

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

**FILED**  
IN CLERK'S OFFICE  
DISTRICT COURT E.D.N.Y.  
★ APR 20 2010 ★  
BROOKLYN OFFICE

CONSUELO CARDENAS and TERRY MAUSKOPF, et al.

-against-

COMPLAINT AND  
DEMAND FOR JURY TRIAL

ABBOTT LABORATORIES,  
TAKEDA PHARMACEUTICALS OF NORTH  
AMERICA, INC., a wholly owned subsidiary  
TAKEDA CHEMICAL INDUSTRIES INC.,  
TAKEDA CHEMICAL INDUSTRIES, INC.,  
And, TAP PHARMACEUTICAL PRODUCTS, INC.,

**CV 10 - 1745**

Case Number **MAUSKOPF, J.**

*Defendants.*

**HORELSKY, M.J.**

Plaintiffs, by their attorneys, **THE LAW OFFICES OF SYBIL SHAINWALD,**  
**P.C.**, on behalf of themselves, upon information and belief, at all times hereinafter  
mentioned, allege as follows:

**JURISDICTION & VENUE**

1. This Court has jurisdiction pursuant to 28 United States Code § 1332,  
based upon diversity jurisdiction in that the Plaintiffs are citizens of States that are  
different from the States where Defendants are incorporated and have their principal  
places of business. The amount in controversy exceeds seventy-five thousand dollars  
(\$75,000.00) as to each Plaintiff.

**PLAINTIFFS**

2. The Plaintiff, Consuelo Cardenas (hereafter "CARDENAS"), is an  
individual and at all times relevant hereto was a resident of the State of California.  
CARDENAS was injected with the drug depot leuprolide acetate, known as Lupron  
Depot® (hereinafter referred to as "Lupron") on several occasions.

3. The Plaintiff, Terry Paulsen (hereafter "PAULSEN"), is an individual and at all times relevant hereto was a resident of the State of Georgia. PAULSEN was injected with Lupron on several occasions.

#### **DEFENDANTS**

4. The Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott also maintains a New York location at 2400 Walden Avenue, Buffalo, New York. Abbott is a highly diversified health care company, whose business is primarily the discovery, development, manufacture, and sale of a wide variety of health care products and services, encompassing pharmaceuticals, nutritionals, diagnostics, and hospital products, including Lupron. Lupron is sold directly to physicians, retailers, wholesalers, health care facilities, and government agencies, and is distributed from Abbott-owned distribution centers.

5. The Defendant, Takeda Pharmaceuticals of North America, Inc. ("Takeda America") is a wholly owned subsidiary of the co-defendant, Takeda Chemical Industries, Ltd., with a headquarters located in One Takeda Parkway, in Deerfield, Illinois 60015. Takeda America's clinical development activities are conducted via Takeda Global Research & Development Center, Inc. Takeda America focuses on a variety of therapeutic areas including diabetes, cardiovascular disease, central nervous system disorders, gastroenterology, bone and joint disorders, chronic kidney disease, gynecological disorders, and infectious disease; and includes Lupron.

6. The Defendant, Takeda Chemical Industries Ltd. ("Takeda") is a Japanese corporation with its principal place of business in Osaka, Japan. Takeda maintains

offices worldwide. Takeda is one of the world's largest pharmaceutical companies and is the largest such company in Japan. The company researches, develops, manufactures and markets a broad range of pharmaceutical products, including Lupron, and formed the wholly-owned subsidiary Takeda Pharmaceuticals of North America, Inc. ("Takeda America") in order to maximize Takeda's international presence.

7. Defendant TAP Pharmaceutical Products, Inc. ("TAP") is a joint venture between Takeda and Abbott, by and through which, acting in concert, each owns and controls a fifty percent (50%) stake in TAP. Takeda's interest in TAP is held through a subsidiary company of Takeda called Takeda America Holdings, Inc. ("Takeda Holdings"), which maintains an office at 555 Madison Avenue, New York, New York 10022.

8. By agreement, Abbott, Takeda, TAP, and a TAP subsidiary, Takeda Pharmaceuticals, Inc., jointly develop and market pharmaceutical products for the American and Canadian markets. Upon information and belief, TAP is directed and controlled by Abbott and Takeda, and TAP focuses its marketing efforts on securing Lupron use and sales by physicians.

#### **FACTUAL BACKGROUND**

9. TAP, along with the companies responsible for its actions (i.e. the co-defendants, ABBOTT, Takeda America, Takeda, and their related entities, jointly, severally, acting in concert, with or through others, and the companies they own, control, or for whose actions they are responsible, has at all relevant times, been involved in and/or responsible for the research, development, testing, manufacturing and sales,

distribution and/or marketing of the drug known as Lupron, directly or indirectly through an agent, affiliate or subsidiary of TAP Products or Defendants.

10. References herein to the knowledge, actions and/or omissions of the “Defendant”, “Defendants” or “TAP” specifically include Abbott and Takeda, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible.

11. Lupron was developed in or around 1985, and was first approved by the Food and Drug Administration (“FDA”) for the palliative treatment of prostate cancer on January 26, 1989.

12. Lupron was approved as a treatment for endometriosis by the FDA on October 22, 1990.

13. In April 1998, TAP submitted a report to the FDA in which researchers disclosed that they were “concerned” because more than one-third of the women they studied who took Lupron did not “demonstrate either partial reversibility” or “a trend toward return” of bone mass in the six months after they stopped taking the drug.

14. In 2001, the FDA approved Lupron “add-back therapy”, designed to counteract the harmful bone-depleting effects of Lupron, which involves the use of a progestin-based hormone replacement known as norethindrone.

15. At least as early as October 22, 1990, and for more than decade, TAP was aware of the continued bone loss incurred by users of Lupron, but took no corrective action, gave no adequate warning, and did not take the drug off the market.

16. Defendants knew, or should have known, that serious long-term health problems are associated with the use of Lupron, including, but not limited to, an

increased risk of significant bone mineral density loss and early development of osteoporosis and osteopenia. Defendants failed to adequately apprise Plaintiffs or Plaintiffs' physicians of such problems and risks.

17. For example, neither the patient information pamphlet, nor the prescribing information provided to physicians and pharmacists, warned of the serious risk of significantly reduced bone mineral density or early development of osteoporosis and osteopenia associated with receiving Lupron injections.

18. To the contrary, Defendants made certain affirmative claims which were distributed and circulated to the medical profession, and to the general public, through advertising, literature, promotional documents, brochures and other materials, which represented Lupron to be a safe and efficacious drug for women with certain gynecological problems such as endometriosis.

19. Upon information and belief, Defendants misrepresented and concealed the risks inherent in the use of Lupron in their applications for FDA approval, and in representations to other governmental employees and/or agencies.

20. Defendants knew, or should have known, based upon the state of knowledge that existed at the time regarding Lupron, and on generally accepted medical and research standards and principles, that serious side effects and long-term health risks resulted from the use of Lupron including, but not limited to, significant loss of bone density mass, early development of osteoporosis and osteopenia.

21. Defendants failed to appropriately and adequately test Lupron before securing FDA approval.

22. Defendants failed to respond adequately to adverse event reports received or of which Defendants became aware, and failed to notify physicians and individuals who were prescribed Lupron.

**FIRST CAUSE OF ACTION vs. ALL DEFENDANTS**  
**(Negligence)**

23. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in paragraphs "1" through "22" inclusive, as if expressly rewritten herein.

24. The negligence of the Defendants, jointly, severally, acting in concert and that of their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- a. Defendants failed to ensure that Lupron was not dangerous to recipients during the course of its use, and that the drug was fit for its intended purpose and of merchantable quality;
- b. Defendants failed to adequately test Lupron before marketing it to women;
- c. Defendants under-reported, underestimated, misstated and minimized the serious and dangerous side effects of Lupron;
- d. Defendants failed to conduct any adequate follow-up and after-market studies on the safety and efficacy of Lupron;
- e. Defendants failed to adequately warn the public and the medical profession of the dangers, contra-indications and side-effects inherent in Lupron, which became known to Defendants, including but not limited to the risk of significant bone mineral density loss, and failed to provide adequate instructions regarding safety precautions to be observed by users,

handlers, and other persons who would reasonably and foreseeably come into contact with Lupron;

- f. Defendants failed to provide Plaintiffs and their physicians with any adequate information and warnings with respect to safe usage of Lupron;
- g. Defendants failed to provide Plaintiffs or their physicians with adequate, information, as it became available, with respect to the risks of using Lupron;
- h. Defendants failed to warn of the hazards of Lupron on packaging labels;
- i. Defendants failed to adequately warn of the dangerous health risks associated with Lupron, including the risk of significant bone mineral density loss and resultant serious and grievous injuries, on consumer and physician information pamphlets.
- j. Defendants, after being apprised of the hazards associated with Lupron, failed to take corrective action, timely issue adequate warnings, recall the drug, publicize the problems and otherwise act in a proper or timely manner to alert the public, such as warning the Plaintiffs or their physicians of the drug's inherent dangers, including but not limited to significant bone mineral density loss, which thereby results in serious, grievous injury;
- k. Defendants failed to establish any adequate procedures to educate their sales representatives or prescribing physicians with respect to the correct usage of Lupron and the risks associated with the drug;

- l. Defendants represented that Lupron was safe and fit for its intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;
- m. Defendants misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Lupron and its associated risks, including the risk of significant bone mineral density loss to persons receiving Lupron;
- n. The misrepresentations made by Defendants were unreasonable given the risks that were known or should have been known to Defendants;
- o. Defendants failed to timely cease the manufacture and/or distribution of Lupron, or recall same, when Defendants knew or should have known that Lupron causes significant bone mineral density loss, and resultant grievous injury; and
- p. Defendants actively encouraged the aggressive dispensation of Lupron and/or failed to discourage the same.

25. As a direct and proximate result of the aforementioned negligence of Defendants, jointly, severally, acting in concert, with or through others, and the companies they own, control, or for whose actions they are responsible, Plaintiffs were caused to sustain severe and grievous injuries, including but not limited to early development of osteoporosis, chronic pain, debilitating pain and fatigue.

26. By reason of the foregoing, Plaintiffs have each been damaged in the sum of FIVE MILLION DOLLARS (\$5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS (\$5,000,000.00) in punitive damages.

**SECOND CAUSE OF ACTION vs. ALL DEFENDANTS**  
**(Strict Products Liability)**

27. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in paragraphs "1" through "26" inclusive, as if expressly rewritten herein.

28. At all times herein mentioned, the Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, manufactured, compounded, tested, distributed, recommended, marketed, merchandized, advertised, promoted, sold, purchased, prescribed, and administered Lupron; and the Plaintiffs used, took, or received administrations of Lupron.

29. Lupron was expected to and did, in fact, reach consumers without substantial change in the condition in which Lupron was produced, manufactured, sold, distributed, and marketed by the Defendants.

30. At all times herein described, Lupron was in an unsafe, defective, and inherently dangerous condition, and was hazardous to users, and specifically to the Plaintiffs, in the condition in which the Lupron was produced, manufactured, sold, distributed, and marketed by the Defendants.

31. At all times herein mentioned, the Defendants knew or had reason to know that Lupron was defective and unsafe.

32. At the time Plaintiffs were injected with Lupron, the drug was being used for the purposes and in a manner normally intended by Defendants.

33. The Plaintiffs, through their own reasonable care, could not have discovered the defects herein mentioned or perceived their danger any sooner than they

did discover such defects. Defendants did intentionally and/or negligently fail to warn the Plaintiffs and others of the dangers associated with the use of Lupron.

34. As a direct and proximate result of the defective and unsafe condition of Lupron, Plaintiffs were caused to sustain severe and grievous personal injuries, as described herein, including but not limited to early development of osteoporosis, chronic pain, debilitating pain and fatigue.

35. By reason of the foregoing, Plaintiffs have each been damaged in the sum of FIVE MILLION DOLLARS (\$5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS (\$5,000,000.00) in punitive damages.

**THIRD CAUSE OF ACTION vs. ALL DEFENDANTS**  
**(Strict Products Liability - Failure to Warn)**

36. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in paragraphs "1" through "35", inclusive, as if expressly rewritten herein.

37. Defendants jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, manufactured and/or supplied Lupron, and placed Lupron into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

38. The Lupron manufactured and/or supplied by Defendants was not accompanied by proper warnings to physicians, the medical community, or to women likely to use Lupron, regarding all possible side effects, health concerns and risks associated with the use of Lupron. The warnings and information which were given to the

medical community and women consumers did not accurately reflect the symptoms, duration, scope or severity of the potential side effects, health concerns, and risks of Lupron.

39. Defendants failed to perform adequate testing which would have shown Lupron's potential to cause serious side effects, health concerns and/or risks.

40. Lupron, as manufactured and/or supplied by Defendants was additionally defective due to inadequate after-market surveillance, post-marketing warnings or instruction because Defendants knew or should have known of the potential side effects, health concerns and/or risks associated with Lupron. Instead, Defendants continued to promote Lupron aggressively.

41. Had adequate warnings or instructions been provided, the Plaintiffs would not have used, taken, or received administrations of Lupron, and would not have suffered the harmful side effects, other injuries and damages described herein, including but not limited to, significant loss of bone mineral density, early development of osteoporosis, chronic pain, debilitating pain and fatigue.

42. As a direct and proximate cause of the defective condition of Lupron which Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, designed, developed, manufactured, produced, tested, sold, marketed, supplied and/or distributed, and the absence of adequate and timely warnings about the potential risks of the drug, Plaintiffs suffered those injuries and damages as described herein, including but not limited to, significant loss of bone mineral density, early development of osteoporosis, chronic pain, debilitating pain and fatigue .

43. By reason of the foregoing, Plaintiffs have each been damaged in the sum of FIVE MILLION DOLLARS (\$5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS (\$5,000,000.00) in punitive damages.

**FOURTH CAUSE OF ACTION vs. ALL DEFENDANTS**  
**(Breach of Express Warranty)**

44. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in paragraphs "1" through "43" inclusive, as if expressly rewritten herein.

45. The Defendants expressly represented to the medical community and Lupron users that Lupron had been or was adequately tested for its intended use, that it was safe and fit for its intended purposes, and that it was of merchantable quality.

46. Members of the medical community relied upon the express representations and warranties of Defendants for use in prescribing, recommending, and/or dispensing Lupron.

47. Users of Lupron, including the Plaintiffs, relied on the express representations and warranties of the Defendants that Lupron was safe and fit for its intended purpose and use.

48. Defendants knew or should have known that said representations and warranties were in fact false, misleading, and untrue in that Lupron was not reasonably safe and fit for its intended use, and was not of merchantable quality. Defendants knew or should have known that Lupron causes or contributes to serious adverse health effects, risks, complications, and other injuries for its users as previously described herein. Consequently, Defendants breached their aforementioned express warranties.

49. As a direct and proximate result of such breach of express warranties by Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, the Plaintiffs suffered and sustained permanent, severe and grievous personal injuries, including but not limited to significant loss of bone mineral density, early development of osteoporosis, chronic pain, debilitating pain and fatigue.

50. By reason of the foregoing, Plaintiffs have each been damaged in the sum of FIVE MILLION DOLLARS (\$5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS (\$5,000,000.00) in punitive damages.

**FIFTH CAUSE OF ACTION vs. ALL DEFENDANTS**  
**(Breach of Implied Warranty)**

51. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in paragraphs "1" through "50" ", inclusive, as if expressly rewritten herein.

52. At all times herein mentioned, Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, created, designed, formulated, fabricated, analyzed, tested, manufactured, produced, packaged, promoted, recommended, marketed, merchandized, advertised, distributed and sold Lupron.

53. The Lupron which Defendants inserted into the stream of commerce was defective, unsafe, and in an inherently dangerous condition, where it was expected to and in fact did reach users, distributors, and other persons, including the Plaintiffs, without substantial change in the condition in which it was manufactured, produced, distributed and sold.

54. Defendants impliedly represented and warranted to Lupron users and the medical community that Lupron was safe, of merchantable quality, and fit for the purpose for which said product was used.

55. Defendants impliedly represented and warranted to the users of Lupron and the medical community that Lupron was or had been appropriately and sufficiently tested for use by women.

56. Defendants knew or should have known that their aforementioned representations and warranties were false, misleading, and inaccurate in that Lupron was unsafe, unreasonably and inherently dangerous, not of merchantable quality, not appropriately and sufficiently tested, and defective. Consequently, Defendants breached their implied warranties.

57. As a direct and proximate result of the aforementioned breach of implied warranties by Defendants, the Plaintiffs suffered and sustained permanent, severe, and grievous personal injuries as set forth herein, including but not limited to significant loss of bone mineral density, early development of osteoporosis, chronic pain, debilitating pain and fatigue.

58. By reason of the foregoing, Plaintiffs have each been damaged in the sum of FIVE MILLION DOLLARS (\$5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS (\$5,000,000.00) in punitive damages.

**SIXTH CAUSE OF ACTION vs. ALL DEFENDANTS**  
**(Fraudulent Misrepresentation)**

59. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in paragraphs "1" through "58", inclusive, as if expressly rewritten herein.

60. At all relevant times, the Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, made false and fraudulent representations to the medical community and to users of Lupron, including but not limited to that Lupron had been tested and found to be a safe and effective drug for, among other things, the treatment of endometriosis.

61. Defendants knew or should have known these misrepresentations to be false. Nevertheless, Defendants willfully, wantonly and recklessly disregarded the falsity of their statements (and misrepresentation by omission); and made representations fraudulently and deceitfully, with the intent they be relied upon and which were reasonably relied upon, inducing women to seek Lupron as treatment for endometriosis; and, inducing the medical community to prescribe, dispense, purchase and administer Lupron to women as such. All of Defendants' above acts and/or omissions evince a callous, reckless, willful, and depraved indifference to the life, health, safety and welfare of the drug's intended users, including the Plaintiffs herein.

62. At the time Defendants made their misrepresentations, users of Lupron, including Plaintiffs, could not by the exercise of their own reasonable care, discover the falsity of Defendants' misrepresentations and instead, reasonably believed them to be true.

63. Defendants sought and in fact did obtain FDA approval of Lupron in its defective form, in part based upon Defendants fraudulent misrepresentations, and Defendants inserted Lupron into the stream of commerce, causing harmful effects to Lupron's users. Defendants knew or should have known that Lupron had been insufficiently tested, lacked adequate warnings, and would lead to serious injury amongst its users. Defendants thereby breached their duty to Plaintiffs, to users of Lupron, and the medical community.

64. As a result of Defendants' fraudulent and deceitful conduct and misrepresentations, jointly, severally, acting in concert, with or through others, and the companies they own, control, or for whose actions they are responsible, the Plaintiffs were caused to sustain permanent, severe, and grievous personal injuries, as set forth herein, including but not limited to significant loss of bone mineral density, early development of osteoporosis, chronic pain, debilitating pain and fatigue.

65. By reason of the foregoing, Plaintiffs have each been damaged in the sum of FIVE MILLION DOLLARS (\$5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS (\$5,000,000.00) in punitive damages.

**SEVENTH CAUSE OF ACTION vs. ALL DEFENDANTS**  
**(Negligent Misrepresentation)**

66. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in paragraphs "1" through "66" inclusive, as if expressly rewritten herein.

67. The Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, had a duty to make accurate representations to the

medical community, the Plaintiffs herein, and the general public. Defendants represented, among other things, that Lupron had been tested and found to be safe and effective for the use as an injectable drug for the treatment of endometriosis.

68. Defendants knew or should have known that the drug had been insufficiently and/or inappropriately tested, that it lacked adequate warnings, and/or that it created a high risk of unreasonable and dangerous side effects and health risks, including but not limited to significant loss of bone mineral density, early development of osteoporosis, chronic pain, debilitating pain and fatigue.

69. Because Defendants did not accurately disclose Lupron's serious side effects and health risks to the medical community, the Plaintiffs, and the general public, Defendants negligently misrepresented Lupron's actual, unsafe condition.

70. As a direct and proximate result of the negligent misrepresentations by Defendants, the Plaintiffs were caused to sustain severe and grievous personal injuries, including but not limited to significant loss of bone mineral density, early development of osteoporosis, chronic pain, debilitating pain and fatigue.

71. By reason of the foregoing, Plaintiffs have each been damaged in the sum of FIVE MILLION DOLLARS (\$5,000,000) in compensatory damages and FIVE MILLION DOLLARS (\$5,000,000) in punitive damages.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs **CONSUELO CARDENAS** and **TERRY PAULSEN**, individually, each demand judgment against Defendants, **TAP PHARMACEUTICAL PRODUCTS, INC., ABBOTT LABORATORIES, TAKEDA PHARMACEUTICALS OF NORTH AMERICA, INC, a wholly owned subsidiary of TAKEDA CHEMICAL INDUSTRIES LTD., and TAKEDA CHEMICAL INDUSTRIES, LTD.**, jointly, severally, on each cause of action, for damages in the amount prayed for, with interest, together with the costs and disbursements of this action, and any and all further relief this Court deems just and proper.

**JURY TRIAL DEMAND**

Plaintiffs demand a trial by jury on all issues so triable.

**Dated:** April 16, 2010

Respectfully submitted,

BY:



SYBIL SHAINWALD (SS-1554)  
Law Offices of Sybil Shainwald, P.C.  
*Attorney for Plaintiffs*  
200 West 57<sup>th</sup> Street, Suite 402  
New York, New York 10019  
(212) 425-5566