UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 11-10466-RGS

MICHAEL J. TERSIGNI

v.

WYETH-AYERST PHARMACEUTICALS, INC., et al.

MEMORANDUM AND ORDER
ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

December 13, 2013

STEARNS, D.J.

Plaintiff Michael Tersigni brought this action against Wyeth-Ayerst Pharmeceuticals, Inc. (Wyeth) on March 17, 2011, alleging that he contracted Primary Pulmonary Hypertension[1] (PPH) from ingesting Wyeth's proprietary drug Pondimin[2] in 1997. In a Second Amended Complaint (SAC), Tersigni asserts claims of Breach of Warranty - defective design (Count I), Breach of Warranty - failure to warn (Count II), Negligence or Products Liability (Count III), Fraudulent Misrepresentation (Count IV), and Fraudulent Concealment (Count V). Wyeth, invoking the "learned intermediary" doctrine, now moves

[1] PPH is also known as Pulmonary Arterial Hypertension (PAH).

[2] Pondimin is a trade name for the drug fenfluramine.

for summary judgment, contesting Tersigni's ability to prove causation.[3]

## TRAVEL OF THE CASE

Tersigni's is one of a myriad of "diet drug" cases spawned by an anti-obesity medication known as "Fen-Phen," a combination of the drugs fenfluramine and phentermine. The medication operates to enhance a patient's levels of serotonin, thereby engendering a sensation of fullness and a resulting loss of appetite. Wyeth, the U.S. manufacturer and distributer of Pondimin, withdrew Pondimin from the market on September 15, 1997 (together with dexfenfluramine, a similarly acting drug branded as "Redux"), in response to a Food and Drug Administration (FDA) advisory. The thousands of Fen-Phen lawsuits blame the drug combination for a host of illnesses, including cardiac valvulopathy, pulmonary hypertension, and neurotoxicity.

The federal Fen-Phen cases were consolidated and transferred by the Judicial Panel on Multidistrict Litigation (MDL) to Judge Louis Bechtle in the Eastern District of Pennsylvania, pursuant to 28 U.S.C. § 1407, for pretrial

[3] Wyeth disputes that Tersigni's PPH was caused by Pondimin, but this cause-in-fact argument is not the focus of this motion for summary judgment. Wyeth also moves to exclude the testimony of Tersigni's expert economist, Dr. Cheryl Blume. The admissibility of her testimony also has no bearing on the outcome of this motion.

management (MDL 1203). A majority of the Fen-Phen cases were resolved by Judge Bechtle pursuant to a nationwide class settlement. Pretrial Order No. 1415 (PTO 1415). *See In re Diet Drugs*, MDL 1203, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000). The settlement included "all persons in the United States who ingested Pondimin and Redux," and while excluding claims based on PPH, it "fully preserved" the right of persons who might develop symptoms of PPH to bring suit. *Id.* at *19 and *31.

After being filed in 2011 in Massachusetts, Tersigni's case was transferred to the MDL 1203 docket for pretrial discovery. In December of 2012, the case was remanded to this court with the notation that all discovery (except that of the economic experts) was complete. After an unsuccessful effort at mediation, Wyeth moved for summary judgment on August 29, 2013. The court heard oral argument on November 22, 2013.

## FACTUAL BACKGROUND

### ***Fen-Phen Diet Drugs***

The idea of using "Fen-Phen" as a treatment for obesity originated in a controversial study published in 1992 by Dr. Michael Weintraub, a University of Rochester pharmacologist (and later a senior official at the FDA). According to the Weintraub study, Fen-Phen had been shown to be significantly more effective than dieting or exercise in treating chronic obesity.

Fen-Phen combined fenfluramine, which causes drowsiness, with phentermine, a mild stimulant, for its countervailing effect. After the Weintraub study was widely publicized in 1995, sales of Pondimin skyrocketed. From January of 1995 to mid-September of 1997, some 4 million persons in the U.S. took Pondimin, while another 2 million took Redux.

Prior to being marketed, Fen-Phen did not undergo safety testing. On August 28, 1997, Dr. Heidi Connelly, a Mayo Clinic researcher, published an article in the New England Journal of Medicine, reporting an abnormal incidence of valvular heart disease among women taking Fen-Phen.[4] After receiving a number of additional reports of cases of heart-valve disease among Fen-Phen users, on September 15, 1997, the FDA requested the voluntary withdrawal of Pondimin and Redux from the market.[5] Wyeth immediately complied.

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[4] Prior to the Mayo study, there had been reports of an increased incidence of PPH among Fen-Phen takers, including an International Primary Pulmonary Hypertension Study that was published on August 29, 1996, in the New England Journal of Medicine. The study concluded that patients who had taken fenfluramine for longer than three months had a twenty-three fold risk of developing PPH. PTO 1415, at *17. A study published in 2000 in the journal CHEST confirmed this association. *Id.*

[5] After a July 8, 1997 press release gave a preliminary account of the Mayo results, the FDA issued a public health advisory regarding Fen-Phen, followed by letters to 700,000 physicians soliciting information about patients taking Fen-Phen.

### *Primary Pulmonary Hypertension (PPH)*

As described by Judge Bechtle, a diagnosis of PPH is "a virtual death sentence." More specifically, he wrote:

> PPH is a disease that affects pulmonary circulation. PPH is characterized by scarring and fibrosis of the pulmonary arteries which carry deoxygenated blood from the right side of the heart to the lungs. This scarring prevents blood cells from effectively absorbing oxygen as they pass the alveoli in the lungs. . . . Ultimately, this dilation and hypertrophy of the right ventricle will cause the heart to fail and result in the patient's death. . . . PPH is a relentlessly progressive disease that leads to death in virtually all circumstances.

PTO 1415, at *16.

Judge Bechtle also noted that PPH is a "diagnosis of exclusion." This means that other "secondary" causes of pulmonary hypertension must be ruled out in order to reach a diagnosis of PPH. Some of these other causes are diseases known to be associated with pulmonary hypertension, including "significant obstructive sleep apnea." PTO 1415, at *17.

### *Tersigni's Ingestion of Pondimin*

On February 4, 1997, Tersigni presented to Dr. Kent E. Sharian, a Connecticut-based physiatrist. Dr. Sharian diagnosed Tersigni with extreme obesity with a BMI over 30 and with other "comorbidities," including hypertension, high cholesterol, and high triglycerides. Dr. Sharian prescribed Tersigni 20 mg doses of Pondimin for six months, from February 4, 1997,

through July 16, 1997. Tersigni had no direct communications with Wyeth. Rather, Tersigni relied on Dr. Sharian's recommendation,[6] as well as the endorsement of a personal friend, in deciding to take Pondimin.

Tersigni stopped taking Pondimin in July of 1997 after Dr. Sharian discontinued his prescriptions in response to medical warnings about the side effects of fenfluramine.[7] Prior to beginning the Pondimin regime, Tersigni had signed a consent form provided by Dr. Sharian. The consent form listed pulmonary hypertension as a possible side effect, but did not mention "primary pulmonary hypertension."

As of February 2011, Tersigni has been diagnosed with PPH with a poor and limited prognosis. Dr. Richard Channick, Tersigni's treating physician, is of the opinion that Tersigni's PPH is attributable to his ingestion of Pondimin. Tersigni has been prescribed medication (Tracleer) to treat his PPH since February of 2012. He has been advised by Dr. Channick that the disease may make it impossible for him to continue working.

***Tersigni's Claims Against Wyeth***

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[6] Tersigni alleges that Dr. Sharian described Fen-Phen as a "wonder-drug."

[7] Between February and July of 1997, Tersigni's weight decreased from 264 lbs to 236.5 lbs. After discontinuing Fen-Phen, Tersigni regained all of the lost weight.

Tersigni alleges that Wyeth failed to adequately warn Dr. Sharian about the dangerous side effects of Pondimin. Tersigni further alleges that the labeling of Pondimin was inadequate, and that Wyeth concealed vital safety information from Dr. Sharian and the FDA. Specifically, the Complaint alleges that "[b]etween 1989 and 1996, Defendants misrepresented in the Pondimin labeling that only four (4) cases of Pulmonary Hypertensions (PH) had been reported in association with fenfluramine use, including only one fatality, despite Defendants' ongoing receipt of ever-increasing numbers of pulmonary hypertension reports (over 100) and fatalities."[8] Moreover, according to the Complaint, despite its awareness of the dangers of pulmonary hypertension, Wyeth did nothing to revise the Pondimin warning label between 1990 and 1996.

Tersigni also alleges that the database of Wyeth's Clinical Drug Safety Surveillance System (CDSSS) contained reports of Adverse Drug Events (ADE's) that Wyeth failed (or delayed) to report to the FDA in a deliberate effort to mislead the FDA and treating physicians.

More specifically, the Complaint alleges that the report for Pondimin submitted by Wyeth to the FDA in June of 1992 disclosed zero reports of

[8] SAC ¶ 60.

pulmonary hypertension among Pondimin patients for the period ending May 1992, while the CDSSS had recorded at least nine cases. Wyeth's August of 1996 report disclosed four instances of pulmonary hypertension for the period ending May 1996, while the CDSSS had compiled thirteen cases during the same period.[9]

Wyeth knew by June of 1994 of a cumulative total of 41 cases of pulmonary hypertension associated with Pondimin, but did not revise the Pondimin label, which listed only four such cases. By the end of 1996, Wyeth was aware of over 90 cases of pulmonary hypertension associated with Pondimin, and of at least 132 associated with Redux worldwide. By the end of 1996, Wyeth knew of twelve deaths from Pondimin-associated pulmonary hypertension, and of twenty-five deaths worldwide associated with Redux. Notwithstanding, the 1996 entry on Pondimin submitted by Wyeth to the Physician's Desk Reference (PDR) continued to falsely state that there had been only four related pulmonary hypertension occurrences and only one fatality.

On June 20, 1996, Wyeth revised the Pondimin label to contain a warnings section that read: "Primary Pulmonary Hypertension: A two-year,

[9] SAC ¶ 69.

international (five country), case control (epidemiological) study identified 95 PPH cases; 20 of these had been exposed to anorexigens in the past and 9 of the 20 had been exposed to anorexigens for longer than three months. In this study, the use of anorexignes for longer than three months was associated with an increase in the risk of developing PPH." In November of 1996, Wyeth updated its label stating that "PPH is a serious condition; the four year survival rate is reported to be 55%."

***Deposition Testimony of Dr. Sharian***

Dr. Sharian testified that the 1992 Weintraub study had given him the medical confidence to prescribe Fen-Phen for his patients. Dr. Sharian stated that Weintraub was the "primary source that I relied on" and that "there may have been other publications, but I don't recall those."[10] After reading Weintraub, he "felt very confident that this combination [Fen-Phen] was safe and effective. And after a four year study by this prestigious medical center, I felt secure in prescribing it."[11] He also stated that after he began prescribing Fen-Phen, he "didn't come across . . . any of those studies" that showed the Weintraub study to be clinically flawed.[12]

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[10] Sharian Dep. 50:2-4.

[11] *Id*. at 269:2-5.

[12] *Id*. at 269:11-12.

When asked about the 1996 PDR entry regarding Pondimin, Dr. Sharian testified that he recalled that it did not mention PPH, although it did warn of less serious "pulmonary hypertension." When asked about the risks of pulmonary hypertension, Dr. Sharian answered "well, according to Weintraub's studies, there weren't any major side effects, so I wasn't very much concerned."[13] He emphasized that "there wasn't much concern," in his view, "because they did this long-term study, placebo, and they didn't report any major side effects . . . and most of the side effects that they recorded were transient, they reversed themselves. . . . I didn't see any life-threatening complications from the Weintraub study."[14]

Dr. Sharian was repeatedly asked about his "custom and practice" in reviewing relevant medical literature and labels. Dr. Sharian testified that his practice was to read the PDR quarterly updates for the medications that he regularly prescribed and that he would have done so for Pondimin.[15] He also testified that it was his custom and practice to read all "dear doctor" letters received from pharmaceutical manufacturers discussing familiar

[13] *Id*. at 285:9-11.

[14] *Id*. at 285:17-24.

[15] *Id*. at 66:1 - 67:4 and 92:11-24.

medications.[16]

Dr. Sharian testified that it also was his practice to weigh the risks and benefits of a medication before prescribing it for a patient. He stated that he considered whether "the advantages of prescribing the medication and avoiding the comorbidities of the future will warrant [his] prescribing it in spite of the potential side effects. In other words, the benefits should exceed the potential side effects."[17] When shown the PDR entries, labeling, and "dear doctor" letters discussing Pondimin that were published in 1996 and 1997, Dr. Sharian testified that he had no specific memory of what he did or did not receive or look at, including the June 1996 revision of the Pondimin label, although it would have been his practice to review the label in conducting his risk/benefit analysis. He did remember that upon leaning of the growing interest in 1995 and 1996 of Pondimin as an effective treatment for obesity, he went back and studied the label to remind himself about the drug.

Dr. Sharian was shown a "dear doctor" letter from Wyeth, dated August of 1996. He answered "I probably did," in response to a question about whether he considered the letter before he prescribed Pondimin to Tersigni,

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[16] *Id.* at 106:2-7.

[17] *Id.* at 67:22 - 68:3.

but he also said that he could not be certain. Regarding a January 1997 "dear doctor" letter sent by Wyeth, Dr. Sharian agreed (after reading it at the deposition) that the letter conveyed a warning that Pondimin carried a risk of PPH, although he did not specifically recall having received it.[18] In response to the question "do you have any reason to believe that you did not receive the Dear Doctor letter?" Dr. Sharian responded "I don't know. That I can't recall."[19] Later, after being shown a Wyeth mailing list that contained his name and address, he responded: "Yes, if it says so, I must have received it, yes."[20]

In a separate line of questioning, Dr. Sharian stated that he was not aware in early 1997 of concerns about the dangers of Fen-Phen, nor was he aware of a warning that the combination had not been "systematically evaluated in large, multi-center placebo-controlled trials."[21] He stated that his first concrete knowledge of serious safety concerns about Fen-Phen was acquired from publicity surrounding the July 1997 warnings. He testified that

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[18] *Id.* at 109:12-23.

[19] *Id.* at 110:15.

[20] *Id.* at 113:16-17. The letter was addressed to Dr. Sharian's business address at 55 Whiting Street, Plainville, CT.

[21] *Id.* at 307:18 - 308:5.

"knowing what I know now with the benefit of hindsight, I probably [would] not choose the Fen-Phen combination."[22] He said that he had stopped prescribing Pondimin in July of 1997 "because it was withdrawn from the market, or there were those *big warnings*."[23] He further stated that "I told [my patients] about too much risk of valvulopathy and pulmonary hypertension and the warnings. I told them that I'm not going to prescribe that anymore."[24]

ANALYSIS

"Under Massachusetts law, a product may be unreasonably dangerous if the manufacturer fails to warn of a non-obvious risk associated with the normal use of the product about which the manufacturer knows or has reason to know." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992). In the ordinary course, the manufacturer of a product that is dangerous in nature or is in a dangerous condition has a duty to warn consumers or others who will foreseeably come in contact with the product. *H.P. Hood & Sons v. Ford Motor Co.*, 370 Mass. 69, 75 (1976). The "learned intermediary" doctrine carves out a "middleman" exception that has a particular relevance to

[22] *Id.* at 303:5-7.

[23] *Id.* at 209:18-19 (emphasis added).

[24] *Id.* at 211:10-13.

pharmaceutical drugs: it permits a drug manufacturer to discharge its duty to warn the consumer by instead providing appropriate warnings to the prescribing physician. *See MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 135 (1985). The justification for the doctrine is that "the prescribing physician, as the 'learned intermediary' standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly." *Garside*, 976 F. 2d at 80. The immunity conferred by the doctrine is, however, limited: when the manufacturer breaches the duty to warn the doctor, it is directly liable to the patient. *MacDonald*, 394 Mass. at 136.

Massachusetts courts apply a burden-shifting test (summarized in *Garside*) in determining whether a plaintiff can establish the elements of a prima facie case of a failure to warn despite the interposition of a learned intermediary: (1) the plaintiff must initially produce evidence raising a triable issue of fact as to whether the manufacturer failed to warn of a non-obvious risk about which it knew (or should have known); (2) if the plaintiff satisfies this burden, a rebuttable presumption arises that the failure to warn was a proximate cause of the plaintiff's consumption of the drug (that is, that the prescribing physician would have heeded an adequate warning); (3) the

manufacturer may then come forward with evidence rebutting the presumption (that is, that the prescribing physician continued to prescribe the drug to other patients despite the warning); (4) in which case, "the plaintiff must produce sufficient evidence to create a triable issue on the question of causation." *Id.* at 81 (citing *MacDonald*, 394 Mass. at 135 and *Restatement (Second) of Torts* § 402A cmt. j (1965)).

In satisfaction of his burden under *Garside*, Tersigni relies principally on evidence of Wyeth's failure to adequately and timely warn about the extent of the risk of PPH (and to a lesser degree of Valvular Heart Disease (VHD)). Tersigni contends that Wyeth's labeling of Pondimin to warn of the risk of PPH was belated and that it understated the extent of Wyeth's knowledge of the association between Pondimin use and PPH. Tersigni notes that Wyeth failed to include the words "primary pulmonary hypertension" on the Pondimin label, as it appeared in the PDR, until November of 1996, well after the risks of PPH were known to Wyeth. A full warning of the risks of PPH appeared only in September of 1997, after the drug had been withdrawn from the market. While not contesting the applicability of the learned intermediary doctrine, Tersigni relies on the deposition testimony of Dr. Sharian that he had no reason, based on the information he had been supplied, to believe that Pondimin posed a fatal risk of contracting PPH, and that given the publicity

surrounding the Weintraub study, he was convinced that Pondimin in a Fen-Phen dosage had no "major side effects."

Wyeth's main contention, which also relies on Dr. Sharian's testimony, is that Tersigni "cannot show that a different or additional warning would have changed the outcome because the prescribing physician was already aware of an association between Pondimin and a risk of PAH [PPH] when he prescribed the medication to plaintiff." Wyeth Mem. at 7. More specifically, Wyeth contends that "Dr. Sharian already knew of the PPH risk between February and July 1997, when he prescribed Pondimin to Mr. Tersigni, but prescribed the drug anyway because of the potential benefit of treating Mr. Tersigni's obesity." Wyeth Reply at 4.

While Wyeth maintains that on this point the evidence is "undisputed," that seems something of an overstatement, particularly given Dr. Sharian's testimony that "knowing what I know now with the benefit of hindsight, I probably [would] not choose the Fen-Phen combination."[25] Moreover, Dr. Sharian's repeated statements that he had relied implicitly on Weintraub – e.g., "I didn't see any life-threatening complications from the Weintraub

[25] Sharian Dep. 303:5-7.

study"[26] – raises a reasonable inference in light of his customary practice of reviewing letters and other information provided about the drugs he was prescribing, that he had received no warning from Wyeth that the Weintraub study was flawed, or that if he did receive a warning, it was insufficient to disabuse him of his belief to the contrary.[27]

In sum, while Dr. Sharian's testimony is ambiguous in some respects, it is sufficient, when considered with evidence that Wyeth suppressed information about the extent of the Pondimin ADE's that it had compiled, to make out a prima facie case of a failure to warn about the risks of PPH.[28]

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[26] *Id.* at 302:5-7.

[27] There is evidence in the record that Wyeth arguably resisted the placement of a black box label on Pondimin. Dr. Sharian referred to "big warnings" (specifically the publicity generated by the Mayo study in July of 1997) as a decisive factor in his decision to stop prescribing Pondimin.

[28] Given this conclusion, the court will only briefly comment on Wyeth's second argument on summary judgment, which is directed to the conceded absence of warnings of the risk of VHD. While recognizing that the learned intermediary defense does not apply with regard to VHD, Wyeth argues that Tersigni cannot make out causation where there is no evidence that he in fact suffers from VHD. For this proposition, Wyeth relies on a Pennsylvania Superior Court decision, *Cochran v. Wyeth*, 3 A.3d 673, 681 (2010), which held that the plaintiff in that case could not "prove proximate causation because the non-disclosed risk did not materialize in physical injury." *Cochran*, of course, is not binding on this court and is directly contradicted by a Massachusetts district court case, *Sanderson v. Upjohn Co.*, 578 F. Supp. 338, 339 (D. Mass. 1984). *Sanderson* held that the nature of a plaintiff's illness, while relevant to damages, is "not dispositive on the issue of the adequacy of [a defendant's] warning." While again, this court is not bound by

ORDER

For the foregoing reasons, Wyeth's motion for summary judgment is DENIED.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE

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the decision of another of its sessions, it deems *Sanderson* to be the stronger of the two opinions. *Cochran* relies for its holding on the law of informed consent, which presumes an objective actor, while *Sanderson* more correctly recognizes that the learned intermediary doctrine calls for a subjective inquiry as to what the prescribing physician would have done had he been supplied with a full and effective warning. The court notes Dr. Sharian's testimony in this regard that an additional warning about a second potentially fatal disease would have influenced his decision not to prescribe Pondimin. *See* Sharian Dep. 211:10-13.