UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KRISTEN WINEINGER, on behalf of herself and all others similarly situated, Plaintiff, v. GRANULES USA, INC. and GRANULES PHARMACEUTICALS, INC., Defendants.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Kristen Wineinger ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendants Granules USA, Inc. and Granules Pharmaceuticals, Inc. (collectively, "Granules" or "Defendants"). 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.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Defendants' manufacturing, distribution, and sale of the generic medication metformin that contains dangerously high levels of N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity.

2. Metformin is a prescription medication that has been sold under brand names such as Glucophage. Metformin is used to control high blood sugar in patients with type 2 diabetes. However, Granules' manufacturing process has caused metformin to contain dangerously high levels of NDMA.

3. NDMA is a semivolatile organic chemical. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-ni-trosamines, a family of potent carcinogens."

While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen, and animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."

4. On March 2, 2020, Valisure, an online pharmacy registered with the U.S. Drug Enforcement Agency and Food & Drug Administration, "detected high levels of N-Nitrodimethylamine ('NDMA') in specific batches of prescription drug products containing metformin."[1] This included metformin manufactured by Granules.[2]

5. Granules had not yet issued a recall of metformin, and continues to tout on its website that it is "committed to excellence in manufacturing [and] quality." However, these representations are false, as Defendants' metformin medication contains the carcinogenic impurity NDMA.

A. Metformin Is Marketed As Safe

6. Granules has always marketed metformin as a safe and effective product, and has continued to do so despite the findings of Valisure.

7. Metformin is one of the most successful drugs in history. Metformin was the fourth most prescribed medication in the United States in 2017, with over 78.6 million

[1] VALISURE, VALISURE CITIZEN PETITION ON METFORMIN 1 (2020), https://www.valisure.com/wp-content/uploads/Valisure-FDA-Citizen-Petition-on-Metformin-v3.9.pdf (last accessed Mar. 9, 2020) (hereinafter "VALISURE PETITION").
[2] *Id.* at 10.

prescriptions.[3]

8. On Granules' website, Granules notes that it is "one of the global leaders in … metformin."

9. Granules also writes on its website that it is "committed to excellence in manufacturing [and] quality."

B. Metformin Contains Dangerous Levels Of NDMA

10. Contrary to the above assertions, metformin contains dangerously high levels of NDMA that would not be present if the medication were properly manufactured. As noted in paragraph 4, *supra*, Valisure has found unacceptable levels of NDMA in samples of metformin, including samples from Granules.

11. While the cause of the NDMA contamination in metformin is still being investigated, Valisure notes that "the presence of NDMA in metformin products may be primarily due to contamination during manufacturing as opposed to a fundamental instability of the drug molecule."[4]

12. The FDA has "set strict daily acceptable intake limits on NDMA in pharmaceuticals of 96 nanograms."[5] But Valisure found that Granules' metformin has an NDMA content that is nearly *twice* the daily intake limit.[6]

Company	Dose (mg)	Type	Lot	NDMA (ng/tablet)	Common Tablets/Day	Times Over Acceptable Daily Intake Limit of NDMA
Granules Pharmaceuticals Inc.	500	Metformin ER	4910134A	41 +/- 5	4	1.7X

[3] *The Top 300 of 2020*, CLINCALC, https://clincalc.com/DrugStats/Top300Drugs.aspx (last accessed Mar. 9, 2020).
[4] VALISURE PETITION 3.
[5] *Id*. at 1.
[6] *Id*. at 10.

13. The presence of NDMA in metformin is particularly troubling because the medication is taken daily.[7]

14. Pursuant to its findings, Valisure recommended a recall of Granules' metformin medications.[8]

C. Plaintiff Was Harmed By Purchasing And Consuming Defective Metformin Manufactured By Defendants.

15. Plaintiff and the Class were injured by the full purchase price of their metformin medications. These medications are worthless, as they contain harmful levels of NDMA. As the medications expose users to NDMA well above the legal limit, the medications are not fit for human consumption. Plaintiff is further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA, 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 the implied warranty of merchantability, (ii) unjust enrichment, (iii) fraudulent concealment, (iv) fraud, and (v) conversion.

PARTIES

17. Plaintiff Kristen Wineinger is a citizen of Indiana who resides in Hendricks County, Indiana. During all relevant time periods, Ms. Wineinger was prescribed, purchased and consumed metformin manufactured by Defendants, most recently on February 13, 2020. Ms. Wineinger originally learned about the metformin defect on the news. Further investigation revealed that Ms. Wineinger has been using the defective metformin manufactured by Granules for some time. When purchasing metformin from Defendants, Ms. Wineinger reviewed the

[7] *Id.* at 1.
[8] *Id.* at 11-12

accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured, free from defects, and safe for their intended use. Ms. Wineinger relied on these representations and warranties in deciding to purchase metformin from Defendants, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased metformin from Defendants if she had known that they were not, in fact, properly manufactured and free from defects. Ms. Wineinger also understood that each purchase involved a direct transaction between herself and Granules because her medication came with packaging and other materials prepared by Granules, including representations and warranties that her medications were properly manufactured and free from defects.

18. Defendant Granules USA, Inc.is a corporation incorporated under the laws of Delaware with a principal place of business at 35 Waterview Boulevard, Parsippany, New Jersey 07054. Granules USA, Inc. is a wholly owned subsidiary of the Indian corporation Granules India Limited. Granules USA, Inc. conducts substantial business in the United States, and specifically in the States of New Jersey and Indiana. Granules USA, Inc. has been engaged in the manufacturing, distribution, and sale of defective metformin in the United States, including in the States of New Jersey and Indiana.

19. Defendant Granules Pharmaceuticals, Inc. is a corporation incorporated under the laws of Delaware with a principal place of business at 3701 Concorde Parkway, Chantilly, Virginia 20151. Granules USA, Inc. is a wholly owned subsidiary of the Indian corporation Granules India Limited. Granules Pharmaceuticals, Inc. conducts substantial business in the United States, and specifically in the States of New Jersey and Indiana. Granules Pharmaceuticals, Inc. has been engaged in the manufacturing, distribution, and sale of defective

metformin in the United States, including in the States of New Jersey and Indiana.

JURISDICTION AND VENUE

20. This Court has personal jurisdiction over Defendants. Defendants purposefully availed themselves of the New Jersey consumer market and distributed metformin to hundreds of locations within this District and thousands of retail locations throughout New Jersey, where metformin was purchased by thousands of consumers every day. The Court also has personal jurisdiction over Defendant Granules USA, Inc. because it is headquartered in New Jersey.

21. The 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, 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.

22. Venue is proper in this District under 28 U.S.C. § 1391(a). Substantial acts in furtherance of the alleged improper conduct, including the dissemination of false and misleading information regarding the nature, quality, and/or ingredients of metformin, occurred within this District.

CLASS ALLEGATIONS

23. Plaintiff seeks to represent a class defined as all persons in the United States who purchased metformin (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 ventures, 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.

24. Plaintiff also seeks to represent a subclass of all Class members who purchased metformin in Indiana (the "Subclass").

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

26. **Numerosity.** The members of the Class and Subclass are geographically dispersed throughout the United States and the State of Indiana 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 and Subclass. Although the precise number of Class members is unknown to Plaintiff, the true number of Class and Subclass members is known by Defendants and may be determined through discovery. Class and Subclass members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendants and third-party retailers and vendors.

27. **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 Subclass and predominate over any questions affecting only individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the metformin manufactured by Defendants contains dangerously high levels of NDMA, thereby breaching the implied warranties made by Defendants and making metformin unfit for human consumption and therefore unfit for its intended purpose;

(b) whether Defendants knew or should have known that metformin contained elevated levels of NDMA prior to selling the medication, thereby constituting fraud and/or fraudulent concealment;

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

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

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

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

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

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

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

28. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and Subclass in that Defendants mass marketed and sold defective metformin to consumers throughout the United States. This defect was present in all of the metformin manufactured by Defendants. Therefore, Defendants breached their implied warranties to Plaintiff and Class and Subclass members by manufacturing, distributing, and selling the defective metformin. Plaintiff's claims are typical in that she was uniformly harmed in

purchasing and consuming the defective metformin. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class and Subclass. Further, there are no defenses available to Defendants that are unique to Plaintiff.

29. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and Subclass. 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 and Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and Subclass.

30. **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 and Subclass members are 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 and Subclass, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class and Subclass 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.

31. In the alternative, the Class and Subclass may also be certified because:

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

(b) the prosecution of separate actions by individual Class and Subclass 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 and Subclass 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 and Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and Subclass as a whole.

COUNT I
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Class And Subclass)

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

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

34. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that metformin (i) would not contain elevated levels of NDMA and (ii) is generally recognized as safe for human consumption.

35. Defendants breached the warranty implied in the contract for the sale of the

defective metformin because it could not pass without objection in the trade under the contract description, the metformin was not of fair or average quality within the description, and the metformin was unfit for its intended and ordinary purpose because the metformin manufactured by Defendants was defective in that it contained elevated levels of carcinogenic and liver toxic NDMA, and as such is not generally recognized as safe for human consumption. As a result, Plaintiff and Class and Subclass members did not receive the goods as impliedly warranted by Defendants to be merchantable.

36. Plaintiff and Class and Subclass members purchased metformin in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

37. The metformin was not altered by Plaintiff or Class and Subclass members.

38. The metformin was defective when it left the exclusive control of Defendants.

39. Defendants knew that the metformin would be purchased and used without additional testing by Plaintiff and Class and Subclass members.

40. The defective metformin was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class and Subclass members did not receive the goods as warranted.

41. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class and Subclass members have been injured and harmed because: (a) they would not have purchased metformin on the same terms if they knew that metformin contained harmful levels of NDMA, and is not generally recognized as safe for human consumption; and (b) metformin does not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT II
Unjust Enrichment
(On Behalf Of The Class And Subclass)

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

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

44. Plaintiff and the Class and Subclass conferred a benefit on Defendants in the form of monies paid to purchase Defendants' defective metformin.

45. Defendants voluntarily accepted and retained this benefit.

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

COUNT III
Fraudulent Concealment
(On Behalf Of The Class and Subclass)

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

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

49. Defendants had a duty to disclose material facts to Plaintiff and the Class and Subclass given their relationship as contracting parties and intended users of metformin. Defendants also had a duty to disclose material facts to Plaintiff and the Class and Subclass, namely that they were in fact manufacturing, distributing, and selling harmful metformin unfit for human consumption, because Defendants had superior knowledge such that the transactions

without the disclosure were rendered inherently unfair.

50. Defendants possessed knowledge of these material facts. Since at least December 2019, Defendants have been aware that NDMA was detected in metformin-containing medications in other nations.[9] During this time, Plaintiff and Class and Subclass members were using their medications without knowing they contained dangerous levels of NDMA.

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

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

53. Plaintiff and the Class and Subclass reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the defective metformin manufactured sold by Defendants had they known it contained unsafe levels of NDMA.

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

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

COUNT IV
Fraud
(On Behalf Of The Class and Subclass)

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

[9] *FDA Investigates NDMA in Metformin*, U.S. PHARMACIST (Dec. 20, 2019), https://www.uspharmacist.com/article/fda-investigates-ndma-in-metformin (last accessed Mar. 9, 2020).

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

58. As discussed above, Defendants provided Plaintiff and Class and Subclass members with materially false or misleading information about the metformin manufactured by Defendants. Specifically, Defendants have marketed metformin as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants' metformin medications contained elevated levels of NDMA.

59. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiff and Class and Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class and Subclass members to purchase defective metformin.

60. Defendants knew or should have known that its metformin was contaminated with this harmful impurity, but continued to manufacture it nonetheless. Since at least December 2019, Defendants have been aware that NDMA was detected in metformin medicines in other nations.[10] During this time, Plaintiff and Class and Subclass members were using the medication without knowing it contained dangerous levels of NDMA.

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

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

[10] *FDA Investigates NDMA in Metformin*, U.S. PHARMACIST (Dec. 20, 2019), https://www.uspharmacist.com/article/fda-investigates-ndma-in-metformin (last accessed Mar. 9, 2020).

COUNT V
Conversion
(On Behalf Of The Class And Subclass)

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

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

65. Plaintiff and the Class and Subclass have an ownership right to the monies paid for the defective metformin manufactured by Defendants.

66. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the defective metformin. Defendants have done so every time that Plaintiff and the Class and Subclass bought metformin over the counter.

67. As a direct and proximate cause of Defendants' conversion, Plaintiff and the Class and Subclass suffered damages in the amount of the payments made for each time they bought metformin over the counter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

(a) For an order certifying the nationwide Class and the Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as the representative for the Class and Subclass and Plaintiff's attorneys as Class Counsel;

(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 Subclass on all counts asserted herein;

[redacted]

(d) For compensatory, statutory, 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 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: March 9, 2020

Respectfully submitted,

[redacted]