UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JUAN HUERTAS, EVA MISTRETTA, MIKE POOVEY. DARRELL STEWART, and JEREMY WYANT, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

AEROPRES CORPORATION, AUX SABLE LIQUID PRODUCTS LP, BAYER HEALTHCARE LLC, BAYER U.S. LLC, BEIERSDORF MANUFACTURING, LLC, BEIERSDORF, INC., BEIERSDORF NORTH AMERICA, INC., and BP ENERGY COMPANY,

Defendants.

Case No. 2:21-cv-20021-SDW-CLW

CONSOLIDATED SECOND AMENDED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Hon. Susan D. Wigenton

Hon. Cathy L. Waldor

TABLE OF CONTENTS

PAGE

Plaintiffs Juan Huertas, Eva Mistretta, Mike Poovey, Darrell Stewart, and Jeremy Wyant ("Plaintiffs")[1] bring this action on behalf of themselves and all others similarly situated against Defendants Aeropres Corporation ("Aeropres"), Aux Sable Liquid Products LP ("Aux Sable"), Bayer Healthcare LLC, Bayer U.S. LLC (collectively, "Bayer"), Beiersdorf Manufacturing, LLC ("Beiersdorf LLC"), Beiersdorf, Inc. ("Beiersdorf Inc."), and Beiersdorf North America, Inc. ("Beiersdorf NA") (collectively, Beiersdorf LLC, Beiersdorf Inc. and Beiersdorf NA are "Beiersdorf" or the "Beiersdorf Defendants"), and BP Energy Company ("BP Energy") (collectively, "Defendants"). Plaintiffs make the following allegations pursuant to the investigation of their counsel, the actions styled *Bayer Healthcare LLC v. Aeropres Corp.*, No. 1:23-cv-04391 (N.D. Ill.) ("*Bayer v. Aeropres*" or "*Bayer* Action") and *Stewart et al. v. Aeropres Corp.*, No. 1:23-cv-13207 (N.D. Ill.), personal knowledge of the allegations specifically pertaining to themselves, and upon information and belief.

NATURE OF THE ACTION

1. This is a class action lawsuit regarding Defendants' manufacturing, distribution, and sale of Lotrimin and Tinactin spray products (the "Products")[2]

[1] The following parties involved in the original action are not included in this amended complaint: Jose Villarreal, Christopher Cadorette, Sean Steinwedel, Jonathan Martin, Don Penales, Jr. However, Plaintiffs reserve their rights to appeal on behalf of these parties.

[2] A complete list of the Products at issue can be found at ¶ 57, *infra*.

without disclosing that the Products contain dangerously high levels of benzene, a carcinogenic impurity that has been linked to leukemia and other cancers. Likewise, Defendants failed to manufacture the Products in compliance with good manufacturing practices, leading to the benzene contamination and causing injury to consumers.

2. Defendant Bayer is one of the largest pharmaceutical companies in the world. Bayer sells Lotrimin and Tinactin products throughout the United States, which are designed to treat Athlete's Foot and other fungal foot infections. Both Lotrimin and Tinactin are drug products regulated by the United States Food & Drug Administration ("FDA") pursuant to the federal Food, Drug and Cosmetics Act ("FDCA").

3. On October 1, 2021, Defendant Bayer announced a recall of unexpired Products as a result of a benzene contamination. According to Bayer, the source of the benzene contamination was the propellant Bayer used in the recalled Products, known as Propellant A-31.

4. Benzene is not an ingredient in Propellant A-31, nor is it an ingredient in the Products.

5. The events leading up to the recall began in August 2021, when Aeropres disclosed to the Beiersdorf Defendants, the manufacturer of the Products, that Propellant A-31 was contaminated with benzene. Beiersdorf immediately

notified Bayer of the contamination. The contaminated Propellant A-31 was produced in an Aeropres facility in Morris, Illinois, and incorporated by Bayer into Bayer's Lotrimin and Tinactin spray Products at Beiersdorf's manufacturing facility located in Cleveland, Tennessee. Aeropres sourced the gas feedstock supply used in Propellant A-31 from BP Energy and Aux Sable.

6. According to Bayer, Aeropres admitted the benzene contamination, stating that "Aeropres regrets this development as it is not in keeping with Aeropres' standards of product manufacture." *Bayer v. Aeropres*, ECF No. 1 ("*Bayer* Compl.") ¶ 5.

7. While Bayer claimed "the levels [of benzene] detected [in the Products] are not expected to cause adverse health consequences in consumers,"[3] this was a lie. In truth, as Bayer admitted in its own lawsuit against Aeropres, the levels of benzene contamination in the Products made them "unreasonably dangerous to Bayer's consumers, according to FDA guidelines." *Bayer v. Aeropres*, ECF No. 32 at 17. As such, the benzene contamination rendered the Products "damaged beyond use or repair" and "unsaleable due to [the] contamination." *Bayer* Compl. ¶¶ 53, 88.

[3] *Bayer Issues Voluntary Recall of Specific Lotrimin® and Tinactin® Spray Products Due to the Presence of Benzene*, FDA (Oct. 1, 2021), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-specific-lotriminr-and-tinactinr-spray-products-due-presence-benzene#:~:text=WHIPPANY%2C%20N.J.%2C%20October%201%2C,some%20samples%20of%20the%20products.

8. "Benzene has been classified as a human carcinogen. The FDA has advised that manufacturers should avoid using benzene in drug manufacturing processes and that, where benzene use is unavoidable to produce a drug product, benzene levels should be restricted to no more than 2 parts per million, unless otherwise justified." *Bayer* Compl. ¶ 37. "Otherwise justified" means the use of benzene in the products is "unavoidable in order to produce a drug product with a significant therapeutic advance."[4]

9. Despite these strict limits, *Defendants' own internal testing* and independent lab testing outlined below show that the Products consistently contain significant benzene levels that exceed the 2 ppm FDA upper limit, including *over 105 times* the 2 ppm limit in one sample.

10. Defendants knew or should have known of the dangerous and carcinogenic effects of benzene and knew or should have known that they were producing Products that contained benzene at levels above, and often dramatically above, 2 ppm. Nevertheless, Aeropres, Aux Sable, Bayer, Beiersdorf, and BP Energy produced, distributed, and sold benzene-containing feedstock supply, Propellant A-31, and millions of cans of Tinactin and Lotrimin AF sprays that contained benzene to the consuming public.

[4] FDA, *Q3C — Tables and List Guidance for Industry* 5 (2018), https://www.fda.gov/media/133650/download.

11. Plaintiffs are purchasers and users of the Products, which, as described below, were recalled by Bayer due to the presence of benzene. Plaintiffs purchased the Products to treat conditions they were intended to treat and used them in accordance with the directions provided on their packaging. Plaintiffs did so because they believed the Products had been manufactured using acceptable standards and practices and were safe for human use.

12. However, in reality, Plaintiffs bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiffs would not have paid as much for the Products as they did—if they would have paid anything at all—had Defendants disclosed the benzene contamination and/or shoddy manufacturing practices of the Products that rendered the Products unsafe. Likewise, Plaintiffs would not have paid as much for the Products as they did—if they would have paid anything at all—had Defendants disclosed there was a material risk that the Products contained benzene, as Plaintiffs are not required to play Russian roulette with their health when choosing foot spray products. In any case, Plaintiffs overpaid for the Products as a result of Defendants' omissions and unfair business practices.

13. Plaintiffs were therefore harmed at the point of purchase of the Products, which were rendered unusable, when they did not receive the benefit of the bargain. Accordingly, Plaintiffs and Class Members were also injured because they were forced to waste portions of the Products or spend additional money to

purchase replacement medications that they would not have purchased but for the Products' benzene contamination.

14. Plaintiffs bring this action on behalf of themselves, the Classes, and Subclasses for equitable relief and to recover damages or equitable relief for: (i) breach of express warranty; (ii) breach of implied warranty; (iii) violation of the consumer protection statutes; (iv) fraud; (v) negligent misrepresentation; and (vi) unjust enrichment.

THE PARTIES

15. Plaintiff Juan Huertas is a citizen and resident of Nassau County, New York.

16. Plaintiff Eva Mistretta is a citizen and resident of Queens County, New York.

17. Plaintiff Mike Poovey is a citizen and resident of Horry County, South Carolina.

18. Plaintiff Darrell Stewart is a citizen and resident of Sussex County, Delaware.

19. Plaintiff Jeremy Wyant is a citizen and resident of Clinton County, Indiana.

20. Defendant Aeropres Corporation is a corporation organized and existing under the laws of the State of Louisiana, with its principal place of business

at 1324 North Hearne, Suite 200, Shreveport, Louisiana 71137. Aeropres manufactured Propellant A-31, which was used in the Products sold to Plaintiffs and the consuming public, at manufacturing plants located in Morris, Illinois and Manhattan, Illinois.

21. Defendant Aux Sable Liquid Products LP is a limited partnership organized and existing under the laws of the state of Delaware, with its principal place of business at Energy Ctr 5, 915 N. Eldridge Parkway, Suite 1100, Houston, TX 77079. Aux Sable also maintains a facility in Morris, Illinois.

22. Defendant Bayer HealthCare LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Bayer Boulevard, Whippany, New Jersey 07981.

23. Defendant Bayer U.S. LLC is a Delaware limited liability company with its headquarters in Whippany, New Jersey.

24. Defendant Beiersdorf Manufacturing, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business located at 4207 Michigan Avenue Road NE, Cleveland, Tennessee 37323.

25. Defendant Beiersdorf Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 301 Tresser Boulevard, Suite 1500, Stamford, Connecticut 06901. On information and

belief, Beiersdorf Inc. is a managing member of Defendant Beiersdorf Manufacturing, LLC, and at all material times controlled in whole or in part Beiersdorf Manufacturing, LLC's conduct.

26. Defendant Beiersdorf NA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 301 Tresser Boulevard, Suite 1500, Stamford, Connecticut 06901. On information and belief, Beiersdorf NA is a managing member of Defendant Beiersdorf Manufacturing, LLC, and at all material times controlled in whole or in part Beiersdorf Manufacturing, LLC's conduct.

27. Defendant BP Energy Company is a corporation existing under the laws of the State of Delaware, with its principal place of business at 501 Westlake Park Boulevard, Houston, Texas, 77079.

JURISDICTION AND VENUE

28. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005 ("CAFA"), 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.

29. Defendant AuxSable is an "unincorporated association" under CAFA and is therefore "a citizen of the State where it has its principal place of business [Texas] and the State under whose laws it is organized [Delaware]." *See* 28 U.S.C. § 1332(d)(10). Defendant Bayer is an "unincorporated association" under CAFA and is therefore "a citizen of the State where it has its principal place of business [New Jersey] and the State under whose laws it is organized [Delaware]." *Id.* Defendant Beiersdorf LLC is an "unincorporated association" under CAFA and is therefore "a citizen of the State where it has its principal place of business [Tennessee] and the State under whose laws it is organized [Delaware]." *Id.* And Defendant Beiersdorf Manufacturing is an "unincorporated association" under CAFA and is therefore "a citizen of the State where it has its principal place of business [Tennessee] and the State under whose laws it is organized [Delaware]." *Id.*

30. This Court has personal jurisdiction over Bayer because Bayer is headquartered in New Jersey.

31. This Court has specific personal jurisdiction over Aeropres, Aux Sable, the Beiersdorf Defendants, and BP Energy because they purposefully availed themselves of the privilege of conducting business and maintaining consistent and substantial contacts with Bayer, which is based in New Jersey.

32. Furthermore, the actions of all Defendants in manufacturing, distributing, and selling the contaminated Products gave rise to the harms faced by

Plaintiffs. The exercise of jurisdiction over all Defendants comports with traditional notions of fair play and substantial justice.

33. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2), because Defendant Bayer resides in this District, and a substantial part of the events giving rise to the claims occurred in this District.

FACTS COMMON TO ALL CLASS MEMBERS

I. BP ENERGY AND AUX SABLE PROVIDE GAS FEEDSTOCK SUPPLY TO AEROPRES THAT IS CONTAMINTED WITH BENZENE

34. Aeropres "is a manufacturer and distributor of high-purity gases to a wide variety of markets" and "is the largest manufacturer and marketer of ecologically safe propellants, which are used in a variety of spray cans from hair spray and mousses to shaving cream and spray paint."[5]

35. Aeropres sourced its gas supply, also known as "feedstock," for its propellants from different companies. In July 2017, Aeropres contracted for the delivery of gas feedstock, including isobutane, butane, and propane, from BP Energy pursuant to the terms and conditions of a Master Agreement for Purchase, Sale, or Exchange of Liquid Hydrocarbons (the "Master Agreement").

36. The Master Agreement states that all products delivered under the contract must meet the specification for that product and that, "[i]f no Product

[5] *About Us*, Aeropres Corporation, https://web.archive.org/web/20200312110019/http://www.aeropres.com/about/.

specification is set forth, all Product delivered under this Contract shall meet the latest GPA specifications for that Product and contain no deleterious substances or concentrations of any contaminants that may make it or its components commercially unacceptable in general industry application." *Bayer v. Aeropres*, ECF No. 73 ("*Aeropres* Compl.") ¶ 14.

37. Benzene was not included in the list of substances that Aux Sable and BP Energy contracted to deliver.

38. BP Energy works "with a range of products across [its] supply, trading [and] shipping operations, [including] traditional hydrocarbons like crude, refined products, petrochemicals, and natural gas."[6] According to Aeropres, BP Energy contracted with Aux Sable in 2021 for the sale and delivery of merchantable gas feedstock. Aeropres alleged that BP Energy was a marketer and seller of the feedstock that was contaminated with benzene. *Aeropres* Compl. ¶ 14.

39. Aux Sable "owns and operates one of the largest natural gas liquids extraction and fractionation facilities in North America."[7]

40. Aeropres received the feedstock gas supply at issue by railcar directly from Aux Sable. *Aeropres* Compl. ¶ 16. BP Energy and Aux Sable were the sole suppliers of gas feedstock supply to Aeropres' plant in Morris, Illinois, where

[6] *What We Do*, BP, https://www.bp.com/en/global/bp-supply-trading-and-shipping/what-we-do.html.

[7] *Aux Sable*, Pembina, https://www.pembina.com/operations/facilities/aux-sable.

Aeropres detected the presence of benzene in feedstock delivered on railcars from Aux Sable. *Id.* ¶ 23.

41. From July 2021 through December 2022, Aeropres sent several letters to BP Energy and Aux Sable, demanding indemnification and informing them of the feedstock test results showing the presence of benzene in the hydrocarbons sold to Aeropres from BP Energy and Aux Sable. *Id.* ¶ 29.

42. Aux Sable and BP Energy were aware their products would be incorporated into final products for human use and application. *Id.* ¶¶ 60, 116. Aux Sable and BP Energy were also aware of their responsibility to ensure their feedstock supply was free of contaminants that would make the feedstock commercially unacceptable. Furthermore, Aux Sable and BP Energy knew or should have known of the presence and risk of the presence of benzene in its feedstock supply.

43. Despite this, Aux Sable and BP Energy failed to conduct adequate testing of their feedstock supply, thereby failing to ensure the feedstock they delivered to Aeropres, which was ultimately incorporated into the propellant used by Bayer and the Beiersdorf Defendants, was free of the carcinogenic benzene.

II. AEROPRES SUPPLIES THE PROPELLANT FOR THE PRODUCTS, WHICH IS ALSO CONTAMINATED WITH BENZENE

44. Pursuant to a July 2017 Quality Assurance Agreement (the "QAA") entered into by Aeropres and Bayer, Aeropres agreed to, and did, supply to Bayer the Propellant A-31 used in the Products. *Bayer* Compl. ¶ 56.

45. Propellant A-31, as supplied by Aeropres, is a liquefied gas that is combined with other ingredients to create the Products. The propellant gases supplied by Aeropres to Bayer are made pursuant to a formula that contains a combination of chemical ingredients. Benzene is not a listed ingredient in this combination.

46. According to Bayer, Aeropres' Good Manufacturing Practices Policy (GMP) Statement, which was appended to the QAA, provided that Aeropres "adheres to Quality System industry best practices," and that the components of Aeropres' propellants, including isobutane, are listed on the "Generally Recognized as Safe" List. *Id.* ¶ 28. In addition, the QAA required Aeropres to "conduct manufacturing and quality control operations of Product according to formulas, instructions and the valid manufacturing procedure set up by [Aeropres] and approved by Bayer, as well as applicable United States Food and Drug Administration ('FDA') requirements and GMP." *Id.* ¶ 29.

47. Beginning in July 2017 and continuing at least through Bayer's recall, Aeropres supplied Propellant A-31 to Bayer (and to the successor manufacturer of the Products, the Beiersdorf Defendants) for use as the propellant in the Products.

48. Aeropres at all times knew that Propellant A-31 was included by Bayer (and Beiersdorf) in the Products, and specifically in products which would be applied to consumers' bodies.

49. Despite this knowledge, Aeropres failed for years to ensure that Propellant A-31 did not contain the well-known carcinogen benzene.

III. BEIERSDORF TAKES OVER MANUFACTURE OF THE PRODUCTS FOR BAYER

50. On May 13, 2019, Bayer AG (the parent company of Bayer Healthcare LLC) and Beiersdorf AG (the parent company of Beiersdorf Manufacturing LLC) entered into an agreement (the "Bayer-Beiersdorf Sale Agreement") for Bayer AG to sell to Beiersdorf AG, among other assets, a manufacturing facility located in Cleveland, Tennessee. Bayer used the Cleveland, Tennessee facility to manufacture various products, including the Lotrimin and Tinactin Products at issue.

51. In connection with the transaction, Beiersdorf Manufacturing, LLC was incorporated in and under the laws of the State of Delaware on June 20, 2019, and on July 1, 2019, Beiersdorf Manufacturing, LLC registered to do business as a foreign LLC with the State of Tennessee. These actions were undertaken in order for Beiersdorf Manufacturing, LLC, with Beiersdorf, Inc. as managing member, to operate the former Bayer plant located in Cleveland, Tennessee, which was used to produce, *inter alia*, the Lotrimin and Tinactin Products at issue.

52. On August 22, 2019, Bayer provided to Aeropres a Notice of Assignment of the QAA, notifying Aeropres of the Bayer-Beiersdorf Sale Agreement, and that, as part of that transaction, the QAA (including all amendments, statements of work, exhibits, and schedules) was assigned to Beiersdorf.

53. On August 26, 2019, Aeropres acknowledged and agreed to the assignment of the QAA to Beiersdorf.

54. On August 30, 2019, the transaction between Bayer and Beiersdorf closed. As part of the transaction, Beiersdorf agreed to manufacture, package, and supply to Bayer finished Lotrimin and Tinactin spray products.

55. As described below, Bayer commissioned testing of Lotrimin and Tinactin samples, which revealed that Lotrimin and Tinactin samples manufactured beginning in September 2018, the date of manufacture of the oldest unexpired lots, were contaminated with benzene.

IV. LOTRIMIN AND TINACTIN AEROSOL PRODUCTS

56. Lotrimin is the brand name for Miconazole Nitrate, which is an antifungal medication. Lotrimin is an over-the-counter ("OTC") medical product that is used to treat vaginal yeast infections, oral thrush, diaper rash, pityriasis versicolor, and types of ringworm including athlete's foot and jock itch. Lotrimin comes in both aerosol (spray) and cream form.

57. Tinactin is the brand name for Tolnaftate, another antifungal medication that is OTC and treats a range of conditions. Tolnaftate has been found to be less useful at treating athlete's foot than Miconazole Nitrate but has been found effective at treating ringworm that is passed from pets to humans. Tinactin comes in both aerosol (spray) and cream form.

58. Bayer and the Beiersdorf Defendants manufacture, market, and sell a variety of Lotrimin and Tinactin aerosol products, including the following Products:

a. Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray

b. Lotrimin Anti-Fungal Jock Itch (AFJI) Powder Spray

c. Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray

d. Lotrimin AF Athlete's Foot Liquid Spray

e. Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray

f. Tinactin Jock Itch (JI) Powder Spray

g. Tinactin Athlete's Foot Deodorant Powder Spray

h. Tinactin Athlete's Foot Powder Spray

i. Tinactin Athlete's Foot Liquid Spray

59. The "Drug Facts" section of each of the Products lists the active and inactive ingredients in the Products. Nowhere in that section, or on the labels in general, is "benzene" listed as an active or inactive ingredient. Nor do the Products disclose or warn on the labels or otherwise, the manufactural failings of Defendants, or of the presence (or risk) of benzene in the Products. The labels further direct consumers to apply the Products directly on the skin of the affected area multiple times a day over the course of several weeks, and/or each time there is an occurrence of the condition, as described below.

60. Lotrimin AF Athlete's Foot Powder Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)"; and (2) "for effective relief of itching, cracking, burning, scaling and discomfort."[8]

61. Lotrimin AF Jock Itch Powder Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most jock itch (tinea cruris)"; and (2) "for effective relief of itching, burning, scaling and discomfort, and chafing associated with jock itch."[9] The label directs users to use the product "twice daily . . . for 2 weeks."[10]

62. Lotrimin AF Athlete's Foot Deodorant Powder Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)"; and (2) "for effective relief of itching, cracking, burning, scaling and discomfort."[11] The label

[8] *Lotrimin AF Powder Spray*, Bayer Livewell, https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Powder_Spray_DrugFacts.pdf.

[9] *Lotrimin AF Jock Itch Powder Spray*, Bayer Livewell, https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_JI_Powder_Spraydrug_facts.pdf.

[10] *Id.*

[11] *Lotrimin AF Deodorant Powder Spray*, Bayer Livewell, https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Deodorant_Powder_Spray_Drug_Facts.pdf.

directs users to use the product "daily for 4 weeks" for "athlete's foot and ringworm" and to use the product "daily for 2 weeks" for "jock itch."[12]

63. Lotrimin AF Athlete's Foot Liquid Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)"; and (2) "for effective relief of itching, cracking, burning, scaling and discomfort."[13] The label directs users to use the product "daily for 4 weeks" for "athlete's foot and ringworm" and to use the product "daily for 2 weeks" for "jock itch."[14]

64. Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray's label lists the following use: (1) "clinically proven to prevent most athlete's foot with daily use."[15] The label directs users to use the product "once or twice daily."[16]

65. Tinactin Jock Itch Powder Spray's "Drug Facts" indicate it should be used in the following ways: (1) "cures most jock itch"; and (2) "for effective relief

[12] *Id.*

[13] *Lotrimin AF Liquid Spray*, Bayer Livewell, https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Liquid_Spraydrug_facts.pdf.

[14] *Id.*

[15] *Lotrimin® AF Athlete's Foot Daily Prevention Deodorant Powder Spray*, Lotrimin, https://www.lotrimin.com/our-products/daily-prevention-athlete-deodorant-powder-spray.

[16] *Id.*

of itching, chafing and burning."[17] The label directs users to use the product "daily . . . for 2 weeks."[18]

66. Tinactin Athlete's Foot Deodorant Spray's "Drug Facts" indicate it should be used in the following ways: (1) "in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)"; (2) to "help[] prevent most athlete's foot with daily use"; and (3) "for effective relief of itching, burning, and cracking."[19] The label directs users to use the product "twice daily . . . for 4 weeks."[20]

67. Tinactin Athlete's Foot Powder Spray's "Drug Facts" indicate it should be used in the following ways: (1) "in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)"; (2) to "help[] prevent most athlete's foot with daily use"; and (3) "for effective relief of itching, burning, and cracking."[21] The label directs users to use the product "twice daily . . . for 4 weeks."[22]

68. Tinactin Athlete's Foot Liquid Spray's "Drug Facts" indicate it should be used in the following ways: (1) "in the treatment of most athlete's foot (tinea

---

[17] *Tinactin JI Powder Spray*, Bayer Livewell, https://www.livewell.bayer.com/deco/omr/Tinactin_JI_Powder_Spray_drugfacts.pdf.

[18] *Id.*

[19] *Tinactin DEO Powder Spray*, Bayer Livewell, https://www.livewell.bayer.com/deco/omr/Tinactin_Deodorant_Powder_Spray_drugfacts.pdf.

[20] *Id.*

[21] *Tinactin AF Powder Spray*, Bayer Livewell, https://www.livewell.bayer.com/deco/omr/Tinactin_AF_Powder_Spray_drugfacts.pdf.

[22] *Id.*

pedis) and ringworm (tinea corporis)"; (2) to "help[] prevent most athlete's foot with daily use"; and (3) "for effective relief of itching, burning, and cracking."[23] The directions included with Tinactin Athlete's Foot Liquid Spray cans directed users to use the product "twice daily . . . for 4 weeks."[24]

V. BENZENE

69. Benzene is a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals. The Department of Health and Human Services has determined that benzene causes cancer in humans.[25] Likewise, the FDA lists benzene as a "Class 1 solvent" that "***should not be employed*** in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity."[26]

70. Benzene is associated with blood cancers such as leukemia.[27] A study from 1939 on benzene stated that "exposure over a long period of time to any concentration of benzene greater than zero is not safe,"[28] which is a comment

---

[23] *Tinactin Liquid Spray*, Bayer Livewell, https://www.livewell.bayer.com/deco/omr/Tinactin_Liquid_Spray_drugfacts.pdf.

[24] *Id.*

[25] *ToxFAQs™ for Benzene*, Agency for Toxic Substances and Disease Registry, https://wwwn.cdc.gov/TSP/ToxFAQs/ToxFAQsDetails.aspx?faqid=38&toxid=14#.

[26] FDA, *Q3C — Tables and List Guidance for Industry* 5 (2018), https://www.fda.gov/media/133650/download (emphasis added).

[27] *Benzene*, National Cancer Institute, Cancer-Causing Substances, https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene.

[28] F.T. Hunter, *Chronic Exposure to Benzene (Benzol). II. The Clinical Effects.*, 21 J. Indus. Hygiene & Toxicology 331 (1939),

reiterated in a 2010 review of benzene research specifically stating: "There is probably no safe level of exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion."[29]

71. The Agency for Toxic Substances and Disease Registry ("ATSDR") warns that "[e]ating foods or drinking liquids containing high levels of benzene can cause vomiting, irritation of the stomach, dizziness, sleepiness, convulsions, rapid heart rate, coma, and death" and that "[i]f you spill benzene on your skin, it may cause redness and sores [and] Benzene in your eyes may cause general irritation and damage to your cornea."[30]

72. According to the American Cancer Society: "IARC classifies benzene as 'carcinogenic to humans,' based on sufficient evidence that benzene causes acute myeloid leukemia (AML). IARC also notes that benzene exposure has been linked with acute lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma, and non-Hodgkin lymphoma."[31]

---

https://scholar.google.com/scholar?hl=en&as_sdt=0%2C39&q=Chronic+Exposure+to+Benzene+%28Benzol%29.+II.+The+Clinical+Effects.&btnG=.

[29] Martyn T. Smith, *Advances in Understanding Benzene Health Effects and Susceptibility*, 31 Ann. Rev. Pub. Health. 133 (2010), https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646.

[30] ATSDR, *Toxicological Profile for Benzene* 5 (2007), https://www.ncbi.nlm.nih.gov/books/NBK591300/.

[31] *Benzene and Cancer Risk*, American Cancer Society, https://www.cancer.org/cancer/risk-prevention/chemicals/benzene.html.

73. Moreover, "[i]f benzene touches the eyes, skin, or lungs, it can cause injury and irritation."[32]

74. According to the National Institute for Occupational Safety and Health, humans can become exposed to benzene through "inhalation, ***skin absorption***, ingestion, ***skin*** and/or eye contact."[33] In fact, multiple FDA studies of sunscreen products demonstrate that chemicals similar in structure to that at issue here are found at high levels in the blood after application of the sunscreen products to exposed skin.

75. The National Institute for Occupational Safety and Health also recommends protective equipment be worn by workers expecting to be exposed to benzene at concentrations of even 0.1 ppm.[34]

VI. THE PRODUCTS CONTAIN DANGEROUS LEVELS OF BENZENE THAT RENDERED THE PRODUCTS UNSALEABLE

76. On August 11, 2021, Aeropres notified Beiersdorf that the Propellant A-31 supplied from Aeropres' Morris, IL production facility may be contaminated with benzene. Recognizing it was at fault, Aeropres stated that it "regrets this

[32] *Benzene*, Centers for Disease Control and Prevention, https://www.cdc.gov/chemical-emergencies/chemical-fact-sheets/benzene.html.

[33] *Benzene*, The National Institute for Occupational Safety and Health (NIOSH), https://www.cdc.gov/niosh/npg/npgd0049.html (emphasis added).

[34] *Id.* (providing guidance for NIOSH's 0.1ppm exposure limit for benzene; select "See Appendix A").

development as it is not in keeping with Aeropres' standards of product manufacture." *Bayer* Compl. ¶ 5.

77. Aeropres warned that "the nature of the hydrocarbon origin of the raw materials precludes our ability to assure that there are no residual solvents in the finished product." Aeropres also informed Beiersdorf that "benzene can only be introduced into Aeropres' products by way of contamination of its natural gas liquid feedstock." *Id*. ¶ 36.

78. On August 13, 2021, Beiersdorf notified Bayer of the benzene contamination. *Id*. ¶ 39.

79. In September 2021, Beiersdorf received results of testing that confirmed benzene levels in samples of certain finished, unexpired Lotrimin and Tinactin products were above the FDA's acceptable limit of 2 parts per million. *Id*. ¶ 40.

80. Bayer also commissioned additional testing of Lotrimin and Tinactin samples which revealed that Lotrimin and Tinactin samples manufactured beginning in September 2018, the date of manufacture of the oldest unexpired lots, were contaminated with benzene. *Id.* ¶ 41.

81. Bayer kept selling benzene-contaminated products, however, and it was not until October 2021 that Bayer announced a recall of "all unexpired Lotrimin AF and Tinactin spray products with lot numbers beginning with TN, CV or NAA,

distributed between September 2018 to September 2021, to the consumer level due to the presence of benzene in some samples of the products."[35] Bayer also instructed consumers to "stop using" the Products. Even then, however, Bayer (falsely) maintained that "the levels detected are not expected to cause adverse health consequences in consumers."[36]

82. As a result of Defendants' failure to keep benzene out of the Products, millions of consumers have been repeatedly and consistently exposed to dangerous levels of a known carcinogen by using the Products as intended and directed by Bayer.[37]

83. In the recall notice, Bayer admitted that "[b]enzene is ***not*** an ingredient in any of Bayer Consumer Health products."[38] In addition, Aeropres informed Beiersdorf that "benzene can only be introduced into Aeropres' products by way of contamination of its natural gas liquid feedstock." *Bayer* Compl. ¶ 36. Thus, the presence of benzene in Bayer's Products appears to be ***the result of contamination*** or a deficiency in the manufacturing process designed, implemented, and used by Defendants to manufacture the Products.

---

[35] *See* fn. 3, *supra*.

[36] *Id.*

[37] *Event Details*, FDA, https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=88677. As discussed further below, Bayer's recall applied to millions of products, with millions of products recalled due to detection of benzene.

[38] *See* fn. 3, *supra*.

84. Accordingly, because the presence of benzene is the result of contamination, benzene ***is*** avoidable in the manufacturing of the Products, and any significant detection of benzene in such products is unacceptable. This is supported by FDA's guidance that manufacturers should avoid using benzene in the drug manufacturing process.

85. As Bayer itself stated, benzene cannot be removed from Propellant A-31 once contamination has occurred. Benzene is soluble in both the liquid and gaseous phase of Propellant A-31. Remediation measures for benzene contamination of Propellant A-31 involve evacuating all tanks and piping containing the propellant, as well as venting the piping to ensure that all liquid has evaporated and the resulting gas was removed. *Bayer* Compl. ¶ 38.

86. The Propellant A-31 used in the Products was manufactured with ingredients from a singular container of feedstock supply. Therefore, if one product is found to contain benzene from its Propellant, it is likely the other products manufactured with Propellant made from the same feedstock supply would also have incorporated benzene-contaminated ingredients.

87. An FDA enforcement report revealed that a total of 44,302,392 Products were subject to Bayer's recall.

88. Of the total number of Products subject to the recall, 20,922,264 were recalled due to the detected presence of benzene, while 23,380,128 products were

recalled because they were manufactured in the same facility in which lots were detected containing benzene.

89. Bayer's recall of products that were manufactured in the same location where benzene was detected reflects how widespread the benzene contamination was. This is also evident in how difficult it is to remove benzene once it is introduced in the manufacturing process.

90. Despite this extensive scope of the recall, Bayer only claimed $1 million in damages for U.S. consumer refunds in the *Bayer* Action, meaning the average recovery per consumer was $0.44. This demonstrates how Bayer's recall provided inadequate compensation and relief for harmed consumers.

91. In October 2021, pharmaceutical testing laboratory Valisure, LLC ("Valisure") tested a sampling of Lotrimin and Tinactin Products that were part of the lots recalled by Bayer. The Valisure results (as set forth herein) confirm that the Products are contaminated with unsafe levels of the carcinogen benzene.

92. Valisure tested 13 Bayer Products from separate lots, 6 of which were Lotrimin Products and 7 were Tinactin Products. Valisure's testing found detectable levels of benzene in **12 of the 13 Products** tested (92%), with benzene levels that significantly exceeded the guidelines established by the FDA of 2 parts ppm for

"drug product[s] with a significant therapeutic advance" in 11 of the 13 Products Valisure tested (85%).[39]

93. The tested Products yielded startling results, including levels of benzene that were 7, 8, 10, 24, 26, 51, 78, and, in one product sample, **over 105 times** the 2 ppm strict limit set by the FDA for drug products (including eight samples that tested **over 10 times** the FDA's limit, and ten samples that tested above twice the 2 ppm FDA limit).

94. Notably, these results contradict Bayer's statement that "the levels detected [in the Products] are not expected to cause adverse health consequences in consumers."[40]

95. The Valisure results concerning the Bayer Products with detectable levels of benzene are set forth in the table below:

Lot	UPC	Product Description	Expiry	Labeled % Active Ingredient	Labeled Inactive Ingredients	Receipt Date	Benzene (ppm)
TN005K8	041100 590367	Lotrimin Athlete's Foot Daily Prevention Deodorant Powder Spray - 4.6 oz	06/2022	1% Tolnaftate	Butylated Hydroxytoluene, Fragrance, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (10.5% v/v), Talc	October 5, 2021	**16.62**
TN006MX	311017 410059	Tinactin Antifungal Liquid Spray - 5.3 oz	10/2022	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (29% v/v)	October 5, 2021	**3.64**

[39] One product tested at a level of 1.60 ppm, between the Limit of Quantification Valisure set at 0.10 ppm to indicate measurable/detectable levels of benzene, and the FDA's 2ppm limit.

[40] *See* fn. 3, *supra*.

Lot	UPC	Product Description	Expiry	Labeled % Active Ingredient	Labeled Inactive Ingredients	Receipt Date	Benzene (ppm)
TN0047R	311017 410097	Tinactin Athlete's Foot Antifungal Treatment Powder Spray - 4.6 oz	05/2023	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (11% v/v), talc	October 5, 2021	**1.60**
TN006TD	311017 410257	Lotrimin AF Antifungal Powder Aerosol Spray, Super Size - 4.6 oz	03/2023	2% Miconazole Nitrate	Isobutane, SD Alcohol 40-B (8% v/v), Stearalkonium Hectorite, Talc	October 4, 2021	**49.61**
TN004BX	041100 587206	Lotrimin Athlete's Foot Daily Prevention Deodorant Powder Spray - 5.6 oz	06/2022	1% Tolnaftate	Butylated Hydroxytoluene, Fragrance, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (10.5% v/v), Talc	October 4, 2021	**20.53**
TN008CY	311017 410318	Lotrimin AF Antifungal Jock Itch Aerosol Powder Spray, Super Size - 4.6 oz	04/2023	2% Miconazole Nitrate	Isobutane, SD Alcohol 40-B (8% v/v), Stearalkonium Hectorite, Talc	October 4, 2021	**156.40**
TN008CZ	311017 410318	Lotrimin AF Antifungal Jock Itch Aerosol Powder Spray, Super Size - 4.6 oz	04/2023	2% Miconazole Nitrate	Isobutane, SD Alcohol 40-B (8% v/v), Stearalkonium Hectorite, Talc	October 4, 2021	**211.46**
TN007TJ	311017 410097	Tinactin Athlete's Foot Antifungal Treatment Powder Spray - 4.6 oz	03/2023	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (11% v/v), talc	October 4, 2021	**155.53**

Lot	UPC	Product Description	Expiry	Labeled % Active Ingredient	Labeled Inactive Ingredients	Receipt Date	Benzene (ppm)
TN008CT	311017 410097	Tinactin Athlete's Foot Antifungal Treatment Powder Spray - 4.6 oz	03/2023	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (11% v/v), talc	October 4, 2021	**103.35**
TN006AT	311017 410097	Tinactin Athlete's Foot Antifungal Treatment Powder Spray - 4.6 oz	12/2022	1% Tolnaftate	Butylated Hydroxytoluene, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (11% v/v), talc	October 4, 2021	**14.98**
TN0067A	311017 410004	Tinactin Deodorant Powder Spray - 4.6 oz	02/2023	1% Tolnaftate	Butylated Hydroxytoluene, Fragrance, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (10.5% v/v), Talc	October 4, 2021	**21.56**
TN008CU	311017 410004	Tinactin Deodorant Powder Spray - 4.6 oz	04/2023	1% Tolnaftate	Butylated Hydroxytoluene, Fragrance, Isobutane, PPG-12-Buteth-16, SD Alcohol 40-B (10.5% v/v), Talc	October 4, 2021	**53.44**

96. Valisure's testing results contrast markedly with Bayer's public statements – and call into question whether Bayer withheld or misrepresented information on testing it conducted or whether Bayer's testing was flawed.

97. Accompanying its recall, Bayer stated that the products were recalled "due to the presence of benzene in some samples of the products" but purposefully downplayed any concerns, noting that the decision to voluntarily recall the products was a "precautionary measure and that the levels detected are not expected to cause adverse health consequences in consumers."[41]

[41] *Id.*

98. While nine of the products tested by Valisure were recalled because benzene was detected in samples from the lot number, two of the products tested by Valisure that contained alarmingly high levels of benzene were recalled because they were manufactured in the same facility as other lots that were found to contain benzene (TN005K8 and TN006AT). Recalling those products was not a precautionary act, but rather recognition that, as Bayer stated, benzene cannot be simply removed from product ingredients once they are contaminated.

99. A third product (TN0047R) that was tested by Valisure and recalled because it was manufactured in the same facility as other lots that contained benzene was found to contain less than 2ppm of benzene. This is still an unacceptable amount of benzene based on FDA guidance. The FDA states that 2ppm of benzene is acceptable only in drug products where the use of benzene is unavoidable. Benzene is not a product listed by Defendants for any of their products, thereby demonstrating that benzene is an unnecessary and avoidable contaminant for Defendants to manufacture their products.

100. The notable consistency with which unacceptable levels of benzene were detected by Valisure in the Products they tested indicates that the Products Plaintiffs and members of the Classes purchased contained impermissible levels of benzene.

101. In addition to such testing, Bayer admitted in the *Bayer* Action, and the court accepted, that, "Bayer commissioned additional testing . . . which revealed that Lotrimin and Tinactin samples manufactured beginning in September 2018, the date of manufacture of the oldest unexpired lots, were contaminated with benzene." *Bayer* Compl. ¶ 41. Furthermore, Bayer stated that, "Bayer had to destroy and write-off millions of dollars' worth of damaged Lotrimin and Tinactin product that was unsaleable due to Aeropres' contamination." *Id.* ¶ 53. Based on these claims made in the *Bayer* Action, Bayer is estopped from arguing that it is implausible that products with lot numbers included in the recall contain unacceptable levels of benzene.

VII. BAYER FILES A LAWSUIT AGAINST AEROPRES, AND AEROPRES FILES A THIRD-PARTY COMPLAINT AGAINST AUX SABLE AND BP ENERGY

102. On July 7, 2023, Bayer commenced an action against Aeropres, alleging that Aeropres supplied the benzene-tainted propellants that Bayer incorporated into its Lotrimin and Tinactin spray products.

103. The *Bayer* Action demonstrates Bayer's knowledge of the harms of benzene, the presence of benzene in its recalled products, and the value reduction of its products caused by the benzene contamination.

104. Notably, Bayer's allegations and arguments in its lawsuit against Aeropres contradict its statements both in its recall and in this action. *Huertas v.*

Bayer US LLC, 120 F.4th 1169, 1180 n.18 (3d Cir. 2024) ("Plaintiffs noted a number of inconsistencies between Bayer's position here and in the *Aeropres* Complaint."). Most dramatically, Bayer admitted in its own complaint that the levels of benzene contamination in the Products made them "*unreasonably dangerous to Bayer's consumers*, according to FDA guidelines." *Bayer v. Aeropres*, ECF No. 32 at 17.

105. Likewise, Bayer admitted the benzene contamination rendered the Products "damaged beyond use or repair" and "unsaleable due to [the] contamination." *Bayer* Compl. ¶¶ 53, 88.

106. Bayer also made at least the following salient allegations:

a. "Aeropres provided Bayer with Propellant A-31 containing benzene in amounts exceeding acceptable limits established by FDA and causing the products to be recalled." *Id.* ¶ 59.

b. "Aeropres breached its express warranties to Bayer by supplying Propellant A-31 that, as Aeropres has in part admitted, was defective and needed to be recalled due to benzene contamination; did not conform with agreed chemical formulae, manufacturing processes, instructions, applicable law, or GMP; did not conform with FDA requirements; did not conform with industry best practices; and the benzene component of the contaminated Propellant A-31 was not listed on the GRAS List." *Id.* ¶ 73.

c. "The Propellant A-31 was not of merchantable quality because, among other things, the Propellant A-31 (a) would not pass without objection in the trade under the contract description; (b) was not of fair average quality within the contract description;

(c) was not fit for the ordinary purposes for which Propellant A-31 is used; and (d) did not run, within the variations permitted by the QAA, of even kind, quality and quantity within each unit and among all units involved." *Id.* ¶ 77.

d. "At the time of contracting, Aeropres had reason to know that Propellant A-31 would be used as an ingredient in Bayer's Lotrimin and Tinactin products, which were intended for sale and use in topical applications in humans." *Id.* ¶ 81.

e. "The Propellant A-31 sold by Aeropres to Beiersdorf was not fit for the purpose of being incorporated into products intended for human topical application." *Id.* ¶ 82.

f. "Bayer relied on Aeropres' skill and judgment to select suitable goods for the purpose of being incorporated into products intended for human topical application." *Id.* ¶ 83.

g. "As a result of the sudden and calamitous event of the contamination of Aeropres' Propellant A-31, Bayer's Lotrimin and Tinactin products were damaged beyond use or repair." *Id.* ¶ 88.

107. These allegations by Bayer were accepted by the Northern District of Illinois court in its decision denying dismissal of five out of seven of Bayer's claims.

108. On July 3, 2024, Aeropres filed a Third-Party Complaint against BP Energy and Aux Sable in the *Bayer* Action, alleging that they supplied the gas feedstock supply that was contaminated with benzene, and ultimately used by Bayer and the Beiersdorf Defendants in the Products.

109. The *Aeropres* Compl. demonstrates that Aeropres, Aux Sable, and BP Energy were aware of the dangers of benzene, as well as the risk of contaminants such as benzene entering their products. Additionally, the *Aeropres* Compl. details supply and manufacturing processes severely lacking procedures and/or testing with which to detect benzene contamination.

110. Critically, Aeropres alleges in its Third-Party Complaint against Aux Sable and BP Energy, *inter alia*, that:

a. "BP Energy and Aux Sable failed to deliver the Products in accord with the quality specifications agreed upon." *Aeropres* Compl. ¶ 37.

b. "[N]either BP Energy nor Aux Sable notified Aeropres of the presence of benzene in the Products." *Id.* ¶ 47.

c. "BP Products and Aux Sable sold gas feedstock products to Aeropres that were not of merchantable quality because they were contaminated with latent defects, specifically, benzene." *Id.* ¶ 57.

d. "At the time of contracting, BP Energy and Aux Sable had reason to know that the gas feedstock would be used by Aeropres as an ingredient in products that were intended for sale and use in humans." *Id.* ¶ 60.

e. "The gas feedstock sold by BP Energy and/or Aux Sable was not fit for the purpose of being incorporated into products intended for human topical application." *Id.* ¶ 61.

f. "Aeropres relied upon BP Energy and Aux Sable for their skill and judgment to select suitable goods for

> the purpose of being incorporated into products intended for human topical application." *Id.* ¶ 62.
>
> g. "Upon information and belief, Aux Sable supplied Aeropres with these ingredients because Aux Sable had entered into a contract to do so with BP Energy, which had agreed to supply Aeropres with these ingredients . . . Thus, it was reasonable for Aux Sable to assume that, if it supplied Aeropres with gaseous component ingredients that were faulty and contaminated with benzene, Aeropres would incorporate such faulty component ingredients into its final product that was sold to Bayer." *Id.* ¶ 102.

111. The allegations in both the *Bayer* Compl. and the *Aeropres* Compl. highlight how Aeropres, Aux Sable, and BP Energy failed as suppliers in the manufacture chain to prevent and timely detect the harmful benzene contamination. Bayer and Aeropres allege that they relied on another party to test and maintain the products to be safe for human application, but no party did so. Thereby, Defendants failed to properly supply, store, and manufacture products that each Defendant knew was destined to be put into products used by humans.

112. The *Bayer* Compl. and the *Aeropres* Compl. further illustrate how Defendants' actions caused the Products to be contaminated, unsaleable, and unsafe to consumers. In fact, Bayer convinced the court in its action that the products Aeropres sold to Bayer, which Bayer went on to use in the Products, were "unreasonably dangerous to Bayer's consumers, according to FDA guidelines." *Bayer v. Aeropres*, ECF No. 32 at 17.

VIII. BENZENE CONTAMINATION RENDERS THE PRODUCTS WORTHLESS

113. As Bayer admits, the levels of benzene contamination in the Products (or the material risk of benzene being in the Products) made them "unreasonably dangerous to Bayer's consumers, according to FDA guidelines" (*Bayer v. Aeropres*, ECF No. 32 at 17), "damaged beyond use or repair" (*Bayer* Compl. ¶ 88), and "unsaleable due to [the] contamination" as such (*id.* ¶ 53).

114. At a minimum, the Products were worth significantly less than what Plaintiffs paid because they contained dangerously high levels of benzene, a known carcinogenic, which made the Products defective, unsafe, and unusable.

115. Bayer stated itself that the Propellant A-31 sold by Aeropres and ultimately incorporated into the Products, "was not fit for the purpose of being incorporated into products intended for human topical application." *Bayer* Compl. ¶ 82. Topical application is the method Bayer instructs consumers to use when applying the Products. Consequently, a contamination making the Product unfit for topical application would make the Product unusable.

116. As OTC drug products regulated by the FDA, the Products must be both safe and effective and are subject to federal current Good Manufacturing Practices ("cGMP") regulations and the FDCA's state-law analogues. These cGMP regulations require OTC medications like the Products to meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(1)(B). Federal and state

regulatory regimes require that labeling for OTC products identify each active and inactive ingredient.[42]

117. 21 C.F.R. § 201.66 establishes labeling requirements for OTC products and defines an inactive ingredient as "any component other than an active ingredient." An "active ingredient" is:

> any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. ***The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form*** intended to furnish the specified activity or effect.

(Emphasis added).

118. 21 C.F.R. § 210.1(a) states that the cGMPs establish:

> minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

119. In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

---

[42] FDA Center for Drug Evaluation and Research, *Guidance for Industry: National Uniformity for Nonprescription Drugs — Ingredient Listing for OTC Drugs* 1 (1998), https://www.fda.gov/media/72250/download.

120. 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.

121. Any drug product not manufactured in accordance with cGMPs is deemed "adulterated" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

122. FDA regulations require a drug product manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

123. A drug product manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug

product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

124. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

125. Defendants disregarded the cGMPs outlined above. If Defendants had not routinely disregarded the FDA's cGMPs, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of the benzene contaminant almost immediately.

126. Further, had Defendants adequately tested the Products for benzene and other carcinogens, reproductive toxins, and impurities, they would have discovered that the Products contained benzene at levels far above the legal limit, making those products ineligible for distribution, marketing, and sale.

127. Defendants' failures described above allowed benzene to be present in the Products. Benzene is a known carcinogenic and thus the Lotrimin and Tinactin products are "adulterated" under the FDCA because they contain a "poisonous or

deleterious substance which may render [the Products] injurious to users. Under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual." 21 U.S.C. § 361(a). In addition, the FDCA deems the Products "adulterated" if they have been "prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been injurious to health." 21 U.S.C. § 361(c).

128. The Products are "misbranded" under the FDCA because their labels do not disclose the presence of benzene, which is an avoidable and unnecessary addition to the Products, rendering them "false" and "misleading." 21 U.S.C. § 362(a).

129. Accordingly, Defendants knowingly, or at least negligently, introduced contaminated, adulterated, and/or misbranded antifungal medications containing dangerous amounts of benzene into the U.S. market.

130. Defendants also knew or should have known about the carcinogenic potential of benzene because it is classified as a Group 1 compound by the World Health Organization and the International Agency for Research on Cancer, thereby defining it as "carcinogenic to humans."

131. Pursuant to 21 U.S.C. § 331(a) of the FDCA, the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded" is categorically prohibited.

Given that the FDA prohibits the sale of adulterated and misbranded products, such products are worthless and have no value.

132. Similarly, the states in which Plaintiffs reside contain food, drug, and cosmetic acts and laws which follow and are consistent with the FDCA, likewise rendering Bayer's sale of "adulterated" and "misbranded" products illegal. The Products, therefore, are worthless and valueless. *See* the Delaware Pure Food and Drug Act, DEL. CODE ANN. tit. 16, § 3301, *et seq.* (*see, e.g.* §§ 3302, 3303); the Indiana Uniform Food, Drug, and Cosmetic Act, IND. CODE § 16-42-1-16(a); the South Carolina Food and Cosmetic Act, S.C. CODE ANN. § 39-25-30; New York Cons. Laws, Education Law (Adulterated and Misbranded Cosmetics) N.Y. EDUC. LAW § 6818.

133. Defendants' failure to control for benzene contamination and sale of its adulterated products constitutes actionable fraud.

134. Plaintiffs and the Class were injured by the full purchase price of the Products because the Products are worthless, as they are adulterated and contain harmful levels of benzene, and Defendants failed to warn consumers of this fact. In other words, Plaintiffs not only would not have paid for the Products but for Defendants' omissions and manufacturing deficiencies, they *could not* have purchased the Products because the Products are adulterated and were illegally sold.

135. In the alternative, had Defendants disclosed the fact the Products contained benzene or were at the material risk of containing the same, Plaintiffs would not have paid as much for the Products as they did. "The logic requires little elaboration: if a product contains a manufacturing flaw so severe that it cannot be used, it is not worth the full price purchasers paid with the understanding they would be able to use all of the product." *Huertas*, 120 F.4th at 1175. Moreover, if a product has an 80% chance of containing a carcinogen, consumers will not pay as much for the product as one that has a 0% chance. Consumers do not play Russian roulette with their health.

136. Plaintiffs and the Class bargained for an antifungal product free of contaminants and dangerous substances and were deprived the basis of their bargain when Defendants manufactured, supplied, and sold them products containing the dangerous substance benzene, which rendered the Products unmerchantable and unfit for use.

137. Plaintiffs and the Class were further deprived of the basis of their bargain because they bargained for products without benzene, as it was not a listed active or inactive ingredient in any of the Defendants' products. The presence of benzene therefore meant the Products were not branded transparently or accurately, and the Product's quality was so reduced due to the contamination so that it made them "unreasonably dangerous to Bayer's consumers, according to FDA guidelines"

(*Bayer v. Aeropres*, ECF No. 32 at 17), "damaged beyond use or repair" (*Bayer* Compl. ¶ 88), and "unsaleable due to [the] contamination" as such (*id.* ¶ 53).

138. As the Products expose consumers to benzene well above the legal limit, the Products are not fit for use by humans. Plaintiffs are further entitled to damages for the injury sustained in being exposed to high levels of acutely toxic benzene.

139. Plaintiffs and members of the Classes were also injured because their exposure to a substance that is a dangerous carcinogen means they will be forced to undergo medical monitoring at considerable expense.

140. Accordingly, Plaintiffs and the Classes seek to recover damages because, *inter alia*, the Products are adulterated, defective, worthless, and unfit for human use due to the presence of benzene, a carcinogenic and toxic chemical impurity and because Plaintiffs and members of the Classes will have to undertake significant monitoring they otherwise would not have to detect the possible development of cancers and other ailments.

IX. THE REFUND OFFERED BY BAYER WAS INADEQUATE TO COMPENSATE CONSUMERS

A. Bayer Required Photographs Of Purchased Recalled Products To Issue Refunds To Limit The Expense Of The Recall

141. Bayer limited the expense of the recall by requiring that individuals (1) visit one of the two websites; (2) fill out the forms presented to them; and

(3) provide a photograph of each product for which consumers seek a refund for. This procedure improperly burdens consumers that have done nothing wrong and does not allow them to collect refunds for Products purchased unless they are able to provide information regarding the purchase *and* provide a photograph of each Product they purchased, even though some of the products are over three years old and were likely discarded.

142. Consumers who could not take photographs of the recalled Products for any reason, including the fact that the product was used and discarded three years ago, were excluded. Consumers were harmed, and deprived of the benefit of the bargain, *at the point of purchase*. By requiring photos of used sprays, Bayer substantially limited compensation to consumers who purchased contaminated recalled Products.

B. The Recall Thus Fails to Adequately Compensate Plaintiffs On A Number Of Levels

143. Taken together, the recall is thus inadequate for at least the following reasons:

a. Bayer did not adequately publicize the refund remedy, such that many consumers were not aware that they could request a refund from Bayer.

b. Bayer has admitted a mere 35,000 consumers submitted a refund request through the recall, out of the hundreds of thousands if not millions who purchased the Products over a three-year span.

c. Bayer claimed in the *Bayer* Action that it refunded $1 million to U.S. customers who purchased the product from stores, and $9 million to stores in the U.S. for lost inventory. Concerningly, this does not align with the likely cost of the over 40 million products subject to the recall.

d. Bayer required consumers to submit a photo of the product, even though the Products are disposable OTC medications that many consumers may no longer have. Thus, the refund remedy excluded innumerable consumers who purchased and used the Products but have no record of the same. This is particularly important given that the contamination extended at least as far back as September 2018, and consumers unlikely had empty bottles of the Products that are three years old.

e. The recall did not promise any changes to Bayer's manufacturing and distribution process to prevent future contamination.

f. The recall did not fully compensate consumers in states like New York, and other states in which Plaintiffs Huertas and Mistretta (and members of the New York Subclasses) reside, where consumers are entitled to statutory damages above the purchase price of the Products under the state's consumer protection laws.

g. It is unknown what criteria Bayer used to determine whether to issue a refund to consumers who purchased the Products.

h. Bayer's notice accompanying the recall downplayed the danger of its Products, and thus the necessity of the recall, by describing the recall as a "precautionary measure and that the levels detected

are not expected to cause adverse health consequences in consumers."[43]

i. Bayer has not compensated consumers for the cost of medical monitoring based on their use of Products contaminated by a known carcinogen.

PLAINTIFFS' ALLEGATIONS

I. JUAN HUERTAS

144. Plaintiff Juan Huertas is a resident of Levittown, New York and has an intent to remain there, and is therefore a citizen of New York. In or about August 2021, Mr. Huertas purchased a canister of Bayer's Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray with the lot number TN009K7 from a CVS in Freeport, New York. Mr. Huertas used the Product as directed on the label.

145. According to Bayer's recall notice, Mr. Huertas's cannister of Lotrimin was recalled because it contained benzene. FDA's enforcement report on Bayer's recall listed the recall reason for lot number TN009K7 as the detection of benzene. As a result of this contamination, Bayer's recall notice instructed that, "[c]onsumers who have the products that are being recalled should stop using."[44]

146. When purchasing the Product, Mr. Huertas reviewed the accompanying labels and disclosures, and he understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Lotrimin was properly

[43] *See* fn. 3, *supra*.

[44] *Id.*

manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. Mr. Huertas relied on these representations and warranties in deciding to purchase the Lotrimin manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin from Defendants if he had known that it was, in fact, not properly manufactured, not free from defects, not safe for its intended use, and not equivalent to Miconazole Nitrate.

147. Mr. Huertas was injured in the following ways as a result of his purchase of Lotrimin:

a. First, Mr. Huertas bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. However, Mr. Huertas received Lotrimin that was not properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate, and was therefore worth less than what Mr. Huertas bargained for. Accordingly, Mr. Huertas overpaid or paid a price premium for the Lotrimin as a result of Defendants' omissions.

b. Second, as a result of the benzene contamination, Mr. Huertas's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless.

c. Third, Mr. Huertas's athlete's foot was still present at the time he had to discard his Lotrimin product, due to the benzene contamination and pursuant to Bayer's recall notice instructions. Mr. Huertas was then forced to buy a replacement product, boric

> acid, to treat his athlete's foot as a result of the benzene contamination in his Lotrimin product. Mr. Huertas would not have purchased this replacement product but for the contamination of his Lotrimin product, which rendered his Product adulterated, misbranded, unsafe to use, and worthless.

II. EVA MISTRETTA

148. Plaintiff Eva Mistretta is a resident of East Elmhurst, New York and has an intent to remain there, and is therefore a citizen of New York. In or about July 2021, Ms. Mistretta purchased a canister of Bayer's Tinactin Athlete's Foot Liquid Spray with the lot number CV01E2X from a Walgreens in Queens, New York. Ms. Mistretta used the Product as directed on the label.

149. According to Bayer's recall notice, Ms. Mistretta's cannister of Tinactin was recalled because it contained benzene. As a result of this contamination, Bayer's recall notice instructed that, "[c]onsumers who have the products that are being recalled should stop using."[45]

150. When purchasing the Product, Ms. Mistretta reviewed the accompanying labels and disclosures, and she understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Tinactin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Tolnaftate. Ms. Mistretta relied on these

[45] *Id.*

representations and warranties in deciding to purchase the Tinactin manufactured by Defendants, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased the Tinactin from Defendants if she had known that it was not, in fact, properly manufactured, free from defects, not safe for its intended use, and not equivalent to Tolnaftate.

151. Ms. Mistretta was injured in the following ways as a result of her purchase of Tinactin:

a. First, Ms. Mistretta bargained for Tinactin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Tolnaftate. However, Ms. Mistretta received Tinactin that was not properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Tolnaftate, and was therefore worth less than what Ms. Mistretta bargained for. Accordingly, Ms. Mistretta overpaid or paid a price premium for the Tinactin as a result of Defendants' omissions.

b. Second, as a result of the benzene contamination, Ms. Mistretta's Tinactin was adulterated, misbranded, illegal to sell, and therefore worthless.

III. MIKE POOVEY

152. Plaintiff Mike Poovey is a resident of Horry County, South Carolina and has an intent to remain there, and is therefore a citizen of South Carolina. Between September 2018 and September 2021, Mr. Poovey purchased multiple canisters of Bayer's Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray in

South Carolina, including at least one with the lot number TN001NK that was subject to the recall. Mr. Poovey used the Product as directed on the label. According to Bayer's recall notice, Mr. Poovey's cannister of Lotrimin was recalled because it contained benzene. As a result of this contamination, Bayer's recall notice instructed that, "[c]onsumers who have the products that are being recalled should stop using."[46]

153. For each product he purchased, Mr. Poovey reviewed the accompanying labels and disclosures, and he understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the Lotrimin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. Mr. Poovey relied on these representations and warranties in deciding to purchase the Lotrimin manufactured by Defendant, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin from Defendants if he had known that it was not, in fact, properly manufactured, free from defects, not safe for its intended use, and not equivalent to Miconazole Nitrate.

154. Mr. Poovey was injured in the following ways as a result of his purchase of Lotrimin:

a. First, Mr. Poovey bargained for Lotrimin that was properly manufactured, free from defects, safe for

[46] *Id.*

its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate. However, Mr. Poovey received Lotrimin that was not properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate, and was therefore worth less than what Mr. Poovey bargained for. Accordingly, Mr. Poovey overpaid or paid a price premium for the Lotrimin as a result of Defendants' omissions.

b. Second, as a result of the benzene contamination, Mr. Poovey's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless.

IV. DARRELL STEWART

155. Plaintiff Darrell Stewart is a resident of Lewes, Delaware and has an intent to remain there, and is therefore a citizen of Delaware. During the Class Period, Mr. Stewart purchased:

a. Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray;

b. Lotrimin Anti-Fungal Jock Itch (AFJI) Powder Spray; Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray;

c. Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray; Tinactin Athlete's Foot Deodorant Powder Spray;

d. Tinactin Athlete's Foot Powder Spray; and

e. Tinactin Athlete's Foot Liquid Spray.

156. Upon information and belief, Mr. Stewart purchased products that were manufactured in the same facility as those Products subject to the recall and during

the recall period. Bayer's recall notice instructed that, "[c]onsumers who have the products that are being recalled should stop using."[47]

157. When purchasing the Products, Mr. Stewart reviewed the accompanying labels and disclosures, and he understood them as representations and warranties by the manufacturers, distributors, and pharmacy that the Lotrimin and Tinactin were properly manufactured, free from defects, safe for its intended use, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate, respectively. Mr. Stewart relied on these representations and warranties in deciding to purchase the Lotrimin and Tinactin manufactured and sold by Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin and Tinactin from Defendants if he had known that it was not, in fact, properly manufactured, free from defects, not safe for its intended use, and not equivalent to Miconazole Nitrate and Tolnaftate.

158. Mr. Stewart was injured in the following ways as a result of his purchase of Lotrimin and Tinactin:

a. First, Mr. Stewart bargained for Lotrimin and Tinactin that were properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. However, Mr. Stewart received Lotrimin and Tinactin that were not

[47] *Id.*

properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate, and were therefore worth less than what Mr. Stewart bargained for. Accordingly, Mr. Stewart overpaid or paid a price premium for the Lotrimin and Tinactin as a result of Defendants' omissions.

b. Second, as a result of the benzene contamination, Mr. Stewart Products were adulterated, misbranded, illegal to sell, and therefore worthless.

V. JEREMY WYANT

159. Plaintiff Jeremy Wyant is a resident of Clinton County, Indiana and has an intent to remain there, and is therefore a citizen of Indiana.

160. Between September 2018 and September 2021, Mr. Wyant purchased canisters of Defendant's Products in Indiana, including (i) Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray, (ii) Tinactin Jock Itch (JI) Powder Spray with the lot number TN00273, (iii) Tinactin Athlete's Foot Powder Spray, and (iv) Tinactin Athlete's Foot Liquid Spray. Mr. Wyant used the Products as directed on the labels.

161. According to Bayer's recall, Mr. Wyant's cannisters of the Products were recalled because they contained benzene. As a result of this contamination,

Bayer's recall notice instructed that, "[c]onsumers who have the products that are being recalled should stop using."[48]

162. When purchasing the Products, Mr. Wyant reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the Products were properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Miconazole Nitrate and Tolnaftate. Mr. Wyant relied on these representations and warranties in deciding to purchase the Products manufactured by Defendant, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Products from Defendant if he had known that they were not, in fact, properly manufactured, free from defects, safe for their intended uses, and not equivalent to Miconazole Nitrate and Tolnaftate.

163. Mr. Wyant was injured in the following ways as a result of his purchase of the Products:

a. First, Mr. Wyant bargained for Lotrimin and Tinactin that were properly manufactured, free from defects, safe for their intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate and Tolnaftate. However, Mr. Wyant received Lotrimin and Tinactin that were ***not*** properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents

[48] *Id.*

of uncontaminated Miconazole Nitrate and Tolnaftate, and were therefore worth less than what Mr. Wyant bargained for. Accordingly, Mr. Wyant overpaid or paid a price premium for the Tinactin as a result of Defendants' omissions.

b. Second, as a result of the benzene contamination, Mr. Wyant's Products were adulterated, misbranded, illegal to sell, and therefore worthless.

NOTICE OF CLAIMS TO AUX SABLE AND BP ENERGY

164. The initial complaint in this action was filed on November 16, 2021.

165. Starting in July 2021 and ending December 2022, Aeropres sent multiple letters to BP Energy and Aux Sable, demanding defense and indemnification and informing them of the tests detecting benzene in the materials BP Energy and Aux Sable supplied to Aeropres.

166. The aforementioned indemnification letters put BP Energy and Aux Sable on notice as to their liability in the ongoing action around the recalled Products within 120 days of the initial complaint filing.

167. BP Energy and Aux Sable had sufficient notice to not be prejudiced in defending against the claims herein.

168. In addition, Plaintiffs and the Class Members did not know, or have reason or means to know, of BP Energy's and Aux Sable's conduct that contributed to the benzene contamination prior to the filing of the Aeropres Action.

169. BP Energy and Aux Sable knew or had reason to know that, but for Plaintiffs' and Class Members' lack of knowledge to identify their involvement in the contamination, BP Energy and Aux Sable would have been named in the original action.

170. For these reasons, the amendments made to named Defendants fulfill the requirements pursuant to Federal Rule of Civil Procedure 15(c)(1)(C) and relate back to the original pleading.

CLASS ACTION ALLEGATIONS

171. Plaintiffs Huertas, Poovey, Stewart, and Wyant seek to represent a class defined as:

> All persons in the United States who purchased the following Lotrimin spray products between September 2018 and September 2021 and whose Lotrimin product has a lot number encompassed by the recall or was manufactured at the same facility as the recalled products during the relevant time, including: (1) Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray; (2) Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray; (3) Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray; (4) Lotrimin AF Athlete's Foot Liquid Spray; (5) Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray (the "Lotrimin Class").

172. Plaintiffs Mistretta, Stewart, and Wyant seek to represent a class defined as:

> All persons in the United States who purchased the following Tinactin spray products between September

2018 and September 2021 and whose Tinactin product has a lot number encompassed by the recall or was manufactured at the same facility as the recalled products during the relevant time: (1) Tinactin® Jock Itch (JI) Powder Spray; (2) Tinactin® Athlete's Foot Deodorant Powder Spray; (3) Tinactin® Athlete's Foot Powder Spray; and (4) Tinactin® Athlete's Foot Liquid Spray (the "Tinactin Class") (collectively with the Lotrimin Class, the "Nationwide Classes").

173. Plaintiff Huertas also seeks to represent the following subclass: All Lotrimin Class members who purchased the Lotrimin products in New York (the "Lotrimin New York Subclass").

174. Plaintiff Poovey also seeks to represent the following subclass: All Lotrimin Class members who purchased the Lotrimin products in South Carolina (the "Lotrimin South Carolina Subclass").

175. Plaintiff Stewart also seeks to represent the following subclass: All Lotrimin Class members who purchased the Lotrimin products in Delaware (the "Lotrimin Delaware Subclass").

176. Plaintiff Wyant also seeks to represent the following subclass: All Lotrimin Class members who purchased the Lotrimin products in Indiana (the "Lotrimin Indiana Subclass").

177. Plaintiff Mistretta also seeks to represent the following subclass: All Tinactin Class members who purchased the Tinactin products in New York (the "Tinactin New York Subclass").

178. Plaintiff Stewart also seeks to represent the following subclass: All Tinactin Class members who purchased the Tinactin products in Delaware (the "Tinactin Delaware Subclass").

179. Plaintiff Wyant also seeks to represent the following subclass: All Tinactin Class members who purchased the Tinactin products in Indiana (the "Tinactin Indiana Subclass").

180. The various state subclasses shall be collectively referred to as the "Subclasses."

181. The Nationwide Classes and the Subclasses shall collectively be referred to as the "Classes."

182. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Classes may be expanded or narrowed by amendment to the complaint or narrowed at class certification.

183. Specifically excluded from the Classes are Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and Defendants' heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

184. **Numerosity.** The members of the proposed Classes are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are hundreds of thousands, if not millions, of individuals that are members of the proposed Classes. Although the precise number of proposed members are unknown to Plaintiffs, the true number of members of the Classes is known by Defendants. Members of the Classes 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.

185. **Typicality.** The claims of the representative Plaintiffs are typical of the claims of the Classes in that the representative Plaintiffs, like all members of the Classes, purchased the Products, which were worthless due to the presence of benzene, a harmful and carcinogenic chemical impurity, and were forced to discard the remainder of their Products due to this contamination. The representative Plaintiffs, like all members of the Classes, have been damaged by Defendants' misconduct in the very same way as the members of the Classes. Further, the factual bases of Defendants' misconduct are common to all members of the Classes and represent a common thread of misconduct resulting in injury to all members of the Classes.

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

a. whether the Products contain, or had a material risk of containing, benzene;

b. whether Defendants knew or should have known that the Products and their ingredients contained, or had a material risk of containing, benzene;

c. whether Defendants had a duty to disclose, and wrongfully failed to disclose, that the Products and their ingredients contained, or had a material risk of containing, benzene;

d. whether Defendants misrepresented and/or wrongfully failed to disclose materials facts in connection with the manufacturing, packaging, labeling, marketing, advertising, distribution, and sale of the Products;

e. whether representations and omissions from Bayer in connection with the labeling of Products were likely to mislead, deceive, confuse or confound consumers acting reasonably;

f. whether Bayer represented to consumers that the Products have characteristics, benefits, or qualities that they do not have;

g. whether Defendants had inadequate testing and safety standards, and had a duty to disclose, and wrongfully failed to disclose same;

h. whether Defendants had knowledge that the representations and omissions in connection with the Products were false, deceptive and misleading;

i. whether Bayer breached express and/or implied warranties;

j. whether Defendants engaged in fraudulent, deceptive, misleading, unlawful, and/or unfair trade practices;

k. whether Bayer made fraudulent and/or negligent misrepresentations and/or omissions, and/or engaged in fraudulent concealment;

l. whether Plaintiffs and members of the Classes are entitled to actual, statutory, and/or punitive damages;

m. whether Bayer unjustly retained benefits;

n. whether Bayer is liable to Plaintiffs and the Classes for unjust enrichment;

o. whether Bayer is liable to Plaintiffs and the Classes for fraud;

p. whether Plaintiffs and the Classes have sustained monetary loss and the proper measure of that loss;

q. whether Plaintiffs and the Classes are entitled to declaratory and injunctive relief; and

r. whether Plaintiffs and the Classes are entitled to restitution and disgorgement from Defendants.

187. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Classes. Plaintiffs have retained counsel who are highly experienced in complex consumer class action litigation, and Plaintiffs intend to

vigorously prosecute this action on behalf of the Classes. Plaintiffs have no interests that are antagonistic to those of the Classes.

188. **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 members of the Classes are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for members of the Classes, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Classes 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.

189. In the alternative, the Classes may be certified because:

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

b. the prosecution of separate actions by individual members of the Classes would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other members of the Classes 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 Classes as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

CAUSES OF ACTION

COUNT I
Breach of Express Warranty
(Against Defendant Bayer on Behalf of All Plaintiffs and Classes)

190. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

191. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Defendant Bayer.

192. In connection with the sale of the Products, Defendant Bayer, as the designer, manufacturer, marketer, distributor, and/or seller, issued written warranties by representing that the Products were antifungal medications that contained only those active and inactive ingredients listed on the Products' labels and were safe and appropriate for human use. Those active and inactive ingredients listed on the Products' labels do not include benzene, a known human carcinogen dangerous to

humans. Bayer further expressly warranted that the Products are antifungal medications used for the treatment of certain infections and are equivalent to the formulation of the Products as approved by the FDA, rather than adulterated antifungal products containing dangerous chemicals that are not equivalent to their generic forms. Further, Bayer expressly warranted that the Products were the brand-name equivalents of Miconazole Nitrate and Tolnaftate. Finally, Bayer provided instructions for repeated daily use for a period of weeks.

193. Bayer made these express warranties regarding the Products' quality and fitness for use in writing through its website, advertisements, marketing materials, and on the Products' packaging and labels. These express warranties became part of the basis of the bargain that Plaintiffs and the Classes entered upon purchasing the Products. The affirmations of fact and/or promises became part of the basis of the bargain, and the contract, that Plaintiffs and the Classes entered into with Bayer upon purchasing the Products.

194. Bayer's advertisements, warranties, and representations were made in connection with the sale of the Products to Plaintiffs and the Classes. Plaintiffs and the Classes relied on Bayer's advertisements, warranties, and representations regarding Bayer Products in deciding whether to purchase Bayer's products.

195. Bayer's Products do not conform to Bayer's affirmations of fact and promises, in that they are not safe, healthy, and appropriate for human use.

196. Bayer therefore breached its express warranties by placing Products into the stream of commerce and selling them to consumers, when their use had dangerous effects and was unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Bayer. These associated health effects substantially impair the use, value, and safety of the Bayer Products.

197. Bayer was aware, or should have been aware, of the presence of the human carcinogen benzene in the Bayer Products and therefore was aware or should have been aware of the toxic or dangerous health effects of the use of the Bayer Products, but nowhere on the package labeling, on Bayer's websites, or other marketing materials did Bayer warn Plaintiffs and members of the Classes of the presence of benzene, or risk of benzene, in the Bayer Products or the dangers it posed.

198. Instead, Bayer concealed the presence of benzene in the Bayer Products and deceptively represented that the Bayer Products were safe, healthy, and appropriate for human use. Bayer thus utterly failed to ensure that the material representations it was making to consumers were true.

199. Benzene was present in the Bayer Products when they left Bayer's possession or control and were sold to Plaintiffs and members of the Classes. The

dangers associated with use of the Bayer Products were undiscoverable by Plaintiffs and members of the Classes at the time of purchase of the Products.

200. Bayer is the manufacturer, marketer, advertiser, distributor, labeler, and seller of the Bayer Products and thus had exclusive knowledge and notice of the fact that the Bayer Products did not conform to the affirmations of fact and promises.

201. In addition, or in the alternative, to the formation of an express contract, Bayer made each of the above-described representations to induce Plaintiffs and members of the Classes to rely on such representations.

202. Bayer's affirmations of fact and promises were material, and Plaintiffs and members of the Classes reasonably relied upon such representations in purchasing the Bayer Products.

203. All conditions precedent to Bayer's liability for its breach of express warranty have been performed by Plaintiffs and members of the Classes.

204. As a direct and proximate cause of Bayer's breach of express warranty, Plaintiffs and the Classes have been injured and harmed because they did not receive the Products as warranted by Bayer and would not have purchased the Products on the same terms if they knew that the Products contained benzene, are not generally recognized as safe, and are not equivalent to their generic forms.

205. On or about November 12, 2021, November 17, 2021, August 9, 2023, and August 15, 2023 prior to filing this complaint, Defendant Bayer was served with

pre-suit notice letters on behalf of Plaintiffs (and applicable Classes) that complied in all respects with U.C.C. §§ 2-313 and 2-607 and 6 Del. C. §§ 2-313 and 2-607. Plaintiffs' counsel sent Defendant Bayer a letter advising Bayer that it breached an express warranty and demanded that Bayer cease and desist from such breaches and make full restitution by refunding the monies received therefrom. True and correct copies of Plaintiffs' counsel's letters are attached hereto as **Exhibit 1**.

206. Plaintiffs and the Classes seek all applicable damages, declaratory relief, injunctive relief, and all other just and proper relief based on Bayer's breaches of express warranty.

COUNT II
Breach of Implied Warranty
(Against Defendant Bayer on Behalf of All Plaintiffs and the Classes)

207. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

208. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Defendant Bayer.

209. Plaintiffs and the Classes are consumers who purchased the Products manufactured, marketed, and sold by Bayer throughout the United States.

210. An implied warranty that the Products were merchantable arose by operation of law as part of the sale of the Products.

211. Bayer, as the designer, manufacturer (until at least mid-2019), marketer, distributor, and/or seller, impliedly warranted that the Products (i) would not contain elevated levels of benzene; and (ii) are generally recognized as safe for human use and were of merchantable quality and fit for their ordinary and intended use.

212. Bayer breached the warranty implied in the contract for the sale of the defective Products because they could not pass without objection in the trade under the contract description, the Products were not of fair or average quality within the description, and the Products were unfit for their intended and ordinary purpose because the Products manufactured, distributed, and sold by Bayer were defective in that they contained elevated levels of carcinogenic and toxic benzene, and as such are not generally recognized as safe for human use. As a result, Plaintiffs and members of the Classes did not receive the goods as impliedly warranted by Bayer to be merchantable.

213. Bayer had exclusive knowledge of the material facts concerning the defective nature of the Products.

214. Plaintiffs and members of the Classes purchased the Products in reliance upon Bayer's skill and judgment and the implied warranties of fitness for the purpose.

215. Benzene existed in the Products when the Products left Bayer's possession or control and were sold to Plaintiffs and members of the Classes. The

presence of benzene in the Products was undiscoverable by Plaintiffs and members of the Classes at the time of their purchases.

216. The Products were not altered by Plaintiffs or members of the Classes.

217. The Products were defective when they left the exclusive control of Bayer.

218. Bayer knew or had reason to know of the specific use for which the Products were purchased, and that the Products would be purchased and used without additional testing by Plaintiffs and members of the Classes.

219. Privity exists because Bayer impliedly warranted to Plaintiffs and members of the Classes through the warranting, packaging, advertising, marketing, and labeling that Products were safe and suitable for use and made no mention of the attendant health risks associated with use of the Products.

220. Further, Plaintiffs and members of the Classes were at all material times the intended third-party beneficiaries of Bayer and its agents in the distribution of the sale of its Products. Bayer exercises substantial control over the outlets that sell the Products, which are the same means by which Plaintiffs and members of the proposed Classes purchased the Products. Bayer's warranties are not intended to apply to distributors but are instead intended to apply to consumers, including Plaintiffs and members of the proposed Classes, to whom Bayer directly markets through labels and product packaging, and who review the labels and product

packaging in connection with their purchases. As a result, the warranties are designed and intended to benefit the consumers, including Plaintiffs and members of the proposed Classes, who purchase the Products. Privity therefore exists based on the foregoing and because Bayer impliedly warranted to Plaintiffs and members of the proposed Classes through the packaging that the Products were safe and suitable for human use.

221. The Products were defectively manufactured and unfit for their intended purpose, and Plaintiffs and members of the Classes did not receive the goods as warranted.

222. As a direct and proximate cause of Bayer's breach of the implied warranty, Plaintiffs and members of the Classes have been injured and harmed because: (a) they would not have purchased the Products on the same terms if they knew that the Products contained harmful levels of benzene, and are not generally recognized as safe for human use; and (b) the Products do not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

223. On or about November 12, 2021, November 17, 2021, August 9, 2023, and August 15, 2023, prior to filing this complaint, Defendant Bayer was served with pre-suit notice letters on behalf of Plaintiffs (and applicable Classes) that complied in all respects with U.C.C. §§ 2-314 and 2-607 and 6 Del. C. §§ 2-314 and 2-607. Plaintiffs' counsel sent Defendant Bayer a letter advising Bayer that it breached an

implied warranty and demanded that Bayer cease and desist from such breaches and make full restitution by refunding the monies received therefrom. True and correct copies of Plaintiffs' counsel's letters are attached hereto as **Exhibit 1**.

224. Plaintiffs and the Classes seek all applicable damages, declaratory relief, injunctive relief, and all other just and proper relief based on Bayer's breaches of implied warranty.

COUNT III
Fraud
(Against Defendant Bayer on Behalf of All Plaintiffs and the Classes)

225. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

226. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Defendant Bayer.

227. Bayer committed both fraudulent misrepresentation and fraudulent omission. Specifically, Bayer (i) misrepresented that the Products were the brand-name equivalents of Miconazole Nitrate and Tolnaftate when they were not, (ii) failed to disclose the presence of benzene (or material risk of the same) in the Products, and (iii) failed to disclose the Products were not properly manufactured, which resulted in the benzene contamination.

228. Bayer had a duty to disclose material facts to Plaintiffs and the Classes given their relationship as contracting parties and intended users of the Products.

Bayer also had a duty to disclose material facts to Plaintiffs and the Classes, namely that it was in fact manufacturing, distributing, and selling harmful products unfit for human use, because Bayer had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

229. Bayer knew or should have known that the Products were contaminated with benzene but continued to manufacture them, nonetheless. Bayer was required to engage in impurity testing to ensure that harmful impurities such as benzene were not present in the Products. Had Bayer undertaken proper testing measures, it would have been aware that the Products contained dangerously high levels of benzene. Further, Bayer's recall stretches back to September 2018, meaning Bayer has known or should have known its Products were contaminated with benzene for years. During this time, Plaintiffs and members of the Classes were using the Products without knowing they contained dangerous levels of benzene.

230. Bayer failed to discharge its duty to disclose these material facts.

231. In so failing to disclose these material facts to Plaintiffs and the Classes, Bayer intended to hide from Plaintiffs and the Classes that they were purchasing and using the Products with harmful defects that were unfit for human use and thus acted with scienter and/or an intent to defraud.

232. Plaintiffs and the Classes reasonably relied on Bayer's failure to disclose insofar as they would not have purchased the defective Products

manufactured and sold by Bayer had they known they contained unsafe levels of benzene.

233. As a direct and proximate cause of Bayer's fraud and fraudulent concealment, Plaintiffs and the Classes suffered damages in the amount of monies paid for the defective Products and other damages, including the need for medical monitoring, attorneys' fees, and costs.

234. As a result of Bayer's willful and malicious conduct, punitive damages are warranted.

COUNT IV
Unjust Enrichment
(Against Defendant Bayer on Behalf of All Plaintiffs and the Classes)

235. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

236. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Bayer.

237. Plaintiffs and the Classes conferred a benefit on Bayer in the form of monies paid to purchase Bayer's defective and worthless Products.

238. Bayer knowingly and voluntarily accepted and retained this benefit.

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

240. As a direct and proximate result, Plaintiffs and the Classes are entitled to recover from Bayer all amounts wrongfully collected and improperly retained by Bayer, plus interest.

241. Plaintiffs and the Classes seek restitution, disgorgement, imposition of a constructive trust, all appropriate declaratory and injunctive relief, and any other just and proper relief available.

COUNT V
Negligent Misrepresentation
(Against Defendant Bayer on Behalf of All Plaintiffs and the Classes)

242. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

243. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Defendant Bayer.

244. Bayer had a duty to Plaintiffs and the Classes to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of Products.

245. Bayer breached its duty to Plaintiffs and the Classes by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiffs and the Classes that did not have the qualities, characteristics, and suitability for use as advertised by Bayer and by failing to promptly remove Products

from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Products.

246. Bayer knew or should have known that the qualities and characteristics of the Products were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Bayer, yet continued selling the Products.

247. Specifically, Bayer knew or should have known that: (1) the manufacturing process used to produce the Products resulted in the presence of benzene in the Products; and (2) the Products were otherwise not as warranted and represented by Bayer.

248. As a direct and proximate result of Bayer's conduct, Plaintiffs and the Classes have suffered actual damages in that they purchased Products that were worth less than the price they paid and that they would not have purchased at all had they known they contained the carcinogen benzene that is known to cause the benzene-caused cancers, which does not conform to the Products' labels, packaging, advertising, and statements.

249. Plaintiffs and the Classes also suffered actual damages in that they were forced to discard the leftover portions of their contaminated Products and/or purchase replacement products upon learning of the contamination in the Products.

250. Plaintiffs and the Classes seek actual and all applicable damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available.

COUNT VI
Violation of the New Jersey Consumer Fraud Act,
N.J. Stat. §§ 56:8-1, *et seq.*
(Against Defendant Bayer on Behalf of All Plaintiffs and the Classes)

251. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

252. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Defendant Bayer.

253. The New Jersey Consumer Fraud Act, N.J. Stat. §§ 56:8-1 ("NJCFA") prohibits any:

> act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise.

See N.J. Stat. § 56:8-2.

254. At all relevant times, Plaintiffs, members of the Classes, and Bayer were "persons" within the meaning of the NJCFA. *See* N.J. Stat. § 56:8-1(d).

255. Bayer willfully and purposefully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of

material facts they intended others to rely upon in connection with the sale of the merchandise as defined by N.J. Stat. § 56:8-1(c) in violation of N.J. Stat. § 56:8-2 as described in the allegations above.

256. Bayer's misrepresentations and omissions in the sale of the Products detailed above were acts or practices in the conduct of trade or commerce.

257. Bayer's misrepresentations and omissions in the sale of the Products detailed above impact the public interest.

258. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair because they inequitably enriched Bayer at the expense of Plaintiffs and members of the Classes.

259. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair because they offended public policy and were so oppressive that Plaintiffs and members of the Classes had little alternative but to submit, which caused consumers substantial injury.

260. Bayer's misrepresentations and omissions in the sale of the Products were unfair in that they violated the well-established public policies of protecting consumers from avoidable dangers and that the manufacturer of products is responsible for ensuring that they are fit for human use.

261. Plaintiffs and members of the Classes have suffered ascertainable loss as a direct and proximate result of Bayer's conduct because (i) Plaintiffs and

members of the Classes did not receive Products that were properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Miconazole Nitrate and Tolnaftate, and were therefore worth less than what Plaintiffs and members of the Classes' bargained for, (ii) as a result of the benzene contamination, Plaintiffs' and members of the Classes' Products were adulterated, misbranded, illegal to sell, and therefore worthless, and (iii) Plaintiffs and members of the Classes were forced to discard the remaining portion of their contaminated Products and/or purchase a replacement product as a result of the contamination, which made the Products unusable.

262. As a direct and proximate result of the foregoing acts and practices, Bayer has received, or will receive, income, profits, and other benefits which it would not have received if it had not engaged in the violations described in this Complaint.

263. As a result, Plaintiffs and members of the Classes seek relief including, *inter alia*, refund of amounts recovered by Bayer for the Products, injunctive relief, damages, treble damages, attorney's fees, and costs pursuant to N.J. Stat. §§ 56:8-2.11 and 56:8-19.

COUNT VII
Violation of New York General Business Law § 349
(Against All Defendants on Behalf of Plaintiffs Huertas and Mistretta and the New York Subclasses)

264. Plaintiffs incorporate by reference and re-allege numbered paragraphs

1–188 as though fully set forth herein.

265. Plaintiffs Huertas and Mistretta bring this individually and on behalf of the members of the Lotrimin New York Subclass and Tinactin New York Subclass (collectively, the "New York Subclasses") against Defendants.

266. New York General Business Law ("GBL") § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

267. In its sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of GBL § 349.

268. Plaintiffs Huertas and Mistretta and members of the New York Subclasses are consumers who purchased the Products from and manufactured by Defendants for their personal use.

269. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, failing to disclose that the Products (i) contained or risked containing dangerously high levels of benzene, (ii) are generally recognized as safe for human use, (iii) were properly manufactured, and (iv) are equivalent to the formulation of the Products as approved by the FDA (i.e., that the Products are the brand name equivalents of Miconazole Nitrate and Tolnaftate).

270. Had Plaintiffs Huertas and Mistretta and members of the New York Subclasses been apprised of these facts, they would have been aware of them and

would not have paid for the Products at all, or would have paid substantially less for the Products than they did. In other words, Plaintiffs Huertas and Mistretta and members of the New York Subclasses overpaid or paid a price premium for the Products as a result of Defendants' omissions.

271. The foregoing deceptive acts and practices were directed at consumers.

272. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the Products to induce consumers to purchase the same. No reasonable consumer would knowingly purchase an antifungal product that may contain high levels of a known carcinogen and reproductive toxin and that was illegal to purchase or sell.

273. By reason of this conduct, Defendants engaged in deceptive conduct in violation of GBL § 349.

274. The actions of Defendants are the direct, foreseeable, and proximate cause of the damages that Plaintiffs Huertas and Mistretta and members of New York Subclasses have sustained from having paid for and used Bayer's products, which were rendered unusable due to the presence of benzene. Further, Plaintiffs Huertas and Mistretta and members of the New York Subclasses were injured because, *inter alia*, they were forced to discard the remainder of their contaminated Products and/or buy a replacement product.

275. As a result of Defendants' violations, Plaintiffs Huertas and Mistretta and members of the New York Subclasses have suffered damages because: (a) they paid a premium price based on Bayer's material omissions; (b) the Products do not have the characteristics, uses, benefits, or qualities as promised; and (c) Plaintiffs Huertas and Mistretta and members of the New York Subclasses were forced to discard the remainder of their contaminated Products and/or buy a replacement product.

276. On behalf of themselves and other members of the New York Subclasses, Plaintiffs Huertas and Mistretta seek to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT VIII
Violation of New York General Business Law § 350
(Against All Defendants on Behalf of Plaintiffs Huertas and Mistretta and the New York Subclasses)

277. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

278. Plaintiffs Huertas and Mistretta bring this claim individually and on behalf of the members of the New York Subclasses against Defendants.

279. GBL § 350 prohibits "[f]alse advertising in the conduct of any business, trade, or commerce." N.Y. Gen. Bus. Law § 350.

280. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect." N.Y. Gen. Bus. Law § 350-a(1).

281. Based on the foregoing, Defendants engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of GBL § 350.

282. Defendants knew consumers, such as Plaintiffs Huertas and Mistretta and members of the New York Subclasses, were purchasing the Products for personal use. Defendants therefore had a duty to ensure the gas feedstock supplied by Aux Sable and BP Energy, and the Propellant A-31 supplied by Aeropres and used by the Beiersdorf and Bayer Defendants in the manufacture of the Products, did not contain carcinogens such as benzene. Defendants also had a duty to ensure the finished Products did not contain carcinogens such as benzene.

283. Defendants thus omitted material facts regarding the true nature of the Products, specifically that the Products contained dangerous levels of benzene, were adulterated, were not properly manufactured, and were unsafe for use as antifungal medications. Had Plaintiffs Huertas and Mistretta and members of the New York Subclasses been apprised of these facts, they would have been aware of them and would not have paid as much for the Products as they did. In other words, Plaintiffs

Huertas and Mistretta and members of the New York Subclasses overpaid or paid a price premium for the Products as a result of Defendants' omissions.

284. As a result of Defendants' omissions of material of fact, Plaintiffs Huertas and Mistretta and members of the New York Subclasses have suffered and continue to suffer economic injury.

285. As a result of violations by Defendants, Plaintiffs Huertas and Mistretta and members of the New York Subclasses have suffered damages due to said violations because: (a) they paid a premium price for the Products based on Defendants' material omissions; (b) the Products do not have the characteristics, uses, benefits, or qualities as promised; and (c) Plaintiffs Huertas and Mistretta and members of the New York Subclasses were forced to discard the remainder of their contaminated Products and/or buy a replacement product.

286. On behalf of themselves and other members of the New York Subclasses, Plaintiffs Huertas and Mistretta seek to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IX
Violation of the Indiana Deceptive Consumer Sales Act,
Ind. Code §§ 24-5-0.5-0.1, *et seq.*
(Against Defendants Aeropres, Bayer, and the Beiersdorf Defendants on Behalf of Plaintiff Wyant and the Indiana Subclasses)

287. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

288. Plaintiff Wyant brings this claim individually and on behalf of the members of the Lotrimin Indiana Subclass and Tinactin Indiana Subclass (collectively, the "Indiana Subclasses") against Aeropres, Bayer, and the Beiersdorf Defendants.

289. Plaintiff Wyant, the Indiana Subclasses, Defendants Aeropres, Bayer, and the Beiersdorf Defendants are each a "person" as defined by Ind. Code § 24-5-0.5-2(a)(2).

290. Defendants Aeropres, Bayer, and the Beiersdorf Defendants are each a "supplier" as defined by Ind. Code § 24-5-0.5-2(a)(3).

291. The sale of Products by Bayer, as supplied and manufactured by Aeropres and the Beiersdorf Defendants, to Plaintiff Wyant and members of the Indiana Subclasses, as well as purchases of the recalled Products by Plaintiff Wyant and the Indiana Subclasses, constitute "consumer transactions" as that term is defined at Ind. Code § 24-5-0.5-2(a)(1).

292. As suppliers of the Products sold by Bayer, Defendant Aeropres and the Beiersdorf Defendants engaged in unfair and deceptive acts in violation of the Indiana Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1, *et seq.* ("IDCSA"), by the practices described above, and by knowingly and intentionally concealing the true nature of the Products from Plaintiff Wyant and members of the Indiana Subclasses. These acts and practices violate, *inter alia*, the following sections of the IDCSA:

a. Ind. Code § 24-5-0.5-3(b)(1): a supplier representing, whether orally, in writing, or by electronic communication, that such subject of a consumer transaction has sponsorship, approval, performance, characteristics, accessories, uses, or benefits it does not have which the supplier knows or should reasonably know it does not have, because the Propellant A-31 and the Products contained benzene and was unsafe for use; and

b. Ind. Code § 24-5-0.5-3(b)(2): a supplier representing, whether orally, in writing, or by electronic communication, that such subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not and if the supplier knows or should reasonably know that it is not, because the Propellant A-31 and the Products contained benzene and was unsafe for use.

293. The unfair or deceptive acts or practices done by Aeropres, Bayer, and the Beiersdorf Defendants occurred repeatedly in their trade or business and were capable of deceiving the purchasing public.

294. Aeropres, Bayer, and the Beiersdorf Defendants knew or should have known that the Products contained unsafe levels of the carcinogen benzene, making them susceptible to failure for their essential purpose, and that they would become useless and worthless as a result of reasonable and foreseeable use by consumers.

295. Aeropres, Bayer, and the Beiersdorf Defendants each owed a duty to Plaintiff Wyant and the Indiana Subclasses to disclose the presence of benzene in the recalled Products as well as the dangers posed by the benzene in the recalled Products because:

a. Aeropres, Bayer, and the Beiersdorf Defendants were each in a superior position to know the true state of facts about the defect within the recalled Products;

b. Plaintiff Wyant and Indiana Subclasses could not reasonably have been expected to learn or discover that the recalled Products contained the carcinogen benzene and thus were not in accordance with the advertisements and representations made by Aeropres, Bayer, and the Beiersdorf Defendants;

c. Aeropres, Bayer, and the Beiersdorf Defendants knew that Plaintiff Wyant and the Indiana Subclasses could not reasonably have been expected to learn or discover the presence of, or dangers posed by, the dangerous levels of benzene in the recalled Products; and

d. Aeropres, Bayer, and the Beiersdorf Defendants actively concealed and failed to disclose the presence of and dangers posed by the levels of benzene within the Recalled Sprays from Plaintiff Wyant and the Indiana Subclasses.

296. By failing to disclose the presence of and dangers posed by the benzene in the Products at the time of sale, Aeropres, Bayer, and the Beiersdorf Defendants knowingly and intentionally concealed material facts and breached their duty not to do so.

297. The facts that Aeropres, Bayer, and the Beiersdorf Defendants concealed or did not disclose to Plaintiff Wyant and the Indiana Subclasses are material in that a reasonable consumer would have considered them to be important in deciding whether to purchase the recalled Products. Had Plaintiff Wyant and members of the Indiana Subclasses known of the presence of benzene in the Products and the dangers it posed, and that the Products were not the brand-name equivalents of Miconazole Nitrate and Tolnaftate, they would not have purchased the recalled Products or would have paid less for the recalled Products. Indeed, Plaintiff Wyant and members of the Indiana Subclasses could not have purchased the Products had this fact been properly represented or disclosed because the presence of benzene renders the Products adulterated, misbranded, and illegal to sell.

298. Plaintiff Wyant's and members of the Indiana Subclasses' injuries were proximately caused by the fraudulent, unfair, and deceptive business practices of Aeropres, Bayer, and the Beiersdorf Defendants.

299. Plaintiff Wyant provided notice of his claims (to the extent notice was required) to Aeropres and the Beiersdorf Defendants on or about August 9, 2023 by

mailing a letter via certified mail, return receipt requested to Aeropres and the Beiersdorf Defendants. True and correct copies of the letters are attached hereto as **Exhibit 2** and **Exhibit 3**. Because Aeropres and the Beiersdorf Defendants did not cure within 30 days, their conduct is "uncured." Therefore, Plaintiff Wyant and members of the Indiana Subclasses are entitled to damages and equitable relief under the IDCSA.

300. Alternatively, the violations of Aeropres, Bayer, and the Beiersdorf Defendants were willful and were done as part of a scheme, artifice, or device with intent to defraud or mislead, and therefore are incurable deceptive acts or omissions under the IDCSA.

301. The IDCSA provides that "[a] person relying upon an uncured or incurable deceptive act may bring an action for the damages actually suffered as a consumer as a result of the deceptive act or five hundred dollars ($500), whichever is greater. The court may increase damages for a willful deceptive act in an amount that does not exceed the greater of: (1) three (3) times the actual damages of the consumer suffering the loss; or (2) one thousand dollars ($1,000)." Ind. Code § 24-5-0.5-4(a).

302. The IDCSA further provides that "[a]ny person who is entitled to bring an action under subsection (a) on the person's own behalf against a supplier for damages for a deceptive act may bring a class action against such supplier on behalf

of any class of persons of which that person is a member." Ind. Code § 24-5-0.5-4(b).

303. Plaintiff Wyant brings this claim individually and on behalf of the members of the Indiana Subclasses to seek all appropriate relief.

COUNT X
Violation of South Carolina's Unfair Trade Practices Act,
S.C. Code §§ 39-5-10, *et seq.*
(Against All Defendants on Behalf of Plaintiff Poovey
and the Lotrimin South Carolina Subclass)

304. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

305. Plaintiff Poovey brings this claim individually and on behalf of the members of the Lotrimin South Carolina Subclass against Defendants.

306. At all relevant times, Plaintiff Poovey, members of the Lotrimin South Carolina Subclass, Defendants Aeropres, Aux Sable, Bayer, BP Energy, and the Beiersdorf Defendants were "persons" within the meaning of S.C. Code § 39-5-10(a). The South Carolina Unfair Trade Practices Act prohibits unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. See S.C. Code § 39-5-20.

307. Defendants willfully engaged in unfair, deceptive, and/or unlawful practices as described in the allegations above, including but not limited to:

a. Failing to detect the presence of carcinogens in the gas feedstock supply, Propellant A-31 and the Products;

b. Knowingly or recklessly making a false representation as to the characteristics and use of Products;

c. Misrepresenting that Products are safe for use; and

d. Failing to disclose the material information that recalled Products contained unsafe Benzene and that recalled Products users were at risk of suffering adverse health effects.

308. Defendants' deceptive acts or practices, misrepresentations, omissions, and suppression of material information in the sale of the Products are acts or practices in the conduct or trade or commerce within the meaning of S.C. Code § 39-5-10(b).

309. Plaintiff Poovey and members of the Lotrimin South Carolina Subclass suffered loss of money as a direct and proximate result of Defendants' unfair and deceptive practices.

310. The unfair and deceptive practices and acts by Defendants described above impact the public interest and are capable of repetition.

311. Defendants' conduct was unfair because it was immoral, unethical, or oppressive in that Plaintiff Poovey and members of the Lotrimin South Carolina Subclass were unaware that the Products they were purchasing contained a harmful contaminant – benzene.

312. Defendants' conduct was deceptive because it was likely to, and did actually, deceive reasonable consumers such as Plaintiff Poovey and members of the Lotrimin South Carolina Subclass, who relied on Defendants' representations in that they would not have acquired the Products had they known that the Products contained the carcinogen benzene and the Products were not the brand-name equivalents Miconazole Nitrate and Tolnaftate.

313. As a direct and proximate result of the foregoing acts and practices, Defendants received, or will receive, income, profits, and other benefits which they would not have received if they had not engaged in the violations described in this Complaint.

314. Plaintiff Poovey brings this claim individually and on behalf of the members of the South Carolina Lotrimin Subclass to seek all appropriate relief.

COUNT XI
Violation of the Delaware Consumer Fraud Act,
6 Del. C §§ 2511, *et seq.*
(Against All Defendants on Behalf of Plaintiff Stewart and the Delaware Subclasses)

315. Plaintiffs incorporate by reference and re-allege numbered paragraphs 1–188 as though fully set forth herein.

316. Plaintiff Stewart brings this claim individually and on behalf of the members of the Lotrimin Delaware Subclass and Tinactin Delaware Subclass

(collectively, the "Delaware Subclasses") against Defendants Aeropres, Aux Sable, Bayer, BP Energy, and the Beiersdorf Defendants.

317. Delaware's Consumer Fraud Act, 6 Del. C. §§ 2511 *et seq.* ("DCFA") prohibits any "act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby, is an unlawful practice."

318. At all relevant times, Plaintiff Stewart, members of the Delaware Subclasses, Defendants Aeropres, Aux Sable, Bayer, BP Energy, and the Beiersdorf Defendants were each a "person" as defined by 6 Del. C. § 2511 (7), which includes individuals, corporations, governments, or governmental subdivisions or agencies, statutory trusts, business trusts, estates, trusts, partnerships, unincorporated associations or other legal or commercial entities.

319. Defendants willfully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of "merchandise" (as defined in the DCFA, 6 Del. C. § 2511(6)) in violation of 6 Del. C., § 2513(a), as described in the allegations above, including but not limited to:

a. Failing to detect the presence of carcinogens in Propellant A-31 and the Products;

b. Misrepresenting that the Products are safe for use, when they were not;

c. Knowingly or recklessly making a false representation as to the characteristics and use of the Products; and

d. Failing to disclose the material information that recalled Products contained unsafe Benzene and that recalled Products users were at risk of suffering adverse health effects.

320. Defendants intended for consumers such as Plaintiff Stewart, and members of the Delaware Subclasses to rely on their misrepresentations or omissions, and Plaintiff Stewart and members of the Delaware Subclasses actually relied on Defendants' misrepresentations and omissions in the sale of the Products detailed above.

321. Defendants' misrepresentations and omissions in the manufacture and sale of the Products detailed above are acts or practices in the conduct of trade or commerce.

322. Defendants' misrepresentations and omissions in the sale of the Products detailed above impact the public interest.

323. Defendants' misrepresentations and omissions in the sale of the Products detailed above also were unfair (as defined by 6 Del. C. § 2511(9)) because they were likely to cause and did actually cause substantial injury to consumers

which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition, and they inequitably enriched Defendants at the expense of the Plaintiff Stewart and members of the Delaware Subclasses.

324. Defendants' misrepresentations and omissions in the sale of the Products detailed above were further unfair because they offend public policy and were so oppressive that Plaintiff Stewart and members of the Delaware Subclasses had little alternative but to submit, which caused consumers substantial injury.

325. Defendants' misrepresentations and omissions in the sale of the Products detailed above are unfair in that they violate the well-established public policies of protecting consumers from avoidable dangers and that the manufacturer of medical devices is responsible for ensuring that they are safe for human use.

326. Plaintiff Stewart and members of the Delaware Subclasses have suffered economic injury as a direct and proximate result of Defendants' conduct.

327. Plaintiff Stewart and members of the Delaware Subclasses were deceived by Defendants' deceptive and unfair acts and practices in that had they known the truth they would not have purchased the Products or would have paid less for the Products.

328. Instead, as a result of Defendants' material misrepresentations and omissions, Plaintiff Stewart and members of the Delaware Subclasses suffered

monetary losses in that (1) the actual value of the merchandise they received was less than the value of the merchandise as represented denying them of the benefit of their bargain; (2) Plaintiff Stewart and members of the Delaware Subclasses paid more than the fair market value of the merchandise they received causing them out-of-pocket damages; and (3) Plaintiff Stewart and members of the Delaware Subclasses were forced to discard their leftover Product and/or purchase a replacement product as a result of the contamination.

329. As a direct and proximate result of the foregoing acts and practices, Defendants received, or will receive, income, profits, and other benefits which Defendants would not have received if they had not engaged in the violations described in this Complaint.

330. Plaintiff Stewart brings this claim individually and on behalf of the members of the Delaware Subclasses to seek all appropriate relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request, individually and on behalf of the alleged Classes, that the Court enter judgment in their favor and against Defendants as follows:

a. For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiffs as the representatives of the Classes, and naming Plaintiffs' attorneys as Class Counsel to represent the Classes;

b. For an order declaring that Defendants' conduct violates the causes of action referenced herein;

c. For an order finding in favor of Plaintiffs and the Classes on all counts asserted herein;

d. For compensatory, actual, 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 Plaintiffs and the Classes their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR JURY TRIAL

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

DATED: February 11, 2025

Respectfully Submitted,

By: */s/ Innessa M. Huot*
Innessa M. Huot

FARUQI & FARUQI, LLP
Innessa Melamed Huot
685 Third Avenue, 26th Floor
New York, NY 10017
Telephone: (212) 983-9330
Facsimile: (212) 983-9331
E-Mail: ihuot@faruqilaw.com

FARUQI & FARUQI, LLP
Timothy J. Peter (Pro Hac Vice)
1617 JFK Boulevard, Suite 1550
Philadelphia, PA 19103
Telephone: (215) 277-5770
Facsimile: (215) 277-5771
E-Mail: tpeter@faruqilaw.com

BURSOR & FISHER, P.A
Philip L. Fraietta
Max S. Roberts*
888 Seventh Avenue
New York, NY 10019
Telephone: (646) 837-7150
Facsimile: (212) 989-9163
E-Mail: pfraietta@bursor.com
mroberts@bursor.com

SILVER GOLUB & TEITELL LLP
Steven L. Bloch*
Ian W. Sloss*
Zachary A. Rynar
1 Landmark Sq., 15th Floor
Stamford, Connecticut 06901
Telephone: (203) 325-4491
Facsimile: (203) 325-3769
E-Mail: sbloch@sgtlaw.com
isloss@sgtlaw.com
zrynar@sgtlaw.com

* *Pro Hac Vice* Application Forthcoming

Attorneys for Plaintiffs

Exhibit 1

BURSOR & FISHER
P.A.

888 SEVENTH AVENUE
NEW YORK, NY 10019
www.bursor.com

ANDREW J. OBERGFELL
Tel: 646.837.7129
Fax: 212.989.9163
aobergfell@bursor.com

November 12, 2021

Via Certified Mail - Return Receipt Requested

Bayer U.S. LLC
100 Bayer Boulevard
Whippany, New Jersey 07981

Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607; and all other relevant state and local laws

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Bayer U.S. LLC ("Bayer" or "You") pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties – and violations of state consumer protection laws, including but not limited to New York General Business Law §§ 349 and 350 – related to our clients, Juan Huertas and Eva Mistretta, and a class of all similarly situated purchasers (the "Class") of defective and falsely labeled Lotrimin and Tinactin medications manufactured and sold by Bayer.

Our clients purchased Lotrimin and Tinactin medications in New York. Specifically, Mr. Huertas purchased Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray with the lot number TN009K7 from a CVS in Freeport, New York, and Ms. Mistretta purchased a canister of Defendant's Tinactin Athlete's Foot Liquid Spray with the lot number CV01E2X from a Walgreens in Queens, New York (the "Foot Sprays"). The Foot Sprays were manufactured by You and sold by You in New York and across the United States. Our clients' Foot Sprays were defective in that they contained elevated levels of benzene, a carcinogenic and toxic chemical impurity that has been lined to leukemia and other cancers. Indeed, you issued a recall of all Foot Sprays sold between September 2018 and September 2021, including those purchased by our clients. The recall included other Lotrimin and Tinactin products. However, the recall is inadequate in that, among other things, it is not adequately publicized, it does not offer refunds to purchasers who may have discarded their Foot Sprays, it does not promise any changes to Your manufacturing and distribution process so as to prevent future contamination, and it recall does not fully compensate consumers in states like New York, where consumers are entitled to statutory damages above the purchase price of the Products under New York's consumer protection laws.

In short, the Foot Sprays that our clients and the Class purchased are worthless, as they contain benzene, rendering them unusable and unfit for humans. You violated express and

implied warranties made to our clients and the Class regarding the quality and safety of the Foot Sprays they purchased. *See* U.C.C. §§ 2-313, 2-314.

This letter also serves as notice of violation of the New York General Business Law ("GBL") §§ 349 and 350, and all other relevant state and local laws. You violated GBL §§ 349 and 350 by failing to disclose that the Foot Sprays contained elevated levels of benzene, rendering the Foot Sprays unsafe for human use. You knew or should have known about these facts. As a result of Your violation of the GBL §§ 349 and 350, our clients and a subclass of all purchasers of the Foot Sprays in New York sustained injury and are entitled to statutory damages of $550 per violation.

On behalf of our clients and the Class, we hereby demand that You immediately make full restitution to all purchasers of the defective and falsely labeled Foot Sprays of all purchase money obtained from sales thereof, in addition to statutory damages as appropriate.

We also demand that You preserve all documents and other evidence which refers or relates 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 the recalled Lotrimin and Tinactin products;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of the recalled Lotrimin and Tinactin products manufactured by You;

3. All tests of the recalled Lotrimin and Tinactin products manufactured by You;

4. All documents concerning the pricing, advertising, marketing, and/or sale of the recalled Lotrimin and Tinactin products manufactured by You;

5. All communications with customers involving complaints or comments concerning the recalled Lotrimin and Tinactin products manufactured by You;

6. All documents concerning communications with any retailer involved in the marketing or sale of the recalled Lotrimin and Tinactin products manufactured by You;

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

8. All documents concerning the total revenue derived from sales of the recalled Lotrimin and Tinactin products.

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

SILVER GOLUB & TEITELL LLP

RICHARD A. SILVER
DAVID S. GOLUB
ERNEST F. TEITELL
JONATHAN M. LEVINE
PAUL A. SLAGER*
ANGELO A. ZIOTAS
PETER M. DREYER*
SEAN K. MCELLIGOTT**
JENNIFER B. GOLDSTEIN*
STEVEN L. BLOCH***
JOAQUIN L. MADRY*
MARCO A. ALLOCCA
DANIEL S. JO****
IAN W. SLOSS*
ZACHARY RYNAR*
SARAH A. RICCIARDI****
NICOLE B. COATES
WILLIAM H. PRICE

OF COUNSEL
MARILYN J. RAMOS*

* ALSO ADMITTED IN NY
** ALSO ADMITTED IN NY AND MA
*** ALSO ADMITTED IN NY AND PA
**** ALSO ADMITTED IN NY AND NJ

PLEASE REPLY TO MAIN OFFICE

MAIN OFFICE
THE HERITAGE BUILDING
184 ATLANTIC STREET
STAMFORD, CONNECTICUT 06901
TEL: (203) 325-4491 FAX: (203) 325-3769

HARTFORD OFFICE
GOODWIN SQUARE
225 ASYLUM STREET 15TH FLOOR
HARTFORD, CONNECTICUT 06103

DANBURY OFFICE
100 MILL PLAIN ROAD
DANBURY, CONNECTICUT 06811

WATERBURY OFFICE
21 WEST MAIN STREET
WATERBURY, CONNECTICUT 06702

WWW.SGTLAW.COM

November 17, 2021

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Scott Partridge
General Counsel and Senior Vice President
Bayer U.S. LLC
100 Bayer Blvd.
Whippany, NJ 07981

Dear Mr. Partridge:

This firm represents Jonathan Martin, Don Penales, Jr., Christopher Cadorette, and Jeremy Wyant (collectively "Plaintiffs"), in connection with claims Plaintiffs have against Bayer U.S. LLC ("Bayer") for wrongfully manufacturing, distributing, and selling defective and falsely labeled Tinactin and Lotrimin Anti-Fungal sprays.

This letter serves as a preliminary notice and demand for corrective action by Bayer pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties – and violations of state consumer protection laws, including but not limited to the California's Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.* (on behalf of Mr. Martin and Mr. Penales), the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-0.1, *et seq.* (on behalf of Mr. Wyant), and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93, §§1, *et seq.* (on behalf of Mr. Cadorette) related to our clients.

On October 1, 2021, Bayer announced the recall of all unexpired lots of the following products due to the presence of benzene, a carcinogen known to cause cancer in humans, in the sprays: (1) Lotrimin AF Athlete's Foot Powder Spray; (2) Lotrimin AF Jock Itch Foot Powder Spray; (3) Lotrimin AF Athlete's Foot Deodorant Powder Spray; (4) Lotrimin AF Athlete's Foot Liquid Spray; (5) Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray; (6) Tinactin Jock Itch Powder Spray; (7) Tinactin Athlete's Deodorant Foot Powder Spray; (8)

Tinactin Athlete's Foot Powder Spray; and (9) Tinactin Athlete's Foot Liquid Spray (collectively, the "Recalled Sprays").

Our clients are purchasers and users of the Recalled Sprays. Plaintiffs purchased the Recalled Sprays to treat conditions the Recalled Sprays were intended to treat and used the Recalled Sprays in accordance with the directions provided on their packaging. Plaintiffs did so because they believe the Recalled Sprays had been manufactured using acceptable standards and practices and that they were safe for human use. However, in reality they had bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiffs and the Class would not have purchased and used the Recalled Sprays had they know they were unsafe and have, therefore, not received the benefit of their bargain.

As a result, the Recalled Sprays purchased by our clients are worthless, as they contain benzene, rendering them unusable and unfit for humans. *See* 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019*); In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021). Bayer violated express and implied warranties made to our clients and the Class regarding the quality and safety of the Recalled Sprays they purchased. *See* U.C.C. §§ 2-313, 2-314.

This letter also serves as statutory notice of our clients' allegations that Bayer has violated the California's Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq*. (on behalf of Mr. Martin and Mr. Penales), the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-0.1, *et seq*. (on behalf of Mr. Wyant), and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93, §§1, *et seq*. (on behalf of Mr. Cadorette) by failing to disclose that the Recalled Sprays contained elevated levels of Benzene, rendering the Recalled Sprays unsafe for human use.

Plaintiffs demand, *inter alia*, that Bayer (1) reimburse Plaintiffs and all similarly situated purchasers of the Recalled Sprays in full for their purchases of the Recalled Sprays; and (2) the Bayer establish and fund a medical monitoring program so that Plaintiffs and all similarly situated purchasers and users of the Recalled Sprays may get tested to determine if their exposure to benzene has caused adverse health effects.

Plaintiffs also demand that Bayer preserve all documents and other evidence which refers or relates 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 Bayer's Recalled Sprays;
2. All documents concerning the design, development, supply, production, extraction, and/or testing of the Recalled Sprays manufactured by Bayer;
3. All tests of the Recalled Sprays manufactured by Bayer;
4. All documents concerning the pricing, advertising, marketing, and/or sale of the Recalled Sprays manufactured by Bayer;
5. All communications with customers involving complaints or comments concerning the Recalled Sprays manufactured by Bayer

6. All documents concerning communications with any retailer involved in the marketing or sale of the Recalled Sprays manufactured by Bayer;
7. All documents concerning communications with federal or state regulators; and
8. All documents concerning the total revenue derived from sales of the Recalled Sprays.

If Bayer contend that any statement in this letter is inaccurate in any respect, please provide us with Bayer contentions and supporting documents immediately upon receipt of this letter. Please contact us right away if Bayer wish to discuss an appropriate way to remedy this matter. If we do not hear from Bayer promptly, we will take that as an indication that Bayer is not interested in doing so.

Very truly yours,

/s/ Steven L. Bloch

Steven L. Bloch

SILVER GOLUB & TEITELL LLP

Steven L. Bloch
One Landmark Square, 15th Fl.
Stamford, CT 06901
(203) 325-4491
sbloch@sgtlaw.com

August 9, 2023

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bayer Healthcare LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

To whom it may concern:

This firm represents Darrell Stewart ("Plaintiff") in connection with claims Plaintiff and a class of all similarly situated purchasers (the "Class") have against Bayer Healthcare LLC ("Bayer") for wrongfully manufacturing, distributing, and selling defective and falsely labeled Tinactin and Lotrimin Anti-Fungal sprays. This letter serves as a preliminary notice and demand for corrective action by Bayer pursuant to 6 Del. C. § 2-607(3)(a) concerning breaches of express and implied warranties.

On October 1, 2021, Bayer announced the recall of all unexpired lots of the following products due to the presence of benzene, a carcinogen known to cause cancer in humans, in the sprays: (1) Lotrimin AF Athlete's Foot Powder Spray; (2) Lotrimin AF Jock Itch Powder Spray; (3) Lotrimin AF Athlete's Foot Deodorant Powder Spray; (4) Lotrimin AF Athlete's Foot Liquid Spray; (5) Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray; (6) Tinactin Jock Itch Powder Spray; (7) Tinactin Athlete's Deodorant Foot Powder Spray; (8) Tinactin Athlete's Foot Powder Spray; and (9) Tinactin Athlete's Foot Liquid Spray (collectively, the "Recalled Sprays").

Plaintiff is a purchaser and user of the Recalled Sprays. Plaintiff purchased the Recalled Sprays to treat conditions the Recalled Sprays were intended to treat and used the Recalled Sprays in accordance with the directions provided on their packaging. Plaintiff did so because he believed the Recalled Sprays had been manufactured using acceptable standards and practices and that they were safe for human use. However, in reality, Plaintiff had bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiff and the Class would not have purchased and used the Recalled Sprays had they known they were unsafe, and they have therefore not received the benefit of their bargain.

As a result, the Recalled Sprays purchased by Plaintiff and the Class are worthless, as they contain benzene, rendering them unusable and unfit for humans. *See* 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.,* 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021). Bayer violated express and implied warranties made to Plaintiff and the Class regarding the quality and safety of the Recalled Sprays they purchased. *See* U.C.C. §§ 2-313, 2-314.

Plaintiff demands, *inter alia*, that Bayer (1) reimburse Plaintiff and all similarly situated purchasers of the Recalled Sprays in full for their purchases of the Recalled Sprays; and (2) establish and fund a medical monitoring program so that Plaintiff and all similarly situated purchasers and users of the Recalled Sprays may get tested to determine if their exposure to benzene has caused adverse health effects.

Plaintiff also demands that Bayer preserve all documents and other evidence which refers or relates 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 Bayer's Recalled Sprays;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of the Recalled Sprays manufactured by Bayer;

3. All tests of the Recalled Sprays manufactured by Bayer;

4. All documents concerning the pricing, advertising, marketing, and/or sale of the Recalled Sprays manufactured by Bayer;

5. All communications with customers involving complaints or comments concerning the Recalled Sprays manufactured by Bayer;

6. All documents concerning communications with any retailer involved in the marketing or sale of the Recalled Sprays manufactured by Bayer;

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

8. All documents concerning the total revenue derived from sales of the Recalled Sprays.

If Bayer contends that any statement in this letter is inaccurate in any respect, please provide us with Bayer's contentions and supporting documents immediately upon receipt of this letter. Please contact us right away if Bayer wishes to discuss an appropriate way to remedy this matter. If we do not hear from Bayer promptly, we will take that as an indication that Bayer is not interested in doing so.

Very truly yours,

/s/ Steven L. Bloch

Steven L. Bloch

SILVER GOLUB & TEITELL LLP

Steven L. Bloch
One Landmark Square, 15th Fl.
Stamford, CT 06901
(203) 325-4491
sbloch@sgtlaw.com

August 15, 2023

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bayer Healthcare LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

To whom it may concern:

This firm represents Darrell Stewart ("Plaintiff") in connection with claims Plaintiff and a class of all similarly situated purchasers (the "Class") have against Bayer Healthcare LLC ("Bayer") for wrongfully manufacturing, distributing, and selling defective and falsely labeled Tinactin and Lotrimin Anti-Fungal sprays. This letter serves as a preliminary notice and demand for corrective action by Bayer pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties.

On October 1, 2021, Bayer announced the recall of all unexpired lots of the following products due to the presence of benzene, a carcinogen known to cause cancer in humans, in the sprays: (1) Lotrimin AF Athlete's Foot Powder Spray; (2) Lotrimin AF Jock Itch Powder Spray; (3) Lotrimin AF Athlete's Foot Deodorant Powder Spray; (4) Lotrimin AF Athlete's Foot Liquid Spray; (5) Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray; (6) Tinactin Jock Itch Powder Spray; (7) Tinactin Athlete's Deodorant Foot Powder Spray; (8) Tinactin Athlete's Foot Powder Spray; and (9) Tinactin Athlete's Foot Liquid Spray (collectively, the "Recalled Sprays").

Plaintiff is a purchaser and user of the Recalled Sprays. Plaintiff purchased the Recalled Sprays to treat conditions the Recalled Sprays were intended to treat and used the Recalled Sprays in accordance with the directions provided on their packaging. Plaintiff did so because he believed the Recalled Sprays had been manufactured using acceptable standards and practices and that they were safe for human use. However, in reality, Plaintiff had bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiff and the Class would not have purchased and used the Recalled Sprays had they known they were unsafe, and they have therefore not received the benefit of their bargain.

As a result, the Recalled Sprays purchased by Plaintiff and the Class are worthless, as they contain benzene, rendering them unusable and unfit for humans. *See* 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021). Bayer violated express and implied warranties made to Plaintiff and the Class regarding the quality and safety of the Recalled Sprays they purchased. *See* U.C.C. §§ 2-313, 2-314.

Plaintiff demands, *inter alia*, that Bayer (1) reimburse Plaintiff and all similarly situated purchasers of the Recalled Sprays in full for their purchases of the Recalled Sprays; and (2) establish and fund a medical monitoring program so that Plaintiff and all similarly situated purchasers and users of the Recalled Sprays may get tested to determine if their exposure to benzene has caused adverse health effects.

Plaintiff also demands that Bayer preserve all documents and other evidence which refers or relates 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 Bayer's Recalled Sprays;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of the Recalled Sprays manufactured by Bayer;

3. All tests of the Recalled Sprays manufactured by Bayer;

4. All documents concerning the pricing, advertising, marketing, and/or sale of the Recalled Sprays manufactured by Bayer;

5. All communications with customers involving complaints or comments concerning the Recalled Sprays manufactured by Bayer;

6. All documents concerning communications with any retailer involved in the marketing or sale of the Recalled Sprays manufactured by Bayer;

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

8. All documents concerning the total revenue derived from sales of the Recalled Sprays.

If Bayer contends that any statement in this letter is inaccurate in any respect, please provide us with Bayer's contentions and supporting documents immediately upon receipt of this letter. Please

contact us right away if Bayer wishes to discuss an appropriate way to remedy this matter. If we do not hear from Bayer promptly, we will take that as an indication that Bayer is not interested in doing so.

Very truly yours,

/s/ Steven L. Bloch

Steven L. Bloch

Exhibit 2

SILVER GOLUB & TEITELL LLP

Steven L. Bloch
One Landmark Square, 15th Fl.
Stamford, CT 06901
(203) 325-4491
sbloch@sgtlaw.com

August 9, 2023

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert R. Wilkie
Aeropres Corporation
1324 North Hearne Ave., Suite 200
Shreveport, LA 71107

Dear Mr. Wilkie:

This firm represents Christopher Cadorette, Juan Huertas, Jonathan Martin, Eva Mistretta, Don Penales, and Jeremy Wyant in connection with claims Plaintiffs and a class of all similarly situated purchasers (the "Class") have against Defendant Aeropres Corporation ("Aeropres") for wrongfully manufacturing, distributing, and/or selling defective and falsely labeled Tinactin and Lotrimin Anti-Fungal sprays.

This letter serves as a preliminary notice and demand for corrective action by Aeropres for violations of state consumer protection laws, including but not limited to California's Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* (on behalf of Mr. Martin and Mr. Penales), the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-0.1, *et seq.* (on behalf of Mr. Wyant), the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93, §§ 1, *et seq*. (on behalf of Mr. Cadorette), and New York General Business Law §§ 349 and 350 (on behalf of Mr. Huertas and Ms. Mistretta) related to our clients.

On October 1, 2021, Bayer Healthcare, LLC ("Bayer") announced the recall of all unexpired lots of the following products due to the presence of benzene, a carcinogen known to cause cancer in humans, in the sprays: (1) Lotrimin AF Athlete's Foot Powder Spray; (2) Lotrimin AF Jock Itch Powder Spray; (3) Lotrimin AF Athlete's Foot Deodorant Powder Spray; (4) Lotrimin AF Athlete's Foot Liquid Spray; (5) Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray; (6) Tinactin Jock Itch Powder Spray; (7) Tinactin Athlete's Deodorant Foot Powder Spray; (8) Tinactin Athlete's Foot Powder Spray; and (9) Tinactin Athlete's Foot Liquid Spray (collectively, the "Recalled Sprays"). According to Bayer, the source of the benzene contamination was the propellant Bayer used in the Recalled Sprays supplied by Aeropres, known as Propellant A-31.

Plaintiffs are purchasers and users of the Recalled Sprays. Plaintiffs purchased the Recalled Sprays to treat conditions the Recalled Sprays were intended to treat and used the Recalled Sprays in accordance with the directions provided on their packaging. Plaintiffs did so because they believed the Recalled Sprays had been manufactured using acceptable standards and practices and that they were safe for human use. However, in reality, Plaintiffs had bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiffs and the Class would not have purchased and used the Recalled Sprays had they known they were unsafe, and they have therefore not received the benefit of their bargain. As a result, the Recalled Sprays purchased by Plaintiffs and the Class are worthless, as they contain benzene, rendering them unusable and unfit for humans. See 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.,* 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021).

This letter serves as statutory notice of our clients' allegations that Aeropres has violated California's Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* (on behalf of Mr. Martin and Mr. Penales), the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-0.1, *et seq.* (on behalf of Mr. Wyant), the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93, §§ 1, *et seq.* (on behalf of Mr. Cadorette), and New York General Business Law §§ 349 and 350 (on behalf of Mr. Huertas and Ms. Mistretta) by failing to disclose that the Recalled Sprays contained elevated levels of Benzene, rendering the Recalled Sprays unsafe for human use.

Plaintiffs demand, *inter alia*, that Aeropres (1) reimburse Plaintiffs and all similarly situated purchasers of the Recalled Sprays in full for their purchases of the Recalled Sprays; and (2) establish and fund a medical monitoring program so that Plaintiffs and all similarly situated purchasers and users of the Recalled Sprays may get tested to determine if their exposure to benzene has caused adverse health effects. In addition, pursuant to New York General Business Law §§ 349 and 350, Mr. Huertas, Ms. Mistretta, and all similarly situated purchasers are entitled to statutory damages of $550 per violation.

Plaintiffs also demand that Aeropres preserve all documents and other evidence which refers or relates 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 the Recalled Sprays;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of the Recalled Sprays and/or Propellant A-31 manufactured by Aeropres;

3. All tests of the Recalled Sprays and/or Propellant A-31 manufactured by Aeropres;

4. All documents concerning the pricing, advertising, marketing, and/or sale of the Recalled Sprays and/or Propellant A-31 manufactured by Aeropres;

5. All communications with customers involving complaints or comments concerning the Recalled Sprays;

6. All documents concerning communications with any retailer involved in the marketing or sale of the Recalled Sprays;

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

8. All documents concerning the total revenue derived from sales of the Recalled Sprays.

If Aeropres contends that any statement in this letter is inaccurate in any respect, please provide us with Aeropres's contentions and supporting documents immediately upon receipt of this letter. Please contact us right away if Aeropres wishes to discuss an appropriate way to remedy this matter. If we do not hear from Aeropres promptly, we will take that as an indication that Aeropres is not interested in doing so.

Very truly yours,

/s/ Steven L. Bloch

Steven L. Bloch

Exhibit 3

SILVER GOLUB & TEITELL LLP

Steven L. Bloch
One Landmark Square, 15th Fl.
Stamford, CT 06901
(203) 325-4491
sbloch@sgtlaw.com

August 9, 2023

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Beiersdorf, Inc.
c/o Corporation Service Company
Goodwin Square
225 Asylum Street, 20th Floor
Hartford, CT 06103

Beiersdorf Manufacturing, LLC
c/o Corporation Service Company
2908 Poston Ave.
Nashville, TN 37203-1312

Beiersdorf North America Inc.
c/o Corporation Service Company
Goodwin Square
225 Asylum Street, 20th Floor
Hartford, CT 06103

To whom it may concern:

This firm represents Christopher Cadorette, Juan Huertas, Jonathan Martin, Eva Mistretta, Don Penales, and Jeremy Wyant in connection with claims Plaintiffs and a class of all similarly situated purchasers (the "Class") have against Defendants Beiersdorf, Inc., Beiersdorf Manufacturing, LLC, and Beiersdorf North America Inc. (collectively, "Beiersdorf") for wrongfully manufacturing, distributing, and/or selling defective and falsely labeled Tinactin and Lotrimin Anti-Fungal sprays.

This letter serves as a preliminary notice and demand for corrective action by Beiersdorf for violations of state consumer protection laws, including but not limited to California's Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* (on behalf of Mr. Martin and Mr. Penales), the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-0.1, *et seq.* (on behalf of Mr. Wyant), the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93, §§ 1, *et seq*. (on behalf of Mr. Cadorette), and New York General Business Law §§ 349 and 350 (on behalf of Mr. Huertas and Ms. Mistretta) related to our clients.

On October 1, 2021, Bayer Healthcare, LLC ("Bayer") announced the recall of all unexpired lots of the following products due to the presence of benzene, a carcinogen known to cause cancer in humans, in the sprays: (1) Lotrimin AF Athlete's Foot Powder Spray; (2) Lotrimin AF Jock Itch Powder Spray; (3) Lotrimin AF Athlete's Foot Deodorant Powder Spray; (4) Lotrimin AF Athlete's Foot Liquid Spray; (5) Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray; (6) Tinactin Jock Itch Powder Spray; (7) Tinactin Athlete's Deodorant Foot Powder Spray; (8) Tinactin Athlete's Foot Powder Spray; and (9) Tinactin Athlete's Foot Liquid Spray (collectively, the "Recalled Sprays"). On information and belief, in or about August 2019 Beiersdorf agreed to manufacture, package, and supply to Bayer finished Lotrimin and Tinactin spray products, including the Recalled Sprays.

Plaintiffs are purchasers and users of the Recalled Sprays. Plaintiffs purchased the Recalled Sprays to treat conditions the Recalled Sprays were intended to treat and used the Recalled Sprays in accordance with the directions provided on their packaging. Plaintiffs did so because they believed the Recalled Sprays had been manufactured using acceptable standards and practices and that they were safe for human use. However, in reality, Plaintiffs had bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiffs and the Class would not have purchased and used the Recalled Sprays had they known they were unsafe, and they have therefore not received the benefit of their bargain. As a result, the Recalled Sprays purchased by Plaintiffs and the Class are worthless, as they contain benzene, rendering them unusable and unfit for humans. See 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.,* 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021)

.

This letter serves as statutory notice of our clients' allegations that Beiersdorf has violated California's Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* (on behalf of Mr. Martin and Mr. Penales), the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-0.1, *et seq.* (on behalf of Mr. Wyant), the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93, §§ 1, *et seq.* (on behalf of Mr. Cadorette), and New York General Business Law §§ 349 and 350 (on behalf of Mr. Huertas and Ms. Mistretta) by failing to disclose that the Recalled Sprays contained elevated levels of Benzene, rendering the Recalled Sprays unsafe for human use.

Plaintiffs demand, *inter alia*, that Beiersdorf (1) reimburse Plaintiffs and all similarly situated purchasers of the Recalled Sprays in full for their purchases of the Recalled Sprays; and (2) establish and fund a medical monitoring program so that Plaintiffs and all similarly situated purchasers and users of the Recalled Sprays may get tested to determine if their exposure to benzene has caused adverse health effects. In addition, pursuant to New York General Business Law §§ 349 and 350, Mr. Huertas, Ms. Mistretta, and all similarly situated purchasers are entitled to statutory damages of $550 per violation.

Plaintiffs also demand that Beiersdorf preserve all documents and other evidence which refers or relates 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 the Recalled Sprays;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of the Recalled Sprays manufactured by Beiersdorf;

3. All tests of the Recalled Sprays manufactured by Beiersdorf;

4. All documents concerning the pricing, advertising, marketing, and/or sale of the Recalled Sprays manufactured by Beiersdorf;

5. All communications with customers involving complaints or comments concerning the Recalled Sprays;

6. All documents concerning communications with any retailer involved in the marketing or sale of the Recalled Sprays;

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

8. All documents concerning the total revenue derived from sales of the Recalled Sprays.

If Beiersdorf contends that any statement in this letter is inaccurate in any respect, please provide us with Beiersdorf's contentions and supporting documents immediately upon receipt of this letter. Please contact us right away if Beiersdorf wishes to discuss an appropriate way to remedy this matter. If we do not hear from Beiersdorf promptly, we will take that as an indication that Beiersdorf is not interested in doing so.

Very truly yours,

/s/ Steven L. Bloch

Steven L. Bloch