IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

CANDACE MELISSA STEWART, Plaintiff, v. PFIZER, INC., a foreign corporation, SUMMIT RESEARCH NETWORK (OREGON) INC., an Oregon corporation, SUMMIT RESEARCH NETWORK MANAGEMENT INC., a foreign corporation, and JAMES BERGTHOLD, M.D. Defendants.	Case No. **1206-07852** COMPLAINT (Product Liability; Medical Negligence) NOT SUBJECT TO MANDATORY ARBITRATION JURY TRIAL DEMANDED Prayer: $999,999.00 Filing Fee: ORS 21.160(1)(c)

Plaintiff alleges:

1.

Plaintiff Candace Melissa Stewart ("Melissa Stewart") is, and was at all times material, a citizen of the state of Oregon and resident thereof.

2.

Pfizer Inc. ("Pfizer") is a Delaware corporation headquartered in New York, New York. Pfizer Inc. is a pharmaceutical research company which, at all times material to this claim, designed, manufactured, sold and distributed various drugs and medications, including but not limited to, the medication Tanezumab, and which purposefully directed its sales activities into Oregon and the Portland metropolitan market.

3.

Summit Research Network (Oregon) Inc. is an Oregon corporation that conducts research and trial studies on drugs medications that are not yet on the market, and distributes such medications, including but not limited to the medication Tanezumab, at its facility in Portland,

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Oregon. As part of the Tanezumab trial study, Summit Research Network (Oregon) Inc. distributed the medication to plaintiff Melissa Stewart.

4.

Summit Research Network Management Inc. is a Delaware corporation headquartered in Portland, Oregon. Summit Research Management Inc. conducts research and trial studies on medications that are not yet on the market, and distributes such medications, including but not limited to the medication Tanezumab, at its facility in Portland, Oregon. As part of the Tanezumab trial study, Summit Research Network Management, Inc. distributed the medication to plaintiff Melissa Stewart. Summit Research Network (Oregon) Inc. and Summit Research Network Management Inc. are hereinafter jointly referred to as "Summit Defendants."

5.

James Bergthold, M.D. ("Bergthold') is an Oregon citizen employed by, or acting as the agent of, Summit Research Network (Oregon) Inc. and/or Summit Research Network Management Inc. as a "principal investigator," and lead the 2009 and 2010 trial study of the medication Tanezumab at the Portland, Oregon facility, in which he distributed Tanezumab to participants in the study, including plaintiff Melissa Stewart.

COMMON ALLEGATIONS

6.

Plaintiff Melissa Stewart agreed to partake in a test-study for the drug Tanezumab in or around September 2009. The study was run by Pfizer, the Summit Defendants, and Bergthold. Plaintiff quit the test-study in April, 2010.

7.

In or around July 2010, plaintiff went to the doctor because she had been experiencing hip and elbow pain, and needed to walk with a cane. In or around early August, plaintiff was unable to walk without a cane, and her doctor diagnosed her with osteonecrosis in her hips. Plaintiff contacted Bergthold, who informed plaintiff that Pfizer had halted the Tanezumab test study on or around June 23, 2010 because of the osteonecrosis risk. Prior to receiving this information from Bergthold, plaintiff had no knowledge that the study had been stopped, or that any of the

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defendants had determined that the risk of osteonecrosis from use of Tanezumab was significant enough that human use of the drug should not be permitted.

8.

Thereafter, Plaintiff informed Pfizer of her osteonecrosis diagnoses, and asked for Pfizer to pay for the cost of her surgery. Pfizer refused to pay for plaintiff's surgery until in or around March 2011, by which time plaintiff's condition had deteriorated to the point she was unable to get out of bed, and needed to be carried from the house for her surgery. Plaintiff underwent two total hip replacement surgeries in or around March 2011 and May 2011. Plaintiff also underwent a laminotomy and foraminotomy to her neck in or around January 2011.

9.

As a result of defendants' actions and her participation in the Tanezumab test-study, plaintiff has sustained a number of injuries and medical conditions, including but not limited to: osteonecrosis in both of plaintiff's hips resulting in total bilateral hip replacement surgeries, disk herniation in her neck resulting in a laminotomy and foraminotomy, right shoulder rotator cuff syndrome, advanced right elbow osteoarthritis, osteoarthritis in both hands, carpal tunnel syndrome, bilateral sensory-motor median neuropathies at the wrist, severe tricompartmental osteoarthritis in her right knee, degenerative changes to both knees, numbness extending from her shoulders to her fingers, and pain in her legs and ankles.

FIRST CLAIM FOR RELIEF

STRICT PRODUCTS LIABILITY
(Against All Defendants)

10.

Plaintiff realleges paragraphs 1- 9 above as though fully set forth herein.

11.

Pfizer designed, manufactured, tested, inspected, sold, and/or distributed the drug Tanezumab, including to plaintiff. Summit Defendants and Bergthold tested, sold, and/or distributed the drug Tanezumab, including to plaintiff. All defendants knew that Tanezumab would be used by ultimate purchasers and consumers, including plaintiff without substantial

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change in condition from the time of manufacture and initial sale and/or distribution. Furthermore, the Tanezumab that plaintiff Melissa Stewart took as a test-study participant was in substantially the same condition as it was when shipped from Pfizer's facilities, and as distributed by the defendants. Plaintiff used the Tanezumab in a reasonable and foreseeable manner.

12.

Defendants are strictly liable for designing, manufacturing, distributing, testing, inspecting, and/or selling Tanezumab in an unreasonably dangerous condition for the use intended in one or more of the following particulars:

a) The designed properties of Tanezumab rendered it dangerous to an extent beyond that which would be contemplated by an ordinary consumer with such knowledge of the drug's characteristics as common to the consumer;

b) On information and belief, there were safer adequate designs other than the one used, which were technologically and economically feasible at the time Tanezumab left Pfizer's control, and which in reasonable probability would have prevented or significantly reduced the risk of osteonecrosis to plaintiff Melissa Stewart's hips, as well as her other injuries and conditions caused by the drug;

c) On information and belief, the Tanezumab consumed by plaintiff Melissa Stewart may have deviated in quality from its specifications or planned output in a manner that rendered the Tanezumab unreasonably dangerous;

d) Tanezumab was distributed and/or sold without any or adequate warnings about the foreseeable risk of osteonecrosis and/or various other medical conditions from which plaintiff has suffered, even when taken as directed;

e) Tanezumab was not properly inspected and/or tested prior to distribution and/or sale, which would have indicated the foreseeable risk of osteonecrosis and/or other various medical condition from which plaintiff has suffered; and

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f) Defendants failed to adequately investigate reports of osteonecrosis and/or other various medical conditions from which plaintiff has suffered, to determine whether Tanezumab was unreasonably dangerous and whether the drug could be redesigned to substantially reduce or eliminate the risk of osteonecrosis and/or other medical conditions.

13.

Defendants caused, contributed to, and/or aggravated numerous injuries and medical conditions, including but not limited to the following injuries to plaintiff Melissa Stewart:

a) Osteonecrosis in both of plaintiff's hips, resulting in total bilateral hip replacement surgeries;

b) Disk herniation in her neck, resulting in a laminotomy and foraminotomy;

c) Right shoulder rotator cuff syndrome;

d) Advanced right elbow osteoarthritis;

e) Osteoarthritis in both hands;

f) Carpal tunnel syndrome;

g) Bilateral sensory-motor median neuropathies at the wrist;

h) Severe tricompartmental osteoarthritis in her right knee;

i) Degenerative changes to both knees;

j) Numbness extending from her shoulders to her fingers; and

k) Pain in her legs and ankles.

14.

As a result of defendants' fault and actions alleged herein, plaintiff Melissa Stewart has incurred past reasonable and necessary expenses for medical treatment, hospitalization, prescription drugs, and doctors' expenses and will incur such expenses in the future, all to her economic damage in an amount to be proven at trial.

15.

As a result of defendants' conduct as alleged herein, plaintiff Melissa Stewart has limited mobility, has and will continue to have substantial pain and has sustained past and future loss of

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enjoyment of life, all to her non-economic damage in an amount to be determined by the jury, to fairly compensate her in accordance with Oregon law in an amount not to exceed $999,999.00.

SECOND CLAIM FOR RELIEF

MEDICAL NEGLIGENCE
(Against Summit Defendants and Bergthold Only)

16.

Plaintiff realleges paragraphs 1-15 above as though fully set forth herein.

17.

At all time material to this case, Bergthold was an agent or employee of the Summit Defendants, acting in the course and scope of his agency or employment.

18.

Bergthold and the Summit Defendants operated a test-study for the drug Tanezumab. Plaintiff Melissa Stewart took part in the study and established a patient-physician relationship with Bergthold, by which Bergthold owed plaintiff a duty of reasonable care.

19.

Bergthold and the Summit Defendants breached their duty of care to plaintiff Melissa Stewart when they failed to meet the standard of care ordinarily used by health care providers in the Portland community by failing to obtain conformed consent from plaintiff in the following ways:

a) Failing to explain alternative methods of treatment instead of the drug Tanezumab;

b) Failing to explain the risks involved with taking Tanezumab, including but not limited to risks of osteonecrosis, especially in patients suffering from arthritis; and

c) Failing to ask plaintiff Melissa Stewart if she wanted a detailed explanation of the risks involved, including by not limited to the risk of osteonecrosis.

Had plaintiff Melissa Stewart known of these risks, she would not have consented to the Tanezumab trial study.

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20.

Bergthold and the Summit Defendants also breached their duty of care in allowing plaintiff Melissa Stewart to participate in the Tanezumab trial study, despite the fact that defendants knew plaintiff suffered from arthritis, and that Tanezumab could cause osteonecrosis in certain patients.

21.

As a result of defendants' breach of duty, plaintiff developed osteonecrosis in both of her hips, resulting in total bilateral hip replacement surgeries, as well as her other medical conditions and injuries set forth above.

22.

As a result of defendants' fault and actions alleged herein, plaintiff Melissa Stewart has incurred past reasonable and necessary expenses for medical treatment, hospitalization, prescription drugs, and doctors' expenses and will incur such expenses in the future, all to her economic damage in an amount to be proven at trial.

23.

As a result of defendants' conduct as alleged herein, plaintiff Melissa Stewart has limited mobility, has and will continue to have substantial pain and has sustained past and future loss of enjoyment of life, all to her non-economic damage in an amount to be determined by the jury, to fairly compensate her in accordance with Oregon law in an amount not to exceed $999,999.00.

THIRD CLAIM FOR RELIEF

NEGLIGENCE
(Against All Defendants)

24.

Plaintiff realleges paragraphs 1-23 above as though fully set forth herein.

25.

At all time material to this case, Bergthold was an agent or employee of the Summit Defendants, acting in the course and scope of his agency or employment.

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26.

All defendants were negligent in one or more of the particulars alleged in paragraph 12 of Count One.

27.

All defendants were negligent in allowing plaintiff to participate in the Tanezumab trial study despite the fact that defendants knew, or from available information in possession of defendants should have known, plaintiff suffered from arthritis and that Tanezumab could cause osteonecrosis in certain patients, including plaintiff. As a result of defendants' negligence plaintiff's sustained osteonecrosis in both of plaintiff's hips, resulting in total bilateral hip replacement surgeries, as well as her other medical conditions and injuries set forth above.

28.

Defendants were negligent in selecting Tanezumab for a test study, as a drug with numerous serious side effects, including but not limited to causing, contributing to, and/or aggravating osteonecrosis, and which ultimately did result in plaintiff's osteonecrosis in both of plaintiff's hips, resulting in total bilateral hip replacement surgeries, as well as her other medical conditions and injuries set forth above.

29.

As a result of defendants' fault and actions alleged herein, plaintiff Melissa Stewart has incurred past reasonable and necessary expenses for medical treatment, hospitalization, prescription drugs, and doctors' expenses and will incur such expenses in the future, all to her economic damage in an amount to be proven at trial.

30.

As a result of defendants' conduct as alleged herein, plaintiff Melissa Stewart has limited mobility, has and will continue to have substantial pain and has sustained past and future loss of enjoyment of life, all to her non-economic damage in an amount to be determined by the jury, to fairly compensate her in accordance with Oregon law in an amount not to exceed $999,999.00.

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FOURTH CLAIM FOR RELIEF

UTPA
(Against All Defendants)

31.

Plaintiff realleges paragraphs 1-30 above as though fully set forth herein.

32.

Defendants, and each of them, violated ORS 646.608(1)(e), (g), (I), and (t).

33.

Defendants' violations of the Oregon UTPA give rise to a right of civil action by plaintiffs herein pursuant to ORS 646.638, including the right to reasonable attorney fees, costs, and other equitable relief as deemed appropriate by the court.

34.

Defendants, and each of them, willfully violated Oregon's UTPA, as the term "willful" is defined pursuant to ORS 646.605(10).

35.

As a result of the violation of the Oregon UTPA by defendants and each of them, plaintiff Melissa Stewart suffered ascertainable loss as alleged herein.

FIFTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY
(Against All Defendants)

36.

Plaintiff realleges paragraphs 1-35 above as though fully set forth herein.

37.

At all times material hereto, defendants represented and warranted to Tanezumab test-study participants, including plaintiff Melissa Stewart, that they would not be included in the study unless they were good candidates for the drug treatment.

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38.

By taking part in the Tanezumab test-study, plaintiff Melissa Stewart relied on defendants' express warranty and representation described above, and such warranty and representation formed part of the basis of the bargain in which plaintiff agreed to act as a participant in the test-study.

39.

Defendants breached their express warranty to plaintiff Melissa Stewart by designing, manufacturing, marketing, and/or distributing a defective product which caused osteonecrosis, and by allowing plaintiff to participate in the study despite their knowledge that plaintiff had arthritis.

40.

Defendants' breach of warranty directly and proximately caused plaintiff Melissa Stewart's injuries as set forth herein.

SIXTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(Against All Defendants)

41.

Plaintiff realleges paragraphs 1-40 above as though fully set forth herein.

42.

Defendants impliedly warranted that Tanezumab was of a merchantable quality and that it was fit, safe, and in proper condition for the ordinary use for which it had been designed, manufactured, marketed and used, aside from the side-effects and risks explicitly set forth in the waiver and agreement signed by plaintiff Melissa Stewart.

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43.

In agreeing to act as a participant in the Tanezumab test study, plaintiff Melissa Stewart relied on defendants' skill and judgment, and on the implied warranty of merchantability.

44.

The Tanezumab drug designed, manufactured, marketed, tested, and/or distributed by defendants was not merchantable in that it caused osteonecrosis in some patients, including plaintiff Melissa Stewart, a condition that defendants failed to disclose when plaintiff agreed to act as a test-study participant, and which rendered the product unreasonably dangerous and unfit for its ordinary purposes.

45.

Defendants' breach of the implied warranty of merchantability directly and proximately caused plaintiff Melissa Stewart's injuries as set forth herein.

SEVENTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
(Against All Defendants)

46.

Plaintiff realleges paragraphs 1-45 above as though fully set forth herein.

47.

Defendants, and all of them, knew or should have known of the particular purpose for which plaintiff Melissa Stewart agreed to participate in the Tanezumab test-study, because the sole purpose for which defendants designed, manufactured, marketed, tested, and/or distributed the drug was for use to resolve chronic neurogenic pain consistent with, or similar to, plaintiff's chronic neurogenic pain.

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48.

Defendants impliedly warranted that Tanezumab was fit for the purpose for which is was designed, manufactured, tested, and/or distributed, and that, by allowing plaintiff Melissa Stewart to participate in the test-study, that it was suitable for use by plaintiff.

49.

Plaintiff Melissa Stewart relied on defendants' skill and judgment, and on the implied warranty of fitness for a particular purpose of treatment of chronic neurogenic pain, when agreeing to participate in the Tanezumab test-study.

50.

Tanezumab was not fit for the particular purpose of treatment of chronic neurogenic pain, in that the drug caused osteonecrosis, and other side-effects and complications, in some patients.

51.

Defendants' breach of the implied warranty of fitness for a particular purpose directly and proximately caused plaintiff Melissa Stewart's injuries as set forth herein.

NOTICE OF INTENT TO SEEK PERMISSION TO AMEND COMPLAINT TO ADD PUNITIVE DAMAGES

52.

Plaintiff hereby notifies the defendants of her intent to seek permission to amend her complaint to add a claim for punitive damages when adequate discovery has been undertaken, and evidence has been obtained to meet the standard required by Oregon law

DEMAND FOR JURY TRIAL

53.

Plaintiff hereby demands trial by jury on all issues.

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PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment against defendants and each of them as follows:

a) Economic damages in an amount to be proven at trial;

b) Non-economic damages in an amount not to exceed $999,999.00 to fairly compensate plaintiff in accordance with Oregon law;

c) Plaintiff's attorney's fees in accordance with ORS 646.638(3);

d) Plaintiff's costs and disbursements incurred herein; and

e) Other relief as the court deems just and equitable.

DATED: June 20, 2012

By: _____

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