



offer evidence that GSK's failure to adequately warn of an association between Avandia and bone fractures was the proximate cause of Mrs. Schatz's injuries.

## **I. UNDISPUTED FACTS**

### ***HEALTH HISTORY***

Mrs. Schatz was diagnosed with type II diabetes in 1993. Her blood sugar was not well controlled with Diabeta, so she was switched to Glucotrol and Glucophage. Mrs. Schatz began seeing Dr. McKimm in 2002, and he prescribed Avandia, as he believed it would better control her blood sugar. Mrs. Schatz reported to Dr. McKimm that she preferred Avandia, and had stopped experiencing episodes of hypoglycemia.

When Mrs. Schatz began treatment with Dr. McKimm in 2002, he was aware of her prior medical history. This included ongoing, chronic back problems, dating back to the early 1990s, for which she had several surgical procedures. She was treated for an injured knee after a fall in 1992, and for bone fractures after falls in 1985 (nasal fracture) and 2001 (fractures of the finger and forearm). In 2002, she was treating chronic back and neck pain with narcotic pain medications. She was also taking thyroid medication, levothyroxine, which is associated with post-menopausal osteoporotic fractures in older women.<sup>2</sup>

In 2007, Mrs. Schatz suffered additional fractures. First, in May 2007, she developed a compression fracture of the spine, after the all-terrain vehicle she was riding hit a series of bumps. And then, in October 2007, she fractured three ribs and a scapula in a fall. Because scapula fractures are rare, Dr. McKimm explored whether Mrs. Schatz had osteoporosis, and finding that she did not, researched whether fractures could be adverse side effects of Avandia

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<sup>2</sup> Mrs. Schatz was born December 2, 1958, and was 43-years-old when she began using Avandia in 2002 and 48- years-old when she suffered her fractures in 2007. Dr. McKimm refers to her as a "younger woman" in his testimony, and Plaintiffs' expert report states that Mrs. Schatz was not an "older woman" and concludes that levothyroxine was no more than a minor contributing factor to her fractures.

usage. Upon learning from GSK that fractures were a rare adverse reaction to Avandia, he discontinued Mrs. Schatz's prescription for Avandia on November 20, 2007.

***AVAILABILITY OF INFORMATION ABOUT THE INCREASED RISK OF FRACTURES***

Before March 2007, the Avandia package insert ("label"), which is designed to communicate important information about medications to prescribing physicians, did not include any warnings or precautions about the risk of bone fractures.

The ADOPT study was published in the New England Journal of Medicine in December 2006. The ADOPT study found that, compared to women taking metformin or glyburide for Type II diabetes, significantly more female patients taking Avandia experienced fractures of the upper arm, hand or foot. Only a small number of women in the study had spinal fractures, and that number was similar across the three drug treatment groups.

The study results were summarized in a Dear Health Care Provider letter GSK distributed to physicians in February 2007.

In March 2007, the Avandia label was revised to include a precaution, which read:

***Fractures:*** An increased incidence of bone fracture has been observed in female patients taking AVANDIA in a long-term trial. The majority of the fractures in the women who received AVANDIA were reported in the upper arm, hand, and foot. These sites of fracture are different from those associated with postmenopausal osteoporosis (e.g. hip or spine). The risk should be considered in the care of patients, especially female patients, treated with AVANDIA, and attention given to assessing and maintaining bone health according to current standards of care.

Although the publication, the letter, and the modified label would have been available for Dr. McKimm to review, he testified that he did not remember whether he did review them.

**II. STANDARD OF REVIEW**

Summary judgment is appropriate if "the materials in the record" show "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of

law.”<sup>3</sup> Summary judgment may be granted only if the moving party persuades the district court that “there exists no genuine issue of material fact that would permit a reasonable jury to find for the nonmoving party.”<sup>4</sup> A fact is “material” if it could affect the outcome of the suit, given the applicable substantive law.<sup>5</sup> A dispute about a material fact is “genuine” if the evidence presented “is such that a reasonable jury could return a verdict for the nonmoving party.”<sup>6</sup>

In evaluating a summary judgment motion, a court “must view the facts in the light most favorable to the non-moving party,” and make every reasonable inference in that party’s favor.<sup>7</sup> A court may not weigh the evidence or make credibility determinations.<sup>8</sup> Nevertheless, the party opposing summary judgment must support each essential element of the opposition with concrete evidence in the record.<sup>9</sup> Where the non-moving party will bear the burden of proof at trial, summary judgment in favor of the moving party is appropriate where the moving party correctly notes that there is an absence of evidence to support essential elements of the non-moving party’s claims.<sup>10</sup>

### **III. DISCUSSION**

The parties agree that Pennsylvania state law governs this case. The Court will begin by examining Plaintiffs’ negligence claims. Plaintiffs’ Amended Complaint asserts separate claims for negligence (Count I) and negligent misrepresentation (Count II). The latter is clearly a failure to warn claim. The former is less clearly pled. However, to the extent that Plaintiffs allege that

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<sup>3</sup> Fed. R. Civ. P. 56(a), (c)(1).

<sup>4</sup> *Miller v. Ind. Hosp.*, 843 F.2d 139, 143 (3d Cir. 1988).

<sup>5</sup> *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

<sup>6</sup> *Id.*

<sup>7</sup> *Hugh v. Butler County Family YMCA*, 418 F.3d 265, 267 (3d Cir. 2005).

<sup>8</sup> *Boyle v. County of Allegheny*, 139 F.3d 386, 393 (3d Cir. 1998).

<sup>9</sup> *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

<sup>10</sup> *Celotex Corp.*, 477 U.S. at 325.

Avandia is defective because there are serious adverse side effects associated with the drug, they cannot state such a negligence claim under Pennsylvania law. In *Hahn v. Richter*, the Pennsylvania Supreme Court held that prescription drugs are “unavoidably unsafe products,” in that they are not without medical risks, but they are not deemed defective and unreasonably dangerous when marketed with proper warnings.<sup>11</sup> Accordingly, Count I states a cause of action only to the extent that it alleges a failure to warn of the side effects of Avandia, and the Court will treat both Counts I and II as negligent failure to warn claims.

Here, GSK acknowledges that it had a duty to warn. With regard to prescription drugs, in Pennsylvania, a manufacturer’s duty to warn is discharged where the patient’s doctor is adequately warned of the risks associated with use of the drug (the “learned intermediary” doctrine).<sup>12</sup> The parties dispute whether GSK breached its duty to provide adequate warnings to physicians via the Avandia label. However, GSK argues that even assuming, for the purpose of this motion, that the warnings contained in the label were inadequate, Plaintiffs have failed to demonstrate that GSK’s failure to warn was a proximate cause of their injuries.

Under the learned intermediary doctrine, to establish that a defendant’s failure to warn is a proximate cause of a plaintiff’s injury, “the prescribing doctor must testify that had he received a different warning, he would have altered his prescribing habits.”<sup>13</sup> Here, GSK argues that Plaintiffs have pointed to no evidence indicating the Dr. McKimm would have made different prescribing decisions with regard to Mrs. Schatz’s treatment for diabetes, before she suffered fractures in May and October 2007, if GSK had provided a different or earlier warning about the risk of bone fractures. GSK points to the following testimony:

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<sup>11</sup> *Hahn v. Richter*, 673 A. 2d 888, 890 (Pa. 1996).

<sup>12</sup> *Lineberger v. Wyeth*, 894 A.2d 141, 149-50 (Pa. Super. 2006)

<sup>13</sup> *Id.* at 150 (quoting *Demmler v. SmithKline Beecham, Corp.*, 671 A.2d 1151, 1155 (Pa. Super. 1996)).

Q: if a patient presented to you today with the same clinical course as Mrs. Schatz presented to you back in 2002—

A: Okay

Q: ---would you prescribe Avandia to that patient today?

A: Yeah, to be honest with you, I would. In a --- younger female that, you know, didn't have any risk factors for heart disease or congestive heart failure---

Although Dr. McKimm's testimony expressly mentions a different risk, at the time of his deposition, Dr. McKimm was aware that bone fractures were the risk at issue in this litigation. He was also aware that Avandia use was a risk factor for bone fractures in some users, as he had personally conducted an inquiry into this issue after Mrs. Schatz suffered her October 2007 fractures. Yet, he testified that, knowing what he knew at the time of his deposition, he would still prescribe Avandia to a patient with the same medical history presented by Mrs. Schatz in 2002. At no point in his deposition does he testify that he would have made different medical decisions about Mrs. Schatz's treatment if GSK had provided different or more prominent warnings about the risk of fractures.

In light of Dr. McKimm's testimony that he would have made the same prescribing decision for a patient with Mrs. Schatz's 2002 medical history if she presented today, it falls to Plaintiffs to point to some evidence suggesting that Dr. McKimm equivocated on this position, creating a genuine issue of material fact. Plaintiffs point out that Dr. McKimm testified that had GSK included a black box warning regarding the risk of bone fractures, that warning would have "caught his eye."<sup>14</sup> He also testified that he does not routinely read entire labels, as all medications carry side effects. However, testifying that he routinely uses black box warnings to weigh risks and benefits, and that a black box warning would have been more salient, is not sufficient to establish a genuine issue of material fact as to whether such a warning would have

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<sup>14</sup> GSK points out that only the FDA can decide that a label should include a black box warning, so the absence of a black box warning cannot be attributed to GSK.

deterred him from prescribing Avandia to Mrs. Schatz for the five years *before* she suffered the 2007 fractures.

Dr. McKimm also testified he regularly relies upon Dear Health Care Provider letters sent by pharmaceutical manufacturers to analyze the risks and benefits of using a medication with a particular patient. However, in this case, a Dear Health Care Provider letter summarizing the bone-fracture findings of the ADOPT study was distributed in February 2007, one month prior to the label change, and approximately three months prior to Mrs. Schatz's compression spine fracture. Dr. McKimm does not recall whether he ever reviewed that letter, but the record reflects that he continued to prescribe Avandia for Mrs. Schatz for approximately nine months following the distribution of that letter.

In fall 2007, recognizing that Mrs. Schatz had recently suffered multiple fractures which were not well-explained by the accidents which had preceded them, Dr. McKimm began investigating the association between Avandia and bone fractures. Upon learning from GSK's pharmaceutical representatives that fractures could be a rare adverse reaction to Avandia, Dr. McKimm immediately removed Ms. Schatz from Avandia and substituted a different medication for diabetes. Despite Plaintiffs' arguments to the contrary, however, this response is simply insufficient to create a genuine issue of material fact as to whether Dr. McKimm would have changed Mrs. Schatz's medication had he learned of this association *before* she suffered those fractures in 2007, especially in light of his testimony.

Plaintiffs' expert, Dr. Sonal Singh, M.D., M.P.H., opined that because few spine and hip fractures occurred among patients enrolled in the ADOPT study, the study may have been underpowered to detect an association between Avandia and spine and hip fractures.<sup>15</sup> He

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<sup>15</sup> Singh Expert Report, Doc. No. 14, Exh. E.

believes that two subsequent studies, published in 2008 and 2012, have demonstrated that Avandia use is associated with an increase in the risk of hip and spine fractures in older women using the drug, and opines that the label should have been updated to reflect these findings. Because these studies were published after Mrs. Schatz had stopped taking Avandia, any label change reflecting the findings would be irrelevant to this case. Moreover, Dr. Singh was careful to note that Mrs. Schatz was not an “older woman” in opining that her use of levothyroxine, which is also associated with an increased risk of bone fractures in older women, was no more than a minor contributing factor in Mrs. Schatz fractures.<sup>16</sup> Dr. McKimm also referred to Mrs. Schatz as “a younger female” in his deposition testimony. Therefore, Dr. Singh’s expert opinion does not create an issue of fact as to whether modifying the Avandia label to caution physicians regarding an increased risk of hip and spine fractures in older women would have deterred Dr. McKimm from prescribing Avandia to Mrs. Schatz from 2002 through November 2007.<sup>17</sup>

The Court holds that Plaintiffs have failed to establish a genuine issue of material fact as to whether Dr. McKimm would have prescribed a different medication for Mrs. Schatz, rather than Avandia, prior to her injuries in 2007, if GSK had provided a different or more prominent warning regarding the risk of bone fractures. Because they have failed to establish an issue for trial with regard to whether GSK’s conduct was a proximate cause of Mrs. Schatz’s injuries, Plaintiffs’ negligence claims must be dismissed.

Next, the Court must determine whether Plaintiffs’ remaining claims must be dismissed as a result of this holding. In addition to the negligence claims, Plaintiffs’ Amended Complaint

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<sup>16</sup> McKimm Dep. Tr. at 60-62.

<sup>17</sup> Similarly, although Dr. Singh opines that GSK was aware of and had a duty to warn of risk of bone fractures prior to 2007, based on animal studies, Plaintiffs have not put forth evidence that Mrs. Schatz’s course of treatment would have differed had information about that risk been disseminated by GSK prior to February 2007.

contained claims of strict liability—failure to warn, breach of warranty, fraudulent misrepresentation, unjust enrichment, and Mr. Schatz’s claim for loss of consortium.

GSK argues that each of Plaintiffs’ claims relies upon the premise that GSK failed to provide adequate warnings about Avandia’s risks, and thus all of their claims must be dismissed under Pennsylvania law. The Pennsylvania Supreme Court has held that “where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer’s negligence, is the only recognized basis of liability.”<sup>18</sup> Thus, the manufacturer of prescription drugs has the duty to exercise reasonable care to provide adequate warnings about the risks inherent in those drugs, and can be held liable for negligence, but cannot be held liable for failure to provide adequate warnings under any other theory.<sup>19</sup>

Plaintiffs argue that some of its claims are not premised on GSK’s alleged failure to adequately warn, and thus should survive summary judgment. However, Plaintiffs devote a mere paragraph to this argument, setting forth their conclusion that they “have asserted multiple other bases for recovery, independent of the failure to warn claim” without stating which claims they believe survive, or setting forth any facts supporting the existence of any other defect in the product. Having reviewed the Amended Complaint, the Court finds that the gravamen of each of Plaintiffs’ claims is GSK’s alleged failure to adequately warn of the potential adverse side effects associated with Avandia use.

#### **IV. CONCLUSION**

For the reasons set forth herein, GSK’s motion for summary judgment will be granted and all claims will be dismissed with prejudice. An appropriate order follows.

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<sup>18</sup> *Hahn*, 673 A. 2d at 891.

<sup>19</sup> *Id.*; See also *Kline v. Pfizer, Inc.*, 2008 WL 4787577, at \*3 (E.D. Pa. Oct. 31, 2008).