UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
Tampa Division

KIM YACHERA, on behalf of herself and all others similarly situated, Plaintiff, v. WESTMINSTER PHARMACEUTICALS, LLC and CVS PHARMACY, INC., Defendants.	Civil Action No.

CLASS ACTION COMPLAINT, DEMAND FOR JURY TRIAL, INJUNCTIVE RELIEF SOUGHT

Plaintiff Kim Yachera ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendants Westminster Pharmaceuticals, LLC ("Westminster") and CVS Pharmacy, Inc. ("CVS"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based on personal knowledge.

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below (the "Class"), is a citizen of a different state than Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

2. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, Defendant Westminster

has its principal place of business in this District, and because Defendants (a) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of the adulterated thyroid medications at issue in this District; (b) conduct substantial business in this District; and (c) are subject to personal jurisdiction in this District.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

3. This is a class action lawsuit regarding Defendants Westminster's manufacturing and distribution of adulterated generic prescription thyroid medications containing Levothyroxine and Liothyronine tablets for oral use, branded as "Thyroid Tablets, USP" or "Thyroid Tablets" (hereafter, "Thyroid Tablets"). In turn, Defendant CVS sold these adulterated generic prescription medications to Plaintiff and other similarly situated consumers.

4. Levothyroxine (tetraiodothyronine sodium) and Liothyronine (liothyronine sodium) are generic prescription medications indicated as replacement or supplemental therapy in patients with hypothyroidism, among other conditions. Levothyroxine was first made in 1927, and it is on the World Health Organization's List of Essential Medicines, the most effective and safe medicines needed in a health system. Likewise, Liothyronine may be used instead of or in addition to Levothyroxine for treating thyroid disorders. Compared to Levothyroxine, Liothyronine has a faster onset of action as well as a shorter biological half-life.

5. Defendant Westminster combines both compounds into a generic formulation consisting of a single oral tablet, which is branded as "Thyroid Tablets, USP" or "Thyroid Tablets." However, due to manufacturing defects originating from overseas laboratories in China, Westminster's formulation has become adulterated.

6. On August 9, 2018, the U.S. Food & Drug Administration ("FDA") posted a notice of a voluntary recall of Thyroid Tablets by Westminster.[1] The recall was due to the adulteration of active pharmaceutical ingredients in the recalled products. Westminster's recall notice states that:

> Westminster Pharmaceuticals, LLC is voluntarily recalling all lots, within expiry, of Levothyroxine and Liothyronine (Thyroid Tablets, USP) 15 mg, 30 mg, 60 mg, 90 mg, & 120 mg to the wholesale level. These products are being recalled as a precaution because they were manufactured using active pharmaceutical ingredients that were sourced prior to the FDA's Import Alert of Sichuan Friendly Pharmaceutical Co., Ltd., which as a result of a 2017 inspection were found to have deficiencies with Current Good Manufacturing Practices (cGMP). Substandard cGMP practices could represent the possibility of risk being introduced into the manufacturing process.

7. As referenced in Westminster's recall notice, the FDA had inspected Westminster's supplier, Sichuan Friendly Pharmaceutical Co., Ltd. ("Sichuan"), from October 23 to 27, 2017. As a result of its inspection, the FDA found "significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API)." The FDA concluded that "[b]ecause [Sichuan's] methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, [Sichuan's] API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)." (emphasis added).

8. First, the FDA found that Sichuan had failed to "ensure that all specifications and test procedures are scientifically sound and appropriate to ensure that [its] API conform[s] to established standards of quality and purity." Specifically, Sichuan "failed to conduct residual

[1] The FDA explains that "[w]hen a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company."

solvent testing" of its active pharmaceutical ingredients. Sichuan had also improperly manufactured certain API "on shared equipment."

9. Second, the FDA found that Sichuan had failed to "adequately validate written procedures for the cleaning and maintenance of equipment." Specifically, Sichuan had "failed to conduct cleaning validation studies to demonstrate that [its] cleaning procedures for non-dedicated equipment are suitable to prevent cross-contamination." Sichuan had also "use[d] multiple solvents … in [its] manufacturing process, but [its] validation did not address the potential carryover of residual solvents from one drug to another."

10. Third, the FDA found that Sichuan had failed to "design a documented, on-going stability testing program to monitor the stability characteristics of API and to use the results to confirm appropriate storage conditions and retest or expiry dates." Specifically, during the FDA's inspection Sichuan was "unable to provide data to support" the shelf-life labeling of certain products. Sichuan had also failed to "commit to develop a complete stability program for [its] API."

11. Fourth, the FDA found that Sichuan had failed to "exercise sufficient controls over computerized systems to prevent unauthorized access or changes to data, and to have adequate controls to prevent omission of data." Specifically, Sichuan had "used a non-validated Excel spreadsheet to calculate assay results" for "product release and stability testing." The FDA's inspector noted that "this spreadsheet lacked password protection and contained unlocked calculation formulas which were incorrect." In fact, the FDA further noted that "[Sichuan's] QC manager acknowledged that the formula in the spreadsheet used to calculate assay results was incorrect."

12. Due to the severity of the FDA's findings, the FDA placed an Import Alert on Sichuan on March 22, 2018. The FDA also "strongly recommended" that Sichuan "engag[e] a consultant qualified to evaluate your operations and assist your firm in meeting CGMP requirements." However, the FDA noted that "[Sichuan's] use of a consultant does not relieve [its] obligation to comply with CGMP."

13. Generic drugs reach the market when the brand-name version of the drug comes off patent, and other competitors are able to seek approval for, market, and sell bioequivalent versions of the brand-name drug. These generic equivalents are supposed to be of equal quality and equal safety. Defendant Westminster, who is in the business of marketing and distributing generic pharmaceuticals, explains on its website:

> Westminster Pharmaceuticals' code of business conduct is the foundation of quality assurance in everything Westminster accomplishes. Westminster Pharmaceuticals is committed to delivering the highest standard of product quality, enabling us to continuously provide superior pharmaceutical products and services to our customers and partners.
>
> …
>
> Under the Westminster Pharmaceuticals label, we work with each partner to achieve mutual long-term success. As we move ahead and expand focus on Research & Development, we're continuing to develop and market additional generic pharmaceutical products. It's the next step towards ensuring greater longevity over every aspect of our product portfolio's lifecycle — so we can continue providing our customers with a greater variety of safe, affordable and reliable generic medications.

(Emphasis added.)

14. However, each of these representations and warranties made by Westminster are false. To the contrary, Westminster's Thyroid Tablets are neither safe nor of "superior" quality. In fact, the FDA found that the active pharmaceutical ingredients used in Westminster's Thyroid

Tablets "are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act."

15. Plaintiff and the Class were injured by the full purchase price of their Thyroid Tablets. These medications are worthless, as they are manufactured with API's that have been found to be adulterated and are not fit for human consumption. Indeed, Plaintiff has been instructed to immediately stop using the medication. Plaintiff is further entitled to statutory damages, damages for the injury sustained in consuming an adulterated medication, and for damages related to Defendants' conduct.

16. Plaintiff brings this action on behalf of the Class for equitable relief and to recover damages and restitution for: (i) breach of express warranty, (ii) breach of the implied warranty of merchantability, (iii) violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, (iv) unjust enrichment, (v) fraudulent concealment, (vi) fraud, (vii) conversion, (viii) strict products liability, (ix) gross negligence, (x) negligence, and (xi) battery.

PARTIES

17. Plaintiff Kim Yachera is a citizen of Pennsylvania who resides in Crum Lynne, Pennsylvania. During all relevant time periods, Plaintiff Yachera was prescribed, purchased, and consumed Thyroid Tablets manufactured and distributed by Defendant Westminster, and sold by Defendant CVS. Plaintiff Yachera originally learned about the Thyroid Tablets recall by receiving a letter dated August 24, 2018 from Defendant CVS, which informed her that Westminster was recalling her medication "**because of potential quality concerns during the manufacturing of the active pharmaceutical ingredients**" (emphasis in original). The letter further states that "**[t]he FDA has reported finding inconsistent levels of the active pharmaceutical ingredients in the Westminster Pharmaceuticals levothyroxine and**

liothyronine tablets it tested" (emphasis in original). The letter further states that "**[t]his may represent a potential health hazard or safety risk to patients who may be using product affected by this recall**" (emphasis in original). The letter further states that "**[y]ou should not continue to use product that is affected by this recall**," and that Ms. Yachera should "**call [her] doctor right away for advice**" (emphasis in original). Plaintiff Yachera has been using Thyroid Tablets distributed by Westminster and CVS for some time. When purchasing her Thyroid Tablets from Defendants Westminster and CVS, Plaintiff Yachera reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured and free from adulteration and defects. Plaintiff Yachera relied on these representations and warranties in deciding to purchase her Thyroid Tablets from Defendants Westminster and CVS, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased her Thyroid Tablets from Defendants Westminster and CVS if she had known that they were not, in fact, properly manufactured and free from adulteration and defects. Plaintiff Yachera also understood that in making the sale, CVS was acting with the knowledge and approval of Westminster and/or as the agent of Westminster. Plaintiff Yachera also understood that each purchase involved a direct transaction between herself and Westminster, because her medication came with packaging and other materials prepared by Westminster, including representations and warranties that her medications were properly manufactured and free from adulteration and defects.

18. Defendant Westminster Pharmaceuticals, LLC is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 3810 Northdale Boulevard, Suite 250, Tampa, Florida 33624. Defendant Westminster conducts substantial

business in the United States, including in the states of Pennsylvania and Florida. Defendant Westminster has been engaged in the manufacturing, sale, and distribution of adulterated generic Thyroid Tablets in the United States, including the states of Pennsylvania and Florida.

19. Defendant CVS Pharmacy, Inc. is a corporation organized under the laws of the State of Rhode Island and Providence Plantations and maintains its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. Among other services, CVS provides pharmacy services. Defendant CVS conducts substantial business throughout the United States, and specifically in the states of Pennsylvania and Florida.

CLASS ALLEGATIONS

20. Plaintiff seeks to represent a class defined as all persons in the United States who purchased or paid for Thyroid Tablets that are subject to Westminster's recall or manufactured with adulterated components from Sichuan (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint venturers, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

21. Plaintiff also seeks to represent a subclass of all Class members in Pennsylvania (the "Pennsylvania Subclass").

22. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

23. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiff, the true number of Class members is known by Defendants. More specifically, Defendants maintain databases that contain the following information: (i) the name of each Class member who was prescribed the adulterated medication; (ii) the address of each Class member; and (iii) each Class member's payment information related to the adulterated medication. Thus, Class members may be identified and notified of the pendency of this action by U.S. Mail, electronic mail, and/or published notice, as is customarily done in consumer class actions.

24. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Thyroid Tablets manufactured, distributed, and sold by Defendants were in fact adulterated, thereby breaching the express and implied warranties made by Defendants and making the medication unfit for human consumption and therefore unfit for their intended purpose, and constituting a clear manufacturing defect for purposes of strict liability and negligence, as well as battery as to the victims of the adulterated medication;

(b) whether Defendants knew or should have known that the Thyroid Tablets were in fact adulterated, thereby constituting fraud and/or fraudulent concealment, and negligence or gross negligence;

(c) whether Defendants have unlawfully converted money from Plaintiff and the Class;

(d) whether Defendants are liable to Plaintiff and the Class for unjust enrichment;

(e) whether Defendants are liable to Plaintiff and the Class for fraudulent concealment;

(f) whether Defendants are liable to Plaintiff and the Class for violations of Pennsylvania's consumer protection laws;

(g) whether Defendants are liable to Plaintiff for breaches of express and implied warranties;

(h) whether Plaintiff and the Class have sustained monetary loss and the proper measure of that loss;

(i) whether Plaintiff and the Class are entitled to declaratory and injunctive relief;

(j) whether Plaintiff and the Class are entitled to restitution and disgorgement from Defendants; and

(k) whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products are deceptive.

25. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class in that Defendants mass marketed and sold adulterated medications to consumers throughout the United States. This adulteration was present in all of the recalled medications manufactured, distributed, and sold by Defendants. Therefore, Defendants breached their express and implied warranties to Plaintiff and Class members by manufacturing, distributing, and selling adulterated Thyroid Tablets. Plaintiff's claims are typical in that both Plaintiff and members of the Class were uniformly harmed in purchasing and consuming the adulterated medications. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class. Further, there are no defenses available to Defendants that are unique to Plaintiff.

26. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on

behalf of the Class. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class.

27. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

28. In the alternative, the Class may also be certified because:

(a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudication with respect to individual Class members that would establish incompatible standards of conduct for the Defendants;

(b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendants have acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

COUNT I
Breach Of Express Warranty
(On Behalf Of The Nationwide Class)

29. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

30. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

31. Plaintiff, and each member of the nationwide Class, formed a contract with Defendants at the time Plaintiff and the other Class members purchased the adulterated Thyroid Tablets. The terms of the contract include the promises and affirmations of fact made by Defendants on the adulterated medication's packaging and through marketing and advertising, including that the product would be "superior" and "safe." This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

32. Defendants further expressly warranted that the Thyroid Tablets would contain only what was stated on the label, and would not contain any adulterations. Defendant expressly warranted that the dosages (i.e. the amount of active pharmaceutical ingredient) listed on the label would be accurate. Plaintiff relied on the express warranty that her medication would contain only what was stated on the label, and that it would not contain any adulterations. Plaintiff relied on the express warranty that her medication contained the dosage (i.e. the amount of active pharmaceutical ingredient) listed on the label. These express warranties further formed the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

33. Defendants purport, through their advertising, labeling, marketing and packaging to create an express warranty that the medication would be of the same quality of the name-brand medication, and that it would be "safe." Westminster also purports to offer "superior pharmaceutical products" vis-à-vis its competitors.

34. Plaintiff and the Class performed all conditions precedent to Defendants' liability under this contract when they purchased the adulterated medication.

35. Defendants breached express warranties about the adulterated Thyroid Tablets and their qualities because Defendants' statements about the adulterated Thyroid Tablets were false and the adulterated medication does not conform to Defendants' affirmations and promises described above.

36. Plaintiff and each of the members of the Class would not have purchased the adulterated medication had they known the true nature of the adulterated medication's ingredients and what the medication contained.

37. As a result of Defendants' breaches of express warranty, Plaintiff and each of the members of the Class have been damaged in the amount of the purchase price of the Thyroid Tablets and any consequential damages resulting from the purchases.

38. On September 28, 2018, prior to filing this action, Defendants were served with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiff's counsel sent Defendants a letter advising them that they breached an express warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached hereto as Exhibit A.

COUNT II
Breach Of The Implied Warranty Of Merchantability

(On Behalf Of The Nationwide Class)

39. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

40. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

41. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that the Thyroid Tablets (i) contained no adulterations and (ii) are generally recognized as safe for human consumption.

42. Defendants breached the warranty implied in the contract for the sale of the adulterated Thyroid Tablets because they could not pass without objection in the trade under the contract description, the goods were not of fair average quality within the description, and the goods were unfit for their intended and ordinary purpose because the Thyroid Tablets manufactured, distributed, and sold by Defendants were adulterated, and as such are not generally recognized as safe for human consumption. As a result, Plaintiff and Class members did not receive the goods as impliedly warranted by Defendants to be merchantable.

43. Plaintiff and Class members purchased the Thyroid Tablets in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

44. The Thyroid Tablets were not altered by Plaintiff or Class members.

45. The Thyroid Tablets were defective when they left the exclusive control of Defendants.

46. Defendants knew that the Thyroid Tablets would be purchased and used without additional testing by Plaintiff and Class members.

47. The adulterated Thyroid Tablets were defectively manufactured and unfit for its intended purpose, and Plaintiff and Class members did not receive the goods as warranted.

48. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class members have been injured and harmed because: (a) they would not have purchased the Thyroid Tablets on the same terms if they knew that the products contained adulterations, and are not generally recognized as safe for human consumption; and (b) the Thyroid Tablets do not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT III
Violation Of Pennsylvania's Unfair Trade Practices and Consumer Protection Law
(On Behalf Of The Pennsylvania Subclass)

49. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

50. Plaintiff brings this claim individually and on behalf of the members of the proposed Pennsylvania Subclass against Defendants.

51. The general purpose of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-1, *et seq.* ("UTPCPL"), is to protect the public from fraud and unfair or deceptive business practices.

52. The UTPCPL declares unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce" described in the statute.

53. Defendants were involved in "trade" and "commerce" as defined by 73 Pa. Stat. Ann. § 201-2(3).

54. Defendants engaged in "unfair methods of competition" and "unfair or deceptive acts or practices" by:

a. Representing that the Thyroid Tablets manufactured and sold by Defendants have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities they do not have (i.e. Defendants represented that their Thyroid Tablets were not adulterated, when in fact the medications were adulterated);

b. Representing that the Thyroid Tablets manufactured and sold by Defendants are of a particular standard, quality or grade, when in fact they are adulterated, rendering them unfit for human use;

c. Advertising the Thyroid Tablets medications with the intent not to sell them as advertised;

d. As described at length in Count I, above, failing to comply with the terms of any written guarantee or warranty given to the buyer at, prior to or after a contract for the purchase of goods or services is made.

55. The UTPCPL provides a private right of action for any person who "suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by any person of a method, act or practice declared unlawful" by the UTPCPL. 73 P.S. § 201-9.2(a).

56. In the course of Defendants' business, they knowingly failed to disclose and actively concealed material facts and made false and misleading statements regarding the adulteration of the Thyroid Tablets.

57. Plaintiff and members of the class relied upon Defendants' false and misleading representations and omissions.

58. As a direct and proximate result of Defendants' unfair or deceptive acts or practices, Plaintiff and the Class members have suffered and will continue to suffer actual damages.

59. Plaintiff, individually and on behalf of the other Class members, seeks the greater of actual damages or $100, whichever is greater, treble damages and an award of attorneys' fees pursuant to 73 P.S. § 201-9.2(a)

COUNT IV
Unjust Enrichment
(On Behalf Of The Nationwide Class)

60. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

61. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

62. Plaintiff and the Class conferred a benefit on Defendants in the form of monies paid to purchase Defendants' adulterated Thyroid Tablets.

63. Defendants voluntarily accepted and retained this benefit.

64. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for adulterated medications unfit for human use, it would be unjust and inequitable for the Defendants to retain it without paying the value thereof.

COUNT V
Fraudulent Concealment
(On Behalf Of The Nationwide Class)

65. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

66. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

67. Defendants had a duty to disclose material facts to Plaintiff and the Class given their relationship as contracting parties and intended users of the medication. Defendants also had a duty to disclose material facts to Plaintiff and the Class, namely that they were in fact manufacturing, distributing, and selling harmful and adulterated medications unfit for human consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

68. Defendants possessed knowledge of these material facts.

69. Defendants failed to discharge their duty to disclose these materials facts.

70. In so failing to disclose these material facts to Plaintiff and the Class, Defendants intended to hide from Plaintiff and the Class that they were purchasing and consuming medications with adulterations that were unfit for human use, and thus acted with scienter and/or an intent to defraud.

71. Plaintiff and the Class reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the Thyroid Tablets manufactured, distributed, and sold by Defendants had they known it was adulterated.

72. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiff and the Class suffered damages in the amount of monies paid for the defective medication.

73. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VI
Fraud
(On Behalf Of The Nationwide Class)

74. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

75. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

76. As discussed above, Defendants provided Plaintiff and Class members with false or misleading material information about the Thyroid Tablets manufactured, distributed, and sold by Defendants, including but not limited to Defendant Westminster's statements that its medications were "superior" and "safe."

77. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class members to purchase the adulterated Thyroid Tablets.

78. Defendants knew that the medications contained adulterations, but continued to manufacture them until the FDA finally discovered the issue during an inspection. During that time, Plaintiff and Class Members were using the medication without knowing it contained adulterations.

79. The fraudulent actions of Defendants caused damage to Plaintiff and Class members, who are entitled to damages and other legal and equitable relief as a result.

80. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VII
Conversion
(On Behalf Of The Nationwide Class)

81. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

82. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

83. Plaintiff and the Class have an ownership right to the monies paid for the adulterated Thyroid Tablets manufactured, distributed, and sold by Defendants.

84. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the adulterated medication. Defendants have done so every time that Plaintiff and the Class have paid to have their prescriptions filled.

85. As a direct and proximate cause of Defendants' conversion, Plaintiff and the Class suffered damages in the amount of the payments made for each time they filled their prescriptions.

COUNT VIII
Strict Liability – Manufacturing Defect
(On Behalf Of The Nationwide Class)

86. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

87. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

88. The adulteration contained in the Defendants' Thyroid Tablets was a mishap in the manufacturing process. The adulterations were not intended to be included in the medication; it was due to an error in the manufacturing process.

89. Due to the adulteration, Thyroid Tablets were not reasonably safe as marketed.

90. Plaintiff and all Class members used the product for its intended purpose, meaning they used the product as prescribed by their respective doctors.

91. There is no way that Plaintiff or Class members could have discovered the adulteration by exercising reasonable care. There was no way for Plaintiff or Class Members to tell by visually observing, tasting, or smelling the medication that it was in fact adulterated. Nothing short of laboratory tests (which should have been done by Defendants for quality control purposes) would have revealed the defect to the unsuspecting consumer.

92. Because Plaintiff and Class members had no way of knowing that their medication was in fact adulterated, Plaintiff and Class members could not have avoided the injury by exercising ordinary care.

93. Defendants were supposed to manufacture, distribute, and sell Thyroid Tablets without any adulterations. The adulteration resulted from a manufacturing defect.

94. Plaintiff and class members suffered harm as a result of consuming this adulterated medication.

95. Because of the adulteration of Westminster's Thyroid Tablets, Plaintiff and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis (i.e., the purchase price of their medications).

96. Because the Thyroid Tablets manufactured, distributed, and sold by Defendants suffered from a manufacturing defect which caused Plaintiff and Class members an immediate and concrete harm, Defendants are strictly liable to Plaintiff.

COUNT IX
Gross Negligence
(On Behalf Of The Nationwide Class)

97. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

98. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

99. Defendants owed a duty of care to Plaintiff to manufacture, distribute, and sell the subject Thyroid Tablets free from adulterations.

100. Defendants breached that duty by manufacturing, distributing, and selling adulterated Thyroid Tablets.

101. Plaintiff and Class members were injured by ingesting a prescription drug containing adulterations, which was negligently present in the Thyroid Tablets manufactured, distributed, and sold by Defendants. Plaintiff and Class members also suffered economic damages from the purchase of their Thyroid Tablets.

102. Because of the adulteration of Thyroid Tablets, Plaintiff and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis (i.e., the purchase price of their medications).

103. Defendants' conduct evinces a reckless disregard for the rights of others, and strongly suggests intentional wrongdoing.

104. Because the Thyroid Tablets manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiff and Class members, and because Defendants failed to act to remediate the adulteration until an FDA

inspection discovered the issue, Defendants are grossly negligent and are liable to Plaintiff for all injuries proximately caused by Defendants' gross negligence.

COUNT X
Negligence
(On Behalf Of The Nationwide Class)

105. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

106. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

107. Defendants owed a duty of care to Plaintiff to manufacture, distribute, and sell the subject Thyroid Tablets free from harmful defects and impurities.

108. Defendants breached that duty by manufacturing, distributing, and selling adulterated Thyroid Tablets.

109. Plaintiff and Class members were injured by ingesting a prescription drug containing adulterations, which was negligently present in the Thyroid Tablets manufactured, distributed, and sold by Defendants. Plaintiff and Class members also suffered economic damages from the purchase of their Thyroid Tablets.

110. Because of the adulteration of Thyroid Tablets, Plaintiff and class-members suffered a concrete and identical harm that can and should be addressed on a class-wide basis (i.e., the purchase price of their medications).

111. Because the Thyroid Tablets manufactured, distributed, and sold by Defendants suffered from a harmful impurity constituting a breach of Defendants' duty to Plaintiff and class members, Defendants are negligent and are liable to Plaintiff for all injuries proximately caused by Defendants' negligence.

COUNT XI
Battery
(On Behalf Of The Nationwide Class)

112. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

113. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Pennsylvania Subclass against Defendants.

114. Defendants manufactured, distributed, and sold the adulterated Thyroid Tablets to Plaintiff and Class members with the knowledge and intent that Plaintiff and Class members would ingest the medication. Defendants thus had knowledge that the adulteration would come into contact the bodies of Plaintiff and Class members.

115. The intended contact, *i.e.* the medication being ingested by Plaintiff, was harmful in nature because the medication was adulterated.

116. As such, Defendants committed an unlawful battery on Plaintiff and Class members, who ingested the medication.

RELIEF DEMANDED

117. WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seek judgment against Defendant, as follows:

A. For an order certifying the nationwide Class and the Pennsylvania Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as a representative of the Class and Pennsylvania Subclass and Plaintiff's attorneys as Class Counsel to represent the Class and Pennsylvania Subclass members;

B. For an order declaring the Defendants' conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiff, the nationwide Class, and the Pennsylvania Subclass on all counts asserted herein;

D. For compensatory, statutory, treble, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief;

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiff and the Class and Pennsylvania Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: October 1, 2018

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Scott A. Bursor*
Scott A. Bursor (State Bar No. 68362)

888 Seventh Avenue
New York, NY 10019
Telephone: (212) 989-9113
Facsimile: (212) 989-9163
Email: scott@bursor.com

EXHIBIT A

BURSOR & FISHER P.A.

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3RD FLOOR
NEW YORK, NY 10019
www.bursor.com

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September 28, 2018

Via Certified Mail – Return Receipt Requested

Westminster Pharmaceuticals, LLC
3810 Northdale Boulevard, Suite 250
Tampa, FL 33624

CVS Pharmacy, Inc.
One CVS Drive
Woonsocket, RI 02895

Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Westminster Pharmaceuticals, LLC ("Westminster") and CVS Pharmacy, Inc. ("CVS") pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranty related to our client, Kim Yachera, and a class of all similarly situated purchasers (the "Class"). Plaintiff and members of the Class were prescribed and purchased adulterated generic prescription thyroid medications containing Levothyroxine and Liothyronine tablets for oral use, branded as "Thyroid Tablets, USP" or "Thyroid Tablets," manufactured and distributed by Westminster and sold by CVS.

On August 9, 2018, the U.S. Food & Drug Administration ("FDA") posted a notice of a voluntary recall of Thyroid Tablets by Westminster. The recall was due to the adulteration of active pharmaceutical ingredients in the recalled products. Westminster's recall notice states that:

> Westminster Pharmaceuticals, LLC is voluntarily recalling all lots, within expiry, of Levothyroxine and Liothyronine (Thyroid Tablets, USP) 15 mg, 30 mg, 60 mg, 90 mg, & 120 mg to the wholesale level. These products are being recalled as a precaution because they were manufactured using active pharmaceutical ingredients that were sourced prior to the FDA's Import Alert of Sichuan Friendly Pharmaceutical Co., Ltd., which as a result of a 2017 inspection were found to have deficiencies with Current Good Manufacturing Practices (cGMP). Substandard cGMP practices could represent the possibility of risk being introduced into the manufacturing process.

As referenced in Westminster's recall notice, the FDA had inspected Westminster's supplier, Sichuan Friendly Pharmaceutical Co., Ltd. ("Sichuan"), from October 23 to 27, 2017. As a result of its inspection, the FDA found "significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API)." The FDA concluded that "[b]ecause [Sichuan's] methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, [Sichuan's] API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)." (emphasis added).

This defect rendered the products unusable and unfit for human consumption. In short, Westminster's Thyroid Tablets that our clients and the Class were purchasing are worthless as they were adulterated, and therefore unfit for human use. Westminster and CVS each violated express and implied warranties made to our clients and the Class regarding the quality and safety of the thyroid medications they purchased. *See* U.C.C. §§ 2-313, 2-314.

On behalf of our clients and the Class, we hereby demand that Westminster and CVS immediately (1) cease and desist from continuing to sell adulterated Thyroid Tablets and (2) make full restitution to all purchasers of the adulterated Thyroid Tablets of all purchase money obtained from sales thereof.

We also demand that Westminster and CVS preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for Westminster's Thyroid Tablets medications;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of Westminster's Thyroid Tablets medications;

3. All tests of the Thyroid Tablets medications manufactured and distributed by Westminster;

4. All documents concerning the pricing, advertising, marketing, and/or sale of the Thyroid Tablets medications manufactured and distributed by Westminster;

5. All communications with customers involving complaints or comments concerning the Thyroid Tablets medications manufactured and distributed by Westminster;

6. All documents concerning communications with any retailer involved in the marketing or sale of the Thyroid Tablets medications manufactured and distributed by Westminster;

7. All documents concerning communications with federal or state regulators; and

8. All documents concerning the total revenue derived from sales of Westminster's Thyroid Tablets medications.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Andrew J. Obergfell

Andrew J. Obergfell

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Kim Yachera, on behalf of herself and all others similarly situated

(b) County of Residence of First Listed Plaintiff Delaware County, PA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Bursor & Fisher, P.A.
888 Seventh Avenue, New York, NY 10019
646-837-7150

DEFENDANTS

Westminster Pharmaceuticals, LLC and CVS Pharmacy, Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	☒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332(d)(2)(A)

Brief description of cause:
Defendants sold adulterated thyroid medication to Plaintiff and class members

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 5,000,001.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 10/01/2018

SIGNATURE OF ATTORNEY OF RECORD s/ Scott A. Bursor

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____