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### Summary of Wyeth v. Rowatt, 126 Nev. Adv. Op. No. 44

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*Nevada Law Journal*

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## **CIVIL PROCEDURE – CHOICE-OF-LAW, JURY INSTRUCTION, and PROOF OF DAMAGES**

### **Summary**

Appeal from a remitted jury verdict in favor of consumers who prevailed in a strict product liability action against a drug manufacturer and its subsidiaries.

### **Disposition and Outcome**

The Court affirmed the district court's remitted verdict, finding (1) the lower court did not err in applying Nevada law, (2) the erroneous jury instruction was harmless, and (3) substantial evidence supported compensatory and punitive awards.

### **Facts and Procedural History**

#### *Historical Development of Hormone Replacement Drugs*

In 1942, Wyeth and Wyeth Pharmaceuticals, Inc. (collectively “appellants” hereinafter) developed and marketed Prematin, an estrogen hormone used to treat menopausal symptoms. During the 1970s, the medical community recognized a link between estrogen use and endometrial cancer,<sup>2</sup> prompting physicians to prescribe progestin along with appellants' estrogen pill.<sup>3</sup>

During the 1980s, appellants applied for FDA approval to study and market the estrogen-progestin combination regimen. In response, the FDA denied permission to market the combination until a large-scale, long-term study was conducted to assess the drugs' safety. Appellants believed the FDA's suggested study would be costly, lengthy, and unpredictable. In fact, appellants confirmed this position by declining to fund a study on women who had taken the estrogen-progestin combination for a number of years.<sup>4</sup>

Beginning in the late 1980s, independent studies linked the prolonged use of estrogen-progestin combination to a significant increase in breast cancer risk. In the following two decades, appellants engaged in a series of questionable acts to minimize the link revealed through these studies:

- In 1992, FDA concluded that the link between estrogen-progestin combination and increased breast cancer risk remained uncertain, a conclusion that appellants credited to their own campaigning efforts.
- In 1994, appellants received FDA approval<sup>5</sup> to market Prempro, a single pill that combined estrogen and progestin hormones. However, in labeling Prempro, appellants inserted deceitful and misleading information.<sup>6</sup>

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<sup>1</sup> By Yan Xiong Li.

<sup>2</sup> Wyeth's own internal documents reflected its knowledge regarding this link between cancerous tumors and hormones.

<sup>3</sup> The progestin supplement was manufactured by another pharmaceutical company.

<sup>4</sup> Wyeth based its decision on a company policy against supporting breast cancer studies.

<sup>5</sup> The FDA conditioned its approval of Prempro on appellants conducting a large-scale clinical study and precise warning labels for the new drug.

- In 2000, appellants began promoting unproven heart and mental health benefits of Prempro.
- Over the years, appellants sponsored 51 ghostwritten articles in the name of independent physicians, which were either composed by its own personnel or based on data it provided.

In 1992, appellants supplied Prempro to a long-term study on postmenopausal women (hereinafter “WHI study”). The WHI study halted in 2002 after a significant number of participants taking Prempro developed breast cancer.<sup>7</sup> Moreover, the WHI study revealed increased risks of coronary heart disease, stroke, and declining cognitive functions after prolonged use of Prempro. Following the WHI study, prescriptions of estrogen-progestin combinations declined by eighty percent. Interestingly, the number of diagnosed hormone-receptor-positive breast cancers<sup>8</sup> also declined during this period.

### *Procedural Background*

Arlene Rowatt, Pamela Forrester, and Jeraldine Scofield (collectively as “respondents” hereinafter) all took hormone replacement therapy drugs manufactured and marketed by appellants for many years before moving to Nevada. After moving to Nevada, respondents continued their regimen of appellants’ drugs until their diagnoses of breast cancers. In 2004, respondents each brought separate actions alleging appellant’s malicious or fraudulent conduct caused their breast cancers and consequent adversities.

At trial, both parties presented expert testimony regarding the issue of causation. Respondents’ experts testified to a causation theory known as “promotion.”<sup>9</sup> Experts also testified that hormone-deficient women, such as respondents, were less likely to develop hormone-receptor-positive cancer.<sup>10</sup> Due to the presence of estrogen and progestin receptors in respondents’ cancerous tumors, experts concluded that “but for the introduction of hormones from appellants’ drugs, respondents would not have developed breast cancer.” Instead of presenting its own causation theory, appellants presented evidence showing that the scientific community remains uncertain about causes of breast cancer and respondents possessed numerous risk factors such as gender, age, breast density, obesity, and history of smoking.

Following expert testimonies, respondents testified to the adversities resulting from their cancer diagnoses:

- Physical pain and mental suffering from surgeries to remove their cancers;
- Pain and suffering from post-surgery treatments such as chemotherapy or radiation;
- Medical expenses to prevent the recurrence of cancer and fear of their cancers returning;
- Severe side-effects from post-surgery medication;

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<sup>6</sup> For example, the labels referred to a human study appellants never actually conducted, and recommended Prempro use for “all women for life” although studies revealed increased breast cancer risk due to prolonged use.

<sup>7</sup> Use of hormone replacement therapy drugs resulted in a quadrupling of relative risk, meaning users were four times more likely to develop breast cancer than the general population.

<sup>8</sup> Cancers whereby the tumors exhibit estrogen, progestin, or other hormone receptors.

<sup>9</sup> When a substance, such as estrogen and progestin hormones, causes already abnormal cells to grow from benign lesion into cancer.

<sup>10</sup> However, testimony also revealed that postmenopausal women suffer increased risk despite decreasing hormone levels.

At the close of evidence, parties settled on a but-for causation instruction, but the district court charged the jury with a substantial-factor instruction.<sup>11</sup> When appellants objected to the jury instruction, the district court modified the pattern substantial-factor instruction by adopting language from experts' "promotion" theory of causation. With the modified instruction, the jury returned a verdict in favor of respondents totaling \$134.6 million in compensatory damages. Moreover, the jury found that appellants acted with malice or fraud, prompting the district court to order the second phase of trial for determining punitive damages.

Prior to the second phase, the district court discovered that punitive damages had been inadvertently included in the jury's compensatory awards. After receiving new instructions, the jury re-deliberated compensatory damages, returning with awards totaling \$35.1 million and \$99 million for punitive damages.

Following this unusual sequence of events, appellants moved for renewed judgment as a matter of law and new trial, or alternatively, remittitur. The district court denied appellants' motions but granted the remittitur, reducing the compensatory and punitive damages to \$23 million and \$57,778, 909 respectively.

## **Discussion**

### *Choice-of-Law Analysis in Cases Involving Slow-Developing Diseases*

Appellants claimed the district court erred in applying Nevada law based on the finding that respondents were diagnosed with cancer in Nevada. In Nevada, choice of law for personal injury cases is governed by section 146 of the Restatement (Second) of Conflict of Laws.<sup>12</sup> Under section 146, the state's law where the injury occurred (place-of-injury rule) governs, unless another state has a more significant relationship with the alleged tortious conduct and the parties (most-significant-relationship test).<sup>13</sup> The injury can be either physical harm or mental disturbance.<sup>14</sup>

In light of competing approaches to applying the place-of-injury rule, the Court adopted the analysis that defined place-of-injury as "the state where the last element necessary for a claim against the tortfeasor occurs."<sup>15</sup> Adopting the 8<sup>th</sup> Circuit's reasoning from *Renfore*, the Court affirmed the district court's application of Nevada law, because the respondents discovered their cancer after moving to Nevada, despite their long history of using the appellants' drugs while living outside Nevada.

Turning to the most-significant-relationship test, the Court rejected appellants' argument that a longer history of drug-use outside Nevada gives other states a more significant relationship

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<sup>11</sup> The district court also withheld a bifurcation instruction based on respondents' objection.

<sup>12</sup> *Gen. Motors Corp. v. Dist. Ct.*, 122 Nev. 466, 474, 134 P.3d 111, 117 (2006).

<sup>13</sup> Restatement (Second) of Conflict of Laws § 146 (1971).

<sup>14</sup> *Id.* at § 146 cmt. b.

<sup>15</sup> *See Renfore v. Eli Lilly & Co.*, 686 F.2d 642, 645-47 (8<sup>th</sup> Cir. 1982) (last event necessary test).

to the alleged conduct or parties. After moving to Nevada, respondents continued taking the drugs, received diagnoses of their breast cancers, endured physical and emotional suffering, and followed up with treatment to monitor their cancers. Since the appellants failed to demonstrate other states had a more significant relationship than Nevada, the Court again upheld the district court's decision respecting choice-of-law.

### *Jury Instructions on Causation*

Appellants claimed that the district court abused its discretion in charging the jury with a substantial-factor causation instruction instead of a but-for causation instruction. Unlike but-for instruction, a substantial-factor instruction is appropriate only if the parties presented evidence supporting two or more causes, each independently sufficient to cause the injury.<sup>16</sup> While respondents' theory pointed to appellants' drug as the sole cause of injury, appellants' evidence merely rebutted respondents' theory without offering any alternative causes. Thus, the Court found evidence supported a but-for causation instruction.

Notwithstanding the district court's error in charging the jury with a substantial-factor instruction, the Court refused to reverse the district court because the error was harmless. Under Nevada Civil Procedure Rules, harmless errors are those that do not affect the party's substantial rights.<sup>17</sup> Prejudicial errors affect the party's substantial rights if "but-for the alleged error, a different result might reasonably have been reached."<sup>18</sup> Turning to the record below, the Court noted evidence that would have allowed a jury to find the appellants liable, even if the district court charged the jury with a but-for causation instruction. Thus, the Court denied reversal on the basis of district court's jury instruction error.

### *Modification of Substantial-Factor Instruction*

Appellants next argued that the district court erred in amending the pattern substantial-factor causation instruction by inserting language that respondents' expert witnesses used.<sup>19</sup> The replacement language originated from the experts' explanation of "promotion" theory during direct examination. However, appellants' own expert recognized "promotion" as a valid scientific principle of causation. Accordingly, the amended causation instruction complied with existing scientific consensus, and since it also conformed to evidence presented at trial, the Court found such modification to be within the district court's discretion.

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<sup>16</sup> Johnson v. Egtedar, 112 Nev. 428, 435-36, 915 P.2d 271, 275-76 (1996).

<sup>17</sup> NEV. R. CIV. P. 61.

<sup>18</sup> Cook v. Sunrise Hosp. & Med. Ctr., 124 Nev. 997, 1006-07, 194 P.3d 1214, 1219-20 (2008).

<sup>19</sup> Instead of the pattern instruction which provides that "a legal cause...is a cause which is a substantial factor in bringing about the injury..." the district court replaced "bringing about" with "producing or promoting." See NEV. J. I. 4.04A.

### *Propriety of Punitive Damages even after Compliance with FDA Regulations*

Appellants challenged the district court's award of punitive damages on the basis that compliance with FDA's testing and labeling requirements should have negated any finding of malice, a necessary element for awarding punitive damages. While such compliance is relevant, the Court also considers the manner by which regulatory requirements are satisfied.<sup>20</sup> In distinguishing cases appellants cited for its position, the Court described appellants' conduct as "fraught with reprehension and deception". Moreover, FDA regulations are widely recognized as *minimal* standards, so drug manufacturers may be required to exceed such standards in order to satisfy their duty to warn.<sup>21</sup>

To illustrate appellants' malicious practices, the Court recounted examples of appellants manipulating scientific studies, sponsoring biased medical articles, and promoting unproven benefits all in an effort to downplay the risk of breast cancer associated with using their drugs. While appellants provided precise drug labels and acquired FDA approval, the Court found the labels to be misleading and woefully inadequate. Thus, the Court refused to relieve the appellants from liability for punitive damages solely due to its compliance with federal regulations.

### *Evidentiary Support for Compensatory and Punitive Awards*

Regarding the remitted compensatory and punitive awards, appellants first argued that the awards lacked support by substantial evidence. Compensatory damages will be reversed or reduced if "given under the influence of passion and prejudice" and shocks the Court's conscience.<sup>22</sup> In considering whether substantial evidence supports the compensatory awards, the Court presumes that the jury believed the evidence presented and inferences based on the evidence.<sup>23</sup> For special damages such as pain and suffering, the jury is entitled to wide latitude.<sup>24</sup>

Here, the Court recounted examples from the record depicting the devastating effects of breast cancers on the respondents and their families. Moreover, while the respondents received positive prognoses, they must live with the constant fear their cancers would return, even after a twenty year remission. Given evidence of both historical and future injuries, the amount of remitted compensatory damages did not shock the Court's conscience.

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<sup>20</sup> See *Silkwood v. Kerr-McGee Corp.*, 769 F.2d 1451, 1456-58 (10<sup>th</sup> Cir. 1985); *Gonzales v. Surgidev Corp.*, 899 P.2d 576, 590 (N.M. 1995).

<sup>21</sup> *Rite Aid v. Levy-Gray*, 876 A.2d 115, 132 (Md. Ct. Spec. App. 2005); see also *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 658 (1st Cir. 1981) and *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 534 (Or. 1974).

<sup>22</sup> *Bongiovi v. Sullivan*, 122 Nev. 556, 581, 138 P.3d 433, 451 (2006).

<sup>23</sup> *Countrywide Home Loans v. Thitchener*, 124 Nev. 725, 739, 192 P.3d 243, 252 (2008).

<sup>24</sup> *Stackiewicz v. Nissan Motor Corp.*, 100 Nev. 443, 454-55, 686 P.2d 925, 932 (1984).

Proceeding to the punitive awards, the Court reached a similar conclusion. To recover punitive damages, respondents must present evidence demonstrating that appellants acted with express or implied malice.<sup>25</sup> Malice may be evidenced by conduct exhibiting a *conscious disregard* for the rights or safety of others.<sup>26</sup> The Court defines conscious disregard as a willful or deliberate failure to prevent harmful consequences, when one knows such consequences are probable.<sup>27</sup>

Here, appellants' conduct fit squarely within the Court's definition of malice. For example, although appellant referred to breast cancer on its drug labels, most such references appeared in reassuring statements despite scientific data to the contrary. Moreover, appellant spent \$200 million annually to market the risky drugs, but not a dime toward conducting human studies to evaluate the drug's safety. Lastly, the Court noted evidence showing appellants maintained a company policy and task force to contain negative publicity tying their drugs with heightened risk of cancer. Because the evidence showed appellant knew of the increased risk of cancer caused by their drugs, and deliberately distorted or concealed that information from physicians and consumers, substantial evidence supported the remitted punitive awards.

#### *Due Process Limitations on Punitive Awards*

Finally, appellants argued that even after the district court's remittitur, the punitive awards were excessively disproportionate to actual injuries, so as to violate its substantive due process rights. Alternatively, appellant argued for a reversal of the punitive awards because the jury's improper inclusion of punitive damages when deliberating compensatory damages, violated its procedural due process rights.

The Fourteenth Amendment's Due Process Clause prohibits punitive damages awards that are "grossly excessive or arbitrary" through substantive and procedural limitations.<sup>28</sup> Whether punitive awards violate defendant's substantive due process rights is based on an assessment of three factors.<sup>29</sup> First, how reprehensible is the alleged misconduct. Second, the ratio of punitive awards to actual harm inflicted. Lastly, the Court will compare the punitive awards to other civil or criminal penalties imposed for comparable misconduct.

Applying this three-factor analysis, the Court found appellants' persistent pattern of deceit and malicious misrepresentations to be highly reprehensible. Since the remitted punitive awards added up to less than three times the compensatory awards, the Court also accepted the

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<sup>25</sup> NEV. REV. STAT. § 42.005 (1) (2007).

<sup>26</sup> NEV. REV. STAT. § 42.001 (3) (2007).

<sup>27</sup> See NEV. REV. STAT. § 42.001 (1) (2007); exceeding "mere recklessness or gross negligence." *Thitchener*, 124 Nev. at 742-43, 192 P.3d at 254-55.

<sup>28</sup> *State Farm Mut. Auto. Ins., Co., v. Campbell*, 538 U.S. 408, 416-17 (2003).

<sup>29</sup> *Bongiovi v. Sullivan*, 122 Nev. 556, 582, 138 P.3d 433, 451-52 (2006).

ratio of punitive awards.<sup>30</sup> Regarding the final factor, both parties presented evidence of similar sanctions ranging from \$5,000 for deceptive trade practices to a \$600 million fine for marketing products with unproven benefits. Nonetheless, the Court relied on statutory parameters set forth under NRS 42.005, and concluded that the punitive awards were proportionate to actual injuries, and thus, not in violation of appellants' substantive due process rights.

Regarding appellants' procedural due process claim, the Court reached the same conclusion by citing to a strong public policy in favor of salvaging the jury verdict, if possible, to avoid a new trial.<sup>31</sup> When the district court discovered the jury verdict error, it undertook proper steps to salvage the verdict by reinstructing the jury and ordering a re-deliberation of compensatory damages. In light of clear public policy, the Court found these steps, along with the district court's remittitur, adequately preserved appellant's procedural due process rights.

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<sup>30</sup> See NEV. REV. STAT. § 42.005 (1)(a) (2007) (statutory parameters for punitive damages).

<sup>31</sup> See *Lehrer McGovern Bovis v. Bullock Insulation*, 124 Nev. 1102, 1111, 197 P.3d 1032, 1038 (2008); *Eberhard Mfg. Co. v. Baldwin*, 97 Nev. 271, 273, 628 P.2d 681, 682 (1981).