IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

MAUREEN E. CALISI,	§	
Plaintiff,	§	
	§	
v.	§	CASE NO. _____
	§	
ABBOTT LABORATORIES,	§	
Defendant.	§	JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Maureen E. Calisi files this suit against Abbott Laboratories and for cause of action would show the Court the following:

Nature of the Case

1. This is a diversity jurisdiction, personal injury products liability case. Plaintiff Maureen Calisi was prescribed Abbott's blockbuster arthritis drug "Humira" and received bi-monthly injections from late 2003 to February 2008. Ms. Calisi was subsequently diagnosed with Stage IE primary diffuse large B-cell lymphoma of the breast, for which she underwent chemotherapy treatment (R-CHOP) and radiation. The Plaintiff alleges, *inter alia*, that Abbott and its agents failed to provide a legally proper warning regarding the risks of Humira, including the risk of cancer, and that her injections of this drug caused her cancer.

Parties

2. Plaintiff Maureen Calisi is a resident of Stoneham, Middlesex County, Massachusetts. She has worked as a bookkeeper for Samtan Engineering in Malden, Massachusetts for many years.

3. Defendant Abbott Laboratories is an Illinois corporation organized and existing under the laws of Illinois, having its principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Presumably its counsel will accept a Rule 4 Notice and Acknowledgment so that no formal service of process will be necessary. If service of process is necessary, Abbott's agent for same is Laura J. Schumacher, 100 Abbott Park Road, Abbott Park, Illinois, 60065. Abbott conducts business throughout the United States, including in the State of Massachusetts.

Jurisdiction and Venue

4. This Court has diversity jurisdiction under 28 U.S.C. § 1332. The amount in controversy, exclusive of interest and costs, is substantially in excess of Seventy-Five Thousand Dollars ($75,000). Venue is proper in this District by virtue of 28 U.S.C. § 1391.

Timeliness of Suit

5. Prior to the filing of this suit, Plaintiff and Abbott shared information on an informal basis. Pursuant to an agreement between the Parties, the statute of limitations was tolled. Therefore, this suit is timely.

Facts

This suit has been necessitated by virtue of the following facts.

The TNF Blocker "Miracle"

6. "Tumor Necrosis Factor" [hereinafter "TNF"] is a naturally occurring substance in the human body. TNF is related to the workings of the body's immune system.

7. Humira, the generic name of which is "ADALIMUMAB," is a "biologic" drug, which means that it is a medicine that has been constituted or reconstituted from natural substances in the body. It was the first such drug in its class that was derived from actual human cells.

8. In 2003, Abbott began the worldwide launch of Humira for rheumatoid arthritis [hereinafter "RA"]. In the treatment of rheumatoid arthritis, Humira is believed to bind specifically to TNF and to block its interaction with certain cell surface TNF receptors, thereby interfering with endogenous TNF activity. Subsequently, it "launched" five other "indications" for this drug.

9. The TNF blocker class of drugs has been heralded by some as a "miracle" treatment for rheumatoid arthritis.[1] Undoubtedly, they do help many people.

[1] Zashin, ARTHRITIS WITHOUT PAIN, *The Miracle of the TNF Blockers*, (Sarah Allison Publishing Company, 2004). The foreword reflects that the principal author, "Dr. Scott J. Zashin has been a paid consultant and/or speaker for the companies whose products are listed in this book." On information and belief it is alleged that Abbott is one of the companies that paid Dr. Zashin, and further that Abbott provided financial

However, in the treatment of any disease with powerful medications, it is always very important for both the prescribing physician and the patient to be able to balance the potential benefits of a medication against the known risks. In the case of Humira, Abbott has downplayed the risk of side effects, including the very real and very dangerous risk of developing lymphoma or other forms of cancer.

10. Humira is Abbott's "flagship" drug, meaning the one that has the most sales. As of the date of filing of this Complaint, Abbott Humira has been "approved in 83 countries and treats nearly 500,000 patients worldwide" for "six different autoimmune diseases." Abbott Annual Report at p. 22 (2010). Moreover, according to Abbott's 2010 Annual Report "nearly 500,000 patients worldwide use Humira. *Id*.

11. From a financial perspective, Humira has certainly been a "miracle" or "blockbuster" for Abbott. Humira first received approval from the U.S. Food and Drug Administration [FDA] on December 31, 2002 for the treatment of moderately to severely active rheumatoid arthritis. Humira was launched in the United States at the beginning of 2003 and reached sales of approximately $246 million in its first year alone. By 2005, a couple years after Humira was prescribed to Maureen Calisi, sales had reached $1.4billion. Since that time, sales revenues have continued to grow. The 2009 worldwide sales were approximately $5.5 billion, and by 2010 they had increased to approximately $6.5 billion. *Id*.

---

or other support for the publication of the book.

Safety Signals from the Clinical Trials

12. According to the 2003 Humira label, the efficacy of Humira for the treatment of rheumatoid arthritis (the malady for which this drug was prescribed to Maureen Calisi) was established in a scant four "pivotal" clinical trials. Only 2,070 patients were treated with the drug during the course of these trials.

13. In spite of the fact that the patients were carefully screened, chosen, and monitored by company paid physicians, a number of them developed lymphoma or other malignancies while on Humira during the course of these few trials.

14. No one knows for sure what causes cancer. However, there are a number of generally recognized "risk factors." Rheumatoid arthritis is, itself, a risk factor, and it may well contribute to cause lymphomas or other malignancies in some patients.

15. However, the data from the Humira clinical trials shows that the *rate* of malignancies in the group of patients treated with Humira was significantly higher than the rate of malignancies in the group that were treated with placebo. The increased rate of lymphomas was statistically significant. This differential in rate was a significant safety signal. It should have prompted a significant warning from Abbott to both physicians and patients about this potential side effect. However, instead of conducting further studies and/or otherwise calling attention to the increased risk of life-threatening side effects front and center in the label, Abbott buried any information

regarding malignancies under more than 190 lines of text in the label. Further, what "warning" information was mentioned severely downplayed the risk.

Red Flags from Adverse Event Data

16. As one can readily see, because clinical trials involve comparatively few patients, it is well recognized within the pharmaceutical industry that adverse event reports received from actual patients in the real world are a major, and important, source of safety information. The FDA's MedWatch program was set up to monitor this information.

17. Although anyone can file a report with the company or the FDA, the majority of such reports are filed by concerned physicians who suspect that a prescription drug is associated with their patient's adverse event.

18. Abbott, like other companies, collects data from all available sources about side effects that are reported to it and makes some attempt to determine the probable association or relationship between the drug and the reported side effect. On information and belief, in one or more instances, Abbott's internal causality assessments for these cases reflected that one or more of them were, more likely than not, "associated with" or causally related to Humira.

19. Some, but not all, of the Company's Adverse Event data is reported to the FDA. However, the law provides that "serious" and "unexpected" events must be reported to the FDA within 15 days of the Company's knowledge of them.

20. By the close of 2003, when the Humira was prescribed for Maureen Calisi, there were a total of 365 serious adverse event reports in the FDA database. Of the 365 serious reports, 25 involved some form of malignancy. This translates to approximately 7% of the reported events, which again, represents a very serious safety signal. Three of the 25 reports of malignancy involved lymphomas.

21. It is widely recognized within the pharmaceutical industry that adverse side effects of medication are vastly unreported. The industry accepted rule of thumb is that the MedWatch system captures somewhere between 1% and 10% of real world events. Therefore, the MedWatch reports put Abbott on notice that, in fact, there were somewhere between 250 and 2,500 real world Humira patients who had experienced Humira-related lymphomas or other malignancies.

22. Because FDA regulations require the drug manufacturer to add a warning – in the warnings section of the label – whenever there is a "reasonable association" between the drug and a dangerous side effect, and further state that "a causal relationship need not be established" before a warning is required, this information from the adverse event database should have prompted Abbott to issue strong warnings about the risk of lymphomas and other forms of malignancies. But Abbott failed to do so until many years later, when the FDA made them do it.

"Diagnosis"

23. Ms. Calisi was first diagnosed with rheumatoid arthritis in January 2003 by her rheumatologist, Dr. Robert S. Pastan. After treatment with nonsteroidals, Plaqueril, and Minocin failed, she was prescribed a low dose of Methotrexate (MTX), a long-standing medication for RA, which caused a rash and itching, followed by Azulfidine. She began Humira injections in late 2003 and MTX was again added in January 2004. Medrol was added in April 2004 and the MTX discontinued.[2]

24. When Ms. Calisi was originally prescribed Humira, the December 2003 package insert, written for the prescribing physician, merely stated, under Warnings, that lymphomas had been observed in patients treated with TNF blocking agents and, in clinical trials, patients treated with Humira had a higher incidence of lymphoma than the general population. However, the Company did nothing to alert prescribing physicians that Humira could have a role in actually *causing* or *contributing* to such lymphomas. To the contrary, its label stated the following:

> While patients with rheumatoid arthritis, particularly those with highly active disease, may be at a higher risk (up to several fold) for the development of lymphoma, the role of TNF blockers in the development of malignancy is not known.

[2] Many times defendants do not have access to information that will enable them to answer allegations of this nature with the specificity required by Rule 8(b)(2), in this case, defense counsel have been provided with medical records and other information prior to the filing. Therefore, they should be able to answer most of these allegations and, thereby, narrow the issues for discovery and trial.

This statement negates any potential risk of lymphoma from Humira itself, and instead puts the "lymphoma blame" on the patients' RA. It is woefully inadequate and downright misleading.

25. Abbott had an obligation to convey complete and truthful information to Ms. Calisi and her physician about the side effects of Humira, including the very significant risk that this medication could trigger iatragenic cancers. Needless to say, if Ms. Calisi had been fully informed, *i.e.,* "warned," about the dangers of Humira-induced lymphoma, she would not have agreed to inject Humira into her body.

Belated Warnings Directly to Patients

26. Abbott did nothing to warn patients directly about the risks of Humira-induced cancers until the FDA required them to do so in 2009. Belatedly, in the FDA-mandated Patient Medication Guide dated September 2010 Abbott now states:

> "For children and adults taking TNF-blocker medicines, including HUMIRA, the chances of getting lymphoma or other cancers may increase."
>
> "Patients with RA, especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma."

27. Moreover, on the home page of the website that Abbott uses to promote Humira directly to patients and the public, www.humira.com, it states "**Certain types of Cancer**. There have been cases of unusual cancers in children and teenagers using

TNF-blocker medicines. For children and adults taking TNF-blocker medicines, including HUMIRA, *the chance of getting lymphoma or other cancers may increase."* [Bold in original; italics added].

28. Even today, however, Abbott does nothing to *quantify* that risk for patients so that they can make fully informed decisions regarding their own bodies. But they do provide a bit more specific data to physicians. For example, under IMPORTANT SAFETY INFORMATION on the Humira Pro website, for Health Care Professionals, Abbott states:

> "In the controlled and open-label portions of Humira clinical trials, there was an approximately **3-fold higher rate** of lymphoma than expected in the general population."

29. Abbott had the data in its possession by the end of 2003 when Humira was prescribed for Maureen Calisi to alert people to the 3- to 5-fold potential risk of cancer for patients taking Humira. Maureen Calisi was entitled to full and fair disclosure of this information before she began to inject Humira.

Cancer

30. In February 2008, Ms. Calisi discovered a mass on her left breast that was larger than a golf ball. In her words, "it came out of nowhere." Without delay, the mass was biopsied at the Winchester Breast Center where she was subsequently diagnosed with Stage IE primary diffuse large B-cell lymphoma of the breast, for which she underwent chemotherapy treatment (R-CHOP) and radiation. The

rheumatologist instructed Ms. Calisi to immediately cease taking Humira. The direct and actual cause of the Plaintiff's lymphoma was her injections of Humira.

31. In addition to suffering personal physical injury, as a result of her diagnosis of lymphoma Plaintiff also suffered lost wages and other economic injury for which the Defendants are liable.

32. Fortunately, Ms. Calisi's lymphoma is now in remission. However, she still must be monitored via radiation studies, and, as a result, her lifetime risk of cancer has been increased. The costs of medical monitoring and the increased risk are also compensable elements of damages under Massachusetts law.

Causes of Action

The foregoing facts give rise to legally cognizable claims against Abbott under the common and/or statutory law of Massachusetts as follows:

33. FIRST - STRICT LIABILITY. Plaintiff asserts a cause of action for strict products liability under the statutory and common law of Massachusetts. Products theories include design defect, failure to warn, and misrepresentation.

34. SECOND - NEGLIGENCE. Defendant Abbott was negligent in the design and testing of the drug Humira, in the marketing of the drug, and in the collection and analysis of adverse event data, and said negligence was a proximate or legal cause of Maureen Calisi's lymphoma. Therefore, Abbott is liable for negligence under the common law of Massachusetts.

35. But for Defendant's negligent conduct as described herein, Plaintiff would not have ingested the drug and would not have suffered the personal injuries and economic harm alleged herein. As a direct and legal result of the negligence of Defendant and/or its agent(s), Plaintiff has sustained serious and permanent injuries including, but not limited to lymphoma, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and losses are continuing in nature as she will have to be routinely evaluated for the rest of her life to determine whether her cancer is in remission or not.

36. THIRD - WARRANTY. Plaintiff had the right to expect Abbott to stand behind its product and to bear the burden for any injuries she sustained as a result of her use of its product under the law of Massachusetts. *Haglund v. Philip Morris, Inc*., 847 N.E.2d 315, 322 (2006) citing *Correia v. Firestone Tire and Rubber Co.*, 446 N.E.2d 1033 (1983), quoting Restatement (Second) of Torts § 402A comment c (1965).Because Defendant Abbott has breached its warranty obligations under Massachusetts law, it is further liable to Plaintiff for her injuries.

Damages and Remedies

37. Plaintiff sues to recover all elements of compensable damages under Massachusetts law, to include compensation for her increased risk of cancer in the future and the medical monitoring costs associated with such. *See Donovan v. Philip*

Morris USA, Inc., 914 N.E.2d 891, 901 (2009). Additionally, she seeks appropriate prejudgment interest thereon, as provided by law.

38. If the evidence at trial demonstrates the level of culpability necessary for an assessment of punitive or exemplary damages, then Plaintiff seeks an award in such amount as the Jury shall deem appropriate.

Jury Demand

39. Plaintiff invokes her constitutional right to trial by jury.

Prayer for Relief

WHEREFORE, Plaintiff prays that Defendant Abbott Laboratories be cited to appear and answer herein, and that upon the final trial of this case, a Final Judgment be entered by this Court in her favor against Defendant for such compensatory and punitive damages as are appropriate, plus interest and costs of litigation, and awarding such other and further relief as is just and proper.

Respectfully submitted,

/s/ Christopher C. Trundy
Christopher C. Trundy
Massachusetts Bar #555622
240 Union Street
New Bedford, MA 02740-5943
Telephone: 508-984-4000
Facsimile: 508-999-1670
Email: christrundy@trundylaw.com

Of Counsel (*Pro Hac* Admittance to be sought]

Arnold Anderson (Andy) Vickery
Texas Bar No. 20571800
Fred H. Shepherd
Texas Bar No. 24033056
VICKERY, WALDNER & MALLIA, LLP
One Riverway, Suite 1150
Houston, TX 77056-1920
Telephone: 713-526-1100
Facsimile: 713-523-5939
Email: andy@justiceseekers.com
Email: fred@justiceseekers.com

Certificate of Courtesy Service

Once Abbott has answered, the CM/ECF system will effectuate service. However, a courtesy copy of this original Complaint has been provided to the following counsel for Defendant Abbott Laboratories:

John Donley, Esq.
Renee D Smith, Esq.
KIRKLAND & ELLIS, LLP
300 North LaSalle Street
Chicago IL 60654

/s/ Arnold Anderson (Andy) Vickery
Arnold Anderson (Andy) Vickery