UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JUAN HUERTAS, EVA MISTRETTA, JOSE VILLARREAL, JEREMY WYANT, MIKE POOVEY, CHRISTOPHER CADORETTE, SEAN STEINWEDEL, JONATHAN MARTIN, DON PENALES, JR, on behalf of themselves and all others similarly situated, Plaintiffs, v. BAYER U.S. LLC, Defendant.	Case No. 2:21-cv-20021-SDW-CLW **FIRST AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs Juan Huertas, Eva Mistretta, Jose Villarreal, Jeremy Wyant, Mike Poovey, Christopher Cadorette, Sean Steinwedel, Jonathan Martin, Don Penales, Jr ("Plaintiffs") bring this action on behalf of themselves and all others similarly situated against Defendant Bayer U.S. LLC ("Bayer" or "Defendant"). Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION

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

without disclosing that the Products contain dangerously high levels of benzene, a carcinogenic impurity that has been linked to leukemia and other cancers.

2. Both Lotrimin and Tinactin are anti-fungal drug products regulated by the United States Food & Drug Administration ("FDA") pursuant to the federal Food, Drug and Cosmetics Act ("FDCA"). The presence of benzene in the Products renders them adulterated and misbranded. As a result, the Products are illegal to sell under federal law and therefore worthless. *See* 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *see also In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021); *Barnes v. Unilever United States, Inc.*, 2022 WL 2915629, at *1, *3 (N.D. Ill. July 24, 2022).

3. While the FDA has made clear that there is no acceptable amount of benzene in consumer products, it has adopted a strict limit of 2 parts per million (ppm) for i) drugs, ii) where benzene is "unavoidable in order to produce a drug product with a significant therapeutic advance."[1] As outlined below, lab testing shows that the Products consistently contain significant benzene levels that far exceed the 2 ppm FDA upper limit and are many times, and in one sample over 105 times, the 2 ppm limit.

[1] https://www.fda.gov/media/133650/download, at 7.

4. Bayer is one of the largest pharmaceutical companies in the world. Bayer sells Lotrimin and Tinactin products throughout the United States and the State of New York.

5. Bayer knew or should have known of the dangerous and carcinogenic effects of benzene and knew or should have known that it was producing Products that contained benzene, indeed products that consistently contained benzene at levels above, and often dramatically above, 2 ppm. Nevertheless, Bayer produced, distributed, and sold millions of cans of Tinactin and Lotrimin AF sprays that contained benzene to the consuming public.

6. 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 that they were safe for human use.

7. However, in reality Plaintiffs bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiffs would not have purchased and used the Products had they known they were unsafe. Plaintiffs were therefore harmed at the point of purchase of the Products when they did not receive the benefit of the bargain. Further, Plaintiffs and other Class

Members were forced to discard the remainder of their Products due to the contamination, or purchase replacement products to treat their conditions. 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 spent but for the Products being contaminated.

8. 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) fraudulent concealment; and (v) unjust enrichment.

PARTIES

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

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

11. Plaintiff Jose Villarreal is a citizen and resident of Boone County, Missouri.

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

13. Plaintiff Jonathan Martin is a citizen and resident of Contra Costa County, California

14. Plaintiff Don Penales, Jr. is a citizen and resident of Sonoma County, California.

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

16. Plaintiff Sean Steinwedel is a citizen and resident of Sussex County, Delaware.

17. Plaintiff Christopher Cadorette is a citizen and resident of Essex County, Massachusetts.

18. Defendant Bayer U.S. LLC is a Delaware limited liability company with its headquarters in Whippany, New Jersey. Bayer distributes the Products throughout the United States. The Lotrimin and Tinactin Products were and are sold at retail stores throughout the states in which Plaintiffs reside and the United States.

JURISIDICTION AND VENUE

19. 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, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and

the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

20. Defendant is an "unincorporated association" under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d), and Defendant 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]." *See* 28 U.S.C. § 1332(d)(10).

21. This Court has personal jurisdiction over Defendant because Defendant is headquartered in New Jersey.

22. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Defendant resides in this District.

FACTUAL BACKGROUND

I. TINACTIN AND LOTRIMIN AF

23. Lotrimin is the brand name for Clotrimazole, 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.

24. 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 Clotrimazole, but has been found

effective at treating ringworm that is passed from pets to humans. Tinactin comes in both aerosol (spray) and cream form.

25. Defendant manufactures, markets, and sells a variety of Lotrimin and Tinactin aerosol products, including:

- Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray
- Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray
- Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray
- Lotrimin AF Athlete's Foot Liquid Spray
- Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray
- Tinactin Jock Itch (JI) Powder Spray
- Tinactin Athlete's Foot Deodorant Powder Spray
- Tinactin Athlete's Foot Powder Spray
- Tinactin Athlete's Foot Liquid Spray

26. 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. The labels further direct consumers to apply the Products multiple times a day over the course of several weeks:

Drug Facts
Active ingredient ***Purpose*** (To Deliver) Miconazole nitrate 2%.....Antifungal
Uses ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis) ▪ for effective relief of itching, cracking, burning, scaling and discomfort
Warnings **For external use only** **Flammable:** Do not use near heat, flame, or while smoking **Do not use** on children under 2 years of age unless directed by a doctor.
When using this product ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.
Stop use and ask a doctor if ▪ irritation occurs ▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily ▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks ▪ if condition persists longer, ask a doctor ▪ this product is not effective on the scalp or nails
Other information store between 20°to 25℃ (68°to 77℉)
Inactive ingredients fragrance, isobutane, SD alcohol 40-B (8% v/v), stearalkonium hectorite, talc
Questions? 1-866-360-3266

Lotrimin Anti-Fungal Athlete's Foot Powder Spray Label

Drug Facts
Active ingredient ***Purpose*** (To Deliver) Miconazole nitrate 2%.....Antifungal
Uses ▪ proven clinically effective in the treatment of most jock itch (tinea cruris) ▪ for effective relief of itching, burning, scaling and discomfort, and chafing associated with jock itch
Warnings **For external use only** **Flammable:** Do not use near heat, flame, or while smoking **Do not use** on children under 2 years of age unless directed by a doctor.
When using this product ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.
Stop use and ask a doctor if ▪ irritation occurs ▪ there is no improvement within 2 weeks
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ use daily for 2 weeks ▪ if condition persists longer, ask a doctor ▪ this product is not effective on the scalp or nails
Other information store between 20°to 25℃ (68°to 77℉)
Inactive ingredients isobutane, SD alcohol 40-B (8% v/v), stearalkonium hectorite, talc
Questions? 1-866-360-3266

Lotrimin Anti-Fungal Jock Itch Athlete's Foot Powder Spray Label

Drug Facts

Active ingredient ***Purpose***
(To Deliver) Miconazole nitrate 2%.....Antifungal

Uses
▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
▪ for effective relief of itching, cracking, burning, scaling and discomfort

Warnings
For external use only

Flammable: Do not use near heat, flame, or while smoking

Do not use on children under 2 years of age unless directed by a doctor.

When using this product ▪ avoid contact with the eyes
▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.
▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

Stop use and ask a doctor if ▪ irritation occurs
▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ▪ wash the affected area and dry thoroughly
▪ shake can well and spray a thin layer over affected area twice daily (morning and night)
▪ supervise children in the use of this product
▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily
▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
▪ if condition persists longer, ask a doctor
▪ this product is not effective on the scalp or nails

Other information
store between 20°to 25℃ (68°to 77℉)

Inactive ingredients fragrance, isobutane, SD alcohol 40-B (8% v/v), stearalkonium hectorite, talc

Questions? 1-866-360-3266

Lotrimin Anti-Fungal Athlete's Foot Deodorant Spray Label

Drug Facts

Active ingredient ***Purpose***
(To Deliver) Miconazole nitrate 2%.....Antifungal

Uses ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
▪ for effective relief of itching, cracking, burning, scaling and discomfort

Warnings
For external use only

Flammable: Do not use near heat, flame, or while smoking

Do not use on children under 2 years of age unless directed by a doctor.

When using this product ▪ avoid contact with the eyes
▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
▪ do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Stop use and ask a doctor if ▪ irritation occurs
▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ▪ wash the affected area and dry thoroughly
▪ shake can well and spray a thin layer over affected area twice daily (morning and night)
▪ supervise children in the use of this product
▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily
▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
▪ if condition persists longer, ask a doctor
▪ this product is not effective on the scalp or nails

Other information store between 20°to 25℃ (68°to 77℉)

Inactive ingredients dimethyl ether, polyoxyl 15 hydroxystearate, SD alcohol 40-B (16.5% v/v)

Questions? 1-866-360-3266

Lotrimin Anti-Fungal Athlete's Foot Liquid Spray Label



Drug Facts

Active ingredient — **Purpose**
(To Deliver) Tolnaftate 1% ..... Antifungal

Use
- clinically proven to prevent most athlete's foot with daily use

Warnings
For external use only

Flammable: Do not use near heat, flame, or while smoking

Do not use on children under 2 years of age unless directed by a doctor

When using this product
- avoid contact with the eyes
- use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Stop use and ask a doctor if irritation occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- to prevent athlete's foot, wash the feet and dry thoroughly.
- shake can well and spray a thin layer of the product on the feet once or twice daily (morning and/or night).
- supervise children in the use of this product.
- pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.

Other information
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients butylated hydroxytoluene, fragrance, isobutane, PPG-12-buteth-16, SD alcohol 40-B (10.5% v/v), talc

Questions? 1-866-360-3266

Lotrimin Anti-Fungal Athlete's Foot Daily Prevention Deodorant Powder Spray Label

Drug Facts

Active ingredient — **Purpose**
(To Deliver) Tolnaftate 1%.....Antifungal

Uses
- cures most jock itch
- for effective relief of itching, chafing and burning

Warnings
For external use only

Flammable: Do not use near heat, flame, or while smoking

Do not use on children under 2 years of age unless directed by a doctor.

When using this product
- avoid contact with the eyes
- use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.
- contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

Stop use and ask a doctor if - irritation occurs - there is no improvement within 2 weeks

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- wash the affected area and dry thoroughly
- shake can well and spray a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- use daily for 2 weeks; if condition persists longer, ask a doctor
- this product is not effective on the scalp or nails

Other information store between 20°to 25°C (68°to 77°F)

Inactive ingredients butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (11% v/v), talc

Questions? 1-866-360-3266

Tinactin Jock Itch Powder Spray Label

Drug Facts
Active ingredient ***Purpose*** (To Deliver) Tolnaftate 1%.....Antifungal
Uses • proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) • helps prevent most athlete's foot with daily use • for effective relief of itching, burning, and cracking
Warnings **For external use only**
Flammable: Do not use near heat, flame, or while smoking
Do not use on children under 2 years of age unless directed by a doctor.
When using this product • avoid contact with the eyes • use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal. • contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120℉.
Stop use and ask a doctor if • irritation occurs • there is no improvement within 4 weeks
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions • wash the affected area and dry thoroughly • shake can well and spray a thin layer over affected area twice daily (morning and night) • supervise children in the use of this product • for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily • use daily for 4 weeks; if condition persists longer, ask a doctor • to prevent athlete's foot, apply once or twice daily (morning and/or night) • this product is not effective on the scalp or nails
Other information • store between 20°to 25℃ (68°to 77°F)
Inactive Ingredients butylated hydroxytoluene, fragrance, isobutane, PPG-12-buteth-16, SD alcohol 40-B (10.5% v/v),talc
Questions? 1-866-360-3266

Tinactin Athlete's Foot Deodorant Powder Spray Label

Drug Facts
Active ingredient ***Purpose*** (To Deliver) Tolnaftate 1%.....Antifungal
Uses ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) ▪ helps prevent most athlete's foot with daily use ▪ for effective relief of itching, burning and cracking
Warnings **For external use only**
Flammable: Do not use near heat, flame, or while smoking
Do not use on children under 2 years of age unless directed by a doctor.
When using this product ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.
Stop use and ask a doctor if ▪ irritation occurs ▪ there is no improvement within 4 weeks
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions ▪ wash the affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily ▪ use daily for 4 weeks; if condition persists longer, ask a doctor ▪ to prevent athlete's foot, apply once or twice daily (morning and/or night) ▪ this product is not effective on the scalp or nails
Other information store between 20°to 25℃ (68°to 77℉)
Inactive ingredients butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (11% v/v), talc
Questions? 1-866-360-3266

Tinactin Athlete's Foot Powder Spray Label

Drug Facts
Active ingredient ***Purpose*** (To Deliver)Tolnaftate 1%.....Antifungal
Uses ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) ▪ helps prevent most athlete's foot with daily use ▪ for effective relief of itching, burning, and cracking
Warnings **For external use only** **Flammable:** Do not use near heat, flame, or while smoking **Do not use** on children under 2 years of age unless directed by a doctor.
When using this product ▪ avoid contact with the eyes ▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal. ▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.
Stop use and ask a doctor if ▪ irritation occurs ▪ there is no improvement within 4 weeks
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions ▪ wash affected area and dry thoroughly ▪ shake can well and spray a thin layer over affected area twice daily (morning and night) ▪ supervise children in the use of this product ▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily ▪ use daily for 4 weeks; if condition persists longer, ask a doctor ▪ to prevent athlete's foot, apply once or twice daily (morning and/or night) ▪ this product is not effective on the scalp or nails
Other information store between 20°to 25℃ (68°to 77℉)
Inactive ingredients butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (29% v/v)
Questions? 1-866-360-3266

Tinactin Athlete's Foot Liquid Spray Label

II. BENZENE

27. 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. Likewise, the Food and Drug Administration ("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." Benzene is associated with blood cancers such as leukemia.2 A study from 1939 on benzene stated that

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

"exposure over a long period of time to any concentration of benzene greater than zero is not safe,"3 which is a comment 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."4

28. 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."[5]

29. 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

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[3] Hunter, F.T. (1939). Chronic Exposure to Benzene (Benzol). II. The Clinical Effects. *Journal of Industrial Hygiene and Toxicology*. 1939 Vol.21 pp.331-54, https://www.cabdirect.org/cabdirect/abstract/19402700388.

[4] Smith, Martyn T. (2010). Advances in Understanding Benzene Health Effects and Susceptibility. *Annual Review of Public Health*. 2010 Vol. 31:133-148, https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646.

[5] BENZENE, https://www.atsdr.cdc.gov/sites/toxzine/benzene_toxzine.html.

> lymphocytic leukemia (CLL), multiple myeloma, and non-Hodgkin lymphoma.[6]

30. Moreover, "[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation."[7]

31. 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."[8] Skin absorption is particularly concerning as there have been multiple FDA studies showing that structurally similar chemicals in sunscreen products are found in the blood at high levels after application to exposed skin.

32. 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.

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[6] American Cancer Society. Benzene and Cancer Risk (January 5, 2016), https://www.cancer.org/cancer/cancer-causes/benzene.html.

[7] Centers for Disease Control and Prevention, Facts About Benzene, https://emergency.cdc.gov/agent/benzene/basics/facts.asp.

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

SUBSTANTIVE ALLEGATIONS

I. BAYER'S TINACTIN AND LOTRIMIN AF SPRAYS CONTAIN UNACCEPTABLE LEVELS OF BENZENE

33. In October 2021, 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." Bayer has instructed users to "stop using" the Products.[9]

34. As a result of Bayer's 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. Each of the Products direct users to apply the spray multiple times per day for prolonged periods of time, often weeks.

35. In the recall notice, Bayer admitted that "[b]enzene is ***not*** an ingredient in any of Bayer Consumer Health products."[10] Thus, the presence of benzene in Defendant's Products appears to be ***the result of contamination*** or a

[9] FDA, Bayer Issues Voluntary Recall of Specific Lotrimin® and Tinactin® Spray Products Due to the Presence of Benzene, 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.

[10] *Id.* (emphasis added)

deficiency the manufacturing process designed, implemented, and used by Bayer to manufacture the Products.

36. Accordingly, because the presence of benzene is the result of contamination, benzene is not unavoidable in the manufacture of the Products, and any significant detection of benzene in such products is unacceptable.

37. 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) show that the Products are contaminated with unsafe levels of the carcinogen benzene.

38. 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, 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.[11]

[11] 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.

39. Notably, these results contradict Bayer's statement that "the levels detected [in the Products]are not expected to cause adverse health consequences in consumers."[12]

40. 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).

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

[12] https://www.tinactin.com/spray-recall.

Lot	UPC	Product Description	Expiry	Labeled % Active Ingredient	Labeled Inactive Ingredients	Receipt Date	Benzene (ppm)
TN005K8	041100590367	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	311017410059	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**
TN0047R	311017410097	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	311017410257	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**

Lot	UPC	Product Description	Expiry	Labeled % Active Ingredient	Labeled Inactive Ingredients	Receipt Date	Benzene (ppm)
TN004BX	041100587206	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	311017410318	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	311017410318	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	311017410097	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	311017410097	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	311017410097	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	311017410004	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	311017410004	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**

42. 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."[13] 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 that Bayer's testing was flawed.

43. 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.

II. CONTAMINTED WITH BENZENE, THE PRODUCTS ARE WORTHLESS.

44. Because the Products contained benzene they were not just worthless to Plaintiffs; they were dangerous to use and could not actually be sold under FDA guidelines.

[13] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-specific-lotriminr-and-tinactinr-spray-products-due-presence-benzene; see also https://www.tinactin.com/spray-recall and https://www.lotrimin.com/spray-recall.

45. 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. § 51(a)(2)(B). Federal and state regulatory regimes require that labeling for OTC products identify each active and inactive ingredient.[14]

46. 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).

47. 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

[14] https://www.fda.gov/media/72250/download.

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

48. 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.

49. 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.

50. 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.

51. 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.

52. "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.

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

54. Further, had Defendant adequately tested the Products for benzene and other carcinogens, reproductive toxins, and impurities, it would have

discovered that the Products contained benzene at levels far above the legal limit, making those products ineligible for distribution, marketing, and sale.

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

56. Defendant 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."

57. Pursuant to 21 U.S.C. § 331(a) of the Food, Drug, and Cosmetics Act, 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.

58. Defendant's failure to control for benzene contamination and sale of its adulterated products constitutes actionable fraud.

59. 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 Defendant has failed to warn consumers of this fact. Such illegally sold products are worthless and have no value. *See Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *see also In re*

Valsartan, Losartan, & Irbesartan Prod. Liab. Litig., 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021) ("This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for."); *Barnes v. Unilever United States, Inc.*, 2022 WL 2915629, at *1 (N.D. Ill. July 24, 2022) ("Barnes alleges that she was deprived of the benefit of her bargain, in that she would not have purchased the products, or would not have purchased them for the listed price, had she known they contained a human carcinogen … [T]his is a sufficient allegation of an injury in fact.").

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

61. 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, damages related to Defendant's conduct, and injunctive relief.

62. Further, Plaintiffs and other Class Members were forced to discard the remainder of their Products due to the contamination or to buy replacement products to treat their athlete's foot or other conditions. Accordingly, Plaintiffs and Class Members were also injured because they were forced to waste portions of the Products or to spend additional money to purchase replacement medications that they would not have spent but for the Products being contaminated.

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

64. 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.

III. 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

65. 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.

66. Consumers who could not take photographs of the Recalled Sprays 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 of contaminated Recalled Sprays. It is noteworthy that, for example, other companies that recalled aerosol spray products due to the presence of benzene did not require photographs of the products.[15]

[15] https://www.ccc-consumercarecenter.com/UCUConfiguration?id=a071i00000zs7tqAAA#etd=::00c?Z9W00Y00MVvu?,TV9Z00ww$; *see also* Coppertone Sunscreen Recall Claim Form: https://secure.sunscreenrecall2021.com/.

B. Plaintiffs And Class Members Require Medical Monitoring

1. Plaintiffs And Class Members Have A Significantly Increased Risk Of Contracting Benzene-Caused Cancer Due To Regular Usage Of The Products

67. As alleged below, Plaintiffs regularly used the Products as directed on the Products' labels to treat medical conditions the Products are intended to treat such as athlete's foot, jock itch, and other conditions.

68. Based on prevailing scientific evidence, and the classifications adopted by numerous agencies, regulatory bodies, and scientific organizations discussed *supra*, exposure to benzene via skin absorption can cause cancer, including leukemia and other blood-related cancers.

69. Plaintiffs used the Products manufactured and distributed by Bayer as directed by the Products' labels. As the labels included above show, this often meant that Plaintiffs applied the Products multiple times a day for a period of time that could last as long as four weeks. These products, unbeknownst to Plaintiffs, contained benzene, a known carcinogen.

70. Thus, as a direct and proximate result of using Bayer's Products for years, Plaintiffs are at a significantly increased risk of contracting Benzene-caused Cancers. Plaintiffs' lengthy duration of exposure to benzene from Bayer's Products warrants additional medical testing not routinely provided to the public at large.

2. Plaintiffs And The Class Members Require Diagnostic Medical Testing That Differs From Routine Medical Care

71. Physicians evaluate a person's exposure to toxic and carcinogenic substances, including benzene, when determining what diagnostic testing and treatment is necessary.

72. A reasonably prudent person would conclude that Plaintiffs' repeated exposure to significant, unsafe levels of benzene over lengthy periods of time necessitates specialized testing (with resultant treatments) that is not generally given to the public at large as a part of routine medical care.

73. The available monitoring regime, discussed in greater detail below, is reasonably necessary and specific for individuals exposed to products known to significantly increase the risk of the Benzene-Caused Cancers because of exposure to benzene. It is different from that normally recommended in the absence of exposure to this risk of harm (in kind and/or frequency) and is not generally available in a general practitioner setting.

74. The available medical monitoring regime will mitigate the development of and health effects associated with the Benzene-Caused Cancers, improving prognosis, outcome, and quality of life, and reducing medical costs.

75. Consistent with best practices, Plaintiffs seek to implement a medical monitoring program which begins with screening to determine whether more

invasive or costly tests are warranted. This screening may be conducted via questionnaire, in-person before a medical practitioner, or via a tele-health appointment.

76. Medical practitioners will review the questionnaire or the results of a screening appointment to determine whether additional testing, such as a blood test, for purposes of diagnosis is required. Leukemia and other Benzene-Caused Cancers are typically found via blood tests and can be detected before symptoms begin.[16]

77. Additional testing may include blood tests and/or bone marrow tests.[17] Blood tests allow doctors to determine whether an individual has abnormal levels of red or white blood cells or platelets, which may suggest leukemia, or can show the presence of leukemia cells.[18] Bone marrow tests are used to determine whether leukemia cells which can avoid detection in blood tests are present.[19]

78. Screening and testing in the medical monitoring program will likely occur for an extended period of time. This permits the medical practitioners to monitor changes in symptoms or follow anomalies that may appear in tests over time, and accommodates latency periods associated with the Benzene-Caused Cancers.

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[16] https://www.mayoclinic.org/diseases-conditions/leukemia/diagnosis-treatment/drc-20374378.

[17] *Id.*

[18] *Id.*

[19] *Id.*

C. The Recall Thus Fails To Adequately Compensate Plaintiffs On A Number Of Levels

79. 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. Bayer has admitted a measly 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.

(b) 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.

(c) The recall did not promise any changes to Bayer's manufacturing and distribution process so as to prevent future contamination.

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

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

(f) 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."[20]

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

[20] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-specific-lotriminr-and-tinactinr-spray-products-due-presence-benzene; see also https://www.tinactin.com/spray-recall and https://www.lotrimin.com/spray-recall.

PLAINTIFF ALLEGATIONS

I. JUAN HUERTAS

80. 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 Defendant'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. According to Defendant's recall notice, Mr. Huertas's cannister of Lotrimin contained benzene. However, Mr. Huertas never received notice of the recall from Defendant for his contaminated Lotrimin product. When purchasing the Product, Mr. Huertas reviewed the accompanying labels and disclosures, and 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 Clotrimazole. Mr. Huertas 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 Defendant 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 Clotrimazole.

81. Mr. Huertas was injured in multiple ways as a result of his purchase of Lotrimin. *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 Clotrimazole. 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 Clotrimazole, and was therefore worth less than what Mr. Huertas bargained for. *Second*, as a result of the benzene contamination, Mr. Huertas's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Mr. Huertas still had a portion of his Lotrimin product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Huertas did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination. And *fourth*, Mr. Huertas was 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

82. 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 Defendant'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. According to Defendant's recall notice, Ms. Mistretta's cannister of Tinactin contained benzene. However, Ms. Mistretta never received notice of the recall from Defendant for her contaminated Tinactin product. When purchasing the Product, Ms. Mistretta reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, 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 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 she would not have purchased the Tinactin from Defendant 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.

83. Ms. Mistretta was injured in multiple ways as a result of her purchase of Tinactin. *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. *Second*, as a result of the benzene contamination, Ms. Mistretta's Tinactin was adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Ms. Mistretta still had a portion of her Tinactin product remaining when she learned of the benzene contamination. As a result of this contamination, Ms. Mistretta did not use and was unable to use the remaining portion of her Tinactin product, and therefore wasted a portion of her Tinactin product as a result of the benzene contamination.

III. JOSE VILLARREAL

84. Plaintiff Jose Villarreal is a resident of Boone County, Missouri and has an intent to remain there, and is therefore a citizen of Missouri. Between September 2018 and September 2021, Mr. Villarreal Defendant's Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray in Missouri. Mr. Villarreal used the Product as directed on the label. Mr. Villarreal's Lotrimin contained benzene. For each product he purchased, Mr. Villarreal reviewed the accompanying labels and disclosures, and 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 Clotrimazole. Mr. Villarreal 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 Defendant 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 Clotrimazole.

85. Mr. Villarreal was injured in multiple ways as a result of his purchase of Lotrimin. *First*, Mr. Villarreal bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole. However, Mr. Villarreal received Lotrimin that was ***not*** properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole, and was therefore worth less than what Mr. Villarreal bargained for. *Second*, as a result of the benzene contamination, Mr. Villarreal's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Mr. Villarreal still had a portion of his Lotrimin product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Villarreal did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination.

IV. JEREMY WYANT

86. Plaintiff Jeremy Wyant is a resident of Clinton County, Indiana and has an intent to remain there, and is therefore a citizen of Indiana. 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. Mr. Wyant's cannisters of the Products contained benzene. 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 Clotrimazole 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 Clotrimazole and Tolnaftate.

87. Mr. Wyant was injured in multiple ways as a result of his purchase of the Products. *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 Clotrimazole 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 of uncontaminated Clotrimazole and Tolnaftate, and were therefore worth less than what Mr. Wyant bargained for. *Second*, as a result of the benzene contamination, Mr. Wyant's Products were adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Mr. Wyant still had a portion of his Products product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Wyant did not use and was unable to use the remaining portion of his Products, and therefore wasted a portion of his Products as a result of the benzene contamination.

V. MIKE POOVEY

88. 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 Defendant's Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray with the lot number TN001NK in South Carolina. Mr. Poovey used the Product as directed on the

label. According to Defendant's recall notice, Mr. Poovey's cannister of Lotrimin contained benzene. For each product he purchased, Mr. Poovey reviewed the accompanying labels and disclosures, and 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 Clotrimazole. 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 Defendant 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 Clotrimazole.

89. Mr. Poovey was injured in multiple ways as a result of his purchase of Lotrimin. *First*, Mr. Poovey bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole. 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 Clotrimazole, and was therefore worth less than what Mr. Poovey bargained for. *Second*, as a result of the benzene contamination, Mr. Poovey's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Mr. Poovey still had a

portion of his Lotrimin product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Poovey did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination.

VI. CHRISTOPHER CADORETTE

90. Plaintiff Christopher Cadorette is a resident of Essex County, Massachusetts and has an intent to remain there, and is therefore a citizen of Massachusetts. Between September 2018 and September 2021, Mr. Cadorette purchased canisters of Defendant's Lotrimin products in Massachusetts, including (i) Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray, and (ii) Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray. Mr. Cadorette used the Products as directed on the label. Mr. Cadorette's cannisters of Lotrimin contained benzene. When purchasing the Products, Mr. Cadorette reviewed the accompanying labels and disclosures, and 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 Clotrimazole. Mr. Cadorette relied on these representations and warranties in deciding to purchase the Lotrimin 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 Lotrimin products

from Defendant if he had known that they were not, in fact, properly manufactured, free from defects, not safe for their intended use, and not equivalent to Clotrimazole.

91. Mr. Cadorette was injured in multiple ways as a result of his purchase of Lotrimin. *First*, Mr. Cadorette bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole. However, Mr. Cadorette received Lotrimin that was ***not*** properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole, and was therefore worth less than what Mr. Cadorette bargained for. *Second*, as a result of the benzene contamination, Mr. Cadorette's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Mr. Cadorette still had a portion of his Lotrimin products remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Cadorette did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination.

VII. SEAN STEINWEDEL

92. Plaintiff Sean Steinwedel is a resident of Sussex County, Delaware and has an intent to remain there, and is therefore a citizen of Delaware. Between September 2018 and September 2021, Mr. Steinwedel purchased canisters of

Defendant's Products in Delaware, including (i) Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray; (ii) Lotrimin Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray; (iii) Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray; (iv) Tinactin Jock Itch (JI) Powder Spray; and (v) Tinactin Athlete's Foot Deodorant Powder Spray. Mr. Steinwedel used the Products as directed on the labels. Mr. Steinwedel's cannisters of the Products contained benzene. When purchasing the Products, Mr. Steinwedel 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 Clotrimazole and Tolnaftate. Mr. Steinwedel 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 Clotrimazole and Tolnaftate.

93. Mr. Steinwedel was injured in multiple ways as a result of his purchase of the Products. *First*, Mr. Steinwedel bargained for Lotrimin and Tinactin that were properly manufactured, free from defects, safe for their intended

use, and the brand-name equivalent of uncontaminated Clotrimazole and Tolnaftate. However, Mr. Steinwedel received Lotrimin and Tinactin that were ***not*** properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Clotrimazole and Tolnaftate, and were therefore worth less than what Mr. Steinwedel bargained for. *Second*, as a result of the benzene contamination, Mr. Steinwedel's Products were adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Mr. Steinwedel still had a portion of his Products product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Steinwedel did not use and was unable to use the remaining portion of his Products, and therefore wasted a portion of his Products as a result of the benzene contamination.

VIII. DON PENALES, JR.

94. Plaintiff Don Penales, Jr. is a resident of California and has an intent to remain there, and is therefore a citizen of California. Between September 2018 and September 2021, Mr. Penales purchased canisters of Defendant's Products in California, including (i) Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray, (ii) Lotrimin AF Athlete's Foot Liquid Spray, (iii) Tinactin Athlete's Foot Powder Spray, and (iv) Tinactin Athlete's Foot Liquid Spray. Mr. Penales used the Products as directed on the labels. Mr. Penales's cannisters of the Products contained benzene. When purchasing the Products, Mr. Penales 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 Clotrimazole and Tolnaftate. Mr. Penales 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 Clotrimazole and Tolnaftate.

95. Mr. Penales was injured in multiple ways as a result of his purchase of the Products. *First*, Mr. Penales bargained for Lotrimin and Tinactin that were properly manufactured, free from defects, safe for their intended use, and the brand-name equivalent of uncontaminated Clotrimazole and Tolnaftate. However, Mr. Penales received Lotrimin and Tinactin that were ***not*** properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Clotrimazole and Tolnaftate, and were therefore worth less than what Mr. Penales bargained for. *Second*, as a result of the benzene contamination, Mr. Penales's Products were adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Mr. Penales still had a portion of his Products product remaining

when he learned of the benzene contamination. As a result of this contamination, Mr. Penales did not use and was unable to use the remaining portion of his Products, and therefore wasted a portion of his Products as a result of the benzene contamination.

IX. JONATHAN MARTIN

96. Plaintiff Jonathan Martin is a resident of Contra Costa County, California and has an intent to remain there, and is therefore a citizen of California. Between September 2018 and September 2021, Mr. Martin purchased Defendant's Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray in California. Mr. Villarreal used the Product as directed on the label. Mr. Martin's Lotrimin contained benzene. For each Product he purchaed, Mr. Martin reviewed the accompanying labels and disclosures, and 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 Clotrimazole. Mr. Martin 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 Defendant 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 Clotrimazole.

97. Mr. Martin was injured in multiple ways as a result of his purchase of Lotrimin. *First*, Mr. Martin bargained for Lotrimin that was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole. However, Mr. Martin received Lotrimin that was ***not*** properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole, and was therefore worth less than what Mr. Martin bargained for. *Second*, as a result of the benzene contamination, Mr. Martin's Lotrimin was adulterated, misbranded, illegal to sell, and therefore worthless. *Third*, Mr. Martin still had a portion of his Lotrimin product remaining when he learned of the benzene contamination. As a result of this contamination, Mr. Martin did not use and was unable to use the remaining portion of his Lotrimin product, and therefore wasted a portion of his Lotrimin product as a result of the benzene contamination.

CLASS ACTION ALLEGATIONS

98. Plaintiffs Huertas, Villarreal, Wyant, Poovey, Cadorette, Steinwedel, Penales, and Martin 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 (the "Lotrimin Class"):

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

- Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray
- Lotrimin AF Athlete's Foot Liquid Spray
- Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray

99. Plaintiffs Mistretta, Wyant, Steinwedel, and Penales 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 (the "Tinactin Class") (collectively with the Lotrimin Class, the "Nationwide Classes"):

- Tinactin® Jock Itch (JI) Powder Spray
- Tinactin® Athlete's Foot Deodorant Powder Spray
- Tinactin® Athlete's Foot Powder Spray
- Tinactin® Athlete's Foot Liquid Spray

100. Plaintiff Huertas also seeks to represent a subclass of all Lotrimin Class members who purchased the Lotrimin products in New York (the "Lotrimin New York Subclass").

101. Plaintiff Villarreal also seeks to represent a subclass of all Lotrimin Class members who purchased the Lotrimin products in Missouri (the "Lotrimin Missouri Subclass").

102. Plaintiff Wyant also seeks to represent a subclass of all Lotrimin Class members who purchased the Lotrimin products in Indiana (the "Lotrimin Indiana Subclass").

103. Plaintiff Poovey also seeks to represent a subclass of all Lotrimin Class members who purchased the Lotrimin products in South Carolina (the "Lotrimin South Carolina Subclass").

104. Plaintiff Cadorette also seeks to represent a subclass of all Lotrimin Class members who purchased the Lotrimin products in Massachusetts (the "Lotrimin Massachusetts Subclass").

105. Plaintiff Steinwedel also seeks to represent a subclass of all Lotrimin Class members who purchased the Lotrimin products in Delaware (the "Lotrimin Delaware Subclass").

106. Plaintiffs Penales and Martin also seek to represent a subclass of all Lotrimin Class members who purchased the Lotrimin products in California (the "Lotrimin California Subclass").

107. Plaintiff Mistretta also seeks to represent a subclass of all Tinactin Class members who purchased the Tinactin products in New York (the "Tinactin New York Subclass").

108. Plaintiff Wyant also seeks to represent a subclass of all Lotrimin Class members who purchased the Tinactin products in Indiana (the "Tinactin Indiana Subclass").

109. Plaintiff Steinwedel also seeks to represent a subclass of all Tinactin Class members who purchased the Tinactin products in Delaware (the "Tinactin Delaware Subclass").

110. Plaintiff Penales also seeks to represent a subclass of all Tinactin Class members who purchased the Tinactin products in California (the "Tinactin California Subclass").

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

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

113. 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.

114. Specifically excluded from the Classes are Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and its heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or

directors, the judge assigned to this action, and any member of the judge's immediate family.

115. **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 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 are known by Defendant. Members of the Classes may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

116. **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 Defendant's misconduct in the very same way as the members of the Classes. Further, the factual bases of Defendant's 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.

117. **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 manufactured by Defendant contain dangerously high levels of benzene, thereby breaching the express and implied warranties made by Defendant and making the Products unfit for human use and therefore unfit for their intended purpose;

(b) whether Defendant knew or should have known the Products contained elevated levels of benzene prior to selling them, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendant is liable to Plaintiffs and the Classes for unjust enrichment;

(d) whether Defendant is liable to Plaintiffs and the Classes for fraud;

(e) whether Plaintiffs and the Classes have sustained monetary

loss and the proper measure of that loss;

(f) whether Plaintiffs and the Classes are entitled to declaratory and injunctive relief;

(g) whether Plaintiffs and the Classes are entitled to restitution and disgorgement from Defendant; and

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

118. **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.

119. **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 Defendant. 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.

120. 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 Defendant;

(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) Defendant has 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

121. Plaintiffs incorporate by reference and re-allege each and every

allegation set forth in paragraphs above as though fully set forth herein.

122. Plaintiffs bring this claim individually and behalf of the members of the proposed Classes against Defendant.

123. In connection with the sale of the Products, Defendant, 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. Those active and inactive ingredients do not include benzene, a known human carcinogen dangerous to humans. Defendant further expressly warrants 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, Defendant expressly warranted that the Products were the brand-name equivalents of Clotrimazole and Tolnaftate. Finally, Defendant provided instructions for repeated daily use for a period of weeks.

124. As a direct and proximate cause of Defendant's breach of express warranty, Plaintiffs and the Classes have been injured and harmed because they 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.

125. On November 12, 2021, prior to filing this action, Defendant was served with a pre-suit notice letter on behalf of Plaintiffs that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiffs' counsel sent Defendant a letter advising them that they breached an express warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copies of Plaintiffs' counsel's letter is attached hereto as **Exhibit 1**.

COUNT II
Breach of Implied Warranty

126. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

127. Plaintiffs bring this claim individually and on behalf of the members of the proposed Classes against Defendant.

128. Defendant, as the designer, manufacturer, 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.

129. Defendant 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 Defendant

were defective in that they containedelevated 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 Defendant to be merchantable.

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

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

132. The Products were defective when they left the exclusive control of Defendant.

133. Defendant knew that the Products would be purchased and used without additional testing by Plaintiffs and members of the Classes.

134. 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.

135. As a direct and proximate cause of Defendant'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 containedharmful 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.

136. On November 12, 2021, prior to filing this action, Defendant was served with a pre-suit notice letter on behalf of Plaintiffs that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiffs' counsel sent Defendant a letter advising them that they breached an implied warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copies of Plaintiffs' counsel's letter is attached hereto as **Exhibit 1**.

COUNT III
Violation of New York General Business Law § 349

137. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

138. Plaintiffs Huertas and Mistretta bring this claim individually and on behalf of the members of the Lotrimin New York Subclass and Tinactin New York Subclass (for this paragraph, the "New York Subclasses") against Defendant.

139. GBL § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

140. In its sale of goods throughout the State of New York, Defendant conducts business and trade within the meaning and intendment of GBL § 349.

141. Plaintiffs and members of the New York Subclasses are consumers who purchased products from Defendant for their personal use.

142. By the acts and conduct alleged herein, Defendant has engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the Products (i) would not contain dangerously high levels of benzene, (ii) are generally recognized as safe for human use, and (iii) are equivalent to the formulation of the Products as approved by the FDA (*i.e.*, that the Products are the brand-name equivalents of Clotrimazole and Tolnaftate).

143. Defendant also materially omitted key facts regarding the true nature of the Products, specifically that the Products containeddangerous levels of benzene, was adulterated, and was unsafe for use as an antifungal treatment.

144. 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 purchased the Products.

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

146. 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.

147. By reason of this conduct, Defendant engaged in deceptive conduct in violation of GBL § 349.

148. Defendant's actions 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 Defendant's products. 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.

149. As a result of Defendant's violations, Plaintiffs Huertas and Mistretta and members of the Subclasses have suffered damages because: (a) they paid a premium price in the amount of the full purchase price of the Products based on Defendant's deceptive conduct; (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.

150. 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 IV
Violation of GBL § 350

151. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

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

153. GBL § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

154. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

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

156. Defendant's false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

157. Defendant's false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

158. Defendant's false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

159. Defendant also materially omitted key facts regarding the true nature of the Products, specifically that the Products containeddangerous levels of benzene, were adulterated, 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 purchased the Products.

160. As a result of Defendant's false, misleading, and deceptive statements and representations of fact, Plaintiffs Huertas and Mistretta and the New York Subclasses have suffered and continue to suffer economic injury.

161. As a result of Defendant's violations, 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 in the amount of the full purchase price of the Products based on Defendant's deceptive conduct; (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.

162. 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 V
Fraud

163. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

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

165. Defendant committed both fraudulent misrepresentation and fraudulent omission. Specifically, Defendant (i) misrepresented that the Products were the brand-name equivalents of Clotrimazole and Tolnaftate when they were not, and (ii) failed to disclose the presence of benzene in the Products.

166. Defendant had a duty to disclose material facts to Plaintiffs and the Classes given their relationship as contracting parties and intended users of the Products. Defendant 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 Defendant had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

167. Defendant knew or should have known that the Products were contaminated withbenzene but continued to manufacture them nonetheless. Defendant was required to engage in impurity testing to ensure that harmful impurities such as benzene were not present in the Products. Had Defendant undertaken proper testing measures, it would have been aware that the Products contained dangerously high levels of benzene. Further, Defendant's recall stretches back to September 2018, meaning 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 it contained dangerous levels of benzene.

168. Defendant failed to discharge its duty to disclose these material facts.

169. In so failing to disclose these material facts to Plaintiffs and the Classes, Defendant 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.

170. Plaintiffs and the Classes reasonably relied on Defendant's failure to disclose insofar as they would not have purchased the defective Products manufactured and sold by Defendant had they known they containedunsafe levels of benzene.

171. As a direct and proximate cause of Defendant's 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.

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

COUNT VI
Unjust Enrichment

173. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

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

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

176. Defendant voluntarily accepted and retained this benefit.

177. 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 Defendant to retain the benefit without paying the value thereof.

COUNT VII
Violation of the NJCFA,
N.J. Stat. §§ 56:8-1, *et seq.*

178. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

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

180. The 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.

181. 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).

182. 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.

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

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

185. 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 the Classes.

186. 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 the Classes had little alternative but to submit, which caused consumers substantial injury.

187. 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.

188. Plaintiffs and the Classes have suffered ascertainable loss as a direct and proximate result of Bayer's conduct because (i) Plaintiffs and 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 Clotrimazole and Tolnaftate, and were therefore worth less than what Plaintiffs and the Classes

bargained for, (ii) as a result of the benzene contamination, Plaintiffs' Products were adulterated, misbranded, illegal to sell, and therefore worthless, and (iii) Plaintiffs and the Classes were forced to discard the remaining portion of their contaminated Products and/or purchase a replacement product as as a result of the contamination, which made the Products unusable.

189. 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.

190. As a result, Plaintiffs and 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 VIII
Violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. Ann. §§ 407.010, *et seq.*

191. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

192. Plaintiff Villarreal brings this claim individually and on behalf of the members of the Lotrimin Missouri Subclass against Defendant.

193. Missouri's Merchandising Practices Act ("Missouri MPA") prohibits any "act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose."

194. At all relevant times, Plaintiff Villarrel, members of the Missouri Lotrimin Subclass, and Bayer were "persons" within the meaning of the Missouri MPA. *See* Mo. Rev. Stat. § 407.010(5).

195. Bayer willfully and purposefully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts in connection with trade or commerce in violation of Mo. Rev. Stat. § 407.020 as described in the allegations above.

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

197. At all relevant times, Plaintiff Villarreal and the Missouri Lotrimin Subclass acted as reasonable consumers would in light of all circumstances.

198. Bayer's unlawful method, acts, and practices as alleged would cause a reasonable person to enter into the transactions that resulted in damages.

199. At trial, Plaintiff Villarreal will present, both individually and on behalf of the Missouri Lotrimin Subclass, evidence that is sufficiently definitive and objective to allow the loss of individual damages to be calculated with a reasonable degree of certainty.

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

201. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair because they inequitably enriched Bayer at the expense of Plaintiff Villarreal and the Missouri Lotrimin Subclass.

202. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair because they offend public policy, and were so oppressive that the Plaintiff Villarreal and the Missouri Lotrimin Subclass had little alternative but to submit, which caused consumers substantial injury.

203. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair in that they violated 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.

204. Plaintiff Villarreal and the Missouri Lotrimin Subclass suffered economic injury as a direct and proximate result of Bayer's conduct.

205. As a direct and proximate result of the foregoing acts and practices, Bayer 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.

COUNT IX
Violation of the Indiana Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1, *et seq*.

206. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

207. 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 Defendant.

208. Bayer is a "person" as defined by Ind. Code § 24-5-0.5-2(a)(2).

209. Bayer is a "supplier" as defined by Ind. Code § 24-5-0.5-2(a)(3).

210. Sales of the Product by Bayer to Plaintiff Wyant and members of the Indiana Subclasses, as well as purchases of the Recalled Sprays 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).

211. Bayer 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*., 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 Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-3:

> (b) [T]he following acts, and the following representations as to the subject matter of a consumer transaction, made orally, in writing, or by electronic communication, by a supplier, are deceptive acts:
>
> (1) 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;
>
> (2) 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.

212. Bayer's unfair or deceptive acts or practices occurred repeatedly in Bayer's trade or business and were capable of deceiving the purchasing public.

213. Bayer knew 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.

214. Bayer owed a duty to Plaintiff Wyant and the Indiana Subclasses to disclose the presence of Benzene in the Recalled Sprays as well as the dangers posed by the Benzene in the Recalled Sprays because:

(a) Bayer was in a superior position to know the true state of facts about the defect within the Recalled Sprays;

(b) Plaintiff Wyant and Indiana Economic Loss Subclass could not reasonably have been expected to learn or discover that the Recalled Sprays contained the carcinogen benzene and thus were not in accordance with Bayer's advertisements and representations;

(c) Bayer knew that Plaintiff Wyant and the Indiana Economic Loss Subclass 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 Sprays; and

(d) Bayer 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 Indiana Economic Loss Subclass.

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

216. The facts Bayer 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 Sprays. Had Plaintiff Wyant and the Indiana Subclasses known of the presence ofbenzene in the Products and the dangers it posed, and that the Products were not the brand-name equivalents of Clotrimazole and Tolnaftate, they would not have purchased the Recalled Sprays or would have paid less for the Recalled Sprays. 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.

217. Bayer's violations 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 Indiana Deceptive Consumer Sales Act.

218. The Indiana Deceptive Consumer Sales Act 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).

219. The Indiana Deceptive Consumer Sales Act 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).

220. Plaintiff Wyant's and the Indiana Subclasses' injuries were proximately caused by Bayer's fraudulent and deceptive business practices.

221. Plaintiff Wyant provided notice of his claims to Bayer on November 17, 2021 by mailing a letter via certified mail, return receipt requested and by providing an electronic copy of the letter to Bayer's General Counsel via electronic mail. A true and correct copy of that letter is attached hereto as **Exhibit 2**. Therefore, Plaintiff Wyant and the Indiana Subclasses are entitled to damages and equitable relief under the Indiana Deceptive Consumer Sales Act.

COUNT X
Violation of South Carolina's Unfair Trade Practices Act, S.C. Code §§ 39-5-10, *et seq.*

222. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

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

224. At all relevant times, Plaintiff Poovey, members of the Lotrimin South Carolina Subclass, and Bayer were "persons" within the meaning of S.C. Code § 39-5-10(a).

225. Bayer's deceptive acts or practice described above were conducted in "trade" or "commerce" within the meaning of S.C. Code § 39-5-10(b).

226. 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;

227. Bayer willfully engaged in unfair, deceptive, and/or unlawful practices as described in the allegations above.

228. Bayer's misrepresentations, omissions, and suppression of material information in the sale of the Products are acts or practices in the conduct or trade or commerce.

229. Plaintiff Poovey and the Lotrimin South Carolina Subclass suffered loss of money as a direct and proximate result of Bayer's unfair, deceptive practices.

230. The unfair and deceptive practices and acts by Bayer described above impact the public interest.

231. Plaintiff Poovey and the Lotrimin South Carolina Subclass relied on Bayer's 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 Clotrimazole and Tolnaftate.

232. As a direct and proximate result of the foregoing acts and practices Bayer 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.

COUNT XI
Violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93, §§1, *et seq.*

233. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

234. Plaintiff Cadorette brings this claim individually and on behalf of the members of the Lotrimin Massachusetts Subclass against Defendant.

235. Bayer is a "person" as defined by Mass. Gen. Laws ch. 93A, § 1(a).

236. Plaintiff Cadorette and the Lotrimin Massachusetts Subclass are actual or potential consumers of Products.

237. Bayer engaged in engaged in deceptive or unfair acts or practices in the in the conduct of any trade or commerce, in violation of Mass. Gen. Laws ch. 93A, § 2(a), including but not limited to the following:

(a) Knowingly or recklessly made a false representation as to the characteristics and use of Products, in violation of 93A, § 2(a);

(b) Represented that Products are safe for use, in violation of 93A, § 2(a);

(c) Advertised the Products as the brand-name equivalents of Clotrimazole and Tolnaftate with an intent not to sell it as advertised, in violation of 93A, § 2(a); and

(d) Failed to disclose the material information that Recalled Sprays contained unsafe Benzene and that Recalled Sprays users were at risk of suffering adverse health effects, in violation of 93A, § 2(a).

238. As detailed throughout this Complaint, Bayer's deceptive trade practices significantly impacted the public, because there are millions of consumers of Products, Plaintiff Cadorette and the Lotrimin Massachusetts Subclass.

239. Bayer's representations and omissions were material because they were likely to deceive reasonable consumers to induce them to purchase the Products without being aware that the Products were unsafe to use and not the brand-name equivalents of Clotrimazole and Tolnaftate.

240. As a direct and proximate result of Bayer's unfair and deceptive acts or practices, Plaintiff Cadorette and the Lotrimin Massachusetts Subclass suffered damages by purchasing the Products because (i) Plaintiff Cadorette and the Lotrimin Massachusetts Subclass did not receive Products that were properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole and Tolnaftate, and were therefore worth less than what Plaintiff Cadorette and the Lotrimin Massachusetts Subclass bargained for, (ii) as a result of the benzene contamination, Plaintiff Cadorette's and the Lotrimin Massachusetts Subclass's Products were adulterated, misbranded, illegal to sell, and therefore worthless, and (iii) Plaintiff Cadorette and the Lotrimin Massachusetts Subclass were forced to discard the remaining portion of their

contaminated Products and/or purchase a replacement product as as a result of the contamination, which made the Products unusable.

241. Bayer's deceptive trade practices caused injury in fact and actual damages to Plaintiff Cadorette and the Lotrimin Massachusetts Subclass in the form of the loss or diminishment of value of the Products Plaintiff Cadorette and the Lotrimin Massachusetts Subclass purchased, which allowed Bayer to profit at the expense of Plaintiff Cadorette and the Lotrimin Massachusetts Subclass. The injuries to Plaintiff Cadorette and the Lotrimin Massachusetts Subclass were to legally protected interests. The gravity of the harm of Bayer's actions is significant and there is no corresponding benefit to consumers of such conduct.

242. Plaintiff Cadorette and the Lotrimin Massachusetts Subclass seek relief under 93A, § 9 including, not limited to, compensatory damages or statutory damages of $25 per violation, whichever is greater, restitution, penalties, injunctive relief, and/or attorneys' fees and costs.

243. Plaintiff Cadorette and the Lotrimin Massachusetts Subclass provided noticed pursuant to Mass. Gen. Laws ch. 93A, § 9(3) to Bayer on November 17, 2021 by mailing a letter via certified mail, return receipt requested and by providing an electronic copy of the letter to Bayer's General Counsel via electronic mail. A true and correct copy of this letter is attached hereto as **Exhibit 2**.

COUNT XII
Violation of the Delaware Consumer Fraud Act, Del. Code tit. 6, §§ 2511, *et seq*.

244. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

245. Plaintiff Steinwedel brings this claim individually and on behalf of the members of the Lotrimin Delaware Subclass and Tinactin Delaware Subclass (collectively, the "Delaware Subclasses") against Defendant.

246. Delaware's Consumer Fraud Act 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."

247. At all relevant times, Plaintiff Steinwedel, members of the Delaware Subclasses, and Bayer were each individuals, corporations, governments, or governmental subdivisions or agencies, statutory trusts, business trusts, estates, trusts, partnerships, unincorporated associations or other legal or commercial entities.

248. Bayer 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 Delaware Consumer Fraud Act, Del. Code tit. 6, § 2511(6)) in violation of Del. Code Ann. tit. 6, § 2513(a), as described in the allegations above.

249. Plaintiff Steinwedel and the Delaware Subclasses relied on Bayer's misrepresentations and omissions in the sale of the Products detailed above.

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

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

252. Bayer's misrepresentations and omissions in the sale of the Products detailed above were unfair because they inequitably enriched Bayer at the expense of the Plaintiff Steinwedel and the Delaware Subclasses.

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

254. Bayer's 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.

255. Plaintiff Steinwedel and the Delaware Subclasses have suffered economic injury as a direct and proximate result of the Bayer's conduct.

256. Plaintiff Steinwedel and the Delaware Subclasses were deceived by Bayer's deceptive and unfair acts and practices in that had they known the truth they would not have purchased Bayer's Products or would have paid less for the Products.

257. Instead, as a result of Bayer's misrepresentation, Plaintiff Steinwedel and 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 Steinwedel and the Delaware Subclasses paid more than the fair market value of the merchandise they received causing them out-of-pocket damages; and (3) Plaintiff Steinwedel and the Delaware Subclasses were forced to discard their leftover Product and/or purchase a replacement product as a result of the contamination.

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

COUNT XIII
Violation of the CLRA,
Cal. Civ. Code §§ 1750 *et seq*.

259. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

260. Plaintiffs Martin and Penales bring this claim individually and on behalf of the members of the Lotrimin California Subclass and Tinactin California Subclass (collectively, the "California Subclasses") against Defendant.

261. Plaintiff Martin, Plaintiff Penales, and the California Subclasses are "consumer[s]" as that term is defined in Cal. Civ. Code § 1761(d).

262. The Products are "goods," as that term is defined in Cal. Civ. Code § 1761(a).

263. Bayer is a "person" as that term is defined in Cal. Civ. Code § 1761(c).

264. Each purchase of a Product by Plaintiff Martin, Plaintiff Penales, and the California Subclasses constituted a "transaction" as that term is defined in Cal. Civ. Code § 1761(e).

265. Bayer's conduct alleged herein violates the following provisions of the CLRA:

(a) Cal. Civ. Code § 1770(a)(5), by negligently, recklessly, and/or intentionally representing that the Products were and are safe for use by individuals when in fact they contain an unsafe chemical, benzene

(b) Cal. Civ. Code § 1770(a)(7), by negligently, recklessly, and/or intentionally representing that the Recalled Sprays were of a particular standard, quality, or grade (*i.e.*, that the Products are the brand-name equivalent of Clotrimazole and Tolnaftate), when they were of another;

(c) Cal. Civ. Code § 1770(a)(9), by negligently, recklessly, and/or intentionally advertising the Products with intent not to sell them as advertised; and

(d) Cal. Civ. Code § 1770(a)(16), by representing that the Products have been supplied in accordance with previous representations when they have not.

266. As a direct and proximate result of these violations, Plaintiff Martin, Plaintiff Penales, and the California Subclasses have been harmed by the misleading marketing described herein in any manner in connection with the advertising and sale of the Products.

267. Plaintiff Martin, Plaintiff Penales, and the California Subclasses seek relief for the injuries they have suffered as a result of Bayer's practices, as provided by the CLRA and applicable law.

268. Plaintiff Martin, Plaintiff Penales, and the California Subclasses have no adequate remedy at law for this claim. Plaintiff Martin, Plaintiff Penales, and the California Subclasses plead their claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

269. Alternatively, legal remedies available to Plaintiff Martin, Plaintiff Penales, and the California Subclasses are inadequate because they are not

"equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view … It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

270. Furthermore:

(a) To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff Martin, Plaintiff Penales, and the California Subclasses fail to sufficiently adduce evidence to support an award of damages.

(b) Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff Martin, Plaintiff Penales, and the California Subclasses seek such relief here.

(c) Legal claims for damages are not equally certain as restitution because claims under the CLRA entail few elements.

(d) A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law." RESTATEMENT (THIRD) OF RESTITUTION § 4(2).

271. Plaintiff Martin, Plaintiff Penales, and the California Subclasses provided Bayer, via certified mail, return receipt requested, notice of the specific complaint and damages in accordance with Cal. Civ. Code § 1761 on November 17, 2021, thirty (30) days prior to the initiation of this claim, and provided and electronic copy of the letter to Bayer's General Counsel via electronic mail on the same date. A true and correct copy of this letter is attached hereto as **Exhibit 2**.

COUNT XIV
Violation of the UCL, Cal. Bus. & Prof. Code §§ 17200 *et seq*.

272. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

273. Plaintiffs Martin and Penales bring this claim individually and on behalf of the members of the California Subclasses against Defendant.

274. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code §17200.

275. Bayer fraudulently represented that the Products were and are properly manufactured, free from defects, safe for their intended uses, and the

brand-name equivalents of uncontaminated Clotrimazole and Tolnaftate. None of these representations were true because the Products contained an unsafe chemical, benzene.

276. As alleged herein, Bayer's conduct was "unlawful" because it violates at least the various consumer protection statutes and common law claims alleged in this Complaint.

277. Defendant has also committed "unlawful" acts by violating the Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 109875, *et seq.* (the "Sherman Act"). Specifically, the Sherman Act prohibits the sale of misbranded drugs and devices. "Any drug or device is misbranded if its labeling is false or misleading in any particular." Sherman Act, Health & Safety Code § 111330. Here, the Products fit within the definition of a "drug" and are "misbranded" because its labeling—specifically, the Products' representations that the Products are the brand-name equivalents of uncontaminated Clotrimazole and Tolnaftate—are false and misleading. Therefore, the marketing of the Products is violative of the Sherman Act and the unlawful provision of the UCL by extension.

278. Bayer's conduct with respect to the labeling, packaging, advertising, marketing, and sale of the Products is unfair because Bayer's conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the

utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

279. Bayer's conduct with respect to the labeling, packaging, advertising, marketing, and sale of the Products is also unfair because the consumer injury is substantial, not outweighed by benefits to consumers or competition, and not one that consumers, themselves, can reasonably avoid.

280. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff Martin, Plaintiff Penales, and the California Subclasses seek an order requiring Bayer to immediately repair or replace the Products.

281. Plaintiff Martin, Plaintiff Penales, and the California Subclasses also seek an order for the restitution of all monies from the sale of the Products, which were unjustly acquired through acts of fraudulent, unfair, or unlawful competition.

282. Plaintiff Martin, Plaintiff Penales, and the California Subclasses have no adequate remedy at law for this claim. Plaintiff Martin, Plaintiff Penales, and the California Subclasses plead their claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

283. Alternatively, legal remedies available to Plaintiff Martin, Plaintiff Penales, and the California Subclasses are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States*

v. Bluitt, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view … It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

284. Furthermore:

(a) To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff Martin, Plaintiff Penales, and the California Subclasses fail to sufficiently adduce evidence to support an award of damages.

(b) Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff Martin, Plaintiff Penales, and the California Subclasses seek such relief here.

(c) Legal claims for damages are not equally certain as restitution because claims under the UCL entail few elements. Further, the "unlawful" prong of the UCL is the only way for Plaintiff Martin, Plaintiff Penales, and the California Subclasses to vindicate violations of the

Sherman Act because the Sherman Act contains no private right of action.

(d) A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law." RESTATEMENT (THIRD) OF RESTITUTION § 4(2).

COUNT XV
Violation of the FAL
Cal. Bus. & Prof. Code §§ 17500 *et seq*.

285. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

286. Plaintiffs Martin and Penales bring this claim individually and on behalf of the members of the California Subclasses against Defendant.

287. The FAL prohibits any statement in connection with the sale of goods "which is untrue or misleading." Cal. Bus. & Prof. Code §17500.

288. As set forth herein, Bayer's claimed that the Product were and are were and are properly manufactured, free from defects, safe for their intended uses, and the brand-name equivalents of uncontaminated Clotrimazole and Tolnaftate. None of these representations were true because the Products contained an unsafe chemical, benzene.

289. Further, Bayer failed to disclose the presence of benzene in the Products, which rendered the Products not properly manufactured, not free from

defects, not safe for their intended uses, and not the brand-name equivalents of uncontaminated Clotrimazole and Tolnaftate.

290. Bayer knew, or reasonably should have known, that all these claims were untrue or misleading.

291. Prospective injunctive relief is necessary given Bayer's refusal to offer details as to when they intend to repair the Recalled Sprays.

292. Plaintiff Martin, Plaintiff Penales, and the California Subclasses are entitled to injunctive and equitable relief, and restitution in the amount they spent on the Products and replacement devices.

293. Plaintiff Martin, Plaintiff Penales, and the California Subclasses have no adequate remedy at law for this claim. Plaintiff Martin, Plaintiff Penales, and the California Subclasses plead their claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

294. Alternatively, legal remedies available to Plaintiff Martin, Plaintiff Penales, and the California Subclasses are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence' of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there

may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view … It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

295. Furthermore:

(a) To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff Martin, Plaintiff Penales, and the California Subclasses fail to sufficiently adduce evidence to support an award of damages.

(b) Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff Martin, Plaintiff Penales, and the California Subclasses seek such relief here.

(c) Legal claims for damages are not equally certain as restitution because claims under the FAL entail few elements.

(d) A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law." RESTATEMENT (THIRD) OF RESTITUTION § 4(2).

COUNT XVI
Negligent Misrepresentation

296. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs above as though fully set forth herein.

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

298. 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.

299. 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.

300. 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.

301. 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.

302. 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.

303. 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.

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

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 Defendant 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 Defendant's 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, 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: September 16, 2022

Respectfully Submitted,

BURSOR & FISHER, P.A.

By: */s/ Philip L. Fraietta*
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**Pro Hac Vice* Application Forthcoming

Attorney for Plaintiffs

CLRA Venue Declaration Pursuant To California Civil Code Section 1780(d)

I, Philip L. Fraietta, declare as follows:

1. I am an attorney at law licensed to practice in the State of New Jersey and a member of the bar of this Court. I am a partner at Bursor & Fisher, P.A., counsel of record for Plaintiffs in this action. I have personal knowledge of the facts set forth in this declaration and, if called as a witness, I could and would competently testify thereto under oath.

2. The Complaint filed in this action is filed in the proper place for trial under Civil Code Section 1780(d) in that a substantial portion of the events alleged in the Complaint occurred in this District, and Defendant resides in this District.

I declare under the penalty of perjury under the laws of the States of New Jersey and New York and the United States that the foregoing is true and correct. Executed in New York, New York this 16th day of September, 2022.

/s/ Philip L. Fraietta
Philip L. Fraietta

Public court record.

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Court: United States District Court for the District of New Jersey
Case number: 2:21-cv-20021-SRC-CF
Filed: 2022-09-16

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