UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MAY PAINTER, NICOLE HESLIP, MATHIAS CONDUFF, NATHANIEL MENDEZ-GUTIERREZ, RODNEY SHAW, MYLES THOMASON and JEFFREY DUPREX, on behalf of themselves and all others similarly situated, **Plaintiffs,** **vs.** **STRIDES PHARMA, INC.** **Defendant.**	**Case No. 7:25-cv-4189** **Jury Trial Demanded** **CLASS ACTION COMPLAINT**

PRELIMINARY STATEMENT

1. No one would choose to rub benzene on their skin every day. Health authorities have classified benzene as a carcinogen since at least the 1970s, and the Food and Drug Administration prohibits benzene in prescription medication under virtually all circumstances. But, without their knowledge, Plaintiffs and many other purchasers of Defendant Strides Pharma, Inc.'s testosterone gel were rubbing benzene on their arms and chests every day because Strides made its drug with an ingredient known to contain benzene and failed to ensure its finished product was benzene-free. By falsely representing that its generic testosterone gel was made in accordance with federally mandated Current Good Manufacturing Practice ("CGMP")

regulations and concealing the fact that its drugs contained benzene, Strides was able to sell adulterated, contaminated drugs that were not lawful to sell, much less what patients' doctors prescribed. Plaintiffs bring economic loss claims arising from their purchases of Strides' contaminated testosterone gel, over 13 million doses of which have now been recalled, and seek to represent a class or classes of purchasers with similar claims.

2. For decades, benzene has been recognized as a Class I carcinogen, and the FDA has deemed its presence in prescription drugs to be "unacceptable" since at least 1997. Under the FDA's CGMP regulations, promulgated pursuant to the Federal Food, Drug & Cosmetic Act ("FD&CA"), drug manufacturers like Strides are required to adopt and adhere to manufacturing, testing, and quality practices to ensure that their drugs are not made with benzene-contaminated ingredients and that benzene-contaminated drugs are not released to the public. Strides failed to do so. Instead, it manufactured its testosterone gel with an ingredient made with benzene—Carbomer 940—long after the FDA warned against its use. Strides also failed to adopt testing and quality assurance procedures sufficient to ensure benzene-contaminated finished product was not released to the public.

3. Strides was only able to sell its contaminated testosterone gel because it misrepresented the gel's quality and purity. Despite its CGMP violations, Strides expressly and falsely represented to its immediate

purchasers—drug distributors and pharmacies—that its drugs complied with all CGMP and other FDA requirements, absent which no one in the chain of distribution will buy, prescribe, nor dispense prescription drugs. Further, to have its drug listed as a generic in the FDA's "Orange Book" and linked to a name brand testosterone gel, enabling its sale under state law and industry norms, Strides falsely represented that its generic was therapeutically equivalent, even though it was not due to concealed carcinogens.

4. Without these false representations of CGMP compliance and therapeutic equivalence—as well as the material omission that its testosterone gel was contaminated with benzene—Strides would not have been able to sell its adulterated gel. Without being listed in the Orange Book, Strides would have been unable to sell its generic drug in the first instance. Further, prescription drugs that are not CGMP-compliant would not be accepted by purchasers, prescribers, pharmacists, or patients. Because of these false representations and omissions, Strides was able to sell adulterated drugs that were unlawful to sell and economically worthless, and all purchasers in the distribution chain reasonably relied on Strides's representations. Strides never should have sold its benzene-contaminated testosterone gel and is obligated to reimburse patients for their purchases.

JURISDICTION AND VENUE

5. The Court has subject-matter jurisdiction under 28 U.S.C. §

1332(d). Plaintiffs are citizens of California, Georgia, New Jersey, Ohio, and Washington, and Defendant is a citizen of New Jersey. The amount in controversy exceeds $5,000,000.

6. The Court has specific personal jurisdiction over Defendant because it manufactured the adulterated drugs at issue in this case at its facility located at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

7. Venue is proper in this District because Defendant's conduct giving rise to this case occurred here.

PARTIES

8. May Painter is a resident of Georgia and consumer of Strides's testosterone gel. They purchased and received Strides's testosterone gel from at least recalled lot 5502262A on or about March 4, 2025. Their out-of-pocket costs for this purchase amounted to approximately twenty-five dollars. They learned of the recall through a friend's social media post.

9. Nicole Heslip resides in California and purchased recalled lot 5502005A of Strides's testosterone gel on or about January 8, 2025. Her out-of-pocket costs for Strides's testosterone gel were a five-dollar copay for each prescription she received. She was informed of the recall by her pharmacy on April 8, 2025.

10. Mathias Conduff is a resident of Washington and received Strides's testosterone gel from recalled lot 5502115A on or about February 20,

2025. Mr. Conduff incurred expenses addressing the recall, including by driving to the pharmacy to pick up a replacement prescription. He heard about the recall from other affected individuals.

11. Nathaniel Mendez-Gutierrez is a Washington resident. He purchased and received Strides's testosterone gel at least five times, with at least one purchase from recalled lot 5502217A. His out-of-pocket costs amounted to a ten-dollar copay for each prescription he received. He learned about the recall through social media.

12. Rodney Shaw is a resident of Ohio. He purchased and received Strides's testosterone gel from recalled lots 5501868A, 5501770A, 5502112A, 5501842A, and 5501868A in June and August of 2024 and December and February of 2025. His out-of-pocket costs for Strides's testosterone gel amounted to approximately fifty dollars for each prescription he received. He was informed of its recall by his insurance company.

13. Myles Thomason is a resident of Ohio. He purchased and received Strides's testosterone gel from recalled lots 5501516A, 5502217A, and 5502092A. He had out of pocket expenses amounting to at least $512.70. He learned of the recall through Reddit.

14. Jeffrey Duprex is a resident of New Jersey who purchased Strides's testosterone gel from recalled lot 5502092A on or about March 3, 2025, among at least six boxes of Strides testosterone gel made with benzene he purchased.

His out-of-pocket costs amounted to a copay between five and ten dollars for each prescription he received. Duprex used one box of the gel before receiving a recall notice from his insurer on April 1st, 2025.

15. Strides Pharma, Inc. is a U.S.-based pharmaceutical company that holds itself out as the "front-end US based business of Strides Pharma Science Limited," a generic pharmaceutical enterprise headquartered in India, which trades on the Bombay Stock Exchange and the National Stock Exchange of India.[1] Strides Pharma, Inc. and its affiliates manufacture and distribute dozens of generic drugs, including testosterone gel. According to the company's submissions to the FDA in connection with the recall and recall letter, the affected "product was manufactured by Strides, Chestnut Ridge, NY 10977."[2]

FACTUAL ALLEGATIONS

Strides's Recall of Benzene-Contaminated Testosterone Gel

16. Testosterone is a widely prescribed drug, typically indicated for conditions such as hypogonadism or as part of hormone therapy. According to a leading drug database, approximately 1.4 million U.S. patients take testosterone per year, which is ordinarily self-administered to the skin in gel

[1] Strides Pharma Inc., *Who We Are*, https://www.stridespharmausa.com.
[2] **Exhibit 1**, California Board of Pharmacy Recall Advisory (quoting Strides's recall letter); **Exhibit 2**, FDA Enforcement Report for Strides Testosterone Gel Recall.

form.[3]

17. Benzene, on the other hand, is a "known human carcinogen that causes leukemia and other blood disorders."[4] The International Agency for Research on Cancer ("IARC") designated benzene as a Class I carcinogen in 1979.[5] According to the FDA, the presence of benzene in drugs is "unacceptable."[6] That has been the FDA's position since at least 1997, when the agency published in the Federal Register the *Q3C Impurities: Residual Solvents* guidance. Benzene "should not be employed in the manufacture of drug substances, excipients [inactive ingredients, such as thickeners], and drug products because of [benzene's] unacceptable toxicity." 62 Fed. Reg. 67377 (Dec. 24, 1997). Updating that guidance in 2018, the FDA reaffirmed that benzene, a "carcinogen," "should not be employed in the manufacture of drug substances, excipients, and drug products."[7]

18. In recent years, after the FDA became aware that some drug

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[3] ClinCalc.com, *Drug Usage Statistics, Testosterone*, https://clincalc.com/DrugStats/Drugs/Testosterone.
[4] FDA, *Reformulating Drug Products that Contain Carbomers Manufactured with Benzene, Guidance for Industry*, 88 Fed. Reg. 89703 (Dec. 28, 2023), https://www.fda.gov/media/175083/download.
[5] *See* IARC, *Monograph on the Evaluation of Carcinogenic Risk to Humans No. 120*, https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Benzene-2018.
[6] FDA, *Reformulating Drug Products*, *supra*.
[7] FDA, *ICH Q3C – Tables and List, Guidance for Industry* (Aug. 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q3c-tables-and-list-rev-4.

manufacturers were nonetheless continuing to release drugs with benzene contamination, the agency initiated a series of instructions and enforcement actions. Pertinent here, "[i]n 2020 FDA identified the potential for unacceptable levels of benzene in certain carbomers (which may be used as thickening agents in drugs)" and began pushing to remove those carbomers—including Carbomer 940—from use in drugs.[8]

19. By 2021, the FDA was overseeing multiple drug (and cosmetic) recalls due to benzene contamination.[9] From 2021–forward, the FDA has overseen almost one hundred recalls of benzene-contaminated drugs, affecting tens of millions of individual doses.[10]

20. In 2021, after evaluating the "root cause" of these recalls, the FDA issued a formal alert to drug manufacturers regarding "the risk of benzene contamination from drug components and other potential risk factors."[11] The FDA again emphasized that "[m]anufacturers should not use benzene in the manufacture of drugs" and warned in part that "contamination may be related

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[8] FDA, *Frequently Asked Questions on Benzene Contamination in Drugs*, https://www.fda.gov/drugs/drug-safety-and-availability/frequently-asked-questions-benzene-contamination-drugs.

[9] *Id*.

[10] **Exhibit 3**, Benzene Recalls 2021–April 2025 (data obtained from FDA).

[11] *See* FDA, *FDA Alerts Drug Manufacturers to the Risk of Benzene Contamination in Certain Drugs*, https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs (current version); **Exhibit 4**, FDA, *FDA Alerts Drug Manufacturers to the Risk of Benzene Contamination in Certain Drugs* (December 23, 2021 Version).

to inactive ingredients such as carbomers (thickening agents)."[12] The agency "remind[ed] drug manufacturers they are required to establish scientifically sound and appropriate specifications and test procedures to assure drug components (active and inactive ingredients) and finished drug products" are free from benzene contamination in drugs, with a "need for a special focus on ingredients that are hydrocarbons or are manufactured with benzene or other hydrocarbons."[13]

21. FDA then repeatedly issued public warning letters to drugmakers whose products are contaminated with benzene, further putting companies like Stride on notice that using benzene to make drugs or releasing drugs with benzene contamination violates CGMP regulations and the Food, Drug & Cosmetic Act. For example, in May 2022, the FDA issued a warning letter finding a drug "adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), in that contamination with the impurity benzene at unacceptable levels demonstrates that the quality assurance within [the drug company's] facility is not functioning in accordance with Current Good Manufacturing Practice (CGMP) requirements."[14] Elaborating, the FDA

[12] *Id.* (current version; also in 2021 version).
[13] *Id.*
[14] FDA, Warning Letter 320-22-14 to David Cosmetic Co., Ltd. (May 2, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/david-cosmetic-co-ltd-627408-05022022.

explained that "[b]ecause benzene contamination is a known risk of the manufacturing process, a finished product specification for benzene [in the pertinent drug] is appropriate under 21 CFR 211.160(b)," and "finished product testing of each batch of drug product is required under 21 CFR 211.165."[15] The FDA has issued similar warning letters to other drugmakers who release drugs with benzene contamination.[16]

22. In 2023, consistent with these actions, the FDA published in the Federal Register guidance "for immediate implementation" entitled Reformulating Drugs Products that Contain Carbomers Manufactured with Benzene. 88 Fed. Reg. 89703 (Dec. 28, 2023). As observed by the FDA since at least 2020, carbomers, or thickeners used to make gel- and cream-form drugs, are a common vector of benzene contamination because some carbomers are

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[15] *Id.*

[16] *See, e.g.*, FDA, Warning Letter 320-22-16 to Mirfeel Korea Co., Ltd. (June 22, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mirfeel-korea-co-ltd-627401-06222022; FDA, Warning Letter to Gordon Laboratories Inc. (August 17, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gordon-laboratories-inc-631432-08172022; FDA, Warning Letter to Virgin Scent Inc. dba Artnaturals (September 1, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/virgin-scent-inc-dba-artnaturals-631780-09012022; FDA, Warning Letter 630566 to Salon Technologies International, Inc. (December 21, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/salon-technologies-international-inc-630566-12212022; FDA, Warning Letter 643600 to Accra-Pac, Inc. dba Voyant Beauty (April 30, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/accra-pac-inc-dba-voyant-beauty-643600-04202023.

made with benzene. Specifically calling out the use of Carbomer 940, the FDA stressed that "[m]anufacturers should not use benzene in the manufacture of drugs" under longstanding CGMP requirements, and that drugs that are not "manufactured . . . in conformity with current good manufacturing practice to assure that the drug meets requirements for safety, and quality and purity characteristics" are "considered adulterated."[17]

23. Despite the FDA's repeated directives, Strides knowingly used a benzene-containing ingredient to make its testosterone gel and put millions of benzene-contaminated drugs into patients' hands. In March 2025, Strides was forced to recall over 13 million testosterone gel packets due to the "Presence of Benzene,"[18] "resulting from an excipient Carbomer 940," which for years FDA has explicitly instructed drugmakers not to use.[19]

24. The resulting benzene contamination was no surprise to Strides. Carbomer 940 and some other carbomers are manufactured with benzene, which is specifically disclosed to manufacturers like Strides in product literature. For example, one leading supplier explains that Carbomer 940 is "synthesized in benzene, a substance that is increasingly restricted for use in

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[17] *Id*.
[18] **Exhibit 2**, FDA, Enforcement Report for Strides Testosterone Gel Recall.
[19] **Exhibit 1**, California Board of Pharmacy Recall Advisory (quoting Strides's recall letter); **Exhibit 5**, Strides Labeling for Testosterone Gel (identifying Carbomer 940 as an ingredient); also available at https://www.stridespharmausa.com/product/testosterone-gel/.

pharmaceutical applications," so the supplier offers "toxicologically preferred" alternatives made without benzene.[20] Carbomers like 940 can contain benzene up to 5,000 parts per million (ppm).[21] As a comparison point, the FDA has a special exception for a narrow class of novel drugs: if it is "unavoidable" to use benzene in drugs offering a "significant therapeutic advance," benzene must be limited to just 2 ppm.[22] Testosterone gel, which was first approved in 1953, is not such a drug, and it is not unavoidable to use Carbomer 940.

25. On the contrary, the other three FDA-approved makers of testosterone gel use a different thickener, Carbomer 980, that is not made with benzene. For example, the "reference listed drug," or lead drug under the FDA's generic approval framework, made by Besins Healthcare, has used Carbomer 980 since at least 2005.[23] The other generics, made by Actavis and Encube

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[20] Lubrizol, *Carbopol Polymer Products*, https://www.lubrizol.com/Health/Pharmaceuticals/Excipients/Carbopol-Polymer-Products.

[21] FDA, *Reformulating Drug Products that Contain Carbomers Manufactured with Benzene, Guidance for Industry* (December 2023).

[22] FDA, *Reformulating Drug Products* at 3 (citing 2018 ICH Q3C guidance); FDA, *Q3C – Tables and List, Guidance for Industry* (August 2018) at Table 1 (identifying 2 ppm as the limit for benzene where "use is unavoidable to produce a drug product with a significant therapeutic advance"); *see also* **Exhibit 6**, FDA, *Risk Factors for Benzene Contamination* (April 2023) ("The ICH Q3C guideline and USP <467> is **not to be interpreted** as recommending that controlling benzene at nmt [no more than] 2 ppm in the drug alone is sufficient in the absence of significant therapeutic advance.") (emphasis in original).

[23] **Exhibit 7,** FDA, 2005 Approval Correspondence to Solvay Pharmaceuticals, Inc., NDA 021015 (enclosing package insert identifying Carbomer 980). The approval for testosterone gel now held by Besins under NDA 021015 has passed through several hands.

Ethicals, Inc., have used Carbomer 980 since at least 2019 and 2021 (Encube's launch), respectively.[24]

26. Strides chose not to use a benzene-free ingredient and chose instead to continue distributing benzene-contaminated drugs until forced to recall millions of them. Based on the available evidence, Strides's benzene contamination affects all lots in distribution and seemingly all historic lots. The contamination is inherent to an ingredient Strides (and Strides alone) chooses to use in testosterone gel, and the scale of the recall—thirty-four large lots, with expiration dates ranging into 2027—is unusually extensive for a drug recall. Those facts indicate that all product was both made with unacceptable levels of benzene and that Strides lacks adequate CGMP quality processes, which should have detected the contamination before the drugs were ever distributed to unknowing patients.

27. The knowing distribution of benzene-contaminated drugs is only Strides's latest CGMP violation. The FDA issued a warning letter to Strides in 2019 due to "significant violations of current good manufacturing practice (CGMP) regulations" and resulting drug adulteration.[25] Violations included the "fail[ure] to establish an adequate quality control unit," "fail[ure] to

[24] **Exhibit 8**, Actavis 2019 Labeling; **Exhibit 9**, Encube 2021 Labeling.
[25] FDA, Warning Letter 320-19-28 to Strides Pharma Science Limited (July 1, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/strides-pharma-science-limited-576722-07012019.

thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications." The FDA also identified "data integrity problems": the "uncontrolled shredding" of lab documents pitched into "a 55-gallon drum in [Strides's] scrap yard" just "days before [FDA's] inspection."[26]

28. The 2019 warning letter was not closed for four years, until 2023. The nature and scale of the above recall indicates that, despite being engaged with the FDA on other issues, Strides persisted in using a benzene-derived ingredient the FDA had specifically instructed drug companies not to use, and the company failed to establish testing, specifications, and controls to prevent the release of benzene-contaminated drugs into the market.

29. Nor is testosterone the only Strides drug with CGMP problems. Since 2020, the company has been forced to undertake at least ten other recalls due to CGMP deviations like releasing drugs with mutagen impurities and failed quality specifications.[27]

30. This history of quality failures from Strides indicates a pattern of knowing or reckless disregard for CGMP and other FDA requirements.

Strides Failed to Comply with CGMP Requirements, Making its Testosterone Gel Adulterated and Nonsaleable

[26] *Id.*
[27] **Exhibit 10**, Strides Recalls (data obtained from FDA).

31. According to the FDA, "[c]onsumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective."[28] Because consumers "usually cannot detect (through smell, touch, or sight) that a drug product is safe or if it will work," drug-making must be closely regulated to keep consumers safe.[29] To that end, the FD&CA and related CGMP regulations set multiple requirements to ensure that medicines are safely made and are what drug-makers say they are. *See, e.g.*, 21 C.F.R. Parts 210–211 (CGMP regulations). When "a company is not complying with CGMP regulations, any drug it makes is considered 'adulterated' under the law" and is unlawful to sell.[30] 21 U.S.C. § 331 ("prohibit[ing]" the sale of "adulterated" drugs); 21 U.S.C. § 351(a)(2)(B) and (b) (providing that drugs that fail to meet USP or CGMP requirements are "adulterated"); 21 U.S.C. § 333 (knowing violations of the FD&CA a felony). These requirements are broadly incorporated into parallel state laws.

32. Under CGMP regulations, every drugmaker is required to have a "quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process

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[28] FDA, *Facts About the Current Good Manufacturing Practices (CGMPs)* https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp.
[29] *Id.*
[30] *Id.*

materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated." 21 C.F.R. § 211.22(a). "The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product." *Id.* at (b). Among its other duties, "[t]he establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by [the Laboratory Controls] subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit." 21 C.F.R. § 211.160(a).

33. It is the drugmaker's responsibility to ensure that its drugs are of the required quality and purity. "Laboratory 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(b).

34. Under the CGMP regulations, the drugmaker must ensure the necessary purity, strength, and quality of its drugs through all phases of

production and throughout the drug's lifecycle. With respect to components sourced from third parties, the "component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality." 21 C.F.R. § 211.84(d)(2). Then, as drugs are being made, "[i]n-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods." 21 C.F.R. § 211.110(c). Before release, "[f]or each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product." 21 C.F.R. § 211.165(a). Finally, "[t]o assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166." 21 C.F.R. § 211.137(a).

35. With respect to required pre-release testing, "[a]cceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels." 21 C.F.R. § 211.165(d).

36. Strides failed to meet the CGMP requirements cited above. There is no question that the company used an "unacceptable" ingredient, Carbomer 940, and failed to adopt adequate quality controls, testing, and acceptance criteria to ensure that its testosterone gel met the required quality and purity standards to avoid benzene exposure.

37. The claims of Plaintiffs and the Class encompass all sales of Strides's adulterated testosterone gel that the company knowingly or recklessly sold despite its failure to comply with applicable CGMP requirements for benzene contamination, as shown by discovery.

The Marketplace, Including Consumers, Relied on Strides's False Representations Regarding CGMP Compliance and Therapeutic Equivalence

38. Strides used a variety of false representations to sell its adulterated testosterone gel. Through its Orange Book listing, Strides affirmatively represented that its adulterated testosterone gel was therapeutically equivalent to the listed name brand and therefore free of unacceptable benzene contamination, when it was not. Strides expressly warranted to its commercial customers via written contracts that its adulterated testosterone gel complied with all applicable CGMP and other regulatory requirements, when it did not. The very nature of Strides's sale of its adulterated testosterone gel through the U.S. pharmaceutical system carried with it the inherent representation that the drugs were made according

to CGMP and other FD&CA requirements, when they were not. And Strides failed to disclose to everyone in the distribution chain, including consumers, the material facts that the drugs were contaminated with benzene, were not made in accordance with CGMP and other requirements, and were not therapeutically equivalent to name-brand testosterone gel.

39. Strides's false representations and omissions were material; without them, Strides could not have sold its adulterated testosterone gel. Distributors, pharmacies, and pharmacists do not trade in prescription drugs that are not CGMP compliant and that do not comply with other FDA standards. Patients, as well as the physicians who prescribe drugs and the pharmacies who dispense them, expect drugmakers like Strides to comply with CGMP and other FDA standards to keep drugs free of unacceptable levels of benzene contamination. That expectation is a function of law, industry practice, and social norms through the chain of distribution.

40. To take another example, generic drugmakers like Strides must also represent to pharmacy "linkage" databases and insurers that their drugs are equivalent to branded drugs (without contamination) to compete for business.[31] Marketing a generic of an approved name-brand drug depends on

[31] *See generally United States Pharm. Corp. v. Trigen Labs, Inc.*, 2011 U.S. Dist. LEXIS 13637 (N.D. Ga. 2011) (explaining how drugmakers use linkage databases to market their drugs to dispensers and other health care providers).

the drug being listed as therapeutically equivalent to the branded version in the FDA's Orange Book, which requires, *inter alia*, the generic to comply with the "identical compendial or other applicable standard of . . . purity" as the branded drug.[32] Absent Orange Book listing, prescribers, dispensers, payers, and patients will not substitute a generic for the branded version or a listed generic. Thus, but for the representation of compliance with the applicable benzene purity standards, Strides could not have sold its drug to downstream patients via the pharmaceutical supply chain.

41. Physicians, who cannot be expected to test individual drugs, rely on drugmakers to make uncontaminated medicine. And patients, who are even less able to discern drug quality, must rely on drugmakers to make and distribute untainted drugs in the first instance. As the FDA explains, "[c]onsumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective," and the "main regulatory standard for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (CGMP) regulations for human pharmaceuticals."[33]

42. Plaintiffs and the Class were the intended beneficiaries of Strides's false warranties of CGMP compliance. CGMP requirements exist to safeguard

[32] 21 CFR § 314.3(b).
[33] FDA, *Facts About the Current Good Manufacturing Practice (CGMP)*, https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp.

patients and the drug supply system. As an experienced pharmaceutical company, Strides knew that the supply chain, and ultimately patients, expect and depend on drugs to comply with federal quality standards. Had Strides disclosed its deviation from CGMP and related requirements, it could not have sold its adulterated drugs. Physicians would not have prescribed them, pharmacies would not have stocked and dispensed them, and patients would not have purchased them. They would instead purchase and consume brand-name testosterone gel or one of the unadulterated generic products on the market. Plaintiffs relied on the representation inherent in Strides's marketing, and explicit in Strides's upstream warranties, that its drugs met federal quality standards and were not adulterated.

43. Strides's adulterated drugs were worth zero dollars. Adulterated drugs must be incinerated, not sold for profit. Strides must therefore reimburse purchasers who did not receive the benefit of their bargain.

Estimated Damages

44. As set out above, the claims of Plaintiffs and the Class are not limited to the testosterone gel Strides recalled but instead encompass the company's knowing or reckless sales of all testosterone gel that was similarly adulterated due to CGMP violations but was not recalled because it was sold before Strides's adulteration came to light. The analysis here focuses on the recalled lots because there is no question that those lots were adulterated—

Strides has admitted as much—and the approximate quantity of product subject to the recalls is publicly available. To date, Strides's recall covers at least 34 lots, comprising 440,364,000 cartons, each containing 30 sachets for individual dosing.

45. Given the sheer size of the recall, the problem reflects systematic failures to carefully screen for the carcinogens in question, eliminate them from the manufacturing process, and prevent contaminated testosterone gel from reaching patients. In essence, the mass distribution of so much contaminated product reflects a deliberate choice to under-prioritize benzene safety. The size of the recall also suggests that all product manufactured during the pertinent window may have been contaminated, although the full facts (including whether other lots are affected) lie in Strides's manufacturing records.

46. Without the benefit of discovery, damages are preliminarily estimated as follows. Online pharmacy data (GoodRx) for leading pharmacies (e.g., CVS, Walgreens) suggests a typical retail price of approximately $100 per 30 sachet-carton, despite the drugs being worthless in their adulterated form. Damages for the 440,000 recalled cartons alone would exceed $44,000,000.

CLASS ALLEGATIONS

47. Plaintiffs seek to represent the following class (the "Class"):

> All natural persons in the United States who purchased Strides's testosterone gel product that was recalled due to benzene contamination or that similarly failed to meet the applicable CGMP requirements but was not recalled.

48. As set out further in the Causes of Action section below, Plaintiffs assert claims under the laws of their states of purchase and seek to represent purchasers from those states and states with laws similar enough to be grouped together with respect to each claim. Plaintiffs intend to present charts or otherwise establish such overlap at class certification and reserve the right to propose subclasses as appropriate.

49. Specifically excluded from the Class 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 any of 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.

50. All members of the Class have suffered a substantially similar injury: the purchase of a worthless, adulterated drug.

51. Adulterated prescription medicine that cannot lawfully be sold can be considered "worthless" and allows the plaintiffs to recover the full purchase price in damages.

52. Subject to additional information obtained through further investigation and discovery, the definition of the Class may be revised as appropriate.

53. *Numerosity*. The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are at least tens of thousands of members in the Class—and likely many more given the scope of the recall. Although the precise number of members of the Class is unknown to Plaintiffs, the true number of members of the Class may be determined through discovery, in particular through pharmacy dispensing records, which provide detailed transactional data at the prescription level.

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

a. whether the testosterone gel at issue was adulterated due to unacceptable levels of benzene contamination;

b. whether the testosterone gel at issue failed to meet CGMP requirements;

c. whether Defendant knew or should have known that the testosterone gel was adulterated and failed to meet CGMP requirements;

d. whether Defendant recklessly disregarded that its adulterated testosterone gel failed to meet CGMP requirements;

e. whether adulterated and contaminated prescription medication is worthless;

f. whether Strides's representations regarding therapeutic equivalence with name-brand testosterone gel necessary for its Orange Book listing were false due to unacceptable levels of benzene contamination;

g. whether Strides intended for its false representations to be transmitted throughout the pharmaceutical supply chain, including to end consumers;

h. whether providers, pharmacists, and patients rely on Strides's affirmative misrepresentations and omissions related to benzene contamination;

i. whether Strides's representations regarding CGMP compliance were false;

j. whether Strides breached its express or implied warranties to consumers;

k. whether using false representations and material omissions to sell prescriptions drugs contaminated with benzene is an unfair, unlawful, deceptive, or misleading practice;

l. whether Plaintiffs and the Class are entitled to damages and the proper measure for such damages.

55. *Typicality*. Plaintiffs' claims are typical of other members of the Class in that, among other things, all members of the Class were similarly situated and were comparably injured through Defendant's wrongful conduct. As explained above, each member of the Class suffered a substantially similar economic injury by purchasing Strides's adulterated and worthless testosterone gel. Further, there are no defenses available to Defendant that are unique to Plaintiffs with respect to her economic damages claims.

56. *Adequacy of Representation*. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have retained counsel that is experienced in complex consumer class action and product liability litigation, and Plaintiffs intend to vigorously prosecute this action on behalf of the Class. Furthermore, Plaintiffs have no interests that are antagonistic to those of the Class.

57. *Superiority*. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The economic damages or other financial detriment suffered by individual members of the

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

CAUSES OF ACTION
COUNT 1: BREACH OF WARRANTY (All Plaintiffs)

58. Strides is a merchant in the sale of testosterone gel—the company makes and distributes the drug nationwide.

59. Strides expressly warranted that its testosterone gel was CGMP-compliant and therapeutically equivalent to non-benzene-contaminated formulations. These representations were "affirmation[s] of fact or promise[s]" and a "description of the goods" that were "part of the basis of the bargain"

when Plaintiffs and similarly situated purchasers bought Strides's prescription testosterone gel. These representations therefore constitute express warranties under the law of each of Plaintiffs' states of purchase and states with substantially similar express warranty statutes. *See* O.C.G.A. §§ 11-2-313(1)(a) and (b); N.J. Stat. §§ 12A:2-313(1)(a) and (b); Ohio Rev. Code §§ 1302.26(A)(1) and (2); Rev. Code Wash. §§ 62A.2-313(1)(a) and (b); Cal. Com. Code §§ 2313(1)(a) and (b).

60. Strides breached its express warranties of CGMP compliance and therapeutic equivalence. Because Strides' generic testosterone gel was contaminated with benzene that the company failed to control for or detect before it was released to the public, the drug was not made in a CGMP-compliant manner. And because the testosterone gel was contaminated with benzene, it was not therapeutically equivalent to the benzene-free name-brand gel with which it is listed in the Orange Book.

61. With respect to each of Plaintiffs' states of purchase, as well as states with similar law, Plaintiffs meet any applicable privity requirements. In Washington, Ohio, and many other states, "contractual privity is not required to create express warranties." *Fortune View Condo. Ass'n v. Fortune Star Dev. Co.*, 90 P.3d 1062, 1065 (Wash. 2004); *see also Caterpillar Fin. Servs. Corp. v. Harold Tatman & Son's, Enters.*, 50 N.E.3d 955, 960 (Ohio Ct. App. 2015) ("[T]here need not be privity to impose liability for breach of an express

warranty."). Similarly, under New Jersey law, "the lack of vertical privity amongst parties in a distributive chain, i.e., a supplier, manufacturer, retailer, and ultimate buyer, does not preclude the extension of the supplier's warranties made to the purchaser." *Chee Li v. BMW of N. Am., LLC*, No. A-0453-15T3, 2017 N.J. Super. Unpub. LEXIS 1477, at *18 (Super. Ct. App. Div. June 19, 2017) (citing *Spring Motors Distribs. v. Ford Motor Co.*, 489 A.2d 660, 674 (N.J. 1985)). In Georgia and states with similar law, Strides extended privity to purchasers through direct-to-patient representations, including in the Medication Guide making representations about the product's characteristics included with every prescription.[34] *See, e.g.*, *Cooksey v. Medtronic, Inc.*, 2021 U.S. Dist. LEXIS 115388 (N.D. Ga. 2021) (explaining how manufacturers can bridge the privity gap by making representations to consumers under Georgia law); *Lee v. Mylan, Inc.*, 806 F. Supp. 2d 1320, 1325–26 (M.D. Ga. 2011) (holding that, "under Georgia law, privity of contract between the manufacturer and ultimate consumer is established when the manufacturer extends an express warranty to the ultimate consumer"). In California, courts recognize "exceptions to the rule" requiring privity for warranty claims "in special cases involving" products including

[34] *See* **Exhibit 5**, Strides Labeling for Testosterone Gel.

"pharmaceuticals." *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1023 (9th Cir. 2008) (collecting cases).

62. In addition to these express warranties, Strides breached the implied warranty of merchantability in each of Plaintiffs' states of purchase. *See*, *e.g.* O.C.G.A. § 11-2-314 (setting out standard UCC provision that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind"). Strides breached the warranty of merchantability for reasons including (1) the testosterone gel at issue was not "fit for the ordinary purposes for which such goods are used," O.C.G.A. § 11-2-314(2)(c), (2) it was not adequately "labeled," *id.* at (2)(e), and (3) it did not "[c]onform to the promises or affirmations of fact made on the container or label," *id.* at (2)(f).

63. As set out above with respect to express warranty claims, Plaintiffs meet any applicable privity requirements. And in Ohio, consumers can pursue implied warranty claims in tort (but not contract) for the reduced value of products irrespective of privity. *Norcold, Inc. v. Gateway Supply Co.*, 154 Ohio App. 3d 594 (2003). To the extent certain states, including Washington, impose more stringent privity requirements on implied than express warranty claims, Plaintiffs nevertheless meet any such requirements because they "can show that [they] [are] the intended third party beneficiar[ies] of a contract between the manufacturer and its direct purchaser." *Tex Enters. v. Brockway Standard*,

66 P.3d 625, 630 (Wash. 2003). All warranties related to CGMP compliance and therapeutic equivalence are ultimately intended to benefit the patients who consume prescription drugs and necessarily rely on the drugmaker's representations regarding drug quality and content.

64. Plaintiffs and similarly situated class members were injured by Strides's conduct when they paid for adulterated and worthless drugs.

65. To the extent pre-suit notice is required under the warranty laws of certain states, Plaintiffs gave pre-suit notice on behalf of themselves and similarly situated class members via a letter dated May 9, 2025, delivered to Strides at the company's New York address on May 12, 2025.

COUNT 2: NEW JERSEY CONSUMER FRAUD ACT, N.J. Stat. § 56:8-1 *et seq.* (and similar state consumer protection statutes)
(Plaintiff Duprex)

66. Under the NJCFA, it is an "unlawful practice" to use "any commercial practice that is unconscionable or abusive, 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 or real estate . . . ." N.J. Stat. § 56:8-2.

67. Strides's false warranties of CGMP compliance and therapeutic equivalence were unlawful within the meaning of § 56:8-2. Strides's omissions of non-compliance and residual benzene contamination were made in knowing

disregard of the truth.

68. Strides intended for purchasers throughout the distribution chain, including Plaintiff Duprex and the Class, to rely on its affirmative misrepresentations and omissions.

69. The Supreme Court of New Jersey has held that "breach of an express warranty may be covered by the CFA as a misleading commercial practice." *Sun Chem. Corp. v. Fike Corp.*, 243 N.J. 319, 338 (2020) (citing N.J.S.A. 56:8-2 (declaring unlawful the use of a "false promise . . . in connection with the sale or advertisement of any merchandise")). "[I]n order to establish an affirmative misrepresentation violative of the Consumer Fraud Act, plaintiffs [are] not required to show [the defendant's] knowledge of the falsity of his statement or intent to deceive." *Vagias v. Woodmont Props., LLC*, 384 N.J. Super. 129 (App. Div. 2006). Here, Strides's express warranty regarding CGMP compliance and therapeutic equivalence was a false promise that violated the CFA.

70. Under the NJCFA, "[a]ny person violating the provisions of the within act shall be liable for a refund of all moneys acquired by means of any practice declared herein to be unlawful," N.J. Stat. § 56:8-2.11, and "[t]he refund of moneys herein provided for may be recovered in a private action," N.J. Stat. § 56:8-2.12.

71. Further, "[a]ny person who suffers an ascertainable loss of moneys or property" due to a violation of the statute is entitled to an "award [of] threefold the damages sustained." N.J. Stat. § 56:8-19. The NJCFA also provides that "the court shall also award reasonable attorneys' fees, filing fees and reasonable costs of suit." *Id.*

72. Plaintiff Duprex and similarly situated class members suffered an ascertainable loss when they paid for adulterated, worthless testosterone gel.

73. But for Strides's false representations and omissions, Plaintiff Duprex and similarly situated class members would not have purchased Strides's contaminated testosterone gel and would not have been economically injured thereby.

74. Plaintiff Duprex and the Class seek to recover a full "refund of all moneys acquired" by means of Strides's NJCFA violation, treble damages, and attorneys' fees and costs.

COUNT 3: GEORGIA FAIR BUSINESS PRACTICES ACT, OCGA § 10-1-390 *et seq.* (and similar state consumer protection statutes) (Plaintiff Painter)

75. Georgia's Fair Business Practices Act forbids "unfair or deceptive acts or practices in the conduct of consumer transactions," O.C.G.A. § 10-1-393, and enables "any person who suffers injury or damages as a result" to bring suit, O.C.G.A. § 10-1-399.

76. Strides's false warranties of CGMP compliance and therapeutic equivalence, and related omissions, were unlawful within the meaning of Georgia's FBPA and literally deceptive.

77. Plaintiff Painter and similarly situated class members relied on the assumption that Strides's testosterone gel met applicable quality standards, which Strides expressly warranted to the pertinent intermediaries in the pharmaceutical distribution chain, knowing that it would induce uniform reliance throughout the chain of distribution, and were injured thereby when they paid for worthless, non-saleable medication.

78. Strides acted intentionally, with the knowledge that it was using a forbidden, benzene-contaminated ingredient, and that the company lacked sufficient quality controls as set forth above, entitling the class to exemplary damages pursuant to O.C.G.A. § 10-1-399.

79. Plaintiff Painter was not required to give Strides 30-days' pre-suit notice before asserting an FBPA claim because Strides "does not maintain a place of business [and] does not keep assets within the state" of Georgia. O.C.G.A. § 10-1-399.

80. The FBPA's statutory bar on class actions, applicable in Georgia state courts, does not apply in federal court. *See, e.g.*, *Lisk v. Lumber One Wood Preserving, LLC*, 792 F.3d 1331 (11th Cir. 2015) (so holding as to Alabama's similar statute under S*hady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*,

559 U.S. 393 (2010)); *accord, e.g.*, *Bank v. Independence Energy Grp. LLC*, 736 F.3d 660, 661 (2d Cir. 2013) (holding that the earlier view "that the *Erie* doctrine required application of state law class-action procedures [] was overturned by the Supreme Court's decision in *Shady Grove*"); *Holster v. Gatco, Inc.*, 618 F.3d 214, 217 (2d Cir. 2010) (same).

COUNT 4: WASHINGTON CONSUMER PROTECTION ACT, RCW 19.86 *et seq.* (and similar state consumer protection statutes) (Plaintiffs Conduff and Mendez-Gutierrez)

81. Washington's CPA forbids "unfair [and] deceptive acts or practices in the conduct of any trade or commerce," RCW 19.86.020, and enables suit by "any person who is injured in his or her business or property" by a violation, RCW 19.86.090.

82. Strides's false warranties of CGMP compliance and therapeutic equivalence, and related omissions, were unlawful within the meaning of Washington's CPA because they had the capacity to deceive the pharmaceutical supply chain that brings drugs to consumers and consumers themselves.

83. Stride's conduct occurred in trade or commerce—the manufacture and distribution of generic pharmaceuticals for patient use.

84. Strides's conduct affects the public interest because it exposed thousands of individuals to an undisclosed carcinogen and undermines the integrity of the drug supply system, which rests on the expectation that

drugmakers like Strides will comply with quality standards.

85. Strides's conduct injured the property of Plaintiffs when they overpaid for worthless, adulterated drugs.

86. But for Strides' false representations and omissions, Plaintiffs would not have been so injured because they never would have purchased Strides's adulterated testosterone gel or even been in a position to purchase it.[35]

COUNT 5: FRAUD (All Plaintiffs)

87. Plaintiffs bring common law fraud claims on behalf of purchasers who live in states that recognize third-party or indirect reliance based on Strides's false representations to its direct customers and states that permit the use of circumstantial evidence to show class-wide reliance in the setting of uniform misrepresentations inducing uniform behavior. Both doctrines are established in Plaintiffs' states (and many others). *See, e.g.*, *Fortis Ins. Co. v. Kahn*, 299 Ga. App. 319, 323 (2009) ("In claims of fraud based upon written representations, the reliance element may sometimes be presumed.") (citing, e.g., *Klay v. Humana, Inc.*, 382 F.3d 1241, 1259 (11th Cir. 2004) ("circumstantial evidence [] can be used to show reliance is common to the

[35] Pursuant to California Civil Code § 1782, Plaintiff Heslip intends to amend to add a claim for violation of California's Consumer Legal Remedies Act ("CLRA") once the thirty-day period from her May 14, 2025, CLRA letter has elapsed, unless Strides makes or commits to making appropriate corrections.

whole class" in the setting of uniform representations inducing uniform behavior)); *Varacallo v. Mass. Mut. Ins. Co.*, 323 N.J. Super. App. Div. 31, 50 (2000) (recognizing "presumption or inference of reliance and causation, where omissions of material fact are common to the class"); *Cope v. Metro Life Ins. Co.*, 82 Ohio St. 3d 426, 430 (1998) ("Courts generally find that the existence of common misrepresentations obviates the need to elicit individual testimony as to each element of a fraud or misrepresentation claim, especially where written misrepresentations or omissions are involved."); *Amato v. General Motors Corp.*, 11 Ohio App. 3d 124, 128 (1982) ("[I]t is held here and how that proof of reliance may be sufficiently established by inference or presumption from circumstantial evidence to warrant submission to a jury without direct testimony from each member of the class."); *McAdams v. Monier, Inc.*, 182 Cal. App. 4th 174, 183 (2010) (California law has long recognized that if "material misrepresentations were made to the class members, at least an inference of reliance would arise as to the entire class"); *Varwig v. Anderson-Behel Porsche/Audi, Inc.*, 74 Cal. App. 3d 578 (1977) (recognizing that California follows the Restatement (Second) of Torts § 533 on indirect reliance)); *Haberman v. Wash. Pub. Power Supply Sys.*, 109 Wn.2d 107 (1987) (same); *Fla. Rock & Tank Lines v. Moore*, 258 Ga. 106 (1988) (same).

88. Strides knowingly and falsely represented that its testosterone gel was CGMP-compliant and equivalent to uncontaminated medicine. Strides

made these representations in its agreements with direct customers like distributors, in its Orange Book listing, in submissions to linkage databases, and by holding out its drug as "Rx Only" on every box of product and in related materials, which inherently includes representations that the drug was lawfully made prescription medication that could be dispensed by a pharmacy to fill prescription orders for testosterone gel.

89. Unlike most consumer purchases, prescription drugs reach patients through a highly concentrated supply chain that depends on uniform representations of compliance with uniform quality and purity standards. Virtually all prescription drugs in the U.S. are distributed and dispensed by a small number of companies who require compliance with CGMP and other FDA standards. For instance, McKesson, Cencora (f.k.a. AmerisourceBergen), and Cardinal Health collectively distribute nearly all the nation's prescription drugs, which are in turn dispensed by large pharmacy chains, dominated by national brands like CVS, Walgreens, and others. There are also only a few major linkage databases like Gold Standard and First Databank, who uniformly rely on a drug's listing in the Orange Book to link drugs as therapeutically equivalent. All those companies depend on drugmakers warranting and satisfying compliance with CGMP and other FDA purity standards. Ultimately, physicians and their patients rely on drugs they prescribe and take complying with those standards and being what they

purport to be. But for Strides's misrepresentations, the commercial entities in the chain of distribution would not have made the testosterone gel at issue available for purchase by consumers. For similar reasons, Plaintiffs and the members of the Class acted in uniform reliance on the representation that Strides's drugs satisfied the required quality standards and were not adulterated. Strides knew and capitalized on the efficacy of its uniform representations, which will allow the Class to prove reliance using common evidence.

90. Strides knew or should have known that its representations that the pills at issue were CGMP-compliant and equivalent to uncontaminated medicine were false. As a drugmaker, Strides is obligated to stay apprised of CGMP regulations and related FDA requirements, but it failed to adopt policies and procedures sufficient to ensure that it complied with these requirements, and it instead chose to sell adulterated drugs that failed to meet them.

91. Strides's false representations were material. Given the well-accepted nature, acceptance, and statutory force of the CGMP requirements, purchasers, such as pharmacies, would not purchase products for their inventory that are not compliant. Likewise, in order to lawfully sell generic prescription drugs, they must be equivalent to the reference drug listed in the

Orange Book. Without therapeutic equivalence, generic prescription drugs cannot be listed or sold.

92. Strides intended for all purchasers down the chain of distribution, including consumers, to rely on them. Strides also knew that its false representations were necessary for its testosterone gel to be listed in the Orange Book as a generic and for its generic testosterone gel to be linked to that name-brand medication and other generics in drug linkage databases.

93. Plaintiffs and each member of the Class were damaged by Strides's fraud: they overpaid for economically worthless, non-saleable drugs. Strides's adulterated drugs cannot lawfully be sold, would not knowingly be purchased over benzene-free competitors, and have no commercial value. Instead, as is the case here, adulterated drugs are incinerated and disposed of as hazardous waste.

94. Plaintiffs and the Class seek to recover the full purchase price of all recalled or otherwise similarly adulterated testosterone gel sold by Strides in the United States. Pursuant to the collateral source rule, damages include both the consumers' out-of-pocket payments and any amounts paid by the consumers' insurers. *See*, *e.g.*, *Chanda v. Fed. Home Loans Corp.*, 215 Cal. App. 4th 746, 752, 155 Cal. Rptr. 3d 693, 698 (2013) ("In determining tort damages, the collateral source rule provides 'that if an injured party receives some compensation for his injuries from a source wholly independent of the

tortfeasor, such payment should not be deducted from the damages which the plaintiff would otherwise collect from the tortfeasor.'") (applying California law); *Olariu v. Marrero*, 549 S.E.2d 121, 123 (Ga. App. 2001) ("Georgia does not permit a tortfeasor to derive any benefit from a reduction in damages for medical expenses paid by others, whether insurance companies or beneficent boss or helpful relatives."); *ML Healthcare Servs., LLC v. Publix Super Mkts., Inc.*, 881 F.3d 1293, 1299 (11th Cir. 2018) (holding that "Georgia's collateral source rule is a substantive rule of damages," and "[t]he substantive component of the rule, which prohibits the reliance on collateral source payments to reduce a plaintiff's damages award, is binding on a federal court sitting in diversity"); *See Emilien v. Stull Techs. Corp.*, 70 F. App'x 635, 642-43 (3d Cir. 2003) (holding with respect to New Jersey's collateral source rule that, "[w]hile the rule has been modified by statute, the modification applies only to civil actions for personal injury or death.") (distinguishing N.J.S.A. 2A:15-97); *Maziarski v. Bair*, 924 P.2d 409, 413 n. 8 (Wash. App. 1996) ("The collateral source rule provides that a tortfeasor may not reduce its liability due to payments received by the injured party from a collateral source.") (collecting cases under Washington law).

95. In states where punitive damages are available, Plaintiffs seek them on the basis that Strides knowingly or recklessly misrepresented and concealed that its testosterone gel was contaminated with benzene, not made

in a CGMP-compliant manner, and not equivalent to its reference drug and the other testosterone gel drugs listed in the Orange Book, which are not contaminated with benzene.

PRAYER FOR RELIEF

Plaintiffs and the Class respectfully request the following relief:

a. Compensatory damages in an amount to be determined at trial;

b. Punitive damages;

c. Statutory damages as available;

d. Treble damages as available;

e. Costs and attorneys' fees;

f. Pre- and post-judgment interest; and

g. All other appropriate relief.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: May 19, 2025

/s/Aaron K. Block
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