. L.W. Looney & Son, Inc., 932 F. Supp. 1344, 1348 (D. Utah 1996) (holding that the adequate warning, which complied with OSHA standards, did not justify an award of punitive damages); In re Miamisburg Train Derailment, 725 N.E.2d 738, 752 (Ohio Ct. App. 1999) (stating that although compliance with industry standards did not negate negligence, such compliance negated the lower court's finding that defendants consciously disregarded the safety of others). Unlike these cases, Wyeth's conduct was fraught with reprehension and deception, and if this court adopts the policy that Wyeth seeks, potentially every company that complied with federal regulations would be absolved of punitive damages, regardless of the manner in which those requirements were allegedly satisfied. See Silkwood v. Kerr-McGee Corp., 769 F.2d 1451, 1456-58 (10th Cir. 1985) (upholding punitive damages award despite defendant's compliance with federal nuclear safety regulations); Gonzales v. Surgidev Corp., 899 P.2d 576, 590 (N.M. 1995) (holding that "compliance with federal regulations does not preclude a finding of recklessness or an award of punitive damages"); Gryc v. Dayton-Hudson Corp., 297 N.W.2d 727, 734-35 (Minn. 1980) (determining that compliance with the Flammable Fabrics Act of 1953, while relevant to the issue of punitive damages, does not preclude a punitive damages award as a matter of law).

Other courts have recognized that FDA regulations for drug manufacturers are generally viewed as establishing minimum standards for product design and warning. <u>Rite Aid v. Levy-Gray</u>,

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876 A.2d 115, 132 (Md. Ct. Spec. App. 2005); <u>see also Brochu v. Ortho</u> <u>Pharmaceutical Corp.</u>, 642 F.2d 652, 658 (1st Cir. 1981) (recognizing that FDA approval of warning language is not necessarily conclusive on the question of the warning's accuracy). The United States Supreme Court has recognized that under the FDA's regulations, a drug manufacturer is responsible for the content of its drug label and ensuring that the warning remains adequate as long as the drug is on the market. <u>Wyeth v. Levine</u>, 555 U.S. ____, 129 S. Ct. 1187, 1197-98 (2009). Thus, if a drug manufacturer knows, or has reason to know, of increased dangers that are not already identified in its drug's label, compliance with the FDA's minimal standard may not satisfy its duty to warn. <u>Stevens</u>, 507 P.2d at 661; <u>McEwen v. Ortho</u> <u>Pharmaceutical Corporation</u>, 528 P.2d 522, 534 (Or. 1974).

Although Wyeth presented evidence that its drug label warned women and physicians that there was a risk of breast cancer, these warnings were inadequate because they were misleading. Evidence was presented that Wyeth financed and manipulated scientific studies and sponsored medical articles to downplay the risk of cancer while promoting certain unproven benefits. The evidence demonstrated that Wyeth used these same publications to mislead respondents' physicians. Additionally, Wyeth recommended and promoted its drug for "all women for life," knowing that a large, longterm study was needed to definitively address breast cancer risks associated with its products. The studies that were developed over the years demonstrated that the breast cancer risk increased over time. While estrogen-progestin hormone therapy remains approved by the FDA and is still available on the market, Wyeth's particular

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drug, Prempro, is in a new lower dosage and carries a more serious warning that recommends its use only as a second-line treatment and for short durations. Therefore, we reject Wyeth's contention that compliance with FDA standards negates its liability for punitive damages, as Wyeth should not be able to benefit from its malicious and deceptive practices. <u>See State Farm Mut. Automobile Ins. Co. v.</u> <u>Campbell</u>, 538 U.S. 408, 416 (2003) (holding that punitive damages are aimed at deterrence and retribution).

The compensatory and punitive damages awards are supported by substantial evidence and are not excessive

Procedural overview

To understand Wyeth's damages arguments, we begin our discussion with a brief overview of the underlying damages phases of the proceedings. In particular, after deliberations, the jury returned verdicts in the amount of \$134.6 million in compensatory damages. The jury found that Wyeth was negligent, its products were defective, and that Wyeth concealed material facts about its products' safety. Thus, the jury found that Wyeth's drugs and actions were a legal cause of respondents' injuries. The jury also found that respondents established by clear and convincing evidence that Wyeth acted with malice or fraud. Because of this last finding, the jury returned for a second trial regarding punitive damages.

Before the punitive damages phase began, the district court discovered that punitive damages were inadvertently awarded in the trial's first phase. Wyeth moved for a mistrial, which was denied. The district court subsequently reinstructed the jury and required it to redeliberate solely on compensatory damages.

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Thereafter, the jury returned a compensatory damages award of \$35.1 million for all three respondents.

The jury received subsequent instructions on assessing punitive damages for the second phase of trial. Evidence was presented regarding Wyeth's financial condition. After deliberating, the jury returned punitive damages awards that totaled \$99 million. Wyeth moved the district court for a new trial based, in relevant part, on irregularities in the deliberations. In the event that the district court denied Wyeth's new trial motion, it also requested that the district court reduce both damages awards. Respondents opposed Wyeth's motions. The district court denied Wyeth's motion for a new trial, but granted the motion for a remittitur. Respondents accepted the remittitur.

As to remitting the compensatory damages awards, the district court found that little evidence was presented regarding respondents' actual damages. The parties had stipulated to the amount of respondents' past medical bills, but no evidence was presented as to the cost of any future medical expenses. The district court recognized that the compensatory damages awards were primarily for respondents' pain, suffering, and emotional distress. The court also found that the jury's premature deliberation of punitive damages impacted the compensatory damages awards. Thus, the district court concluded that the compensatory damages verdicts were the result of passion and prejudice.

The district court thereafter remitted the compensatory damages awards from \$35.1 million to \$23 million. In remitting the awards, the district court reduced the past damages awards from

approximately \$7.5 to about \$4.5 million. As for future damages, the district court reduced the \$36 million awarded to respondents Rowatt and Scofield to \$3 million and \$2.75 million, respectively, and remitted respondent Forrester's future damages award from \$40 million to \$3.4 million. When it reduced the compensatory awards, the district court noted that it was not discounting the significant injuries respondents suffered. It recognized that respondents' cancer diagnoses had serious lifelong physical and emotional consequences and that there existed the possibility of recurrence.

With regard to reducing the punitive damages awards, the district court abated those verdicts from \$31 to \$10 million for respondent Rowatt, \$33 to \$12 million for respondent Scofield, and \$35 to \$13 million for respondent Forrester. This decision was based on evidence that Wyeth provided a breast cancer warning, although arguably inadequate, and that it sponsored some limited testing. Respondents accepted the remittitur of \$57.8 million in punitive damages.

Standard of review

This court will affirm a damages award that is supported by substantial evidence. <u>Foster v. Dingwall</u>, 126 Nev. ____, ____, 227 P.3d 1042, 1045 (2010) (compensatory damages); <u>Bongiovi v.</u> <u>Sullivan</u>, 122 Nev. 556, 581, 138 P.3d 433, 451 (2006) (punitive damages). We will reverse or reduce the amount of an excessive compensatory damages award that was "given under the influence of passion or prejudice" and when it shocks our conscience. <u>Bongiovi</u>, 122 Nev. at 577, 138 P.3d at 448; <u>Hernandez v. City of Salt Lake</u>, 100 Nev. 504, 508, 686 P.2d 251, 253 (1984). When considering a damages award, we presume that the jury believed the evidence

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offered by the prevailing party and any inferences derived from the evidence. <u>Countrywide Home Loans v. Thitchener</u>, 124 Nev. 725, 739, 192 P.3d 243, 252 (2008).

Compensatory damages awards

Wyeth argues that the compensatory damages awards are not supported by substantial evidence as respondents presented little evidence of actual past and future damages, and thus, the awards are excessive as they are disproportionate to the injuries suffered.

Based on our review of the appellate record, we conclude that substantial evidence supports the compensatory damages awards and that the reduced awards are not excessive. A jury is given wide latitude in awarding special damages. <u>Id.</u> at 737, 192 P.3d at 251. Damages for pain and suffering are peculiarly within the jury's province. <u>Stackiewicz v. Nissan Motor Corp.</u>, 100 Nev. 443, 454-55, 686 P.2d 925, 932 (1984).

Respondents all developed a debilitating disease, breast cancer, as a result of Wyeth's actions, or lack thereof. The evidence supported the jury's finding that Wyeth was negligent in failing to conduct appropriate studies on breast cancer and that it concealed material facts about its products' safety. The evidence showed that Wyeth knew in the mid-1970s that certain body organs, such as breast tissue, responded negatively to hormones. Yet Wyeth failed to conduct or participate in any meaningful study of the estrogenprogestin drug combination until it gave its drug to the WHI study in 1992. Wyeth knew also, by the late 1970s, that physicians were

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commonly prescribing the drug combination to treat menopause and prevent osteoporosis. And when published medical studies linked estrogen-progestin hormone therapy to an increased breast cancer risk, Wyeth sought to downplay the studies' results and divert attention from the information.

Experts testified that respondents were hormone deficient, yet estrogen and progestin receptors were present in their tumors. Because of the hormone receptors in respondents' tumors, the fact that respondents' were hormone deficient, and the fact that they were taking hormone therapy drugs, respondents' experts concluded that the drugs caused their cancers.

Respondents testified that their cancer diagnoses had a devastating impact on them and their families. Two of the women underwent a mastectomy and one a lumpectomy; all underwent the removal of lymph nodes to detect if their cancer had spread. Respondent Rowatt's hospital stay was longer due to her preexisting heart condition, as she had to be removed from her blood thinning medication before she could go into surgery and had to be put back on the medication after the surgery.

After their surgeries, respondents suffered through various aftereffects. Because of the fluid collection in their body, each respondent had to wear breast drains for several weeks. The removal of their lymph nodes caused numbress in their arms; respondent Rowatt's numbress is permanent and she has a hole under her arm where the lymph nodes were removed. The surgeries left scarring, which respondent Scofield testified is a daily reminder of her cancer. Two of the respondents underwent chemotherapy and

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one radiation. Each respondent was also prescribed medication to prevent the recurrence of the cancer. Respondent Forrester experienced a painful side effect from the medicine, which prevented her from functioning normally; she had to discontinue the medication.

While respondents were given good prognoses following their treatments, expert testimony suggested that there is always a chance that the cancer may return, even 20 years later. They each testified that while they have been in remission, they persistently worry and fear that the cancer will return. Respondent Rowatt and her husband testified that she tries to lead a normal life, but finds herself doing all that she can because she is not sure of what her future holds. Respondent Scofield testified that her cancer is like a shadow that knows she is afraid of it and that follows her everywhere. Testimony was presented that respondents' future medical treatment involved regular blood tests and mammograms.

Based on the evidence presented to the jury, we conclude that the compensatory damages awards after remittitur are not excessive because they are supported by substantial evidence and the awards do not shock our conscience.¹⁰ <u>Bongiovi</u>, 122 Nev. at 577, 138

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¹⁰Wyeth attempts to argue that the damages awards are excessive as compared to damages awards rendered in similar cases. Any such consideration would be an abuse of discretion. <u>See Wells</u>, <u>Inc. v. Shoemake</u>, 64 Nev. 57, 74, 177 P.2d 451, 460 (1947). Thus, we reject this argument on appeal.

P.3d at 448; <u>Hernandez</u>, 100 Nev. at 508, 686 P.2d at 253; <u>see</u> <u>generally Deloughery v. City of Chicago</u>, 422 F.3d 611, 616-17, 619 (7th Cir. 2005) (recognizing that when the defendant's motion for remittitur is granted and the plaintiff accepts the remittitur, the defendant may still challenge the amount of the remittitur as excessive). Thus, because the reduced compensatory damages awards are not excessive, we conclude that the district court did not abuse its discretion in denying Wyeth's motion for a new trial. <u>Nelson v. Heer</u>, 123 Nev. 217, 223, 163 P.3d 420, 424-25 (2007) (providing that a district court's decision regarding a new trial motion is reviewed for an abuse of discretion).¹¹

¹¹We reject Wyeth's contention that the jury's compensatory damages verdict was further tainted by passion and prejudice because the jury improperly considered potential harm to nonparties based on respondents' closing arguments. In particular, respondents in closing stated that Wyeth's drugs caused a sufficient number of deaths or injuries to fill two football stadiums and that the decrease in breast cancer rates was attributable to the drop in estrogenprogestin prescriptions after the WHI study was released. To determine whether a defendant's conduct is so reprehensible as to warrant the imposition of punitive damages, a jury may consider evidence of actual harm to nonparties, as that may show that the defendants' conduct, which harmed the plaintiffs, may also present a substantial risk to the general public. See Phillip Morris USA v. Williams, 549 U.S. 346, 355 (2007). Further, Wyeth's argument that the district court improperly refused to prohibit respondents' counsel from reading the "Race for the Cure" poem to the jury in closing arguments lacks merit. To the extent that the complained-of closing arguments inflamed the jury's passion and prejudice against Wyeth, we conclude that the district court properly reduced the respondents' compensatory damages award in light of the conflicting evidence presented, as previously discussed.

Punitive damages awards

<u>Substantial evidence supports the jury's finding of</u> <u>malice</u>

Wyeth argues that its explicit and detailed warnings about breast cancer risk associated with its products accurately reflected then-existing science and disclosed the limits of that knowledge. Wyeth argues that malice could not exist because its drugs are safe and to this day, Prempro and Premarin remain FDAapproved and continue to be prescribed. Respondents contend that Wyeth's warning labels were inadequate because they gave false assurances.

A plaintiff may recover punitive damages when evidence demonstrates that the defendant has acted with "malice, express or implied." NRS 42.005(1). "'Malice, express or implied,' means conduct which is intended to injure a person or despicable conduct which is engaged in with a conscious disregard of the rights or safety of others." NRS 42.001(3). A defendant has a "[c]onscious disregard" of a person's rights and safety when he or she knows of "the probable harmful consequences of a wrongful act and a willful and deliberate failure to act to avoid those consequences." NRS 42.001(1). In other words, under NRS 42.001(1), to justify punitive damages, the defendant's conduct must have exceeded "mere recklessness or gross negligence." Thitchener, 124 Nev. at 742-43, 192 P.3d at 254-55.

The evidence shows that while the words "breast cancer" appear ten times in the Prempro label, in many instances the term appeared in reassuring statements. For instance, the warning stated that the relationship between progestin and breast cancer is unknown, that the majority of studies show no increase in breast

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cancer risk, and that the rate of breast cancer that showed up in Wyeth's human study did "not exceed that expected in the general population." To the contrary, the evidence showed that before Prempro was marketed, there was scientific data that confirmed an increased risk in breast cancer with the prolonged use of estrogen plus progestin. Respondents also presented evidence that Wyeth never conducted a human study. Testimony showed that Wyeth spent \$200 million each year marketing these drugs, but did not perform sufficient drug testing regarding breast cancer and its products to determine whether they were safe to use.

Evidence further demonstrated that Wyeth financed and manipulated scientific studies and sponsored articles that deliberately minimized the risk of breast cancer while promoting other unproven benefits. It also implemented a policy to dismiss scientific studies that showed any link between breast cancer and hormone therapy drugs and to distract the public and medical professionals from the information as well.

Over the years, Wyeth organized task forces to contain any negative publicity about hormone therapy and breast cancer. Wyeth's strategy to undermine scientific studies linking an increased risk of breast cancer to estrogen-progestin hormone therapy included ghostwriting multiple articles. The evidence further showed that Wyeth worked to keep a European study that exposed the unusually high breast cancer risk for thin women confidential. As a result of the study, Wyeth updated its European warnings, but never updated its United States labels. As respondent Scofield is a thin woman, this additional warning would have applied to her. The Prempro

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Low, which is available to consumers today, carries the strongest warning possible, and its use is suggested only as a second-line treatment for a short duration.

Based on the warning's language and Wyeth's actions, we conclude that a jury could reasonably determine that while Wyeth warned of breast cancer, it also tried to hide any potential harmful consequences of its products. Thus, substantial evidence supports the jury's conclusion that Wyeth acted with malice when it had knowledge of the probable harmful consequences of its wrongful acts and willfully and deliberately failed to act to avoid those consequences such that punitive damages were warranted.¹²

The punitive damages awards are not excessive

Wyeth alternatively contends that the awards should be reversed because its due process rights have been violated, as the awards are purportedly excessive. Respondents disagree.

Whether a punitive damages award violates a defendant's due process rights is subject to de novo review. <u>Bongiovi</u> <u>v. Sullivan</u>, 122 Nev. 556, 582-83, 138 P.3d 433, 451-52 (2006). Awards of punitive damages are generally limited by procedural and substantive due process concerns. <u>State Farm Mut. Automobile Ins.</u> <u>Co. v. Campbell</u>, 538 U.S. 408, 416-17 (2003). The Fourteenth Amendment's Due Process Clause prohibits punitive damages awards that are grossly excessive or arbitrary. <u>Id.; Bongiovi</u>, 122

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¹²Because we conclude that the finding of malice was supported by substantial evidence, we do not need to consider whether the finding of fraud was also supported.

Nev. at 582, 138 P.3d at 451. When reviewing punitive damages awards, we consider three guideposts: "(1) the degree of reprehensibility of the defendant's conduct, (2) the ratio of the punitive damages award to the actual harm inflicted on the plaintiff, and (3) how the punitive damages award compares to other civil or criminal penalties that could be imposed for comparable misconduct." <u>Bongiovi</u>, 122 Nev. at 582, 138 P.3d at 451-52 (internal quotations and citations omitted).

As to the reprehensibility of Wyeth's conduct, the harm caused in this case was physical—breast cancer and its resulting surgeries and treatment. Wyeth's misrepresentations and concealment of data showed reckless disregard for the health and safety of the users of its drugs. Its conduct involved repeated actions in that the evidence supported many examples of it misrepresenting the risks and benefits of its products. The harm suffered by respondents was the result of Wyeth's malicious activities and deceit.

Regarding the ratio of the punitive damages awarded to the compensatory damages awards, the remitted punitive damages awards here are less than three times the compensatory awards. This is well within the accepted ratios. <u>See NRS 42.005(1)(a)</u>.

As to how the punitive damages awards compare to other civil penalties that could be imposed for comparable misconduct, Wyeth notes that the most pertinent Nevada civil sanction for engaging in deceptive trade practices is \$5,000. Respondents' regulatory expert testified, however, that fines can be imposed against a manufacturer for marketing unproven benefits. She testified that a recent comparable fine for a company that promoted

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its drug for unapproved benefits was \$600 million. We reject Wyeth's arguments and conclude that the reduced punitive damages awards are well within NRS 42.005's statutory parameters. The awards are both reasonable and proportionate to the amount of harm caused to respondents and to the compensatory damages award. Thus, the remitted punitive damages awards do not violate Wyeth's due process rights.

Because the punitive damages awards do not violate Wyeth's due process rights, we now consider whether reversal is nevertheless warranted because of the improper jury deliberations.

The jury's improper deliberations were cured

Finally, Wyeth challenges the punitive damages awards based on a purported procedural due process violation. Wyeth argues that the jury's verdict should be reversed and remanded to the district court for further proceedings because the jury improperly deliberated and awarded punitive damages without receiving proper instructions. Respondents argue that while the jury improperly considered punitive damages, the problem was corrected when the district court required the jury to deliberate the compensatory damages a second time.

During the settling of the jury instructions, the district court informed the parties that it was going to instruct the jury that should it find that malice or fraud existed, a second proceeding would take place. Respondents objected, as it would have a prejudicial effect on the jury if it knew that it would have to return for another proceeding. Thus, respondents urged the district court to remove the

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Here. the district properly bifurcated the court underlying proceedings. The jury was instructed on liability and compensatory damages, and asked to determine if Wyeth could be held liable for punitive damages. Neither the instructions nor the verdict form requested that the jury award an amount for punitive damages, even if it found that Wyeth acted with malice or fraud. When the district court learned that the jury awarded punitive damages in the trial's first phase, the court reinstructed the jury and sent them back to deliberate compensatory damages a second time. The district court properly attempted to salvage the jury's verdict so as to avoid a new trial.

The district court later recognized, however, that the premature jury deliberations on punitive damages had significantly tainted the jury's verdicts as being the result of passion and prejudice. This is evident from the fact that in the first initial deliberations, the jury returned verdicts totaling \$134.5 million, which improperly included an award for punitive damages. After being reinstructed on compensatory damages, the jury returned three verdicts totaling \$35.1 million. Thereafter, the jury awarded punitive damages that totaled \$99 million. Combined, the two awards amount to \$134.1 million, only \$500,000 less than their original award. Because the awards were still tainted by the jury's passion and prejudice, the district court granted Wyeth's motion to reduce the awards. The district court reduced the jury's punitive

damage verdict from \$35 to \$13 million for Ms. Forrester, from \$31 to \$10 million for Ms. Rowatt, and from \$33 to \$12 million for Ms. Scofield.

Thus, while the jury's improper deliberations may not have been salvaged in light of the subsequent punitive damages awards, the verdicts were spared when the district court granted the remittitur and reduced the awards. Therefore, the district court did not abuse its discretion in reinstructing the jury and then denying Wyeth's new trial motion because it salvaged the verdicts by granting the remittitur. <u>See Lehrer</u>, 124 Nev. at 1110, 197 P.3d at 1037-38 (reviewing a district court's decision regarding a jury verdict for an abuse of discretion).¹⁴

¹⁴Wyeth also argues that the district court erroneously granted attorney fees to respondents pursuant to NRS 17.115 and NRCP 68 because it rested on an error about prior verdicts and a conclusory assertion that Wyeth had acted in bad faith, without the evaluation of the factors required in <u>Beattie v. Thomas</u>, 99 Nev. 579, 588-89, 668 P.2d 268, 274 (1983). The record reflects, however, that the district court properly considered the <u>Beattie</u> factors, and thus, no abuse of discretion occurred. <u>See Wynn v. Smith</u>, 117 Nev. 6, 13, 16 P.3d 424, 428-29 (2001) (reviewing an award of attorney fees under NRS 17.115 and NRCP 68 for an abuse of discretion); <u>Yamaha Motor Co. v. Arnoult</u>, 114 Nev. 233, 252 n.16, 955 P.2d 661, 673 n.16 (1998) (providing that no one <u>Beattie</u> factor is determinative).

CONCLUSION

The district court did not err or abuse its discretion in denying Wyeth's motions for judgment as a matter of law or its motion for a new trial, and therefore, we affirm the district court on all issues presented.

Cherry Cherry J.

We concur:

C.J. a Parraguirre

J. Hardesty

45 J. Douglas J. Saitt

J. Gibbons

SUPREME COURT OF NEVADA