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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
NEWARK VICINAGE

SHERYL BOYER, on behalf of herself and all others similarly situated, Plaintiff, vs. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	Civil Action No. CIVIL ACTION **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

PRELIMINARY STATEMENT

1. American patients trust that their medicines will be free of concealed carcinogens. This putative class action arises because the defendant, Breckenridge Pharmaceutical, Inc., broke that trust. Breckenridge has recalled many millions of duloxetine pills—a generic version of Cymbalta—because they contained excessive levels of a carcinogen, N-nitroso-duloxetine.

2. Scientists at Breckenridge's parent company have described N-nitroso-duloxetine as "carcinogenic and harmful in duloxetine drug products."[1] But, despite Breckenridge's knowledge of the risk, it nevertheless sold more than fifty million pills that were unacceptable under the applicable guidance from the Federal Food and Drug Administration ("FDA") and related standards of the United States Pharmacopeia ("USP"), a pharmaceutical quality standards organization whose work is incorporated into the Food, Drug & Cosmetic Act and FDA requirements.

3. Despite failing to meet the USP standard due to concealed carcinogens, Breckenridge expressly and falsely labelled its duloxetine pills "USP" on each bottle and in related materials. Without this false representation of USP compliance, Breckenridge would not have been able to

[1] Fukuda et al., Simple and Practical Method for the Quantitative High-Sensitivity Analysis of N-Nitroso Duloxetine in Duloxetine Drug Products Using LC-MS/MS, ACS Omega (2024), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10956082/pdf/ao4c00136.pdf.

sell the pills. Prescription drugs that are not USP-compliant would not be accepted by purchasers, prescribers, or pharmacists, and Breckenridge would have been unable to link its generic drug to the named-brand Cymbalta in drug databases used for dispensing and purchasing. Thus, by falsely representing the USP compliance of its drugs, Breckenridge was able to sell adulterated drugs that were unlawful to sell and therefore economically worthless. Breckenridge never should have sold those pills and is obligated to reimburse patients for their purchases.

JURISDICTION AND VENUE

4. The Court has subject-matter jurisdiction under 28 U.S.C. § 1332 (d). Plaintiff is a citizen of Tennessee and Defendant is a citizen of New Jersey and Delaware. The amount in controversy exceeds $5,000,000, as detailed below.

5. The Court has personal jurisdiction over Defendant because its headquarters are in New Jersey. *See* Complaint (Doc. 1 ¶ 6), *Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.*, No. 1:24-cv-00571-UNA (D. Del.) ("Breckenridge is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 200 Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922."); *accord* Breckenridge Pharmaceutical, Inc., 2023 Florida Profit Corporation Annual Report (April 13,

2023) ("Current Principal Place of Business: 200 Connell Drive, Suite 4200, Berkeley Heights, NJ 07922").

6. Venue is proper in this District because Defendant is headquartered here and because its conduct giving rise to this case occurred here.

PARTIES

7. Sheryl Boyer is a resident of Tennessee and a consumer of Breckenridge's duloxetine drug. She purchased at least two prescriptions of Breckenridge's nitrosamine-contaminated duloxetine with December 2024 expiration dates, which have now been recalled, although the company has failed to notify her of the recall.

8. Breckenridge is a U.S.-based pharmaceutical company ultimately owned by Towa Pharmaceutical, Inc., a Japanese public company. Breckenridge and its affiliates manufacture and distribute dozens of generic drugs, including duloxetine. Based on the product description in the recall notice published by the FDA, Breckenridge's duloxetine drug was manufactured by "Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain" and distributed by "Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922." Based on publicly available information, Breckenridge's leadership team was in and working from the Berkeley Heights headquarters

by at least mid-2023, during the distribution and marketing period for the product at issue.

FACTUAL ALLEGATIONS

9. Duloxetine is an SSNRI (serotonin-noradrenaline reuptake inhibitor) marketed for chronic mood symptoms and chronic pain. Duloxetine is the generic form of Cymbalta, which Breckenridge launched shortly after Cymbalta went off-patent. Duloxetine, including its branded and generic versions, is reportedly the 27th most-prescribed medications in the U.S., with more than 20 million prescriptions annually.[2] Breckenridge's duloxetine appears to be a flagship product for the company.

10. On or about April 29, 2024, the FDA revealed that Breckenridge was recalling many millions of duloxetine tablets due to "CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the [FDA's] proposed interim limit."[3] To date, the recall appears to cover 570,296 bottles ranging in count size from 90- to 500- to 1000-count. Even if all bottles were 90-count, the recall would involve over 51 million individual tablets; since the recall covers 500- and 1000-count bottles, the true number is likely much higher. Given the sheer size of the

[2] ClinCalc.com, Duloxetine, Drug Usage Statistics, United States, 2013–2021, https://clincalc.com/DrugStats/Drugs/Duloxetine.
[3] FDA, Enforcement Report, Breckenridge Pharmaceutical, Event ID 94483, https://www.accessdata.fda.gov/scripts/ires/?Event=94483.

recall, the problem reflects systematic failures to carefully screen for the carcinogens in question, eliminate them from the manufacturing process, and prevent contaminated pills from reaching patients. In essence, the mass distribution of so much contaminated product reflects a deliberate choice to under-prioritize nitrosamine 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 Breckenridge's manufacturing records.

11. The carcinogen in question, N-nitroso-duloxetine (NDLX), is in the family of nitrosamines, which drug regulators and testing authorities consider "high potency mutagenic carcinogens."[4] Although nitrosamines can be present in small amounts in water and certain foods, they are mutagenic, especially when people are chronically exposed to them. As the pharmaceutical quality standards body, the U.S. Pharmacopeia, explains, despite the background presence of "some level of nitrosamines" in the environment, "their presence in medicine, even at trace level poses high safety risks to patients because

[4] *See, e.g.*, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, M7(R2) (3 April 2023), https://database.ich.org/sites/default/files/ICH_M7%28R2%29_Guideline_Step4_2023_0216_0.pdf; FDA, M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, Guidance for Industry (July 2023), https://www.fda.gov/media/170461/download#:~:text=This%20group%20of%20high%2Dpotency,%2C%20and%20alkyl%2Dazoxy%20compounds.

Nitrosamine impurities are probable human carcinogens."[5]

12. Nitrosamine contamination first emerged as an issue of concern in drug-making in 2018, when the presence of harmful levels was detected in certain blood pressure medications.[6] Subsequently, nitrosamines were discovered in other medications. Thereafter, the FDA, along with partner agencies in Europe, Japan, and scientific groups, published guidance and ultimately recommended interim limits designed to ensure that nitrosamine risk was mitigated to levels below which cancer risk was minimal while long-term solutions are devised. A number of medications have been recalled since then due to nitrosamine impurities, so manufacturers like Breckenridge are on notice of this problem and the need to address it.

13. In fact, scientists from Breckenridge's parent company, Towa Pharmaceutical, recently published a paper describing NDLX as "carcinogenic and harmful in duloxetine drug products," while proposing methods for screening for it.[7]

14. While working to establish long-term solutions, the FDA has

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[5] USP, General Chapter <1469> Nitrosamine Impurities, https://www.usp.org/sites/default/files/usp/document/stakeholder-forum/pnp/highlights-of-1469-nitrosamine-impurities.pdf.

[6] *See generally* FDA, Information About Nitrosamine Impurities in Medications, https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications.

[7] Fukuda et al., Simple and Practical Method for the Quantitative High-Sensitivity Analysis of N-Nitroso Duloxetine in Duloxetine Drug Products Using LC-MS/MS, ACS Omega (2024), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10956082/pdf/ao4c00136.pdf.

established interim acceptable intake ("AI") limits for nitrosamines. The agency's "recommended AI limit is based on a safety assessment that includes evaluation of the mutagenic and carcinogenic potential of the impurity and represents the level at or below which FDA has determined that the impurity or impurities would not pose a safety concern for patients."[8]

15. Based on the FDA's characterization of NDLX's carcinogenic potency, the AI is only 600 ng/day (temporarily relaxed from 100 ng/day to account for potential drug shortages).[9] A nanogram is tiny, only a billionth of a gram. FDA's recall announcement indicates Breckenridge's pills are contaminated beyond that level.

16. USP drug purity and quality standards are incorporated into federal law through the Food, Drug & Cosmetic Act and FDA's Current Good Manufacturing Practice regulations and set baseline expectations in the pharmaceutical industry.[10] As the USP explains, "[e]levated levels of nitrosamines" in medications "pose a risk of physical harm to patients and can undermine trust in medicine quality, harming patients who may be reluctant

[8] FDA, Updated Information: Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs), Guidance for Industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/updated-information-recommended-acceptable-intake-limits-nitrosamine-drug-substance-related.
[9] *Id.*
[10] *See, e.g.*, 21 U.S.C. § 351 (incorporating non-compliance with USP standards as a standard for adulteration).

to take the medicines they need to stay healthy."[11] Through published standards and guidance, USP offers tools for drugmakers to ensure compliance with the pertinent nitrosamine AI levels. For instance, USP has promulgated testing methods and reference standards for nitrosamine detection and purity analyses, including USP General Chapter <1469> Nitrosamine Impurities.[12]

17. USP compliance requires strict control of dangerous impurities, such as nitrosamines, in drug products. Under USP <476> Control of Organic Impurities in Drug Substances and Drug Products, for example, "[m]anufacturers shall validate or verify, as appropriate, analytical procedures and must demonstrate their suitability for the detection and quantitation of impurities in drug substances and drug products. Manufacturers shall develop acceptance criteria for impurities that are justified by appropriate safety considerations and consistent with current applicable regulatory guidances"—such as FDA's AI limits. Further, "[f]or impurities known or suspected to be unusually toxic (e.g., mutagenic impurities)"—such as nitrosamines—"the limit of detection and limit of quantitation of the analytical procedures shall be commensurate with the acceptance criteria and the current applicable regulatory guidances to ensure patient safety."

[11] *Id.*
[12] *See, e.g.*, USP, Nitrosamine Impurities, https://www.usp.org/impurities/nitrosamine-impurities.

18. Because the USP standard expressly incorporates "current applicable regulatory guidances," Breckenridge was required to meet the FDA's AI levels for nitrosamine impurities in order to label and market its duloxetine drug as USP-compliant.

19. Breckenridge falsely represented that it its duloxetine met USP standards. Breckenridge expressly markets its duloxetine as USP-complaint, in the name of the drug, on the bottle, and on marketing materials: "Duloxetine Delayed-release Capsules, USP."[13] Despite this labelling and marketing, Breckenridge failed to meet at least the USP standards cited above because it failed to develop appropriate testing/detection procedures or acceptance criteria sufficient to comply with FDA guidance related to nitrosamine impurities, and Breckenridge failed to ensure that non-compliant drugs were not released to patients.

20. Breckenridge's false representations were material; without them, Breckenridge could not have sold its duloxetine. The USP designation carries not just legal significance, but also marketing significance. Distributors, pharmacies, and pharmacists do not trade in USP-listed drugs that are not USP compliant. Patients, as well as the physicians who prescribe drugs and the pharmacies who dispense them, expect drugmakers like Breckenridge to

[13] *See, e.g.*, Breckenridge, Medication Guide, Duloxetine Delayed-release Capsules, USP, http://bpirx.com/UploadedFiles/duloxetine%20Med%20Guide.pdf.

comply with USP and FDA standards to keep drugs free of unacceptable levels of nitrosamine contamination. That expectation is a function of law, industry practice, and social norms all down the chain of distribution.

21. To take another example, drugmakers contractually warrant to their immediate "customers"—distributors and pharmacies—that their drugs comply with USP and FDA standards. Generic drugmakers like Breckenridge must also represent to pharmacy "linkage" databases and insurers that their drugs are equivalent to branded drugs (without contamination) to compete for business.[14] Marketing a generic drug generally depends on 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 [i.e., USP] or other applicable standard of . . . purity" as the branded drug.[15] Absent Orange Book listing, prescribers, dispensers, payers, and patients are unlikely to substitute a generic for the branded version or a listed generic. Thus, but for the representation of compliance with the applicable nitrosamine purity standards, Breckenridge could not have sold its drug to downstream patients via the pharmaceutical supply chain.

[14] *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).
[15] 21 CFR § 314.3(b).

22. 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."[16]

23. Had Breckenridge disclosed its deviation from USP requirements and the FDA's AI levels, Breckenridge could not have sold its drugs. Physicians would not have prescribed them, pharmacies would not have stocked and dispensed them, and patients would not have purchased them.

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

25. Without the benefit of discovery, damages are preliminarily estimated as follows. Online pharmacy data (GoodRx) for leading pharmacies (CVS, Walgreens) suggests a typical retail price of approximately $0.76–0.95 per tablet, varying based on dosage size and bottle volume. Assuming that

[16] FDA, Facts About the Current Good Manufacturing Practice (CGMP), https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp.

there are "only" 51,000,000 tablets at issue, and every tablet sold at the low end of the price range (while being economically worthless), damages to the class would exceed $41,000,000.

CLASS ALLEGATIONS

26. Plaintiff seeks to represent the following class (the "Class"):

> All natural persons in the United States who purchased Breckenridge's duloxetine product that was recalled due to nitrosamine impurities or that similarly failed to meet the applicable USP requirements but was not recalled.

27. 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.

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

29. Adulterated prescription medicine that cannot lawfully be sold can be considered "worthless" and allow the plaintiff to recover the full purchase price in damages.

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

31. *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, Plaintiff reasonably estimates that there are at least tens of thousands of members in the Class—and likely many more given that Breckenridge's recalls alone involved more than 51 million tablets. Although the precise number of members of the Class is unknown to Plaintiff, the true number of members of the Class may be determined through discovery, in particular through pharmacy dispensing records. Members of the Class may be notified of the pendency of this action by mail and/or electronic publication through the distribution records of Defendant, pharmacy benefits managers ("PBMs"), and other third-parties in the highly concentrated pharmaceutical distribution system.

32. *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 duloxetine pills at issue were adulterated due to unacceptable levels of nitrosamine impurities;

b. whether the duloxetine pills at issue failed to meet USP requirements;

c. whether Defendant knew or should have known that the duloxetine tablets were adulterated and failed to meet USP requirements;

d. whether adulterated and contaminated duloxetine is worthless;

e. whether providers, pharmacists, and patients rely on Breckenridge's affirmative USP representations;

f. whether the designation "USP" on the pill bottles at issue was false;

g. whether Breckenridge committed fraud; and

h. whether Plaintiff and the Class are entitled to damages and the proper measure for such damages.

33. *Typicality*. Plaintiff's 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 Breckenridge's adulterated and worthless

duloxetine pills. Further, there are no defenses available to Defendant that are unique to Plaintiff with respect to her economic damages claims.

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

35. *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: FRAUD

36. Breckenridge knowingly and falsely represented that the duloxetine pills at issue were USP-compliant. Breckenridge made this representation on each and every bottle of pills it sold and in related materials.

37. Breckenridge knew or should have known that its representation that the pills at issue were USP-compliant was false. As a drugmaker, Breckenridge is obligated to stay apprised of the latest FDA guidance documents and related USP requirements related to nitrosamine impurities. Beyond that, however, a research paper published by scientists at Breckenridge's parent company—Towa Pharmaceutical in Japan—shows that the enterprise was aware of both the risks of nitrosamine impurities and how to test for them. But despite closely related scientists writing a study on the topic, Breckenridge failed to adopt policies and procedures sufficient to ensure that it complied with FDA guidance and USP requirements, and it instead chose to sell adulterated drugs that failed to meet these requirements.

38. Breckenridge's false representations regarding USP compliance were material. Given the well-accepted nature, acceptance, and statutory force

of the USP requirements, purchasers, such as pharmacies, would not purchase products for their inventory that are not compliant with applicable USP requirements.

39. Plaintiff, members of the Class, and their physicians and pharmacists were justified in relying on Breckenridge's representations, which Breckenridge knew and relied on in the distribution of its drugs. Drugmakers operate in a highly regulated environment, and everyone who touches the healthcare system depends on drugmakers to make accurate and honest representations regarding the content, efficacy, and safety of their drugs. It was justified for purchasers, including consumers, to rely on the accuracy of express, factual representations that Breckenridge made on each bottle of its duloxetine pills and elsewhere.

40. By making these false representations, Breckenridge intended for everyone in the distribution chain, including consumers, their physicians, and their pharmacists, to read and rely on its representations. Regardless of whether any individual consumer read these materials, however, Breckenridge knew and intended that physicians and pharmacists would rely on these fraudulent misrepresentations and that patients would be prescribed and purchase adulterated duloxetine pills as a result.

41. Plaintiff anticipates seeking to prove the reliance element, on an indirect reliance theory, via common proof due to Breckenridge's uniform

representations and the unique characteristics of the U.S. drug supply system. The Class's reliance proof will focus on Breckenridge's uniform representations to a small number of commercial entities through which drugs must pass before they are sold to individual patients, who would not have made Breckenridge's adulterated duloxetine available for purchase by patients had Breckenridge not misrepresented the pills' status.

42. As described above, 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 (here, compliance with FDA's NDLX AI limits). Virtually all prescription drugs in the U.S. are distributed and dispensed by a small number of companies who require compliance with USP and FDA standards. For instance, McKesson, 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 USP and FDA purity standards. Ultimately, physicians and their patients depend on drugs they prescribe and take complying with those standards,

given the built-in requirement of the pharmaceutical distribution system that drugmakers are responsible for selling only compliant drugs.

43. But for Breckenridge's misrepresentations, the commercial entities in the chain of distribution would not have made the tablets at issue available for purchase by consumers. Breckenridge knew and capitalized on the efficacy of its uniform representations, which will allow the Class to prove indirect reliance on a common basis. *See, e.g.*, *Varacallo v. Mass. Mut. Ins. Co.*, 323 N.J. Super. 31, 47 (2000) (holding that common reliance may be "satisfied by proof of indirect reliance where a party deliberately makes false representations with the intent that they be communicated to others for the purpose of inducing the others to rely upon them") (cleaned up); *accord Restatement (Second) of Torts* § 533 (same).

44. Plaintiff and each member of the Class were damaged by Breckenridge's fraud: they overpaid for economically worthless, non-saleable drugs. *See, e.g.*, *Debernardis v. IQ Formulations, Ltd. Liab. Co.*, 942 F.3d 1076, 1084–85 (11th Cir. 2019) (holding that an "adulterated . . . product that Congress judged insufficiently safe for human ingestion" plausibly has "no value," and "[w]hen a plaintiff receives a worthless product, his benefit of the bargain damages will be equal to the entire purchase price of the product"); *see also Marrache v. Bacardi, U.S.A., Inc.*, 17 F.4th 1084, 1100-01 (11th Cir. 2021) (same); *Eli Lilly & Co. v. Air Express Int'l USA, Inc.*, 615 F.3d 1305, 1317 (11th

Cir. 2010) (holding that "the exposure to sub-freezing temperatures rendered [a drug product] worthless" because it became adulterated and therefore "unsaleable"); *United States v. Gonzalez-Alvarez*, 277 F.3d 73 (1st Cir. 2002) (defining the value of adulterated products as zero dollars for federal sentencing purposes); *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219 (3d Cir. 2005) (holding that the courts can order restitution of the purchase price of adulterated goods).

45. New Jersey law governs the fraud claims of Plaintiff and members of the Class regardless of where each person purchased the duloxetine pills. The choice-of-law analysis in this case is controlled by the Supreme Court of New Jersey's recent decision *In re Accutane Litigation*, 194 A.3d 503 (N.J. 2018). There, the state supreme court addressed choice-of-law in the context of consolidated products liability litigation in which the residents of 45 different jurisdictions (including New Jersey) brought claims against a New Jersey-based drug manufacturer. Even though *Accutane* involved personal injury claims under which there is a "presumption that the law of the state where the injury occurred applies," *id.* at 520, the state supreme court nevertheless held that "New Jersey has the most significant relationship to the occurrence and the parties," *id.* at 524.

46. In *Accutane*, "the injuries caused by the [alleged conduct] occurred in forty-four other jurisdictions, but New Jersey is 'where the alleged conduct

causing the injury occurred' – the manufacturing and labeling of Accutane." *Id.* at 521 (citation omitted). Further, the state supreme court considered the "most significant *Restatement* factors" in a mass tort setting to be the "'certainty, predictability and uniformity of result'" and the "'ease in the determination and application of the law to be applied.'" *Id.* (quoting *Restatement (Second) of Conflict of Laws* § 6). "Applying a single standard to govern the adequacy of the label warnings in the 532 individual cases will ensure predictable and uniform results – rather than disparate outcomes among similarly situated plaintiffs . . . ." *Id.* at 523. Thus, in the aggregate setting where plaintiffs are in various states but bring claims related to conduct centralized in New Jersey, "New Jersey has the most significant relationship to the occurrence and the parties, overcoming the presumption that the law of the place of injury governs." *Id.*

47. Here, the analysis in *Accutane* points even more strongly to the uniform application of New Jersey law. Because this is not a personal injury case and the class seeks only economic damages, there is no baseline presumption that the law of the state of injury should apply to each plaintiff, and it is therefore not necessary to overcome such a presumption to apply New Jersey law. *Compare Restatement (Second) of Conflict of Laws* § 146 (establishing presumption in "personal injury" cases that "the local law of the state where the injury occurred determines the rights and liabilities of the

parties, unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in § 6 to the occurrence and the parties"), *with Restatement (Second) of Conflict of Laws* § 148 (establishing various factors in "fraud and misrepresentation" cases to determine "the most significant relationship" where "the plaintiff's action in reliance took place in whole or in part in a state other than that where the false representations were made").

48. While there is no baseline presumption pointing away from New Jersey to overcome in this fraud case, the considerations that the *Accutane* court considered sufficient to overcome the presumption in that case and find that New Jersey had the most significant relationship apply with equal force here. Therefore, New Jersey law controls the fraud claims of Plaintiff and the Class regardless of where Breckenridge's adulterated duloxetine was sold. To the extent that decisions that predate or fail to address *Accutane* have taken different approaches or reached different conclusions, those decisions are no longer good law.

49. Applying New Jersey law to all claims against Breckenridge raises no Due Process concerns. Breckenridge is a New Jersey drugmaker, it appears that much of its conduct related to the claims at issue took place in New Jersey, and Breckenridge has every reason to expect that it is subject to New Jersey law. *See McCarrell v. Hoffmann-La Roche, Inc.*, 153 A.3d 207, 211 (N.J. 2017)

("Our jurisprudence has long recognized that this State has a substantial interest in deterring its manufacturers from placing dangerous products in the stream of commerce.").

50. Plaintiff and the Class seek to recover the full purchase price of all recalled or otherwise adulterated duloxetine medication sold by Breckenridge in the United States. These damages include both the consumers' out-of-pocket payments and any amounts paid by the consumers' insurers, which are recoverable under New Jersey's traditional collateral source rule. *See Emilien v. Stull Techs. Corp.*, 70 F. App'x 635, 642-43 (3d Cir. 2003) ("While 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).

COUNT 2: NEW JERSEY CONSUMER FRAUD ACT

51. In addition to constituting common law fraud, Breckenridge's false labeling of the products at issue as USP-compliant violated the New Jersey Consumer Fraud Act ("NJCFA"). *See* N.J. Stat. § 56:8-1 *et seq.*

52. 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.

53. Breckenridge's express representation that the products at issue were USP-compliant was false.

54. Breckenridge intended for purchasers throughout the distribution chain, including Plaintiff and the Class, to rely on its affirmative misrepresentation that the products at issue were USP-compliant.

55. In addition to its affirmative misrepresentation of USP compliance, Breckenridge knowingly concealed, suppressed, or omitted the material fact that the products at issue were adulterated and contaminated with unacceptable levels of nitrosamine impurities. It was unconscionable for Breckenridge to conceal that its prescription medication contained carcinogens at unacceptable levels. Breckenridge's knowledge of both the risks caused by nitrosamine contamination and the need to test for nitrosamine impurities is shown, among other things, by the research paper published on precisely these topics by scientists at Breckenridge's parent company in Japan, Towa Pharmaceuticals. But Breckenridge nevertheless chose to sell adulterated medicine to the public.

56. 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.

57. 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.*

58. As set out above, Breckenridge's recalled or otherwise adulterated duloxetine pills were economically worthless and could not have been sold had Breckenridge disclosed the nitrosamine contamination rather than concealing it. Plaintiff and members of the Class therefore suffered ascertainable damages in the full purchase price of the products at issue.

59. Plaintiff and the Class seek to recover treble damages, attorneys' fees, and costs under the NJCFA for all of Breckenridge's sales of the affected products nationwide. For the same reasons set out in Count One, the New Jersey Supreme Court's recent decision in *Accutane* controls. The state supreme court's holding there addressed a New Jersey statute that was in direct conflict with the equivalent state statutes of many of the forty-four other jurisdictions in which plaintiffs had been injured. The Supreme Court of New Jersey nevertheless applied New Jersey's statutory law to all claims in that action, despite the presumption that the law of the state of injury generally applies in personal injury actions. As set out in Count One, there is even more reason to apply New Jersey law uniformly in this consumer fraud case dealing

with false, uniform representations used to sell prescription drugs distributed by a New Jersey drugmaker out of New Jersey.

PRAYER FOR RELIEF

Plaintiff and the Class respectfully request the following relief:

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

b. Treble damages under the NJCFA;

c. Costs and attorneys' fees;

d. Pre- and post-judgment interest; and

e. All other appropriate relief.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all issues so triable.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, undersigned counsel for plaintiff hereby certifies that the matter in controversy here is not the subject of any action pending in any other court, arbitration, or administrative proceeding.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, undersigned counsel for plaintiff hereby certifies that this action is excluded from compulsory arbitration because the monetary demand exceeds $150,000, exclusive of interest and costs and any claim for punitive damages.

ANDERSON & SHAH, LLC
Attorneys for Plaintiff Sheryl Boyer, on behalf of herself and all others similarly situated

By: */s/Roshan D. Shah*
Roshan D. Shah, Esq.

Dated: May 29, 2024

THE BLOCK FIRM LLC
Attorneys for Plaintiff Sheryl Boyer, on behalf of herself and all others similarly situated

By: */s/Aaron K. Block**
Aaron K. Block

* *pro hac vice* admission forthcoming

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

SHERYL BOYER

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

SEE ATTACHED ATTORNEY LIST

DEFENDANTS

BRECKENRIDGE PHARMACEUTICAL, INC.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332

Brief description of cause:
Products Liability

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
5/29/2024

SIGNATURE OF ATTORNEY OF RECORD
/s/ Roshan Shah

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

PLAINTIFF'S LIST OF ATTORNEYS

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