UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine)	**MDL 1203**
MICHAEL TERSIGNI, **Plaintiff** **v.** **WYETH, et al.,** **Defendants**	**Civil Action No. 1:11-cv-10466-RGS**

PLAINTIFF'S TRIAL MEMORANDUM

Pursuant to this Court's Order Setting Civil Case for Jury Trial, dated February 24, 2014, Plaintiff submits this Trial Memorandum with the following disclosures relative to the jury trial currently scheduled in this matter for July 21, 2014.

I. NEUTRAL STATEMENT

The parties have agreed to the following neutral statement to be read to the jury prior to the start of evidence:[1]

This case involves a claim by Plaintiff Michael Tersigni (hereinafter "Plaintiff") that he was injured by a prescription diet medication made by the Defendant, a pharmaceutical company called Wyeth. Wyeth was formerly known as American Home Products Corporation or AHP. The diet medication at issue in this case is called Pondimin, which is sometimes called by its chemical name, "fenfluramine."

Plaintiff alleges that he took Pondimin in combination with another diet drug called phentermine for approximately six months in 1997. This combination of drugs was often known as fen-phen. Plaintiff further alleges that he developed a disease known as Primary Pulmonary Hypertension, or "PPH" and that his PPH was caused as a result of taking Pondimin. Plaintiff also alleges that Wyeth failed to adequately and timely warn physicians, including Mr. Tersigni's physician, Dr. Kent Sharian, about the risk[s] of PPH and Valvular Heart Disease "VHD" associated with Pondimin, and that if an adequate warning had been provided to Dr. Sharian, Plaintiff would not have been prescribed Pondimin and would not have developed PPH.

[1] Wyeth has filed this same statement at Doc. # 193.

Wyeth denies all of Plaintiff's claims. Wyeth maintains that the warning it provided for Pondimin to Dr. Sharian was adequate. Wyeth maintains that Plaintiff does not have PPH, but rather a condition known as pulmonary hypertension with left heart disease, which is unrelated to the use of diet drugs like Pondimin. Wyeth further maintains that neither Pondimin nor any alleged inadequate warning caused Plaintiff's injuries.

II. STIPULATED FACTS

The parties intend to file the Stipulated Facts on July 15, 2014 pursuant to this Court's approval of a twenty-four hour extension.

III. OTHER STIPULATIONS

The parties have agreed to additional evidentiary and procedural points:

1. Order on Certain Evidence and Argument the Parties Have Agreed to Exclude or Limit.[2]

2. Joint Stipulation and Agreement on Cross-Examination Exhibits. [Doc. # 194].

3. Stipulation Regarding Keith Altman. [Doc. #110].[3]

4. The parties have also agreed to provide opposing side the name of the witness, exhibits (including medical literature), and demonstratives to be used forty-eight (48) hours in advance of calling said witness. [Doc. 100].

5. With respect to medical literature, the parties agree that such literature is to be treated like learned treatises pursuant to F.R.E. 803(18), and are therefore not included in either exhibit list.

6. The parties have agreed that demonstrative evidence to be used for Opening Statements and Closing Arguments, shall be made available to opposing side no less than 24 hours prior to being used.

7. With the exception of certain objections raised in Wyeth's motions *in limine* and objections to certain exhibits, it is Plaintiff's understanding that Wyeth will not contest the authenticity of most documents (Fed. R. Evid. 901), so long as the document (1) was produced by Wyeth in the MDL Diet Drug Litigation or in other Diet Drug Cases; (2) bears a Wyeth, IPI or FDA bates number; and (3) was not subsequently altered, modified, combined, or rearranged after being produced.

[2] Wyeth has agreed to file this Stipulation. At the time of filing this Memo, the Stipulation had not yet been filed.

[3] Plaintiff will refile this Stipulation to remove Mr. Altman's name as he has entered an appearance on behalf of Mr. Tersigni.

IV. LIST OF WITNESSES

With respect to those witnesses, attorneys and other support staff who will be presenting evidence, testimony or who will be present in the Court room during the course of the trial, Plaintiff lists those individuals on the parties Joint Submission of Voir Dire at Doc. #191.

With respect to trial witnesses, Plaintiff anticipates calling the following individuals:

A. Plaintiff's anticipates the following witnesses to be called live at trial:

1. **Michael Tersigni**: Address: 1480 Ocean Drive, Condo 3-F, Vero Beach, FL 32963.
2. **Richard Channick, M.D.**: Address: Pulmonary & Critical Care Medicine, 55 Fruit Street, Bullfinch 148, Boston, MA 02114.
3. **Cheryl Blume, Ph.D**.: Address: Pharmaceutical Development Group, Inc., 13902 North Dale Mabry Ave., Suite 230, Tampa, FL 33618.
4. **Stuart Rich, M.D.:** Address: Duchossois Center for Advanced Medicine, 5758 S. Maryland Ave., Chicago, Illinois 60637.
5. **David E. Consigli, Jr., CPA, ABV**: Address: Richardson & Company, 165 Village Street, Medway, MA 02053.
6. **Edmond Provder, CLCP**: Address: Occupational Assessment Services, Inc., The Rothman Center, Second Floor, Suite 4A, 300-3 Route 17 South, Lodi, NJ 07644-3810.

B. Time permitting (and depending on how proof develops at trial), Plaintiff anticipates presenting the deposition or trial testimony of the following witnesses by video:

1. **Leslie S. Fang, MD**: Address: 151 Merrimac Street #300, Boston, MA 02114.
2. **Kent Sharian, MD**: Address: 117 Crest Drive, Middlebury, CT 06762.
3. **Patti Acri** (Wyeth – Senior Director, Product Information & Labeling).
4. **Jeanette Pascuzzi-Heacock** (Wyeth – Director of Marketing).
5. **Joseph Mahady** (Wyeth – President of Wyeth-Ayerst North America).
6. **Amy Myers** (Wyeth – Associate Director of Safety Surveillance Division).
7. **Ronald Notvest** (Wyeth – Senior Product Manager).
8. **Carrie Smith-Cox** (Wyeth – Vice President of Women's Health Care Products Division).
9. **Fred Wilson** (Wyeth – Associate Director of Clinical Development Division. Medical Monitor for Pondimin).

V. DEPOSITION DESIGNATIONS

Plaintiff submits the following designations only to which there exists objection:

1. Patti Acri, at **Exh. 1**.
2. Joseph Mahady, at **Exh. 2**.
3. Amy Myers, at **Exh. 3**.
4. Ronald Notvest, at **Exh. 4**.
5. Jeanette Pascuzzi-Heacock, at **Exh. 5**.
6. Carrie Smith-Cox, at **Exh. 6**.
7. Fred Wilson at **Exh. 7**.
8. Leslie Fang, at **Exh. 8**.
9. Kent Sharian, at **Exh. 9**.

VI. JOINT LIST OF EXHIBITS TO WHICH THERE IS NO OBJECTION[4]

Wyeth has agreed to file the parties' joint list of exhibits to which there is no objection and which are marked by number. Plaintiff understands the this list includes those exhibits the parties intend to use in their case-in-chief since the parties have agreed to serve any exhibit to be used on cross-examination of a witness within 24 hours of said witnesses testimony.

VII. EXHIBITS TO BE OFFERED AT TRIAL TO WHICH THERE EXISTS OBJECTION[5]

Wyeth has agreed to file the parties' joint list of exhibits to which there remain objections and which are marked by letter.

VIII. MOTIONS IN LIMINE

All motions *in limine* have been filed.

IX. DISPUTES AS TO THE LAW

There exists dispute as to the law in Massachusetts. Notwithstanding the Motions *in*

[4] Wyeth has agreed to file the parties' Joint Exhibit Lists. At the time of filing this Memo, the Exhibit Lists had not yet been filed so Plaintiff was unable to reference the docket number.
[5] *Id*.

Limine, Plaintiff submits that those disputes are highlighted in the parties proposed jury instructions and generally include disputes as to the following:

1. The duty to warn. Wyeth contends that Plaintiff's burden is to prove that it failed to warn Dr. Sharian of the risks ***of PPH***. Plaintiff, on the other hand, contends that Wyeth has a duty under Massachusetts law to provide adequate warnings, which the manufacturer knows or should know is dangerous, is under a duty to give warning of those dangers to persons who it is foreseeable will come in contact with, and consequently be endangered by, that product.[6] And that a failure by a manufacturer to give an adequate warning regarding reasonably foreseeable risks constitutes negligence.[7] The adequacy of Wyeth's warnings related to Pondimin depends upon all the circumstances known or reasonably discoverable by Wyeth at the time it marketed the drug.[8] In other words, the jury may still find the label inadequate even if the label warned of the exact injury suffered by Mr. Tersigni.[9] Wyeth contests this point of law. In addition to other points submitted in Plaintiff's proposed failure to warn instruction.

Wyeth also asserts that its duty warn stops at the date of the last written prescription. Massachusetts, however, recognizes that a manufacturer will be held to the standard of knowledge of an expert in the appropriate field and has a continuing duty to warn of risks discovered following the sale of the product.[10]

2. Violations of Safety Regulations. Wyeth objects to the jury being told about federal regulations that outline a drug manufacturers' responsibilities under the law. Plaintiff submits that these Federal Regulations are relevant and just like the law of negligence is important for the jury to understand. Plaintiff has identified these points in his *Proposed Jury Instructions* and is the subject of a *Motion for Judicial Notice* of these Regulations.

3. Causation. Wyeth conflates the burden of proof associated with an expert's opinion, to a reasonable degree of medical certainty to plaintiff's burden of proof with respect to proving Wyeth's negligence was a substantial contributing factor in causing Plaintiff to develop PAH. Plaintiff submits that his burden of proof as to causation is preponderance of the evidence and that his experts' opinions are to be based upon a reasonable degree of scientific certainty. In addition, Wyeth fails to account for the law in Massachusetts, specifically, *Sanderson v. The Upjohn Company*, 578 F. Supp. 338, 340 (Dist. Mass. 1984) that permits a jury to consider what

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[6] *MacDonald v. Ortho Pharm. Corp.*,394 Mass. 131, 135, 475 N.E.2d 65 (1985), quoting *H.P. Hood & Sons v. Ford Motor Co.*, 370 Mass. 69, 75, 345 N.E.2d 683 (1976).

[7] *Yates v. Norton Co.*, 403 Mass. 70, 74 (1988); *Casagrande v. F.W. Woolworth Co.*, 340 Mass. 552, 555 (1960).

[8] *Sanderson v. The Upjohn Company*, 578 F. Supp. 338, 340 (Dist. Mass. 1984) ("The legal adequacy of Upjohn's warnings depends upon all circumstances known or reasonably discoverable by Upjohn at the time it marketed its drug.").

[9] *Id.*

[10] *Vassallo v. Baxter Healthcare Corp.*, 428 Mass. 1, 23 (1998); *Thayer v. Pittsburgh-Corning Corp.*, 45 Mass. App. Ct. 435, 437 (1998).

was known to the defendant about all risks and benefits to assess whether the warning was adequate and whether Dr. Sharian would have heeded an adequate warning had he received it.

X. PROPOSED VOIR DIRE

The parties joint proposed *voir dire* has been filed. [Doc. 191].

XI. JURY INSTRUCTIONS AND VERDICT FORM

Plaintiff submits his proposed jury instructions at **Exh. 10**, and his proposed verdict form at **Exh. 11**. Plaintiff has no objection to Wyeth's proposed preliminary jury instructions to be read prior to the start of evidence. Wyeth's proposed preliminary jury instructions also include the parties agreed upon neutral statement.

XII. ESTIMATE AS TO LENGTH OF TRIAL

This Court has ordered eighteen hours to be allotted to each side to present direct and cross examination. Plaintiff anticipates the trial to last two weeks given a daily trial schedule of Monday, 9-4, and Tuesday's through Fridays, 9-1.

Respectfully submitted,

/s/ Paula S. Bliss
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CERTIFICATE OF SERVICE

I hereby certify that on July 14, 2014 a copy of the foregoing *Plaintiff's Trial Memorandum* was filed electronically and will be sent to all parties by operation of the Court's electronic filing system and/or electronic mail. Parties may access this filing through the Court's system.

/s/ Paula S. Bliss
Counsel for Plaintiff