UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

BARBARA KRUK, individually and on behalf of all others similarly situated,

Plaintiff,

v. Case No. 8:18-cv-2927

AUROBINDO PHARMA LTD., an Indian corporation; SCIEGEN PHARMACEUTICALS, INC., a New York corporation; WESTMINSTER PHARMACEUTICALS, LLC, a Delaware limited liability company; WALMART INC., a Delaware corporation,

Defendants.
_____/

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL
INJUNCTIVE RELIEF SOUGHT

Plaintiff, Barbara Kruk ("Plaintiff"), brings this action, individually and on behalf of all others similarly situated, against Defendants Aurobindo Pharma Ltd., ScieGen Pharmaceuticals, Inc., Westminster Pharmaceuticals, LLC, and Walmart Inc. Plaintiff alleges as follows upon personal knowledge as to facts pertaining to herself, and upon information and belief based on the investigation of her counsel as to all other matters.

NATURE OF THE CASE

1. Plaintiff brings this class action on behalf of herself and all others similarly situated regarding Defendants' respective manufacturing, distribution, and sale of generic irbesartan prescription medications containing an active pharmaceutical

ingredient ("API") adulterated with *N*-nitrosodiethylamine ("NDEA"), a probable human carcinogen.

2. Irbesartan is a prescription medication mainly used to treat high blood pressure and diabetic nephropathy.

3. Due to manufacturing defects originating in Defendant Aurobindo Pharma Ltd.'s ("Aurobindo") facility in India, certain batches of irbesartan active pharmaceutical ingredient were supplied to Defendant ScieGen Pharmaceuticals, LLC ("ScieGen"), and thus introduced to the United States market, that were adulterated with the probable human carcinogen, NDEA (the "Adulterated Irbesartan").

4. After ScieGen used the Adulterated Irbesartan to manufacture and produce finished generic prescription irbesartan tablets, ScieGen shipped the tablets containing Adulterated Irbesartan to Defendant Westminster Pharmaceuticals ("Westminster") in or about Tampa, Hillsborough County, Florida.

5. Westminster, in turn, further manufactured, labeled, packaged, and distributed the tablets containing Adulterated Irbesartan to pharmaceutical retailers nationwide, including Defendant Walmart Inc. ("Walmart").

6. Plaintiff purchased and ingested tablets containing Adulterated Irbesartan from her local Walmart pharmacy as part of a medical treatment regimen.

7. Generic drugs such as irbesartan are marketed and sold to consumers such as Plaintiff when the patent for the brand-name version of the drug expires, and other competitors are able to seek approval for, market, and sell bioequivalent versions of the

brand-name drug. These generic equivalents, such as irbesartan, are supposed to be of equal quality and equal safety as the brand-name drugs.

8. Plaintiff and the putative class members were injured by paying the full purchase price of their medications containing Adulterated Irbesartan and by paying for incidental medical expenses. These medications are worthless because they are contaminated with carcinogenic and harmful NDEA and are thus not fit for human consumption.

9. Plaintiff brings this action both individually and on behalf of the putative class members for equitable relief and to recover economic damages and restitution for: (1) strict product liability; (2) failure to warn; (3) breach of contract; (4) breach of implied warranty of merchantability; (5) unjust enrichment; (6) fraudulent concealment; (7) conversion; (8) negligence; and (9) gross negligence; and (10) violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.* ("ICFA").

PARTIES

10. Plaintiff, Barbara Kruk, is an individual who is a citizen of the State of Illinois, domiciled in DuPage County, Illinois. During all relevant time periods, Plaintiff was prescribed, purchased, and consumed Adulterated Irbesartan manufactured, distributed, and sold by Defendants.

11. When purchasing her Adulterated Irbesartan manufactured and distributed by Defendants, Plaintiff reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturers, distributors, and

pharmacy (in her case, Walmart), that the medications were properly manufactured and free from adulteration and defects.

12. Plaintiff relied on these representations and warranties in deciding to purchase the irbesartan manufactured, distributed, and sold by Defendants, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased Defendants' medication contaminated with Adulterated Irbesartan if she had known that such medication was not, in fact, properly manufactured and free from adulteration and defects.

13. Plaintiff also understood that each purchase involved a direct transaction between herself and Defendants, because her medication came with packaging and other materials prepared by Defendants, including representations and warranties that her medication was properly manufactured and free from adulteration and defects.

14. On information and belief, Defendant Aurobindo is a corporation organized and existing under the laws of the Republic of India. It maintains its principal place of business in Hitech City, Hyderabad, India. Aurobindo presently maintains its United States headquarters, through its American subsidiary Aurobindo Pharma USA Inc., in East Windsor, New Jersey. Aurobindo has been engaged in the manufacturing, distribution, and sale of Adulterated Irbesartan in the United States, including but not limited to within the State of Illinois and within the State of Florida.

15. Defendant Aurobindo's purposeful availment of the benefits and protections of the State of Florida commenced on or about July 7, 2001, when Aurobindo applied to the Florida Secretary of State's Division of Corporations for authorization to

transact business in Florida as a foreign corporation. Aurobindo's application was granted on or about that date, and Aurobindo was thus authorized by the Florida Secretary of State's Division of Corporations to transact business in Florida as a foreign corporation. Aurobindo thereafter maintained a registered agent in Miami-Dade County, Florida in connection with its Florida foreign corporation authorization until its Florida registration was revoked on or about September 21, 2001 for its failure to file an annual report with the Florida Secretary of State, Division of Corporations.

16. On information and belief, Aurobindo supplies active pharmaceutical ingredients ("API"), including irbesartan API, to United States manufacturers, who in turn produce finished product, with the expectation and actual knowledge that its API will be purchased and/or used in other drug products purchased throughout the United States, including within the State of Florida and within this District.

17. Aurobindo touts in its most recent annual report that it is a "leading global pharmaceutical company producing generic formulations and active pharmaceutical ingredients (APIs)."

18. Defendant ScieGen is a corporation organized under the laws of the State of New York. It maintains its principal place of business in Hauppauge, Suffolk County, New York. ScieGen has been engaged in the manufacturing, national distribution, and national sale of Adulterated Irbesartan, including within the State of Florida and within this District.

19. Defendant Westminster is a limited liability company organized under the laws of the State of Delaware. Westminster is registered with the Florida Department of

State's Division of Corporations to do business in Florida as a foreign limited liability company, and it maintains a registered agent for service of process in Florida in Tampa, Hillsborough County, Florida. Westminster maintains its principal place of business in Tampa, Hillsborough County, Florida. Westminster has been engaged in the manufacturing, national sale, and national distribution of Adulterated Irbesartan, including within Florida and within this District.

20. Defendant Walmart Inc. is a corporation organized under the laws of the State of Delaware. It maintains its principal place of business in Bentonville, Arkansas.

21. Walmart is registered with the Florida Department of State's Division of Corporations to do business in Florida as a foreign profit corporation, and it maintains a registered agent for service of process in Florida in Broward County, Florida.

22. Walmart conducts more business in Florida than in all but one of the United States, including Arkansas. Walmart operates 384 separate retail stores in Florida under at least two different brands, maintains 8 distribution centers in Florida, employs at least 107,296 individuals in Florida, and collected $996.9 million dollars in taxes on behalf of the State of Florida for the fiscal year 2018.[1] Walmart additionally maintains its Latin American headquarters in Miami-Dade County, Florida.

JURISDICTION AND VENUE

23. This Court has jurisdiction over this action pursuant § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the

[1] *Location Facts*, WALMART, https://corporate.walmart.com/our-story/locations/united-states/florida#/united-states/florida (last visited Nov. 15, 2018).

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.

24. On information and belief, at all times relevant Defendants purposefully directed their business activities at the State of Florida and purposefully availed themselves of the privilege of conducting business in Florida.

25. On information and belief, at all times relevant Defendants each benefitted from Florida's system of laws, infrastructure and business climate for the sale of their products, including prescription irbesartan.

26. On information and belief, Defendants' manufacture, marketing, distribution and/or sale of Adulterated Irbesartan and medications containing Adulterated Irbesartan resulted in millions of dollars in profits to Defendants. Defendants' profits are a direct result of their selection of Florida and this District in which to conduct business.

27. On information and belief, at all times relevant Aurobindo delivered the Adulterated Irbesartan into the stream of commerce with the knowledge and expectation that it would thereafter be processed, packaged, and labeled in Hillsborough County, Florida, and distributed from Hillsborough County, Florida for sale throughout the State of Florida specifically, and the United States generally.

28. On information and belief, at all times relevant ScieGen sold and/or distributed and/or delivered prescription medication containing Adulterated Irbesartan to customers within Florida and within this District, including its customer, Westminster.

29. On information and belief, negotiations and/or dealings concerning ScieGen's distributions or sales of Adulterated Irbesartan to Westminster occurred within Florida and within this District.

30. On information and belief, at all times relevant Walmart solicited and /or purchased prescription medications containing Adulterated Irbesartan for the purpose of resale from vendors within Florida and within this District, including Westminster. The material terms of Walmart's resale of Westminster products, including Adulterated Irbesartan, were decided upon in whole or in part within this District.

31. Plaintiff's causes of action arise out of Defendants' contacts and activities within Florida and within this District. Defendants are subject to personal jurisdiction in this District pursuant to Florida Statute § 48.193 because Plaintiff's claims arise from Defendants' actions in conducting and engaging in business in the State of Florida, and Defendants' commission of tortious acts in the State of Florida.

32. Additionally, this Court has general personal jurisdiction over Westminster, which is headquartered in Florida, within this District.

33. Additionally, this Court has general personal jurisdiction over Walmart, as Walmart's contacts with and business operations in Florida are sufficiently continuous, systematic, and voluminous to render Walmart essentially at home in Florida.

34. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the acts giving rise to Plaintiff's claims occurred in this District and because Defendants are subject to personal jurisdiction within this District.

BACKGROUND AND DEFENDANTS' CONDUCT

35. Irbesartan is a generic drug generally used to treat high blood pressure and diabetic nephropathy, a complication of type 2 diabetes which affects the kidneys.

36. Irbesartan is the generic form of the brand-name drug Avapro. Avapro was initially approved by the United States Food & Drug Administration ("FDA") and marketed in the United States in 1997.

37. At all times during the period alleged herein, Defendants each represented and warranted to consumers that their generic irbesartan products were therapeutically equivalent to and otherwise the same as brand Avapro, were otherwise fit for their ordinary use, and were otherwise manufactured and distributed in accordance with applicable laws and regulations.

38. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

39. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

40. By contrast, generic drug companies submit an Abbreviated New Drug Application ("ANDA"). Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

41. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is accepted as evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

42. In other words, generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

43. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

44. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug. Pharmacists, physicians, and patients can fully expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the

same labeling as the RLD delivered to consumers in each and every prescription of its generic products.

45. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to assure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

46. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

47. Any drug not manufactured in accordance with cGMPs is deemed "adulterated" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B).

48. Drugs are deemed to be adulterated if the manufacturer fails to comply with cGMPs to assure the drugs' safety, quality, purity, identity, and strength and/or if they are contaminated. *See* 21 U.S.C. § 351(a)(2)(A), (B). Federal law prohibits a manufacturer from directly or indirectly causing adulterated drugs to be introduced or

delivered for introduction into interstate commerce. *See id.* § 331(a). States have enacted laws adopting or mirroring these federal standards.

49. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

50. The FDA investigated Aurobindo's manufacturing plant located in Hyderabad, India in April 2017.

51. The FDA subsequently issued Aurobindo a "Form 483," a standard document used to identify conditions that may violate the Food, Drug, and Cosmetic Act and also violate cGMPs.

52. The FDA's April 2017 inspection revealed that Aurobindo was, at the time of that inspection, failing to maintain its facilities in an acceptable state and failing to maintain its manufacturing equipment in an appropriate state, that Aurobindo's laboratory controls did not include appropriate test measures, and that Aurobindo's batch distribution processes were not the subject of thorough reviews.

53. In February, 2018, the FDA returned for another investigation of Aurobindo's Hyderabad manufacturing plant.

54. As a result of this follow-up investigation, the FDA issued Aurobindo with another Form 483, repeating the same quality-control concerns—unsanitary equipment,

as well as, notably, the presence of mosquitos in close proximity to drug product—that could alter the safety, identity, strength, quality, or purity of its manufactured drug product.

55. As a result of Aurobindo's poor quality-control measures and failure to comply with cGMPs, its irbesartan API became adulterated and contaminated by NDEA.

56. NDEA is not an FDA-approved ingredient for branded Avapro or generic irbesartan. None of Defendants' irbesartan products (or any irbesartan product, for that matter) identify NDEA as an ingredient on their products' labels or elsewhere.

57. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.

58. The Orange Book is a public document; Defendants sought and received the inclusion of their products in the Orange Book upon approval of their irbesartan ANDAs.

59. In securing FDA approval to market generic irbesartan in the United States as an Orange Book-listed therapeutic equivalent to Avapro, Defendants were required to demonstrate that their generic irbesartan products were bioequivalent to brand Avapro.

60. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

61. By introducing their irbesartan products into the United States market under the name "irbesartan" as a therapeutic equivalent to Avapro and with the FDA-approved label that is the same as that of Avapro, Defendants represented and warranted to end users that their products are in fact the same as and are therapeutically interchangeable with Avapro.

62. Defendants' irbesartan products were accompanied by an FDA-approved label.

63. By presenting consumers with an FDA-approved irbesartan label, Defendants, as manufacturers, distributors, and sellers of irbesartan, made representations and express or implied warranties to consumers of the "sameness" of their products to Avapro, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated.

64. The presence of NDEA in the Adulterated Irbesartan: (1) renders Defendants' irbesartan products non-bioequivalent (*i.e.*, not the same) to Avapro and thus non-therapeutically interchangeable with Avapro, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs thus rendering Defendants' irbesartan products non-therapeutically equivalent to Avapro, and thus breaching Defendants' warranties of sameness; and (3) results in Defendants' irbesartan containing an ingredient that is not also contained in Avapro, also breaching Defendants' warranty of sameness (and warranty that the products contained the ingredients listed on each Defendants' FDA-approved label).

65. Each Defendant willfully, recklessly, and/or negligently failed to ensure their irbesartan products' labels and other advertising or marketing statements accurately conveyed information about their products.

66. Due to its status as a probable human carcinogen as listed by both the International Agency for Research on Cancer ("IARC") and as determined by pharmaceutical regulators such as the European Medicines Agency and the FDA, NDEA is not an FDA-approved ingredient in irbesartan. The presence of NDEA in the Adulterated Irbesartan results in Defendants' irbesartan products being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of Avapro), breaching Defendants' implied warranties of merchantability and/or fitness for ordinary purposes.

67. For these and other reasons, Defendants' irbesartan is therefore adulterated. *See* 21 U.S.C. § 351.

68. Medications containing Adulterated Irbesartan are essentially worthless. No consumer would purchase an Adulterated Irbesartan product, or is even allowed to purchase adulterated irbesartan, because it was illegally introduced into the United States. This is especially so given that alternative, non-adulterated irbesartan products or competing medications with the same approved indications were available from other manufacturers.

69. Plaintiff and the putative class members' causes of action accrued on or about October 26, 2018, when the FDA announced that Aurobindo had recalled several Batches of irbesartan API that it had dispatched to ScieGen (the "Aurobindo Recall").[2]

70. Aurobindo recalled 22 Batches of its irbesartan API, all supplied to ScieGen, and all contaminated with NDEA:

S.No	Manufacturing Batch Number	Dispatch Batch Number	Date of Manufacture	Date of Distribution	Retest/ Expiry Date	Dispatch Qty	Name and Location of the Customer	NDEA Impurity Result ug/g
1	1601100782	1601101589	Jan-2016	Jan-2016	Dec-2016	90.29 Kg	Sciegen Pharmaceuticals INC, USA	0.23
2	1601100783	1601101590	Jan-2016	3l-Jan-2016	Dec-2016	59.61 Kg	Sciegen Pharmaceuticals INC, USA	0.28
3	1701111861	1701113404	l3-Sep-2017	7-0ct-2017	12-Sep-2020	88.48 Kg	Sciegen Pharmaceuticals INC, USA	0.47
4	1701112170	1701113405	l8-Sep-2017	7-0ct-2017	l7-Sep-2020	90.92 Kg	Sciegen Pharmaceuticals INC, USA	0.15
5	1701112501	1701113406	20-Sep-2017	7-0ct-2017	l9-Sep-2020	93.02 Kg	Sciegen Pharmaceuticals INC, USA	1.61
6	1701112056	1701113407	l3-Sep-2017	7-0ct-2017	l2-Sep-2020	88.82 Kg	Sciegen Pharmaceuticals INC, USA	0.53
7	1701112558	1701114283	2-0ct-2017	25-0ct-2017	l-Oct-2020	63.76 Kg	Sciegen Pharmaceuticals INC, USA	0.6

[2] *Aurobindo Pharma Limited Issues Voluntary Recall of Irbesartan Drug Substance due to the Detection of Trace Amounts of NDEA (NNitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient (API)*, U.S. FOOD & DRUG ADMINISTRATION (Oct. 26, 2018), https://www.fda.gov/Safety/Recalls/ucm624547.htm.

S.No	Manufacturing Batch Number	Dispatch Batch Number	Date of Manufacture	Date of Distribution	Retest/ Expiry Date	Dispatch Qty	Name and Location of the Customer	NDEA Impurity Result ug/g
8	1701112558	1701114284	2-0ct-2017	25-0ct-2017	l-Oct-2020	27.06 Kg	Sciegen Pharmaceuticals INC, USA	0.6
9	1701I12559	1701114285	3-0ct-2017	25-0ct-2017	2-0ct-2020	91.82 Kg	Sciegen Pharmaceuticals INC, USA	0.45
10	1701112589	1701114286	6-0ct-2017	25-0ct-2017	5-0ct-2020	90.32 Kg	Sciegen Pharmaceuticals INC, USA	0.28
11	1701113300	1701114289	7-0ct-2017	25-0ct-2017	6-0ct-2020	91.32 Kg	Sciegen Pharmaceuticals INC, USA	0.32
12	1701113301	1701114291	8-0ct-2017	25-0ct-2017	7-0ct-2020	90.12 Kg	Sciegen Pharmaceuticals INC, USA	0.32
13	1701113302	1701114708	l7-0ct-2017	30-0ct-2017	l6-0ct-2020	80.82 Kg	Sciegen Pharmaceuticals INC, USA	0.85
14	1701113312	1701114709	20-0ct-2017	30-0ct-2017	19 Oct 2020	86.82 Kg	Sciegen Pharmaceuticals INC, USA	0.88
15	1701115460	1701117039	23-Nov-2017	2l-Dec-2017	22-Nov-2020	16.72 Kg	Sciegen Pharmaceuticals INC, USA	0.31
16	1701115974	1701117040	29-Nov-2017	2l-Dec-2017	28-Nov-2020	91.12 Kg	Sciegen Pharmaceuticals INC, USA	0.26
17	1701115460	1701117041	23-Nov-2017	2l-Dec-2017	22-Nov-2020	89.79 Kg	Sciegen Pharmaceuticals INC, USA	0.31
18	1701115738	1701117042	24-Nov-2017	21-Dec-2017	23-Nov-2020	90.42 Kg	Sciegen Pharmaceuticals INC, USA	0.38

S.No	Manufacturing Batch Number	Dispatch Batch Number	Date of Manufacture	Date of Distribution	Retest/ Expiry Date	Dispatch Qty	Name and Location of the Customer	NDEA Impurity Result ug/g
19	1701115739	1701117043	25-Nov-2017	2l-Dec-2017	24-Nov-2020	89.79 Kg	Sciegen Pharmaceuticals INC, USA	0.44
20	1701115740	1701117044	26-Nov-2017	2l-Dec-2017	25-Nov-2020	93.42 Kg	Sciegen Pharmaceuticals INC, USA	0.34
21	1701115741	1701117045	27-Nov-2017	21-Dec-2017	26-Nov-2020	93.72 Kg	Sciegen Pharmaceuticals INC, USA	0.39
22	1701115742	1701117046	28-Nov-2017	21-Dec-2017	27-Nov-2020	93.62 Kg	Sciegen Pharmaceuticals INC, USA	0.31

(https://www.fda.gov/Safety/Recalls/ucm624547.htm)

71. In turn, the FDA announced that, on October 30, 2018, ScieGen had issued its own recall of irbesartan that it supplied to Westminster as well as Golden State Medical Supply, Inc. (the "ScieGen Recall").[3]

72. The ScieGen recall specified which irbesartan Lots sent to Westminster were subject to the recall:

Details of batches sent to Westminster

The Irbesartan tablets subject to recall are packed in 30-count and 90-count bottles. To help identify any recalled product, the NDCs, product description, lot numbers and expiration dates are listed below. These lots were distributed nationwide in the USA to Westminster's direct accounts.

[3] *Sciegen Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Irbesartan Tablets, USP 75 Mg, 150 Mg, and 300 Mg Due to the Detection of Trace Amounts of NDEA (N-Nitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient (API)*, U.S. FOOD & DRUG ADMINISTRATION (Oct. 30, 2018), https://www.fda.gov/Safety/Recalls/ucm624593.htm.

DC#	Product Description	Lot#	Expiration Date
69367-119-01	Irbesartan 75mg Tablets, 30 count bottle	B160002A	Sep-19
69367-119-03	Irbesartan 75mg Tablets, 90 count bottle	B160002B	Sep-19
69367-120-01	Irbesartan 150mg Tablets, 30 count bottle	B161005A	Sep-19
		C161002A	Feb-20
69367-120-03	Irbesartan 150mg Tablets, 90 count bottle	B161005B	Sep-19
		C161002B	Feb-20
69367-121-01	Irbesartan 300mg Tablets, 30 count bottle	B162008A	Sep-19
		C162002A	Feb-20
69367-121-03	Irbesartan 300mg Tablets, 90 count bottle	B162008B	Sep-19
		C162002B	Feb-20

(https://www.fda.gov/Safety/Recalls/ucm624593.htm)

73. Because the ScieGen Recall specifically referenced it, Westminster joined in the FDA's irbesartan recall efforts.

74. Westminster's public-facing website features a link to the ScieGen Recall, as well as an explanation from Westminster CEO Gajan Mahendiran: "The recall of Irbesartan Tablets was unexpected but initiated with public health and safety at the forefront of this decision. The NDEA impurity found in the API was not present in the initial batches of API and only present in the most recent batches, which are being recalled. Westminster will remain diligent and steadfast in its approach to quality, efficacy, and the safety of its patients."[4]

75. The above statement is not Westminster's only claimed commitment to diligence, quality, and safety—as for its "mission," Westminster commits to a culture of responsibility and trust: "Our governance, ethical practices and policies are focused on

[4] *Manufacturing Excellence*, WESTMINSTER, https://www.wprx.com/ (last visited Nov. 9, 2018).

building a culture of responsibility where our everyday actions are governed by a duty of trust."[5]

76. As for its manufacturing processes specifically, Westminster claims to bring "a level of consistent excellence **throughout the research and development process** solidifying excellence behind each of its products."[6]

77. Despite its claimed commitment to maintaining an excellent, diligent and responsible culture of trust, including in its research and development efforts, Westminster's CEO claims the recent Adulterated Irbesartan recall originating with Aurobindo was "unexpected."

78. However, Aurobindo, the initial source of the Adulterated Irbesartan that Westminster marketed and distributed nationally, has been repeatedly criticized by the FDA in recent years for lax and substandard manufacturing practices as discussed above.

79. Westminster's representations and warranties regarding its devotion to quality, diligence, and excellence in both research and manufacturing are false. To the contrary, the Adulterated Irbesartan that Westminster marketed, sold, and distributed nationally is not safe, is not excellent, and is not the product of a diligent and quality-conscious research and manufacturing process.

80. Plaintiff purchased and ingested Adulterated Irbesartan from the Walmart pharmacy located at 2552 W. 75th St., Naperville, Illinois. Walmart is a "direct account"

[5] *Id.*
[6] *Id.* (emphasis added).

of Westminster, from whom it received medications containing Adulterated Irbesartan for the purpose of resale.

81. On or about October 30, 2018, Plaintiff received a notice from Walmart recalling medications the Lots subject to the ScieGen Recall which had been sent to Westminster.

82. Plaintiff and the putative class members suffered economic damages when they paid to purchase Adulterated Irbesartan. Plaintiff and the putative class members would not have purchased the worthless Adulterated Irbesartan from Defendants had they known that it was contaminated with NDEA.

83. Plaintiff and the putative class members are subject to increased risk of cancer and disease as a result of their consumption of the Adulterated Irbesartan.

84. Plaintiff and the putative class members are in need of medical monitoring as a result of their consumption of the Adulterated Irbesartan.

CLASS ALLEGATIONS

85. Plaintiff and each putative class member purchased and/or ingested Adulterated Irbesartan that was subject to the Aurobindo Recall and the ScieGen Recall.

86. Plaintiff brings Counts I through IX below, both individually and as a class action, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and/or 23(b)(3), on behalf of a nationwide class of consumers who purchased Adulterated Irbesartan (the "Class"):

> All persons or entities who purchased and/or consumed Adulterated Irbesartan. Excluded from the Class are: (1) Defendants, and any entity in which any Defendant has a controlling interest, or which has a controlling interest in Defendant; (2) Defendants' respective legal representatives, assigns and successors; and (3) the judge(s) to whom this action is assigned and any member of the judge's immediate family.

87. Plaintiff brings Count X below, both individually and as a class action, pursuant to Fed R. Civ. P. 23(a), 23(b)(2) and/or 23(b)(3), on behalf of a subclass of consumers who purchased Adulterated Irbesartan in Illinois (the "Subclass"):

> All persons or entities who, while in Illinois, purchased and/or consumed Adulterated Irbesartan. Excluded from the Subclass are: (1) Defendants, and any entity in which any Defendant has a controlling interest, or which has a controlling interest in any Defendant; (2) Defendants' respective legal representatives, assigns and successors; and (3) the judge(s) to whom this action is assigned and any member of the judge's immediate family.

88. Plaintiff reserves the right to redefine the Class and Subclass prior to class certification.

89. The rights of each member of the Class and Subclass (collectively the "Class Members") were violated in a similar fashion based upon the Defendants' uniform actions.

90. These and other questions of law or fact which are common to the Class Members predominate over any questions affecting only individual members of the Class.

a. **Typicality**: Plaintiff's claims are typical of the claims of the Class Members since Plaintiff and all Class Members purchased and/or consumed the Adulterated Irbesartan. Further, Plaintiff and all Class Members sustained monetary and economic injuries arising out of Defendants' wrongful conduct by, *inter alia*, purchasing and/or consuming the Adulterated Irbesartan (either out-of-pocket or via co-payments made to their pharmacy or healthcare professionals) and they unknowingly purchased Adulterated Irbesartan. Had this material information, *i.e.*, that the Adulterated Irbesartan

was adulterated, been disclosed to Plaintiff and the Class Members, and/or regulators, Plaintiff and the Class Members would not have purchased or consumed the Adulterated Irbesartan. Plaintiff is advancing the same claims and legal theories on behalf of herself and all Class Members.

b. **Adequacy**: Plaintiff is an adequate representative of the Class and Subclass because her interests do not conflict with the interests of the respective Class Members that she seeks to represent; Plaintiff has retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class and Subclass will be fairly and adequately protected by Plaintiff and her counsel.

c. **Superiority**: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and Class Members. The injury suffered by each individual Class Member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible Class Members to individually and effectively redress the wrongs done to them. Even if the Class Members could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

d. **Ascertainability**: Class Members are readily ascertainable and can be identified by Defendants' records.

91. This action has been brought and may be properly maintained as a class action for the following reasons:

a. **Numerosity**: The Class Members are so numerous that their individual joinder is impracticable. Plaintiff is informed and believes that the proposed Class and Subclass contains thousands of individuals or entities that purchased Adulterated Irbesartan, either out-of-pocket or via co-payments. The Class and Subclass are therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class Members is unknown to Plaintiff at this time.

b. **Existence and Predominance of Common Questions of Fact and Law**: Common questions of law and fact exist as to all Class Members. These questions predominate over any questions affecting individual Class Members. These common legal and factual questions include, but are not limited to, the following:

i. Whether the Adulterated Irbesartan met the Defendants' warranties;

ii. Whether the Adulterated Irbesartan consisted of merchantable goods at the time of sale;

iii. Whether the Adulterated Irbesartan was fit for its intended purpose;

iv. Whether Defendants made fraudulent, false, deceptive, and/or misleading statements in connection with the sale of the Adulterated Irbesartan;

v. Whether Defendants omitted material information when it sold the Adulterated Irbesartan;

vi. The date on which Defendants knew or reasonably should have known that the Adulterated Irbesartan was adulterated;

vii. Whether Defendants' recall notice was timely and/or sufficient;

viii. Whether Defendants' breached the terms of an express and/or implied warranty;

ix. The appropriate nature of class-wide equitable relief; and

x. The appropriate measure of restitution and/or measure of damages to award to Plaintiff and the Class Members.

COUNT I
Strict Product Liability
(Individually and on behalf of the Class)

92. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

93. Plaintiff brings this claim individually and on behalf of the Class.

94. At all times relevant to this action, Defendants designed, tested, manufactured, packaged, marketed, supplied, distributed, promoted, and/or sold the Adulterated Irbesartan, placing the drug into the stream of commerce.

95. At all relevant times, the Adulterated Irbesartan was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition to consumers, including Plaintiff and the Class.

96. The Adulterated Irbesartan was expected to reach, and did reach, users and/or consumers, including Plaintiff, and the Class without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

97. The Adulterated Irbesartan was unreasonably dangerous because it was adulterated and contaminated by NDEA, a probable human carcinogen.

98. The Adulterated Irbesartan was not accompanied by adequate labeling, instructions for use and/or warnings to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff and the Class, of the potential risks associated with its use, thereby rendering Defendants liable to Plaintiff and the Class.

99. The Adulterated Irbesartan was unsafe for normal or reasonably anticipated use.

100. The Adulterated Irbesartan was defective in formulation because when the drug left the hands of the Defendants, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

101. The Adulterated Irbesartan was also defective and unreasonably dangerous in that the foreseeable risk of injuries from consuming the Adulterated Irbesartan exceeded the benefits associated with the formulation of the Adulterated Irbesartan.

102. The Adulterated Irbesartan is unreasonably dangerous; a) in construction or composition; b) in design; c) because an adequate warning about it was not provided; and d) because the Adulterated Irbesartan did not conform to an express warranty about the product.

103. The Adulterated Irbesartan as manufactured, distributed, supplied, and/or sold by the Defendants was also defective due to inadequate testing before being exposed to Plaintiff and the Class.

104. The Adulterated Irbesartan as manufactured, distributed, supplied and/or sold by Defendants was defective and after Defendants knew or should have known of the risk of injuries from use and/or ingestion, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly marketing and advertising; and, further, they continued to affirmatively promote Adulterated Irbesartan as safe and effective.

105. In light of the potential and actual risk of harm associated with the consumption of the Adulterated Irbesartan, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that the Adulterated Irbesartan should not have been marketed in that condition.

106. Although Defendants knew or should have known of the defective nature of the Adulterated Irbesartan, they continued to manufacture, market, distribute and/or

sell it so as to maximize sales and profits at the expense of the public health and safety. Defendants thus acted with conscious and deliberate disregard of the foreseeable harm caused by the Adulterated Irbesartan.

107. Plaintiff and the Class could not, through the exercise of reasonable care, have discovered the risk of serious injury and/or death associated with and/or caused by their consumption of the Adulterated Irbesartan.

108. As a direct and proximate result of Defendants' conduct, Plaintiff and the Class purchased and/or consumed Adulterated Irbesartan, and, as a result, Plaintiff and the Class suffered harm and loss.

109. Information provided by the Defendants to the medical community and to consumers concerning the safety and efficacy of the Adulterated Irbesartan, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects resulting from consumption of the Adulterated Irbesartan.

COUNT II
Failure to Warn
(Individually and on behalf of the Class)

110. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

111. Plaintiff brings this claim individually and on behalf of the Class.

112. Defendants violated a state-law duty of care by failing to report known risks associated with the consumption of the Adulterated Irbesartan.

113. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and the Class and their physicians, of the true risks of the Adulterated Irbesartan, including the risks associated with the consumption of NDEA. Defendants owed a duty to exercise ordinary care. Defendants breached their duty to exercise ordinary care to supply, manufacture, distribute, and/or sell irbesartan to Plaintiff and the Class that was not adulterated.

114. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Adulterated Irbesartan.

115. Defendants failed to perform or otherwise facilitate adequate testing or failed to reveal and/or concealed testing performed on the irbesartan.

116. As a direct and proximate cause of the Defendants' conduct, Plaintiff and the Class suffered economic loss.

117. Defendants' conduct was reckless. Defendants risked the lives and health of consumers, including Plaintiff and the Class, based on the suppression of knowledge relating to the safety and efficacy problems associated with the Adulterated Irbesartan.

118. Upon information and belief, Defendants made a conscious decision not to notify the FDA, healthcare professionals, and the public, thereby putting increased profits over the public safety, including the safety of the Plaintiff and the Class. Defendants' actions and omissions as alleged herein demonstrate an utter disregard for human safety, warranting the imposition of punitive damages.

COUNT III
Breach of Contract
(Individually and on behalf of the Class)

119. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

120. Plaintiff brings this claim individually and on behalf of the Class.

121. Plaintiff and each member of the Class formed a contract with Defendants at the time they purchased the Adulterated Irbesartan.

122. The terms of the contract include the promises and affirmations of fact in the advertising, and on the packaging and labeling for the medicine, including that the Adulterated Irbesartan would not be adulterated with harmful and carcinogenic impurities such as NDEA.

123. Defendants represented that the Adulterated Irbesartan was safe and unadulterated. The promises and affirmations of fact became part of the basis of the bargain and are a part of the contract between Plaintiff, the members of the Class, and the Defendants.

124. Defendants also represented that the Adulterated Irbesartan was safe, efficacious and fit for its intended purposes, that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

125. Plaintiff and each member of the Class relied on Defendants' representations that the Adulterated Irbesartan would not be adulterated with harmful and carcinogenic impurities such as NDEA.

126. Plaintiff and each member of the Class performed all conditions precedent pursuant to their contract with Defendants.

127. Defendants breached the contract because the Adulterated Irbesartan was adulterated and contaminated with the carcinogen NDEA.

128. Plaintiff and each member of the Class have been damaged in the amount of the purchase price of the Adulterated Irbesartan and consequential economic damages, including incidental medical expenses, resulting therefrom.

COUNT IV
Breach of Implied Warranty of Merchantability
(Individually and on behalf of the Class)

129. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

130. Plaintiff brings this claim individually and on behalf of the Class.

131. Defendants, as the designers, manufacturers, distributors and/or sellers of the Adulterated Irbesartan, impliedly warranted that the Adulterated Irbesartan purchased by Plaintiff and the Class Members was safe for human consumption, that the Adulterated Irbesartan was not adulterated, and that the Adulterated Irbesartan did not contain NDEA.

132. Defendants breached the warranty implied in the contract for the sale of the irbesartan because the Adulterated Irbesartan could not pass without objection in the trade under the contract description, it was not of the quality described, and it was unfit for its intended and ordinary purpose because it was adulterated, containing NDEA and

therefore unfit for human consumption. As a result, Plaintiff and the Class did not receive irbesartan as impliedly warranted by the Defendants to be merchantable.

133. Plaintiff and the Class purchased the Adulterated Irbesartan in reliance on the Defendants' implied warranties of fitness for a particular purpose.

134. Plaintiff did not alter the Adulterated Irbesartan.

135. The Class did not alter the Adulterated Irbesartan.

136. The Adulterated Irbesartan was defective when it left the exclusive control of the Defendants.

137. The Adulterated Irbesartan was defectively manufactured and unfit for its intended purpose and Plaintiff and the Class did not receive the Adulterated Irbesartan in the condition warranted.

138. As a direct and proximate result of the Defendants' breach of the implied warranty, Plaintiff and the Class have been harmed and injured because (a) they would not have purchased the Adulterated Irbesartan containing NDEA if they had known that such irbesartan was adulterated by NDEA; (b) the Adulterated Irbesartan does not have the characteristics, ingredients, uses, or benefits as promised by the Defendants; (c) the Adulterated Irbesartan has never been tested for human consumption; (d) the Adulterated Irbesartan has never been tested for efficacy; and (e) the Adulterated Irbesartan is worthless.

COUNT V
Unjust Enrichment
(Individually and on behalf of the Class)

139. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

140. Plaintiff brings this claim individually and on behalf of the Class.

141. Plaintiff and the Class conferred a benefit on Defendants by purchasing the Adulterated Irbesartan, which was worthless, adulterated, dangerous, and contained NDEA.

142. Defendants voluntarily accepted and retained the conferred benefits by accepting payment for the Adulterated Irbesartan.

143. It is inequitable and unjust for Defendants to retain the revenues obtained from purchases of the Adulterated Irbesartan by Plaintiff and the Class because Defendants misrepresented the qualities of the Adulterated Irbesartan and the Adulterated Irbesartan could not be used for the manner represented by Defendants.

144. Accordingly, because Defendants will be unjustly enriched if allowed to retain such funds, Defendants must pay restitution to Plaintiff and the Class in the amount which Defendants were unjustly enriched by each purchase of the Adulterated Irbesartan.

145. Plaintiff and the Class do not have an adequate remedy at law against Defendants, in the alternative to the other causes of action alleged herein.

COUNT VI
Fraudulent Concealment
(Individually and on behalf of the Class)

146. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

147. Plaintiff brings this claim individually and on behalf of the Class.

148. Defendants had a duty to disclose material facts to Plaintiff and the Class that they were in fact manufacturing, distributing and/or selling irbesartan that was adulterated, contained NDEA and that the Adulterated Irbesartan was unfit for human consumption.

149. Defendants knew or should have known that they should have disclosed such material facts to consumers such as Plaintiff and the Class.

150. Defendants had superior knowledge such that the purchases of the Adulterated Irbesartan by Plaintiff and the Class were inherently unfair.

151. Upon information and belief, Defendants possessed knowledge of the material facts.

152. Upon information and belief, Defendants may have thus withheld their knowledge of the contamination. During that time, Plaintiff and the Class purchased and/or consumed the Adulterated Irbesartan without knowing that they were consuming NDEA.

153. Defendants failed to discharge their duty to disclose material facts.

154. Upon information and belief, Defendants, with scienter and/or an intent to defraud, intended to hide from Plaintiff and the Class that they were purchasing and

consuming Adulterated Irbesartan that was contaminated by NDEA rendering the medicine unfit for human consumption.

155. Plaintiff and the Class reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the Adulterated Irbesartan manufactured, distributed and/or sold by Defendants had they known it was contaminated with NDEA and thus adulterated.

156. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff and the Class suffered damages in the amount of money paid for the Adulterated Irbesartan and incidental medical expenses.

COUNT VII
Conversion
(Individually and on behalf of the Class)

157. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

158. Plaintiff brings this claim individually and on behalf of the Class.

159. Defendants exercised control over the money paid by the Plaintiff and the Class which is inconsistent with the right of Plaintiff and the Class Members to possession of the money paid to purchase the Adulterated Irbesartan.

160. Plaintiff and the Class have a right to possession of the money paid to purchase the Adulterated Irbesartan.

161. Demand for return of their money by Plaintiff or the Class would be futile.

COUNT VIII
Negligence
(Individually and on behalf of the Class)

162. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

163. Plaintiff brings this claim individually and on behalf of the Class.

164. Defendants supplied, manufactured, distributed and/or sold irbesartan as a drug for consumption by the Plaintiff and the Class.

165. Defendants had a duty to exercise ordinary care to supply, manufacture, distribute and/or sell irbesartan to Plaintiff and the Class that was not adulterated.

166. Defendants breached their duty of care owed to the Plaintiff and the Class by:

a. Supplying, manufacturing, distributing and/or selling irbesartan to Plaintiff and the Class Members that was adulterated because it was contaminated by NDEA;

b. Failing to maintain appropriate quality control procedures thereby allowing NDEA to contaminate irbesartan purchased and/or consumed by Plaintiff and Class Members;

167. Defendants' breach of the duty of care proximately caused damage to Plaintiff and the Class Members.

COUNT IX
Gross Negligence
(Individually and on behalf of the Class)

168. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as though fully set forth herein.

169. Defendants' conduct resulted in an extreme risk to the Plaintiff and the Class.

170. Upon information and belief, Defendants knew, or should have known of the extreme risk to Plaintiff and the Class but continued with their conduct anyway.

171. The Defendants' conduct was more than just negligence, it amounts to gross negligence and amounted to recklessness or aggravated negligence resulting from an extreme departure from the ordinary standard of care owed to Plaintiff and the Class.

172. The Defendants' conduct was so unreasonable and dangerous that it was highly probable that harm would result.

173. The Defendants' conduct created circumstances constituting an imminent or clear and present danger.

COUNT X
Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.* ("ICFA")
(Individually and on behalf of the Subclass)

174. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.

175. Plaintiff brings this claim individually and on behalf of the Subclass against Defendants.

176. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 502/1 et seq. ("ICFA") prohibits deceptive acts and practices in the sale of products, including the Adulterated Irbesartan.

177. Plaintiff and the Subclass are "consumers" or "persons," as defined under the ICFA.

178. Defendants' conduct as alleged herein occurred in the course of trade or commerce.

179. Defendants supplied Adulterated Irbesartan to Illinois retailers, including the Walmart pharmacy located at 2552 W. 75th Street in Naperville, where it was purchased by Plaintiff.

180. Defendants profited from their transactions occurring with Illinois retailers.

181. Defendants misrepresented on their labels and otherwise the characteristics of the Adulterated Irbesartan, the ingredients in the Adulterated Irbesartan, and the uses or benefits of the medications containing Adulterated Irbesartan.

182. Additionally, Defendants misrepresented, and deceived Plaintiff and the Subclass into believing, that the Adulterated Irbesartan was safe for human consumption, that the Adulterated Irbesartan did not contain NDEA, and that the Adulterated Irbesartan was not adulterated.

183. In fact, the Adulterated Irbesartan did not have the characteristics, ingredients, uses or benefits represented, it was not safe for human consumption, it did contain NDEA, and it was adulterated. This offends public policy, and has caused and

continues to cause substantial injury to Plaintiff and the Class, and constitutes an unfair and deceptive trade practice.

184. Upon information and belief, and given the fact that Defendants was responsible for supplying, manufacturing, distributing and/or selling the Adulterated Irbesartan to Plaintiff and the Subclass, Defendants knew or should have known at all relevant times that the irbesartan was adulterated because it contained NDEA and was not safe for human consumption. Nonetheless, Defendants falsely represented that the Adulterated Irbesartan purchased by the Plaintiff and the Subclass was safe for human consumption when it was not.

185. Defendants intended for consumer, including Plaintiff and the Subclass, to rely on its representations that the Adulterated Irbesartan was safe for human consumption when choosing to purchase the drug. Plaintiff and the Subclass relied on such representations in making their decision to purchase the Adulterated Irbesartan.

186. As a direct and proximate result of Defendants' deceptive and unfair trade practices, Plaintiff and the Subclass suffered actual damages, including monetary losses for the purchase price of the Adulterated Irbesartan which was not safe for human consumption and was worthless, and incidental medical expenses.

187. Defendants' conduct violates the ICFA and pursuant to 815 ILCS 505/10a Plaintiff and the Subclass are entitled to damages in an amount to be proven at trial, reasonable attorneys' fees, injunctive relief prohibiting Defendants' unfair and deceptive practices going forward, medical monitoring, and any other penalties or awards that may be appropriate under applicable law.

RELIEF REQUESTED

WHEREFORE, Plaintiff, individually and on behalf of the Class and Subclass, requests judgment against Defendants, jointly and severally, as follows:

A. That the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure, and issue an order certifying the Class and Subclass as defined above and designating Plaintiffs' counsel as counsel for the Class and Subclass;

B. Awarding Plaintiff and the Class Members judgment in the amount of their economic losses as well as punitive damages for the conduct alleged herein;

C. Allowing for medical monitoring for the Plaintiff and Class Members;

D. Awarding reasonable attorney's fees and costs;

E. Awarding prejudgment and postjudgment interest;

F. Any and all other relief, both legal and equitable, that the Court may deem just and appropriate.

DEMAND FOR TRIAL BY JURY

Plaintiff, both individually and on behalf of the putative classes, hereby demands a jury trial pursuant to Federal Rule of Civil Procedure 38(b) on all issues so triable in this action.

Dated: December 1, 2018

Respectfully submitted,

BARBARA KRUK, individually and on behalf of all others similarly situated

By: */s/ John Sawin*

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