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

Debra Butler, on behalf of herself and all others similarly situated, and as Executor of the Estate of Mary Louise Cormier, Plaintiff, vs. GLENMARK PHARMACEUTICALS INC., USA, Defendant.	Civil Action No. **CIVIL ACTION** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

PRELIMINARY STATEMENT

1. Potassium chloride is both a life-saving medication and a life-ending drug: it is on the World Health Organization's list of essential medicines, while also being the terminal agent in the three-drug protocol used to execute the condemned. The principal distinction has to do with dose. Properly dosed, potassium chloride addresses hypokalemia, or low potassium. At higher doses, potassium chloride induces hyperkalemia, leading to cardiac arrest and death.

2. Defendant Glenmark Pharmaceuticals, Inc. failed to meet the required dosing standards for its "Potassium Chloride Extended-Release Capsules, USP," a generic of the popular medication Actavis. Specifically, despite labelling its drug "USP," Glenmark failed to meet the minimum dissolution time standards mandated by the United States Pharmacopoeia, a federally recognized institution that develops pharmaceutical quality standards. Those standards ensure that too much potassium chloride is not released too quickly into a patient's bloodstream—*i.e.*, that the pills are extended-release capsules, not rapid-release capsules.

3. Glenmark's pills that failed to meet these standards were both dangerous and worthless. They were dangerous because they can cause a potassium overdose with effects more like the drug's intended application in

executions rather than medicine—cardiac arrest and death. That is what happened to Mary Louise Cormier. After taking Glenmark's adulterated potassium chloride, Mrs. Cormier's potassium levels shot up to 6.9 mmol/L—so unnaturally high the ER doctor ordered the test to be re-run, confirming the dangerous levels induced by Glenmark's defect. As a result, Mrs. Cormier suffered cardiac arrest, and, shortly thereafter, death.

4. Glenmark's adulterated potassium chloride pills were worthless because prescription medicine that fails to meet applicable USP requirements is illegal to sell and has no economic value. Adulterated prescription medicine must be incinerated, not sold. No doctor would knowingly prescribe it; no drug distributor would knowingly purchase it; no pharmacy would knowingly dispense it; and no patient would knowingly ingest it. Glenmark has essentially acknowledged as much. In June 2024, Glenmark was forced to recall tens of millions of potassium chloride extended-release capsules for failing to meet the USP standards it claims, exposing Glenmark's patients to a "reasonable probability" of "serious adverse health consequences or death." Based on the expiration dates, this problem extends back years, possibly affecting every capsule Glenmark sold in recent years.

5. Glenmark knew or willfully disregard the fact that its potassium chloride failed to meet USP standards. This is not Glenmark's first brush with massive quality failings. As described below, Glenmark has been repeatedly

cited for unsafe drug-making practices and has been forced to recall tens of millions of other pills because they are, *inter alia*, contaminated with carcinogens and filth, non-sterile, and subject to other serious quality deficiencies. Glenmark nevertheless chose to falsely represent that its pills were "USP" compliant, knowing and intending that everyone in the chain of distribution down to the patient would reasonably rely on Glenmark's express representation.

6. In short, Glenmark has apparently built a business model around putting profits ahead of patient safety. Glenmark must be held to account for enriching itself by killing people. As set out below, Plaintiff and members of the Class she seeks to represent are entitled to recover the full economic value of all adulterated potassium chloride they purchased, including but not limited to the recalled lots. On behalf of herself individually, Plaintiff also seeks personal injury damages related to the suffering and death of Mrs. Cormier.

JURISDICTION AND VENUE

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

8. The Court has personal jurisdiction over Defendant because its headquarters are in New Jersey at 750 Corporate Drive, Mahwah, New Jersey 07430-2009.

9. Venue is proper in this District because Defendant is headquartered in Bergen County and because Defendant's conduct giving rise to this case occurred therein.

PARTIES

10. Debra Butler is the daughter of Mrs. Cormier and the executor of her estate. Plaintiff and the estate are residents of Maine. According to Mrs. Cormier's pharmacy, she purchased and received Glenmark potassium chloride extended-release capsules from recalled lots 17232343 and 17231339 on or about June 25, 2024. She ingested them shortly thereafter, just prior to her cardiac arrest.

11. Glenmark is the North American arm of Glenmark Pharmaceuticals, a multinational pharmaceutical company headquartered in Mumbai. Glenmark's North American arm markets dozens of generic pharmaceuticals in the United States from its offices in New Jersey, including coordinating the manufacture, marketing, and distribution of the pills at issue in this case.

FACTUAL ALLEGATIONS

12. Potassium chloride extended-release capsules are longstanding, essential medicines primarily indicated for the treatment of hypokalemia, or low potassium. Several drugmakers offer generic and branded potassium chloride drugs. Potassium chloride is one of the country's most commonly

prescribed medicines, ranked #35 by one count, with over 4.5 million patients taking almost 17 million prescriptions a year.[1] In addition to its therapeutic properties, however, excessive potassium chloride can induce cardiac arrest, and it is so used in the lethal injection protocol.

13. According to the FDA's Orange Book, where generic drugmakers like Glenmark position their drugs as equivalent to branded drugs, Glenmark has marketed potassium chloride in the United States since at least 2016.

14. On or about June 25, 2024, the FDA revealed that Glenmark was "recalling 114 batches"—millions of potassium chloride capsules—due to "Failed Dissolution Specifications."[2] FDA primarily designated the recall as Class I, the most serious type, used where "there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[3]

15. According to Glenmark's press release, the defect "may cause high potassium levels, also known as hyperkalemia, which can result in irregular

[1] ClinCalc.com, Drug Usage Statistics, Potassium Chloride, https://clincalc.com/DrugStats/Drugs/PotassiumChloride.
[2] FDA, Glenmark Pharmaceuticals Inc., USA Issues Voluntary Nationwide Recall for Potassium Chloride Extended-Release Capsules, USP (750 mg) 10mEq K Due to Failed Dissolution, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/glenmark-pharmaceuticals-inc-usa-issues-voluntary-nationwide-recall-potassium-chloride-extended#recall-announcement.
[3] FDA, Recalls Background and Definitions, https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions.

heart beat that can lead to cardiac arrest."[4] Patients "who require chronic use of potassium chloride extended-release oral capsules, especially in those patients with underlying comorbidities or conditions that cause altered excretory mechanisms for potassium such as hypertension, heart failure, or renal dysfunction, there is a reasonable probability of developing hyperkalemia that may lead to" consequences including "cardiac arrythmias, severe muscle weakness, and death." In other words, the most typical patients—those who depend on Glenmark every day to manage chronic conditions—are the most vulnerable to "severe potential life threatening adverse events" and death.

16. To date, the Class I recall covers more than 46 million capsules. By definition, this recall involves "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."[5]

17. In addition, another sixty-odd lots are subject to a Class II recall, defined as "a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where

[4] FDA, Glenmark Pharmaceuticals Inc., USA Issues Voluntary Nationwide Recall for Potassium Chloride Extended-Release Capsules, USP (750 mg) 10mEq K Due to Failed Dissolution, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/glenmark-pharmaceuticals-inc-usa-issues-voluntary-nationwide-recall-potassium-chloride-extended#recall-announcement.

[5] FDA, Recalls: Background and Definitions https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions

the probability of serious adverse health consequences is remote."[6] Based on the expiration dates for the Class II recall pills, which are further out, those pills are only slightly less dangerous (while being just as adulterated) because they are later in line for distribution to and consumption by patients. Glenmark has not publicized the pill quantity for the Class II recall, but, based on the number of affected lots, it is likely comparable in size to the Class I recall.

18. Based on the size and expiration date range, the dissolution defect was likely present—and either undetected or disregarded—for several years. The scale of the known problems, particularly given Glenmark's history of quality problems, suggests a systematic disregard for drug safety.

19. Glenmark falsely represented that its potassium chloride met USP standards. Glenmark expressly markets its potassium chloride, extended-release capsules as USP-complaint, in the name of the drug, on the bottle, and on marketing materials: "Potassium Chloride Extended-Release Capsules, USP."[7] Despite this labeling and marketing, Glenmark failed to use and/or meet at least the USP standard governing minimum dissolution time. In practice, Glenmark's drug was effectively a rapid-release drug more suitable

[6] *Id.*

[7] Glenmark, RX Generic Product Catalog, https://glenmarkpharma-us.com/potassium-chloride-extended-release-capsules-usp/ (describing the product as the "Generic Version of Potassium Chloride Extended-Release Capsules USP [Actavis]") (brackets in original).

for an execution rather than the "extended-release" drug the company promised patients.

20. Glenmark's false representations were material; without them, Glenmark could not sell its potassium chloride drugs. 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 Glenmark to comply with USP and FDA standards. 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 Glenmark must also represent to pharmacy "linkage" databases and insurers that their drugs are equivalent to branded drugs to compete for business.[8] 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,

[8] *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).

inter alia, the generic to comply with the "identical compendial [i.e., USP] or other applicable standard of . . . purity" as the branded drug.[9] 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 USP standards, Glenmark could not sell its drug to downstream patients via the pharmaceutical supply chain.

22. Physicians, who cannot be expected to test individual drugs, rely on drugmakers to comply with their claimed drug safety and quality requirements. And patients, who are even less able to discern drug quality, must rely on drugmakers to make and distribute compliant 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."[10]

23. Had Glenmark disclosed its deviation from USP requirements, the company could not sell its drugs. Physicians would not have prescribed them, pharmacies would not have stocked and dispensed them, and patients would not have purchased them. Glenmark knew that its misrepresentations

[9] 21 CFR § 314.3(b).
[10] FDA, Facts About the Current Good Manufacturing Practice (CGMP), https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp.

regarding USP compliance were necessary to sell its adulterated drugs, and Glenmark intended for everyone down the chain of distribution to rely on those representations.

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

25. On information and belief, it is likely that Glenmark sold adulterated potassium chloride that was not included in the recalls because it had already expired by the time Glenmark's defects became public. Glenmark knew or should have known that any such potassium chloride failed to meet the required USP standards, yet Glenmark nevertheless chose to sell it based on the false representation that the medicine was USP-compliant. The statute of limitations for claims related to purchases of all such adulterated-but-not-recalled pills has been tolled by Glenmark's fraudulent concealment.

26. Without the benefit of discovery, class economic damages related to the recalled lots, which is likely underinclusive as discussed above, are preliminarily estimated as more than $50 million based on the scope of the recalls and publicly available information regarding average prices per pill.

27. Glenmark's deception did not only cause pocketbook injuries; it put lives at risk, fatally in the case of Mrs. Cormier. On June 27, 2024, Mrs.

Cormier presented to the MaineHealth Emergency Department with new-onset symptoms of minimal responsiveness, lethargy, and soft, monosyllabic answers. According to the ED physician, laboratory testing revealed "a lactate of 10.9, troponin of 1300, bicarb of 8, potassium of 6.9," indicators of potassium-related "cardiogenic shock." Due to the surprisingly high levels, the labs "were redrawn to assure it was real, and they were." Given Mrs. Cormier's "grav[e]" state, her family made the difficult decision to transition her to hospice care, where she passed shortly thereafter.

28. After her death, Mrs. Cormier's family received notice of Glenmark's recall. According to the FDA recall database, Glenmark initiated the recall on May 30, 2024, and thus identified the problems sooner. But it waited another month to begin notifying patients like Mrs. Cormier. Her death was, therefore, entirely avoidable—had Glenmark not sold defective drugs in the first place and had Glenmark promptly communicated to patients to avoid them.

29. This was not Glenmark's first or only serious quality deficiency. Since 2019, Glenmark has received two FDA warning letters citing the company for "significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals," rendering the company's

drugs "adulterated within the meaning of" the Food, Drug, and Cosmetic Act.[11] Among other violations, the FDA cited Glenmark for "fail[ing] to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications," "fail[ing] to establish adequate written procedures for production and process control designed to ensure" Glenmark's drugs "have the identity, strength, quality, and purity they purport or are represented to possess," "fail[ing] to establish and follow required laboratory control mechanisms," and "fail[ing] to prepare batch production and control records with complete information." Both warning letters remain open, demonstrating that Glenmark has yet to correct these serious problems.

30. In addition, in recent years Glenmark has been forced to undertake over sixty other recalls, affecting tens of millions of pills for serious quality problems, ranging from the presence of carcinogens, to the presence of filth like mold, to impurities and non-sterility, to unidentified "cGMP deviations" severe enough to warrant a recall.[12]

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[11] FDA, Warning Letter Database, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/glenmark-pharmaceuticals-limited-582701-10032019 (Warning Letter dated October 3, 2019); https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/glenmark-pharmaceuticals-limited-637314-11222022 (Warning Letter dated November 22, 2022).

[12] *See* FDA, Enforcement Report for Glenmark, https://www.accessdata.fda.gov/scripts/ires/index.cfm#tabNav_advancedSearch.

31. Glenmark's overall course of conduct shows that it has chronically and systemically chosen to put its own profits ahead of patient health and safety. For patients like Mrs. Cormier, Glenmark's greed was fatal. For Plaintiff and all members of the Class she seeks to represent, Glenmark enriched itself by selling worthless, adulterated prescription medication based on affirmative misrepresentations that its potassium chloride had the required quality that patients expect and on which they are entitled to rely.

CLASS ALLEGATIONS

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

> All natural persons in the United States who purchased Glenmark's potassium chloride product that was recalled due to failed dissolution standards or that similarly failed to meet the applicable USP requirements but was not recalled.

33. 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.

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

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

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

37. *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 Glenmark's recalls alone involved more than 46 million capsules. 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.

38. *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 potassium chloride capsules at issue were adulterated due to failed dissolution specifications;

b. whether the potassium chloride capsules at issue failed to meet USP requirements;

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

d. whether adulterated and contaminated potassium chloride capsules are worthless;

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

f. whether the designation "USP" regarding the capsules issue was false;

g. whether Glenmark committed fraud; and

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

39. *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 with respect to economic loss claims 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 Glenmark's adulterated and worthless potassium chloride capsules. Further, there are no defenses available to Defendant that are unique to Plaintiff with respect to her economic damages claims.

40. *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.

41. *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

42. Glenmark knowingly and falsely represented that the potassium chloride capsules at issue were USP-compliant. Glenmark made this representation on each and every bottle of pills it sold and in related materials, in its agreements with distributors and pharmacy customers, in its Orange Book listing, and in submissions to linkage databases.

43. Glenmark knew or should have known that its representation that the pills at issue were USP-compliant was false. As a drugmaker, Glenmark is obligated to stay apprised of USP requirements, but it failed to adopt policies and procedures sufficient to ensure that it complied with USP requirements,

and it instead chose to sell adulterated drugs that failed to meet these requirements.

44. Glenmark'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.

45. Glenmark knew its false representations regarding USP compliance were material, and it intended for all purchasers down the chain of distribution, including consumers, to rely on them. Glenmark also knew that its false representations regarding USP compliance and bioequivalence were necessary for its potassium chloride to be listed in the Orange Book as a generic for the name-brand Activis and for its generic potassium chloride to be linked to that name-brand medication and other generics in drug linkage databases.

46. Plaintiff, members of the Class, and their physicians and pharmacists were justified in relying on Glenmark's representations, which Glenmark 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 Glenmark made on each bottle of its potassium chloride capsules and elsewhere.

47. By making these false representations, Glenmark 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, Glenmark knew and intended that physicians and pharmacists would rely on these fraudulent misrepresentations and that patients would be prescribed and purchase adulterated potassium chloride capsules as a result.

48. Plaintiff anticipates seeking to prove the reliance element, on an indirect reliance theory, via common proof due to Glenmark's uniform representations and the unique characteristics of the U.S. drug supply system. The Class's reliance proof will focus on Glenmark'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 Glenmark's adulterated potassium chloride capsules available for purchase by patients had Glenmark not misrepresented the pills' status.

49. 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. 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 rely on drugs they prescribe and take complying with those standards and being what they purport to be.

50. But for Glenmark's misrepresentations, the commercial entities in the chain of distribution would not have made the tablets at issue available for purchase by consumers. Glenmark 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). Further, no reasonable consumer would knowingly buy

adulterated prescription medicine that is not actually what their doctor prescribed, and all consumers were relying on Glenmark's representations regarding USP compliance and bioequivalence when they purchased its drugs.

51. Plaintiff and each member of the Class were damaged by Glenmark'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).

52. New Jersey law governs the fraud claims of Plaintiff and members of the Class regardless of where each person purchased Glenmark's 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.

53. 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.*

54. Here, the analysis in *Accutane* points even more strongly to the uniform application of New Jersey law with respect to the economic loss claims Plaintiff asserts on behalf of the Class. Because 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").

55. 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 Glenmark's adulterated potassium chloride capsules were 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.

56. Applying New Jersey law to all class claims against Glenmark raises no Due Process concerns. Glenmark is a New Jersey drugmaker, it appears that much of its conduct related to the claims at issue took place in New Jersey, and Glenmark 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.").

57. Plaintiff and the Class seek to recover the full purchase price of all recalled or otherwise adulterated potassium chloride capsules sold by Glenmark 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

58. In addition to constituting common law fraud, Glenmark'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*.

59. 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.

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

61. Glenmark 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.

62. In addition to its affirmative misrepresentation of USP compliance, Glenmark knowingly concealed, suppressed, or omitted the material fact that the products at issue were adulterated. It was

unconscionable for Glenmark to conceal that its prescription medication could overdose patients.

63. 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.

64. 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.*

65. As set out above, Glenmark's recalled or otherwise adulterated potassium chloride capsules pills were economically worthless and could not have been sold had Glenmark 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.

66. Plaintiff and the Class seek to recover treble damages, attorneys' fees, and costs under the NJCFA for all of Glenmark'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.

COUNT 3: STRICT LIABILITY

67. Acting in her individual capacity as the executor of Mrs. Cormier's estate, Plaintiff also seeks to recover for Mrs. Cormier's suffering, death, and all attendant injuries.

68. As explained above, Glenmark knowingly or recklessly distributed defective potassium chloride capsules, misrepresenting their dosing characteristics, and then delayed notifying Mrs. Cormier or her health care providers, directly causing her cardiac arrest and death.

69. Glenmark's tablets were not reasonably fit, suitable, or safe for their intended purpose.

70. Glenmark is liable under theories of manufacturing defect, failure to contain adequate warnings and instructions, and breach of warranty.

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. Punitive damages;

d. Costs and attorneys' fees;

e. Pre- and post-judgment interest; and

f. 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 Debra Butler, on behalf of herself and all others similarly situated and as the Executor of the Estate of Mary Louise Cormier

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

Dated: August 30, 2024

THE BLOCK FIRM LLC
Attorneys for Plaintiff Debra Butler, on behalf of herself and all others similarly situated and as the Executor of the Estate of Mary Louise Cormier

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

* *pro hac vice* admission forthcoming