UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON
AT SEATTLE

SHARON CARROLL, individually and on behalf of all persons similarly situated, Plaintiff, v. GLENMARK PHARMACEUTICALS INC., USA, Defendant.	NO. 2:26-cv-00327 **CLASS ACTION COMPLAINT** ***JURY TRIAL DEMANDED***

CLASS ACTION COMPLAINT

Plaintiff Sharon Carroll (Plaintiff) files this Complaint against Defendant Glenmark Pharmaceuticals Inc., USA ("Glenmark") relating to Glenmark's manufacture, distribution, and sale of dangerous, unsafe, adulterated, misbranded, and otherwise defective or flawed carvedilol-containing drugs ("Carvedilol" or the "Product").[1]

[1] As used herein, "Carvedilol" refers to Glenmark's carvedilol drugs, while "carvedilol" – lower case – refers to any generic carvedilol drug.

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INTRODUCTION

1. This case arises Glenmark's Carvedilol, which was contaminated with nitrosamine impurities and manufactured in manner that was not compliant with current Good Manufacturing Practices ("cGMPs") in violation of various states' laws. Glemark's Carvedilol was adulterated, misbranded, unsafe non-merchantable, unfit for intended and ordinary purposes, inherently defective or flawed, and not of the quality that Glenmark represented.

2. Carvedilol is a generic version of the branded drug Coreg® or its extended-release version Coreg ER®, which is a beta-blocker. The drug is a front-line therapy to treat high blood pressure, congestive heart failure, and other heart-related conditions.

3. Prior to genericization, Coreg was a 'blockbuster' branded drug, with annual sales around $1 billion at its peak.

4. Once approved, generic versions of Coreg quickly gained market share. Glenmark first obtained approval from the United States Food and Drug Administration ("FDA") to sell its generic Carvedilol in September 2007.

5. The generic carvedilol market grew quickly. As of 2025, the United States carvedilol market was estimated to be valued at nearly $2 billion annually,

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and projected to reach $3.7 billion by 2035.[2]

6. Glenmark represented and warranted to consumers and TPPs that its Carvedilol was therapeutically equivalent to, and otherwise the same as, the actual FDA-approved brand name drug Coreg. Specifically, Glenmark represented and warranted that its Carvedilol was fit for intended and ordinary uses, merchantable, met the specifications of Glenmark's FDA-approved labeling materials, and that Glenmark manufactured and distributed its Carvedilol in accordance with all applicable laws and regulations, including specifically cGMPs as incorporated by state laws.

7. A therapeutic equivalent, among other things, must (i) have the same efficacy *and* safety as an approved drug, (ii) have the same identity, strength, quality, and purity as an approved drug, (iii) be adequately labeled, and (iv) be manufactured in compliance with cGMPs.[3]

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[2] https://www.researchnester.com/reports/carvedilol-drug-market/4019#:~:text=Carvedilol%20Drug%20Market%20Outlook:,assessed%20at%20USD%202%20billion

[3] Orange Book Preface to 43rd Edition, U.S. FOOD & DRUG ADMIN. (Jan. 24, 2023), *available at* https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-

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8. In reality, however, Glenmark's Carvedilol was not therapeutically equivalent to FDA-approved Coreg. Glenmark's Coreg did not have the same safety profile, or same identity, strength, quality and purity, as FDA-approved Coreg because Glenmark's Carvedilol contained a dangerous, undisclosed nitrosamine known as N-Nitroso-Carvedilol I. Glenmark's Carvedilol was not manufactured in a cGMP-compliant manner and therefore without any assurance that Carvedilol was of the appropriate quality and properly labeled.

9. When a drug is manufactured in a non-cGMP compliant manner, that means the manufacturer cannot assure that the drug meets the appropriate quality, purity, identity or strength. Because a manufacturing process failure and testing/quality assurance failure lay at the heart of Glenmark's process for making Carvedilol, the Products were not made in a cGMP-compliant manner, which rendered the products adulterated and misbranded, and therefore unsellable and worthless (or alternatively, certainly worth some amount less), whether or not a given pill contained nitrosamines or not. *See, e.g.*, 21 U.S.C. § 351; *see also* 21 U.S.C. § 331.

10. As a result, Glenmark's Carvedilol was a dangerous unapproved

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preface#:~:text=Any%20drug%20product%20in%20the,source%20or%20coded%20as%20non%2D.

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drug, and was adulterated, misbranded, or both (and thereby rendered worthless, or alternatively, certainly worth some amount less), through contamination with a genotoxic, probable human carcinogenic nitrosamine[4] and lack of cGMP compliance concerning product testing, manufacture, and quality oversight. Indeed, Glenmark has a documented history of cGMP compliance failures at one, if not more, of its overseas facilities at which it manufactured and tested Carvedilol.

11. Glenmark had actual or constructive notice of nitrosamine potential contamination and the dangerousness of these genotoxic, carcinogenic compounds. Nitrosamines and their routes of synthesis have been well known for decades. Scientific literature has long taught about nitrosamines, as well as their detection and avoidance. International scientific guidance endorsed by the FDA, EMA, and other regulatory bodies, identify nitrosamines as dangerous compounds within the "cohort of concern" that require manufacturers to

[4] As discussed *infra*, the FDA, International Agency for Research on Cancer ("IARC"), European Medicines Agency ("EMA"), World Health Organization ("WHO"), U.S. Environmental Protection Agency ("EPA"), and other reputable agencies around the world consider nitrosamines to be genotoxic and probable human carcinogens.

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characterize and control such impurities.[5] FDA guidance issued in 2019, in the wake of the 2018 valsartan recalls due to unprecedented nitrosamine contamination, made clear there were *no* acceptable levels of nitrosamines permitted any drugs at that time.[6] Other nitrosamine-instigated recalls followed in 2019, 2020, and 2021. All of the foregoing predated Glenmark's Carvedilol recalls beginning in 2025 (*see infra*).

12. Glenmark willfully disregarded the scientific and industry guidance, and knowingly and fraudulently manufactured, sold, labeled, marketed, or distributed adulterated or misbranded Carvedilol for purchase in the United States by consumers and TPPs.

13. In or about March 2025, the FDA announced a nationwide recall of more than 732,000 bottles of Glenmark's Carvedilol. The FDA cited cGMP

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[5] ICH Guidance for Industry, *M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*.

[6] *General Advice Ltr.,* U.S. FOOD & DRUG ADMIN. (2019) ("FDA has determined that there is no acceptable specification for nitrosamines . . .Therefore, FDA advises that nitrosamines should be absent[.]"), *available at* https://www.fda.gov/media/122643/download.

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deviations, including the presence of the nitrosamine impurities, as the reasons for the recall.[7]

14. In or about August 2025, the FDA announced further recalls of Glenmark's Carvedilol for nitrosamine contamination.[8]

15. Glenmark itself stated its market withdrawal of Carvedilol was due to nitrosamine impurities.

16. Glenmark attributed the nitrosamine contamination to its failure to control nitrite levels in excipients used during the drug manufacturing process.

17. On information and belief, N-Nitroso-Carvedilol I contamination in Glenmark's Carvedilol dates back many years, at which point Glenmark had actual or, at a minimum, constructive notice of the contamination and cGMP failures concerning the testing, manufacture, and quality oversight of its Carvedilol. Indeed, because N-Nitroso-Carvedilol I contamination is a process impurity (i.e., a byproduct of the chemical synthesis/manufacturing process), not a degradation or extraneous contaminant impurity, it would be expected that the nitrosamine would exist in every batch or lot.

18. The N-Nitroso-Carvedilol I contamination in Glenmark's Carvedilol was controllable or avoidable. That other generic manufacturers of carvedilol

[7] https://www.accessdata.fda.gov/scripts/ires/?Event=96861

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continue to sell their product to this day with no troubling nitrosamine contamination underscores the feasibility of avoiding the contamination, had Glenmark exercised appropriate care.

19. Plaintiff and other class members paid for contaminated Carvedilol that was illegally placed into the stream of commerce by Glenmark. Glenmark's willful introduction of its Carvedilol into the market caused many consumers and TPPs to sustain substantial economic damages as a result of paying for VCDs that were falsely represented as approved drugs, but that were not (and which were adulterated and/or misbranded) because of nitrosamine contamination and/or cGMP failures in the manufacture of Carvedilol. Further, Carvedilol was adulterated, misbranded, or otherwise improper because they were not made in a cGMP-compliant manner (whether or not a particular tablet contained a particular amount of nitrosamines or not).

20. Glenmark's Carvedilol was not fit for intended and ordinary use and was not merchantable, and Glenmark has been unjustly enriched through the sale of these knowingly adulterated, misbranded, unapproved, and otherwise flawed drugs. Glenmark's conduct, as detailed in this Complaint, also constitutes actionable common law fraud, consumer fraud, negligence and negligence per se,

[8] https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=97370.

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and negligent misrepresentation, and violates state laws and federal law (as incorporated by state laws).

PARTIES

21. Plaintiff Sharon Carroll is a citizen and/or resident of Washington. During the class period, Plaintiff Carroll purchased Glenmark's Carvedilol in Washington, including but not limited to purchases on or about March 16, 2024, October 4, 2024, March 31, 2025, and July 2, 2025. Each time, the product purchased bore a unique National Drug Code ("NDC"), either NDC 68462-0164-05 (e.g., on March 16, 2024) or NDC 68462-0163-05 (e.g., on October 4, 2024, March 31, 2025, and July 2, 2025), which denoted that it was indeed sold, manufactured, and/or distributed into the United States supply chain by Glenmark.

22. The Carvedilol bearing NDCs 68462-0164-05 and NDC 68462-0163-05 that Plaintiff purchased were within expiry just as the same Carvedilol bearing those same NDCs that were tested and found to contain nitrosamines, and which were subject to Glenmark's recalls, as described *infra*. As Plaintiff's purchases of these NDCs were all within expiry as the same NDCs tested and found to contain nitrosamines as described *infra*, on information and belief all of the Carvedilol purchased by Plaintiff were contaminated with nitrosamines, not cGMP-complaint, not as safe as represented, and otherwise defective or flawed.

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23. Glenmark expressly and impliedly warranted and represented to Plaintiff Carroll that the Carvedilol she purchased was FDA approved, the same as FDA-approved brand-named equivalent Coreg product, was safe and merchantable and fit for ordinary and intended purpose, not contaminated with any carcinogenic impurities, was made in a cGMP-compliant manner and was not otherwise defective or flawed.

24. Contrary to these representations, Plaintiff Carroll's Carvedilol was not properly manufactured, was all contaminated with nitrosamines, and was not the same as brand-name Coreg as a result. This is so because (i) Glenmark's uniform manufacturing practices renders all of their Carvedilol defective and contaminated with nitrosamines, and (ii) the prescriptions were filled during the period when the manufacturing defects were in place and/or around the same time as the testing and recalls described *infra*. As a result, the Carvedilol purchased by Plaintiff Carroll was not as safe as represented, and did not perform as expected. Among other things, she has suffered physical impact in the form of exposure to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences.

25. The Carvedilol purchased also was not made in a cGMP-compliant manner (e.g., not made with adequate quality assurances that the product was free

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from nitrosamine contamination; had been properly tested and evaluated; had the same safety profile as FDA-approved Coreg; etc.). Had Plaintiff Carroll known the product was not as represented because it was contaminated with a nitrosamine and not made in a cGMP-compliant manner, Plaintiff Carroll would not have paid for Glenmark's Carvedilol, or alternatively would have paid some amount less for it, or further alternatively would have sought a different carvedilol product. In fact, Plaintiff Carroll would not have been able to purchase the Carvedilol in the first place because, due to the nitrosamine contamination and non-cGMP compliant manufacture of Carvedilol, Plaintiff Carroll's Carvedilol was adulterated, misbranded, and thus, worthless (or alternatively, certainly worth some amount less).

26. Defendant Glenmark Pharmaceuticals, Inc., USA ("Glenmark") is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, NJ 07430-2009. Glenmark, on its own or through its subsidiaries or affiliates, regularly conducts business throughout the United States and its territories and possessions. Glenmark is a wholly-owned subsidiary of Glenmark Pharmaceuticals Ltd. based in India. At all times material to this case, Glenmark has been engaged in the manufacturing, sale, or distribution of Carvedilol. Glenmark directly oversees or controls the manufacture of the active pharmaceutical ingredient ("API") for Carvedilol, as well as the finished-dose

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Carvedilol. Glenmark has distributed or sold Carvedilol throughout the United States for which persons have paid and reimbursed, to Glenmark's benefit.

JURISDICTION AND VENUE

27. This Court has federal subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendant, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

28. This Court has personal jurisdiction over Defendant under 28 U.S.C. § 1407, and because Defendant conducts business in in this state and has intentionally availed itself of the markets within this state through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

29. Venue is proper in this District because at least some of the class's claims alleged in this action accrued in this District, Plaintiff resides in this District, Plaintiff purchased Glenmark's Carvedilol in this District, and Defendant regularly transacts its affairs in this District.

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FACTUAL ALLEGATIONS

I. Background

A. Prescription Drug Reimbursement

30. The pharmaceutical supply chain in the United States consists of four major actors: pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").

31. Pharmaceutical manufacturers produce and/or distribute drugs to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality and utilization management screens by PBMs.

32. Third-party payors ("TPPs" contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug costs. In some instances, PBMs are responsible for placing drugs, such as Carvedilol, on the TPPs' formularies.

33. In managing formularies, TPPs and their PBMs reasonably expect that generic prescription drugs reimbursable on their formularies are the same as

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the respective FDA-approved branded drugs. The TPPs permitted carvedilol, including Glenmark's Carvedilol, to be included on their formularies based on the Defendant's misrepresentations that its Carvedilol was bioequivalent, therapeutically and pharmacokinetically equivalent, and the same as FDA-approved branded Coreg, complied with all current Good Manufacturing Practices ("cGMPs"), and were safe for consumption.

34. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the co- payment, and the higher likelihood that plan beneficiaries will purchase the drug instead of a more expensive alternative. As a result, higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to aid prescribers' adherence to the formulary.

35. The following chart, published by the Wall Street Journal,[9] broadly illustrates the pharmaceutical supply chain:

[9] Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*, WALL ST. J. (Oct. 3, 2016), https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336.

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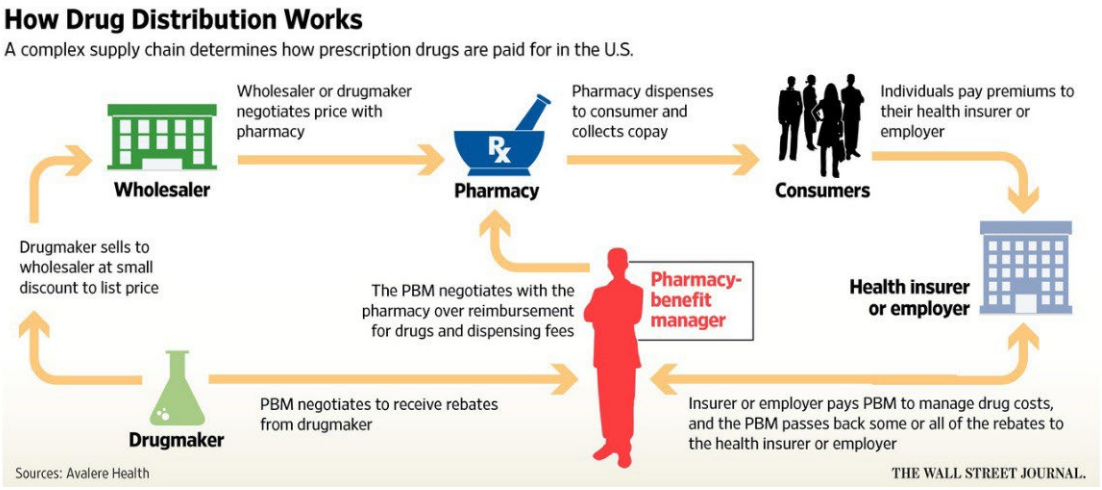

36. When patients present their prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the patient's prescription is filled, the pharmacy submits a claim to the PBM for reimbursement. PBMs then accumulate those individual reimbursements and present them to TPPs for payment.

B. Prescription Drug Product Identification and Tracing

37. For each approved product (whether brand or generic) the FDA issues a unique 10- digit code (the National Drug Code, or NDC) that follows the product from manufacturing through retail dispensing. The NDC embeds details about the specific product, including the identity of the manufacturer (or labeler), the strength, dosage form, and formulation of the drug, and the package size and

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type.[10]

38. The NDC is a critical component of each and every transfer of a prescription drug (from the manufacturer to the wholesaler; from the wholesaler to the retailer; and from the retailer to the consumer) and, therefore, every transaction is accompanied by and labeled with the NDC. This same code is used by TPPs and PBMs in the real-time claims adjudication process to identify the precise dollar amount they will reimburse the pharmacy for a particular prescription drug purchase.

39. Retail prescription labels display the NDC of the dispensed product, which is part of the electronic dispensing record. In many cases, the "lot" number will also appear on the prescription bottle provided to the consumer and, thus, specifically indicate whether the recall applies to the particular pills in the bottle.[11]

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[10] *National Drug Code Directory*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm; *National Drug Codes Explained*, DRUGS.COM, https://www.drugs.com/ndc.html.

[11] A lot number is an identification number tied to a particular lot of pills from a single manufacturer.

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40. The lot number is also used to report issues arising around a particular drug. For example, lot numbers are used by pharmacists to report Adverse Events ("AE") (that is, patient-specific side effects or complications associated with the use of a prescription drug). This is an important part of drug safety monitoring in the United States and has led to recalls or relabeling of numerous drugs. Pharmacists make such reports using the FDA's MedWatch system using Form 3500.[12]

C. The Drug Supply Chain Security Act Requires Tracing of Product

41. The Drug Supply Chain Security Act ("DSCSA")[13] was enacted in 2013, and requires prescription drug manufacturers, wholesalers, repackagers, and pharmacies to "[e]xchange information about a drug and who handled it each time it is sold in the U.S. market."

42. The DSCSA was implemented as one part of the Drug Quality and Security Act ("DQSA"), aimed at addressing vulnerabilities in the drug supply

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[12] *Instructions for Completing Form FDA 3500*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500#Section%20B:%20Adverse%20Event%20or%20Product%20Problem.

[13] 21 U.S.C. § 360eee.

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chain, and facilitating tracing of certain prescription drugs in finished dosage form through the supply chain.[14]

43. While the DSCSA was enacted in 2013, participants in the pharmaceutical supply chain maintained similar information as a part of their ordinary course of business prior to the enactment of the DSCSA.

44. The DSCSA generally requires participants in the drug supply manufacturing chain (starting from the manufacturer, through the wholesaler, to the retail pharmacy) to retain, for every pharmaceutical drug transaction, the following information about that transaction: product name; National Drug Code; container size; number of containers; lot number; date of transaction; date of shipment; and name and address of the entity transferring ownership and taking ownership of the product.

45. The DSCSA requires that this data be kept in a manner to allow these authorized participants to respond within 48 hours to requests from appropriate federal or state officials—in the event of a recall or for the purpose of investigating suspect product or an illegitimate product—for the transaction

[14] Daniel R. Levinson, *Drug Supply Chain Security: Dispensers Received Most Tracing Information*, U.S. DEPT. HEALTH & HUM. SERVS., at 2 (Mar. 2018), https://oig.hhs.gov/oei/reports/oei-05-16-00550.pdf.

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history of the pharmaceutical product.[15]

46. The supply chain for distribution of prescription drugs in the United States is highly concentrated. This means that data obtained from a relatively small number of market participants can provide detailed information about the large majority of carvedilol (including Carvedilol) sales, transfers, and prescription fills.

47. The entire process of reimbursing pharmacies and consumers for end-purchases depends on the ability to know the precise drug and packaging that was dispensed, as well as the manufacturer of that drug. This system has necessarily resulted in very high levels of data standardization in this industry. Although pharmacies maintain their own "pharmacy log" data reflecting dispensing, sales and return activity, the key elements are fundamentally similar.

48. Because pharmacies require similar information for their own tracking and inventory systems, and wholesalers sell to multiple pharmacy chains, the key elements are fundamentally the same.

49. Further, all pharmacies must use the basic data fields, definitions and

[15] *Title II of the Drug Quality and Security Act*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act.

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formats provided in the Telecommunications Guidelines developed by the National Council for Prescription Drug Programs, the use of which was made mandatory in 2003 under regulations implementing the Health Insurance Portability and Accountability Act (HIPAA).[16] Because of these HIPAA requirements, all of these inter-related systems (Manufacturers, Wholesalers, Retailers, and TPPs) use a common language to identify products.

50. As a general matter, for Medicare and Medicaid compliance, pharmacies typically keep prescription records for ten years.[17]

51. A key part of the DSCSA is the requirement that "product tracing information should be exchanged" for each transaction and retained for at least six years,[18] including the following transaction information ("TI"):[19]

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[16] 45 C.F.R. § 162.1802.

[17] 42 C.F.R. § 423.505(d).

[18] *Protect Your Patients*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/113114/download; 21 U.S.C. §§ 360eee-1(b)(1)(A)(ii), (c)(bb)(BB)(II)(v)(I), and (d)(1)(A)(iii).

[19] *Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Overview of Product Tracing Requirements*, U.S. FOOD & DRUG ADMIN., at 8-9 (Sept. 2015), https://www.fda.gov/media/93779/download.

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a. Proprietary or established name or names of the product;

b. Strength and dosage form of the product;

c. National Drug Code (NDC) number of the product;

d. Container size;

e. Number of containers;

f. Lot number of the product;

g. Date of the transaction;

h. Date of the shipment, if more than 24 hours after the date of the transaction; and

i. Business name and address of the person from whom and to whom ownership is being transferred.

52. For example, the DSCSA also mandates use of a composite "product identifier" that Defendant was required to begin applying to prescription drug packages and cases.[20]

[20] *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry*, U.S. FOOD & DRUG ADMIN. (Sept. 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-identifier-requirements-under-drug-supply-chain-security-act-compliance-policy-guidance.

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53. The term "product identifier" "means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier . . . the standardized numerical identifier, lot number, and expiration date of the product."[21]

54. Publicly available Guidelines published by AmerisourceBergen require that "each Prescription Drug lowest saleable unit" it receives from a manufacturer must have the clearly indicated product identifier on the unit label.[22] In addition, case labels and partial case labels must list the lot number and expiration date.[23] The Guidelines illustrate these requirements as reproduced below.

[21] 21 U.S.C. § 360eee(14).

[22] *AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide*, AMERISOURCEBERGEN, at 14 (Jan. 2019), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf.

[23] *Id.* at 15-16.

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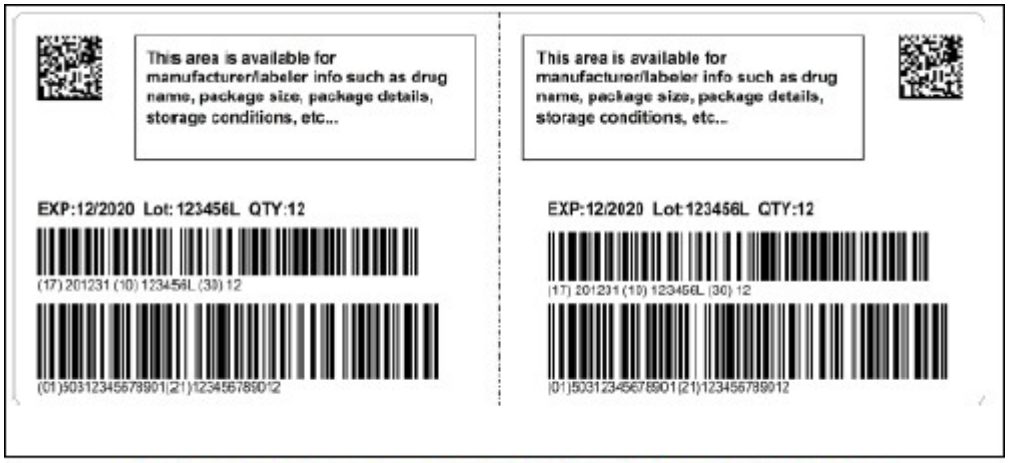
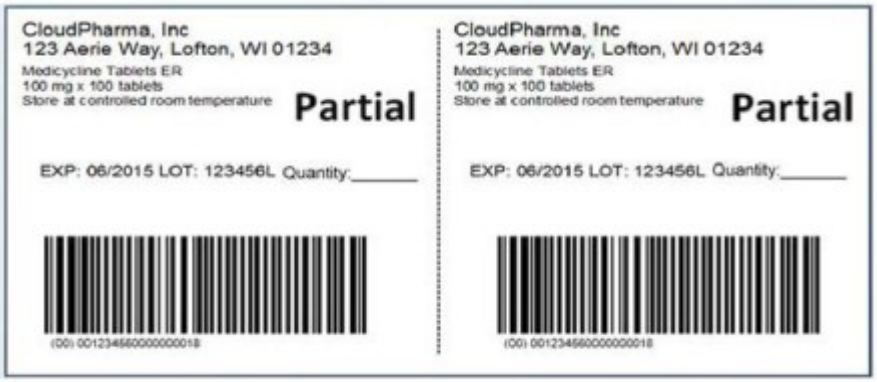
AmerisourceBergen Manufacturer Labeling Requirements[24]

DSCSA RX Serialized Unit Label



Example of Rx Serialized Homogenous Case Label



Example Partial Case Labeled with SSCC

[24] *Id.* at 14-16.

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D. The Drug Approval Framework

55. Brand drug companies submitting a New Drug Application ("NDA") must demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

56. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new drug for sale and marketing in the United States.

57. An NDA is supposed to provide enough information to permit the FDA to decide (i) whether the drug is safe and effective for its proposed uses and whether the benefits of the drug outweigh the risks; (ii) whether the drug's proposed labeling is appropriate and what it should contain; and (iii) whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.[25]

58. As the FDA puts it, the submitted NDA documentation "is supposed to tell the drug's whole story," including "what the ingredients of the drug are."[26]

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[25] *See, e.g.*, *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

[26] *Id.*

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59. If a branded drug manufacturer ceases to manufacture a drug that meets all terms of its NDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

60. If a branded drug manufacturer ceases to manufacture a drug that meets all terms of its NDA approval, or, in other words, when the drug is not the same as its corresponding brand-name drug, the manufacturer may no longer rely on the drug's labeling.

61. A drug's labeling must "contain a summary of the essential scientific information needed for safe and effective use. . . [It]shall be informative and accurate and neither promotional in tone nor false and misleading[.]" 21 C.F.R. § 201.56.

E. Approval of the NDA for Coreg

62. Coreg is known generically as carvedilol, which is also the name of the drug's active pharmaceutical ingredient ("API"). Coreg is a beta-blocker prescribed to treat high blood pressure, heart failure, and related conditions. At a very high level, the drug works by blocking β_1 and β^2 adrenergic receptors, thereby lowing blood pressure or heart rate.

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63. The FDA approved Coreg in 1995, with subsequently approvals to treat other conditions in 1997 and 2001. The FDA approved the extended release ("ER") formulation of Coreg in October 2006.

64. Coreg's FDA-approved labeling specifies the active and inactive ingredients, precautions, warnings, and other use and safety information. Neither N-Nitroso-Carvedilol I specifically, nor nitrosamines generally, are listed on the FDA-approved labeling.

F. Drugs Must Be Manufactured in Compliance with Good Manufacturing Practices

65. Under federal law, pharmaceutical drugs must be manufactured in accordance with cGMPs to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B). States' laws incorporate these standards.

66. Moreover, 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words,

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

67. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards for: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

68. Under federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring the continuing quality of the subcontractors' operations.

69. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

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> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process 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. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

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

71. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

72. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength,

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quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

73. All quality-related personnel must "have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions." 21 C.F.R. §211.25(a). This includes, specifically, appropriate training on cGMPs. *Id.* Personnel responsible for the manufacture and processing of drugs must have sufficient education, training, and experience "to provide assistance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess." *Id.* § 211.25(b). Similar requirements exist for consultants. 21 C.F.R. § 211.34.

74. Quality personnel must appropriately review all production records and investigate and explain any discrepancies or failures. *See* 21 C.F.R. § 211.192. Also, as applicable, a quality technical agreement also should be in place as to quality-related aspects of cGMP. *See, e.g.*, 21 C.F.R. §§ 211.80, 211.82, 211.86, 211.142, 211.196, 211.63. An overarching goal of these efforts and cGMP is to ensure that a drug is safe and "has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." 21 C.F.R. § 210.1(a).

75. Collectively, the CMP expectations related to quality comprise the requirement for an effective pharmaceutical quality system, referred to as ICH

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Q10 pharmaceutical quality system, that includes proper adherence to cGMPs, and complements the ICH Q8 pharmaceutical development and ICH Q9 quality risk management.[27]

G. Adulterated or Misbranded Drugs Are Illegal to Sell

76. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B); 21 C.F.R. § 210.1(b). States have enacted laws adopting or mirroring these federal standards.

77. Among the ways a drug may be adulterated or misbranded are:

a. "[I]f it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health";[28]

b. "[I]f . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity

[27] *See, e.g.*, *ICH Guidance for Industry, Q10 Pharmaceutical Quality System,* , U.S. FOOD & DRUG. ADMIN. (April 2009), https://www.fda.gov/media/71553/download.

[28] 21 U.S.C. § 351(a)(2)(A).

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with current good manufacturing practice to assure that such drug meets the requirements . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess";[29]

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and . . . its quality or purity falls below, the standard set forth in such compendium";[30] or

d. "If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[31]

78. A drug is misbranded:

a. "If its labeling is false or misleading in any particular";[32]

[29] 21 U.S.C. § 351(a)(2)(B).

[30] 21 U.S.C. § 351(b).

[31] 21 U.S.C. § 351(d).

[32] 21 U.S.C. § 352(a)(1).

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b. "If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use";[33]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient";[34]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users";[35]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein";[36]

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[33] 21 U.S.C. § 352(c).

[34] 21 U.S.C. § 352(e)(1)(A)(ii).

[35] 21 U.S.C. § 352(f).

[36] 21 U.S.C. § 352(g).

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f. "[I]f it is an imitation of another drug";[37]

g. "[I]f it is offered for sale under the name of another drug;"[38]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof";[39]

i. If the drug is advertised incorrectly in any manner;[40] or

j. If the drug's "packaging or labeling is in violation of an applicable regulation."[41]

79. The manufacture and sale of any adulterated or misbranded drug is prohibited under federal law.[42]

80. The introduction into commerce of any adulterated or misbranded drug is also prohibited.[43]

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[37] 21 U.S.C. § 352(i)(2).

[38] 21 U.S.C. § 352(i)(3).

[39] 21 U.S.C. § 352(j).

[40] 21 U.S.C. § 352(n).

[41] 21 U.S.C. § 352(p).

[42] 21 U.S.C. § 331(g).

[43] 21 U.S.C. § 331(a).

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81. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[44]

82. Glenmark's contaminated, unapproved Carvedilol was adulterated or misbranded, or both, for the reasons demonstrated above.

83. Plaintiff references federal law in this Complaint not in any attempt to enforce it, but to demonstrate that its state-law tort claims do not impose any additional obligations on Glenmark beyond what is already required of it under federal law.

II. The Drugs Purchased by Plaintiff Were Not Carvedilol, But Adulterated and Misbranded Carvedilol-Containing Drugs, Not of the Same Quality

84. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also

[44] 21 U.S.C. § 331(c).

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includes components of drugs, such as active pharmaceutical ingredients.[45]

85. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[46]

86. Accordingly, the FDA requires the submission of an NDA by manufacturers whenever a new active ingredient is added to a drug, as the drug has become a new and differing drug from those previously approved by the FDA. Absent such an application, followed by a review and approval by the FDA, the new drug remains a distinct, unapproved product.[47]

87. This new and unapproved drug with additional active ingredients (such as nitrosamines in the subject VCDs) cannot have the same label as the

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[45] *Human Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/regulated-products/human-drugs#drug.

[46] 21 C.F.R. § 210.3(b)(7).

[47] *See* 21 C.F.R. § 310.3(h).

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brand-name drug, as the two products are no longer the same and do not share therapeutic equivalence (e.g., do not have the same safety profile).

88. At the very least and alternatively, drugs with differing and dangerous ingredients than brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[48]

89. Here, N-Nitroso-Carvedilol I and/or other nitrosamines resulted from the deficient manufacturing process of Carvedilol, rendering Carvedilol different than the FDA-approved versions of Coreg. Importantly, N-Nitroso-Carvedilol I and other nitrosamines can cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, N-Nitroso-Carvedilol I and other nitrosamines are, by definition, an active ingredient in a drug.

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[48] *See generally Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA*, U.S. DEP'T JUST. (May 13, 2013), https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false.

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90. Because Carvedilol purchased or paid for by Plaintiff and other class members was never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs (i.e., never assessed the impact on the safety and efficacy profile of a product that contains nitrosamines).

91. The presence of additional active ingredients or components (i.e., N-Nitroso-Carvedilol I and/or other nitrosamines) and potentially other deviations from Coreg rendered Glenmark's Carvedilol of a lesser quality and a different safety profile than FDA-approved Coreg, and indeed, the FDA-approved version of Glenmark's Carvedilol.

92. Contaminated and adulterated Carvedilol is not a substitute for FDA-approved Coreg and has no value or practically no value to a purchaser of Carvedilol.

93. Plaintiff and other Class Members paid or reimbursed for an FDA-approved generic version of FDA-approved Coreg, but that is not what was received.

94. Plainly, Glenmark did not deliver the product paid for by Plaintiff and other Class Members.

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III. Defendant Made False Statements or Omissions About Its Carvedilol

95. A manufacturer must give adequate directions for the use of a pharmaceutical drug so that a "layman can use a drug safely and for the purposes for which it is intended,"[49] and conform to requirements governing the appearance of the label.[50]

96. "Labeling" encompasses all written, printed, or graphic material accompanying the drug or device,[51] and therefore broadly includes nearly every form of promotional activity, including not only "package inserts" but also advertising.

97. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[52]

98. If a manufacturer labels a drug but omits ingredients and/or undisclosed risks, that renders the drug misbranded.[53]

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[49] 21 C.F.R. § 201.5.

[50] 21 C.F.R. § 801.15.

[51] *See id.*

[52] *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

[53] 21 C.F.R. §§ 201.6; 201.10.

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99. Because Glenmark did not disclose that its Carvedilol contained N-Nitroso-Carvedilol I or other nitrosamines, the subject drugs were misbranded.

100. In addition, by referring to its drugs as "Carvedilol," Defendant was making false statements. The Carvedilol sold, and which Plaintiff and other Class Members paid for, was a different, new unapproved drug not therapeutically or pharmaceutically equivalent to FDA-approved Coreg, on account of a different undisclosed safety profile, different identity, purity and quality, and not being made in a cGMP-compliant manner.

101. It is unlawful to introduce a misbranded drug into interstate commerce.[54] Thus, the Carvedilol paid for by Plaintiff and other Class Members was unlawfully distributed and sold.

IV. Defendant Misrepresented That Carvedilol Was Manufactured in Compliance with Current Good Manufacturing Practices

102. Under federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to make a prescription

[54] 21 U.S.C. § 331(a).

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drug, or to contract out prescription drug manufacturing, without sufficiently ensuring the continuing quality of the manufacturing operations.

103. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process 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. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

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

105. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

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

107. As noted *supra*, a firm must have appropriate systems and personnel in place to assure a drug has the safety, identity, strength, quality, and purity that it purports or is represented to possess. *See, e.g.*, 21 C.F.R. §§ 210.1(a), 211.25(a)-(b), 211.34, 211.80, 211.82, 211.86, 211.142, 211.63 211.192 211.196, 211.63.

108. Glenmark's Carvedilol did not conform to cGMP-required safety and quality parameters, which demonstrates inadequate production, process, and quality oversight by Glenmark.

109. Glenmark's failure to conform to cGMPs resulted in the production, and ultimate sale and reimbursement, of a product that was so contaminated and adulterated with high—not merely trace—levels of nitrosamines that it could not be considered the same as FDA-approved Coreg, yet Glenmark still falsely labeled or held out its products as the same as FDA-approved Coreg in all material respects.

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V. Nitrosamines Are Dangerous, Genotoxic Carcinogens

110. Nothing in the FDA-approved NDA for Coreg, or the FDA-Approved ANDA for Glenmark's Carvedilol, indicated that nitrosamines are or might be present in the drug. That is, neither Coreg nor any generic carvedilol (including Carvedilol) made according to the FDA-approved process, under appropriate quality oversight as required by cGMP, should include any undisclosed nitrosamines.

111. Nitrosamines are semi-volatile chemicals that form during industrial and natural processes. Nitrosamines have no known, let alone FDA approved, therapeutic benefit.

112. The ICH M7 Guidance specifically refers to nitrosamines as being within the "cohort of concern," comprised of high potency mutagenic carcinogens.[55] The Guidance teaches that dangerous compounds like nitrosamines should be characterized, and methods developed to eliminate or

[55] *ICH Guidance for Industry, M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk*, U.S. FOOD & DRUG. ADMIN. (Mar. 2018), https://www.fda.gov/media/85885/download. Earlier iterations of the ICH M7(R1) Guidance classified nitrosamines the same way.

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control them. Every iteration of the ICH M7 Guidance dating back to 2006 similarly classified nitrosamines and warned of the need for "compound-specific toxicity data" beyond that for other substances.[56]

113. Agencies ranging from IARC and WHO,[57] to the EPA,[58] to the American Conference of Governmental Industrial Hygienists,[59] to the Agency for

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[56] *See, e.g.*, *ICH Guidance for Industry, M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk*, EUROPEAN MEDICINES AGENCY, *at* https://www.ema.europa.eu/en/ich-m7-assessment-control-dna-reactive-mutagenic-impurities-pharmaceuticals-limit-potential#document-history-section (collecting iterations of guidance back to issuance in 2006).

[57] *See, e.g.*, IARC Scientific Publications, No. 14, Lyon, France: International Agency for Research on Cancer, 1976; *Environmental Aspects of N-Nitroso Compounds*, Vol. 1. (E.A. Walker, M. Castegnaro, L. Griciute, and R.E. Lyle, eds.), IARC Scientific Publications, No. 19, Lyon, France: International Agency for Research on Cancer, 1978; *N-Nitroso Compounds: Analysis, Formation and Occurrence*. (E.A. Walker, M. Castegnaro, L. Griciute, and M. Borzsonyi, eds.), IARC Scientific Publications, No. 31, Lyon, France: International Agency for Research on Cancer, 1980.

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Toxic Substances and Disease Registry[60] to the U.S. Department of Health and Human Services ("DHHS")[61] classify various nitrosamine compounds as probable human carcinogens.[62]

114. Anecdotally, nitrosamines have also been used in intentional poisonings.[63]

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[58] *Technical Fact Sheet N-Nitroso-dimethylamine (NDMA)*, U.S. ENVIRONMENTAL PROTECTION AGENCY (Nov. 2017), *available at* https://www.epa.gov/sites/production/files/2017-0/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[59] *Id.*

[60] *Id.*

[61] *Id.*

[62] *Pharmacology and Toxicology Guidance for Industry, Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches,* U.S. FOOD & DRUG. ADMIN. (Dec. 2018).

[63] *See* Chase Purde, *A common blood-pressure medicine is being recalled because of a toxic ingredient*, QUARTZ (July 18, 2018), https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/.

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115. Nitrosamines are not new. The scientific community has been aware of nitrosamine formation and carcinogenicity for several decades. The chemical reactions leading to nitrosamine formation have been described as textbook chemistry.[64] The carcinogenicity of nitrosamines has been well documented since at least the 1950s.[65]

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[64] Sun, Z., Liu Y.D., and Zhong, R.G. (2010) Theoretical Investigation of *N*-Nitrosodimethylamine Formation from Nitrosation of Trimethylamine, *J. Phys. Chem. A*. 114, 455-465; 29; International Agency for Research on Cancer (1978); Some *N*-nitroso compounds, in *IARC Monogr. Eval. Carcinog. Risk Chem. Hum.* pp 83-175, IARC, Lyon, FR.

[65] Magee, P. N., and Barnes, J. M. (1956) The production of malignant primary hepatictumors in the rat by feeding dimethylnitrosamine, *Brit J Cancer 10*, 114-122; *see also, e.g.*, De Flora, S. *et al.*, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, The Lancet, Oct. 31, 1981, at 993-94; Maura, *et al.*, *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 Tox. Lttrs. 97-102 (1983); De Flora S., *et al.*, *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255-60 (1983).

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116. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as at least 2005,[66] and likely earlier. The scientific literature instructed for decades that companies should evaluate their products for the potential of nitrosamine formation.[67]

117. The chemical reaction leading to the formation of N-Nitroso-Carvedilol I is no exception to this. Nitrosamines of this type form when the API reacts with nitrites or nitrates during the manufacturing process. The chemical reaction is straightforwardly expressed as follows:[68]

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[66] Lutz Müller et al., *A rationale for determining, testing, and controlling specific impurities in pharmaceuticals that possess potential for genotoxicity*, REGUL. TOXICOLOGY & PHARMACOLOGY (Dec. 26, 2005), https://www.sciencedirect.com/science/article/abs/pii/S0273230005002084?via%3Dihub.

[67] *Id.*

[68] https://qvents.in/ndsris-n-nitrosocarvedilol-glenmark-recalls-several-lots-of-cardiovascular-drug/.

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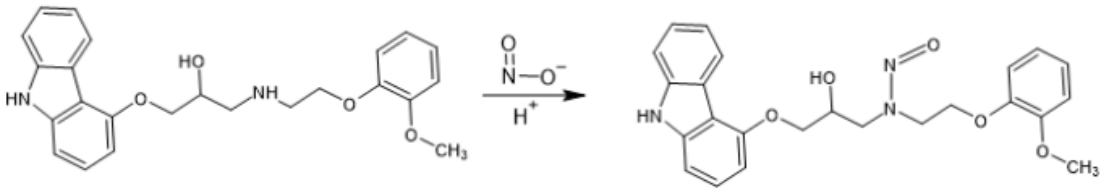

Carvedilol N-Nitroso Carvedilol

118. The scientific literature also taught about nitroso compound formation for years prior to Glenmark's eventual recalls in 2025.

119. Certainly, the entire pharmaceutical industry was acutely aware of nitrosamines in drug substance or drug product since at least mid-2018. Then, some of the largest drug product recalls in FDA's history occurred concerning nitrosamine contamination of blood pressure medications valsartan, losartan, and irbesartan.[69] In the wake of those unprecedented recalls, the FDA explained that

[69] *See generally*, *FDA Updates and Press Announcements on Angiotension II Receptor Block (ARB) Recalls (Valsartan, Losartan, and Irbesartan),* U.S. FOOD & DRUG ADMIN, *at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

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no level of nitrosamines were permissible in drugs.[70] The FDA specifically advised the industry to be sure to evaluate their products for nitrosamines at that time, to the extent firms had not yet done so (which they should have been doing under ICH M7(R1) Guidance and other guidance and literature).[71]

120. In 2021, Pfizer recalled its smoking cessation drug Chantix due to nitrosamine formation.[72] The root cause of the contamination was a very similar reaction as that which is responsible for N-Nitroso-Carvedilol I in Carvedilol.[73]

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[70] *General Advice Ltr.,* U.S. FOOD & DRUG ADMIN. (2019) ("FDA has determined that there is no acceptable specification for nitrosamines . . .Therefore, FDA advises that nitrosamines should be absent[.]"), *available at* https://www.fda.gov/media/122643/download.

[71] *Id.*

[72] *FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)*, *available at* https://www.fda.gov/drugs/drug-alerts-and-statements/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix.

[73] *See, e.g.*, Boetzel, et al., *A Nitrite Excipient Database: A Useful Tool to Support N-Nitrosamine Risk Assessments for Drug Products*, J. of Pharm. Sciences 112 (2023) 1615-1624.

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121. Further, it was known prior to Glenmark's recalls that drug products containing an active ingredient like carvedilol with a secondary amine functional group were vulnerable to nitrosating agents from excipients or other ingredients, leading to the formation of nitrosamines.

122. In fact, FDA guidance explicitly directed drug manufacturers to identify such potential reactions during the manufacture of drug product:

> Drug product manufacturers and applicants should conduct risk assessments to determine the potential for small-molecule nitrosamine impurities and NDSRIs in drug products. A risk assessment should involve collaboration with the API manufacturer to aid in the identification of the API ROS or other process conditions of the API's manufacture that put the drug product at risk for nitrosamine impurities. The risk assessment should also include evaluation of any pathway (e.g., degradation and nitrosamine precursor impurities such as dimethylamine or other secondary amine precursors) that may introduce the risk of nitrosamine formation during drug product manufacture or storage. . . .If a nitrosamine impurity is detected, manufacturers and applicants should investigate the root cause and implement changes in the manufacturing process to prevent or reduce nitrosamine impurities[.][74]

123. Moreover, "[m]anufacturers and applicants should also evaluate whether nitrosamines could form in a finished drug product over the drug product's shelf life. If a nitrosamine is introduced to the drug product through exogenous sources that can be avoided, manufacturers and applicants should

[74] https://www.fda.gov/media/141720/download.

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eliminate the source of nitrosamine impurities."[75]

124. A manufacturer's obligations to test for nitrosamines is ongoing: "To meet the current good manufacturing practice (CGMP) regulations in 21 CFR part 211, subpart E, and be consistent with the ICH guidance for industry *Q10 Pharmaceutical Quality System* (April 2009), drug product manufacturers and applicants should continue testing each API lot for nitrosamine impurities."[76]

125. Thus, Glenmark was on actual and constructive notice of the need to have adequate quality systems in place to detect, characterize, analyze, and quantify nitrosamines years before its Carvedilol recalls in 2025. There is no indication that Glenmark ever undertook an appropriate evaluation of its Carvedilol to ascertain the likelihood of nitrosamine formation, let alone develop a cGMP-compliant way to detect, and to avoid or at least to minimize, nitrosamine formation.

126. Because the nitrosamine contamination was a process-related impurity—i.e., it was not isolated, a one-off accident, etc.—it is plausible and, under the weight of industry literature and guidance, reasonably expected that every batch and every lot of finished product manufactured would experience the same cGMP deficiency.

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[75] *Id.*

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127. Generally speaking, a process impurity is an unintended chemical entity or potential chemical reaction introduced during the manufacturing process. Such impurities generally originate from raw materials, catalysts, reagents, intermediates, environmental conditions, or by-products formed during synthesis. According to ICH Guidance Q3A(R2), process (and degradation) impurities should be evaluated for their potential, characterized, monitored, and controlled or eliminated.

128. Since commercial manufacturing processes are validated for repeatability, process impurities present will be present in all subsequent production batches. This is due in part to pharmaceutical manufacturing aiming to ensure uniform mixing of active ingredients and general content uniformity. Thus, the distribution of any impurity is expected with certain assumptions to be also uniformly distributed in the drug product.

129. Regulatory agencies require drug manufacturers to establish scientifically justified specifications for impurities to ensure batch uniformity. According to 21 CFR Part 211, batch-to-batch consistency must be maintained through validated manufacturing processes, ensuring that any impurity identified persists predictably across all commercial batches.

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[76] *Id.*

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130. The same principles and quality-by-design carry through to drug products. The entire framework of drug product manufacturing is to ensure repeatable consistency and within-specifications uniformity in the product manufacture.

131. Based on established regulatory guidelines, industry standards, and empirical data, it is reasonable to conclude that a process impurity, once present, will consistently appear in every batch of the finished drug product unless actively removed or degraded during formulation.

132. In other words, the manufacture of a drug product, such as MCDs, must by design, regulation, and expectation result in the routine, systematic production of like-quality products, such that both desired components as well as unwanted impurities are consistently, uniformly present in each product made during the common-by-design manufacturing process.

133. Therefore, an impurity such as the one in Carvedilol—which as detailed herein resulted from a chemical reaction during a singular manufacturing process that utilizes by design the same components every time—would be widespread and systematically present in every product manufactured.

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VI. Defendant's Carvedilol Was Contaminated, Adulterated and Misbranded

134. In or about March 2025, the FDA announced a nationwide recall of more than 732,000 bottles of Glenmark's Carvedilol. The FDA cited cGMP deviations, including the presence of the nitrosamine impurities, as the reasons for the recall.[77] Glenmark's recall advised that nitrosamine impurities "may increase the risk of cancer" and "may be associated with a potential increased cancer risk in humans." Glenmark further advised pharmacy, wholesale, and retail customers to "quarantine such product immediately and not dispense any further."

135. In or about August 2025, the FDA announced further recalls of Glenmark's Carvedilol for nitrosamine contamination.[78] Glenmark again cited the presence nitrosamines as the basis for these recalls, and reiterated its earlier statements about carcinogenicity and quarantine.

136. Glenmark itself stated its market withdrawal of Carvedilol was due to nitrosamine impurities.

137. All of Glenmark's Carvedilol was manufactured through the same process, with the same components (e.g., carvedilol API, excipients, etc.).

[77] https://www.accessdata.fda.gov/scripts/ires/?Event=96861.

[78] https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=97370.

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VII. Defendant's cGMP Violations and Other Wrongful Conduct Resulted in Its Carvedilol Being Adulterated, Misbranded, and/or Unapproved

138. If Defendant had not routinely disregarded the FDA's cGMPs, or had fulfilled its quality assurance obligations, Defendant would have identified the presence of these nitrosamine contaminants almost immediately. This is evident from the basic chemistry of nitrosamines, the longstanding scientific study and literature about nitrosamine formation and carcinogenicity, the industry guidance recommending the evaluation and testing for nitroso compounds, and the other nitrosamine-related recalls described above.

139. Industry and regulatory standards called for firms to have processes in place to detect, characterize, analyze, and quantify nitrosamines well before Glenmark initiated its recalls in 2025.

140. Prior to initiating recalls in the United States, Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management.

141. For example, 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

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> In-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).

142. Similarly, 21 C.F.R. § 211.100 and § 211.22(b), among other provisions, requires quality control units to ensure sufficient written and other procedures exist to assure the identity, strength, quality, and purity of the drug product.

143. And, as discussed above, the quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API or finished-dose manufacturer that made Glenmark's Carvedilol, whether Glenmark itself or a firm contracted on Glenmark's behalf. As the seller of Carvedilol in the United States, Glenmark bore non-delegable responsibility to ensure Carvedilol was made in a cGMP-compliant manner.

144. The quality control units responsible for Glenmark's Carvedilol were grossly deficient in fulfilling their responsibilities.

145. As noted *supra*, scientific and industry knowledge of nitrosamine formation pre-dated Glenmark's recalls by years. Glenmark had an obligation to evaluate its Carvedilol, and the components thereof, to determine whether the

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possibility of nitrosamine formation existed, to test for nitrosamines, and to take steps to reduce or eliminate nitrosamines in Carvedilol. Glenmark did not do any of this.

146. If the foregoing sampling-related, testing-related, and quality- related cGMPs were properly observed by Glenmark, the nitrosamine contamination in Glenmark's Carvedilol would have been discovered almost immediately, and Defendant was thus (at minimum) on constructive notice from the moment its Carvedilol became contaminated.

147. Not only did Glenmark fail to eliminate nitrosamines from its Carvedilol, but the amount of nitrosamines found in Carvedilol as reported by the FDA, which would be expected to be the same in all product given the root cause being a process impurity, was above the acceptable intake limit. Notably, that limit should apply only when nitrosamines are not avoidable in a drug product. Here, nitrosamines were avoidable, but Glenmark failed to take appropriate steps to detect, characterize, and eliminate nitrosamines in its Carvedilol.

148. Glenmark obtained its Carvedilol from a manufacturing facility in India operated by Glenmark's corporate affiliate, Glenmark Pharmaceuticals Ltd. ("Glenmark-India"). The two firms, Glenmark and Glenmark-India, share personnel and other resources. For instance, Glenmark is the United States agent for Glenmark-India's regulatory submissions to the FDA.

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149. On information and belief, Glenmark-India manufactured Carvedilol for Glenmark at two facilities in India, one in Goa (the "Goa Facility") and one in Pithampur/Madhya Pradesh (the "Pithampur Facility"). Both facilities have had longstanding, serious cGMP deficiencies.

150. For instance, after years of reported cGMP failures, the FDA sent Glenmark-India a Warning Letter in November 2022 noting many "significant violations of" cGMPs. These deviations included failures to investigate discrepancies or failures in drug product batches; "to establish adequate written procedures for production and process control designed to assure that the drug products you manufacturer have the identity strength, quality, and purity they purport or are represented to possess"; "to establish and follow required laboratory control mechanisms"; and to prepare maintain proper batch and control records." "Because [Glenmark-India's] methods, facilities or controls for manufacturing, processing, packing or holding do not conform to CGMP, your drug products are adulterated[.]"

151. After years of escaping regulatory inspections, the FDA inspected Glenmark-India's drug manufacturing facility in Pithampur, Madhya Pradesh, 454774 India, in February 2025.

152. This investigation resulted in an FDA Warning Letter issued in July 2025 to Glenmark-India. The FDA Warning Letter summarized numerous

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"significant violations of" cGMPs. "Because [Glenmark-India's] methods, facilities or controls for manufacturing, processing, packing or holding do not conform to CGMP, your drug products are adulterated[.]" Among the serious cGMP violations were Glenmark-India's " failures to investigate discrepancies or failures in drug product batches; "to follow an adequate written testing program designed to assess the stability characteristics of drug products"; and "to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure . . . drug products conform to appropriate standards of identity, strength, quality, and purity."

153. The FDA even noted in the July 2025 Warning Letter that many cGMP violations were similar to those found Glemark's "company's network," including the Goa Facility, a facility in Himachal Pradesh, and Glenmark's own facility in North Carolina.

154. Although the precise products mentioned are redacted in the warning letters, even if these observations did not directly relate to Carvedilol, they are certainly indicative and probative of Glenmark's, and it's corporate family's, lax approach to cGMP compliance as to some of the very same quality components that would be involved in the detection of nitrosamines in Carvedilol.

155. Glenmark knowingly, recklessly, or negligently introduced

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adulterated or misbranded Carvedilol containing dangerous amounts of nitrosamines into the U.S. market. Glenmark failed to recall its Carvedilol earlier because it feared permanently ceding market share to competitors. It did not institute the recalls until after the FDA's February 2025 inspection of the Pithampur Facility.

VIII. Defendant's Warranties and Fraudulent and Deceptive Statements to Purchasers Regarding Its Carvedilol

156. Defendant made and breached express and implied warranties and also made affirmative and implied misrepresentations and omissions to purchasers about its adulterated or misbranded VCDs.

157. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" known as the Orange Book.[79] The Orange Book is a public document; Defendant sought and received the inclusion of its Carvedilol in the Orange Book upon approval of its ANDA.

158. Defendant's Carvedilol is accompanied by an FDA-approved label. By presenting purchasers with an FDA-approved Carvedilol label, Defendant

[79] *Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

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made representations and express or implied warranties of the "sameness" of its product to the Orange Book listed Carvedilol, and in turn Coreg, and that its products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels or were not adulterated or misbranded or not made in a CMP-compliant manner.

159. The Carvedilol produced and sold by Defendant were not FDA-approved carvedilol.

160. By introducing its Carvedilol into the United States marketed as a generic carvedilol drug equivalent to Coreg, Defendant represented and warranted to purchasers that its Carvedilol was in fact the same as the approved version of Carvedilol and, in turn, Coreg. Much of the drug supply chain, including the most critical components of that supply chain (for example, patients and purchasers) rely on these representations and warranties.

161. In addition, Defendant affirmatively misrepresented and warranted to purchasers through its websites, brochures, and other marketing or informational materials that its Carvedilol complied with cGMPs and did not contain (or were not likely to contain) any components or impurities besides those identified on the products' FDA-approved labels.

162. The presence of nitrosamines in Defendant's Carvedilol: (1) renders Defendant's Carvedilol non-equivalent (that is, not the same) to listed carvedilol

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and in turn Coreg, thus breaching Defendant's express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendant's Carvedilol worthless (or alternatively, certainly worth less), thus breaching Defendant's express warranties of sameness; and (3) results in Defendant's Carvedilol containing an ingredient or component or impurity that is not also contained in the FDA-approved label, also breaching Defendant's express warranty of sameness (and express warranty that the products contained the ingredients or component or impurities listed on Defendant's FDA-approved label). Defendant willfully, recklessly, or negligently failed to ensure its Carvedilol labels and other advertising or marketing statements accurately conveyed information about its products.

163. The presence of nitrosamines in Defendant's Carvedilol and serial and willful failures to comply with cGMPs and other shortcomings in Defendant's drug manufacturing processes have resulted in Defendant's Carvedilol being adulterated or misbranded or not compliant with cGMPs.

164. At all relevant times, Defendant also impliedly warranted that its Carvedilol was merchantable and fit for its ordinary purposes.

165. Naturally, due to their status as probable human carcinogens as listed by both the IARC and others, nitrosamines are not FDA-approved ingredients in Carvedilol, carvedilol, or Coreg. The presence of nitrosamines or impurities in

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Defendant's Carvedilol means that Defendant has violated implied warranties to Plaintiffs and other Class Members. The presence of nitrosamines in Defendant's Carvedilol makes the product non-merchantable and not fit for its ordinary purposes, breaching Defendant's implied warranty of merchantability and/or fitness for ordinary purposes.

166. For these and other reasons, Defendant's Carvedilol are, therefore, adulterated, misbranded, or unapproved, and not compliant with cGMPs, and it was illegal for Defendant to have introduced or sold such Carvedilol in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

167. Adulterated, misbranded, or unapproved Carvedilol contaminated with cancer- causing compounds, or manufactured in a non-cGMP compliant manner, are essentially worthless (or alternatively, certainly worth less). No reasonable purchaser (including Plaintiff) would purchase (or reimburse for) these nitrosamine-laden Carvedilol. Nor could they, as adulterated, misbranded, or unapproved Carvedilol cannot be legally sold or purchased within the United States. At a minimum, adulterated, misbranded, or unapproved Carvedilol was worth less than their non-contaminated equivalents. Further, adulterated, misbranded, and/or unapproved Carvedilol does not possess the same safety and efficacy profiles as their branded equivalents. As such, the Carvedilol was not what it was supposed to be.

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168. Because of the seriousness of the impurity—unsafe levels of a carcinogen—all or virtually all purchasers immediately stopped paying for the tainted drug products after receiving notice of the recall; in fact, Glenmark advised the pharmacy supply chain to quarantine the recalled product. Even in the absence of nitrosamines, the cGMP failures at Defendant Glenmark's manufacturing process meant its products were adulterated for lack of adequate quality assurances.

IX. Fraudulent Concealment and Tolling

169. Plaintiffs' and Class Members' causes of action accrued no earlier than the date(s) the FDA announced the recall of Glenmark's Carvedilol. Plaintiff exercised reasonable diligence but could not discover the nitrosamine contamination or Glenmark's cGMP violations, each of which independently rendered its Carvedilol adulterated, misbranded, and a non-approved new drug, because Glenmark's wrongful acts were concealed from Plaintiff and the public, and facts pertinent to same were within Glenmark's possession and control. Glenmark's conduct as alleged herein constitutes a continuing violation of applicable laws.

170. Alternatively, any statute of limitation or prescriptive period is equitably tolled because of fraudulent concealment. Glenmark affirmatively concealed from Plaintiff and other Class Members its unlawful conduct.

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Defendant affirmatively strove to avoid disclosing its knowledge of its cGMP violations related to Carvedilol, and of the fact that Carvedilol was adulterated and/or misbranded and contaminated with nitrosamines and were not the same as the FDA-approved generic and Coreg.

171. For instance, Glenmark did not reveal to the public that its Carvedilol contained nitrosamines or was otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to FDA-approved Coreg.

172. To the contrary, Glenmark continued to represent and warrant that its Carvedilol was the same as Coreg, and continued to sell its Carvedilol in the United States after the 2018 valsartan recalls (when industry focus on nitrosamines became especially acute, even though the industry and literature knew of nitrosamine formation much earlier).

173. Because of this, Plaintiff and other Class Members did not discover, nor could they have discovered through reasonable and ordinary diligence, Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendant's false and misleading explanations, or obfuscations, lulled Plaintiff and Class Members into believing that the prices paid for Defendant's Carvedilol were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

174. As a result of Defendant's affirmative and other acts of concealment,

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any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and other Class Members exercised reasonable diligence by, among other things, promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff was unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable any complaint to be filed sooner.

CLASS ACTION ALLEGATIONS

175. Plaintiff seeks to represent a Nationwide Class and Washington Subclass under Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) as defined below:

> **Nationwide Class:** All individuals and entities in the United States and its territories and possessions who paid any amount of money for Carvedilol (intended for personal or household use) that was manufactured, distributed, or sold by Defendant.
>
> **Washington Subclass:** All individuals and entities who paid any amount of money for Carvedilol (intended for personal or household use) that was purchased or dispensed in Washington that was manufactured, distributed, or sold by Defendant.

176. Plaintiffs allege additional sub-classes for all purchasers in each State, territory, or possession—or combinations of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment—that paid any amount of money out of

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pocket for Carvedilol (intended for personal or household use) that was manufactured, distributed, or sold by Defendant (collectively, with the Washington Subclass above, the "Subclasses").

177. Collectively, the foregoing Nationwide Class and the Subclasses are referred to as the "Class."

178. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendant and affiliated entities, and their employees, officers, directors, and agents; (c) Defendant's legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

179. Plaintiff reserves the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

180. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

181. **Numerosity:** While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially hundreds of entities nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

182. **Existence and predominance of common questions of law and fact:** Common questions of law and fact exist as to all Class Members and

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predominate over any questions affecting individual Class and Subclass members. These common legal and factual questions include, but are not limited to, the following:

a. Whether Defendant made express or implied warranties of "sameness" to Plaintiff and Class Members regarding its Carvedilol;

b. Whether Defendant's Carvedilol were, in fact, the same as the FDA-approved generic and FDA-approved branded product consistent with such express or implied warranties;

c. Whether Defendant's Carvedilol was contaminated with nitrosamines or similar contaminants;

d. Whether Defendant's Carvedilol containing nitrosamines or similar contaminants was adulterated or misbranded;

e. Whether Defendant violated cGMPs regarding the manufacture of its Carvedilol;

f. Whether Defendant falsely claimed that its Carvedilol was the same as Coreg and thus therapeutically interchangeable;

g. Whether Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;

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h. Whether Plaintiff and other Class Members have been injured as a result of the Defendant's unlawful conduct, and the amount of their damages;

i. Whether a common damages model can calculate damages on a class-wide basis;

j. When Plaintiff's and Class Members' causes of action accrued; and

k. Whether Defendant fraudulently concealed Plaintiff's and Class Members' causes of action.

183. **Typicality:** Plaintiff's claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff has substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

184. **Adequacy of Representation:** Plaintiff is committed to pursuing this action and has retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiff and their counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiff

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has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

185. The elements of Rule 23(b)(2) are met. Defendant has acted on grounds that apply generally to Class Members so that preliminary or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

186. **Superiority:** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Although many other Class Members have claims against Defendant, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

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CAUSES OF ACTION

COUNT I
BREACH OF EXPRESS WARRANTIES

187. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

188. Plaintiff, and each member of the Class, formed a contract with Defendant at the time Plaintiff and the other Class Members paid for the VCDs. The terms of the contract include the promises and affirmations of fact made by Defendant on the Carvedilol packaging and through marketing and advertising, including that the product would be bioequivalent and therapeutically equivalent to and the same as FDA-approved Coreg or an FDA-approved generic equivalent, and would be of same "quality" and have the same safety and efficacy profile as FDA-approved Coreg or an FDA-approved generic equivalent. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain and are part of the standardized contract between Plaintiff and the members of the Class and Defendant.

189. Adulterated and misbranded drugs are illegal to sell. Nitrosamine contamination, and manufacture in a non-cGMP compliant manner, each independently establish a drug's adulteration or misbranding. Defendant's distribution and sale of its Carvedilol was a direct affirmation that its Carvedilol was not adulterated, i.e., did not contain any nitrosamine contaminants, and was

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made in a cGMP-compliant manner. These express and implied affirmations were false.

190. Further, Defendant affirmed in its product labeling (e.g., label, package insert, medication guide) that its Carvedilol was therapeutically equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Coreg. These express and implied affirmations were false. Defendant's Carvedilol did *not* have the same safety profile as FDA-approved Coreg. Defendant failed to disclose the facts of nitrosamine contamination and manufacture in a non-cGMP compliant manner. Defendant's Carvedilol further lacked the appropriate identity, quality, and purity. Defendant's Carvedilol was not safe as warranted, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant that posed the unreasonable risk of genotoxicity and carcinogenicity.

191. Defendant's product labeling (e.g., label, package insert, medication guide) were required to be truthful, accurate, and non-deceptive, and to adequately advise of any precautions or safety-related risks. Defendant's Carvedilol product labeling failed to do so, insofar as it did not disclose known or knowable risks relating to nitrosamine contamination and that Carvedilol was not manufactured in a cGMP-compliant manner, and therefore there was no adequate quality assurance.

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192. Defendant's sale of Carvedilol expressly warranted the products were compliant with compendial standards, USP requirements, Orange Book requirements. These affirmations were false, because Defendant's Carvedilol was not therapeutically equivalent to FDA-approved Coreg, with inter alia a different safety profile, different identity, purity, and quality characteristics, and not made in a cGMP-compliant manner.

193. Defendant expressly warranted that its Carvedilol was merchantable, and fit for ordinary use, as an FDA-approved pharmaceutical that is therapeutically equivalent to and the same as FDA-approved Coreg. In other words, Defendant expressly warranted that its products were the same as FDA-approved Coreg or an FDA-approved generic equivalent, in terms of therapeutic equivalence, safety profile, possessing the same identity, purity, and quality, and assurance of being made in a cGMP-compliant manner.

194. Defendant sold Carvedilol that it expressly warranted was compliant with cGMPs and were not adulterated or misbranded. Indeed, the very fact that Defendant sold Carvedilol in the stream of commerce warranted it was cGMP-compliant and not adulterated because adulterated products are illegal to sell or dispense.

195. Defendant's Carvedilol did not conform to Defendant's express representations and warranties because the product was not manufactured in

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compliance with cGMPs, contained nitrosamine contaminants, was not therapeutically equivalent, lacked the same safety profile as FDA-approved Coreg, had different identity, purity, and quality characteristics, and was adulterated and misbranded.

196. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2- 313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-

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313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2- 313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.

197. At the time that Defendant marketed and sold its Carvedilol, it recognized the purposes for which the products would be used, and expressly warranted the products were the same as FDA-approved Coreg, made in a cGMP-compliant manner, were not contaminated with nitrosamines, and were not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase or reimbursement by Plaintiff and other Class Members including but not limited to express representations made in referring to its Carvedilol.

198. Plaintiff and each member of the Class were reasonably expected purchasers who would use, consume or be affected by (or whose insureds would use, consume, or be affected by) the adulterated, misbranded, and sub-standard Carvedilol manufactured and sold by Defendant.

199. Defendant breached its express warranties with respect to its Carvedilol as it was not of merchantable quality, was not fit for their ordinary purpose, was contaminated with nitrosamines, did not comply with cGMPs and was adulterated and misbranded.

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200. Plaintiff and each member of the Class would not have (and could not have) paid for the Carvedilol had they known these drugs were not the same as FDA-approved Coreg, did not contain the same ingredients or components or impurities, did not have the same safety and efficacy profile of as FDA-approved Coreg, and contained nitrosamines. They did not receive the expected benefit of the bargain by receiving Carvedilol that contained undisclosed dangerous nitrosamines and/or were made in a non-cGMP compliant manner, either of which rendered the products adulterated, misbranded, illegal to sell, and therefore worthless (or alternatively, certainly worth less).

201. Defendant's Carvedilol did not fulfill the intended purpose. Plaintiff and other Class Members bargained for an adequately made, adequately labeled product that did not pose significant undisclosed risks. But Defendant's Carvedilol was not adequately made, was not adequately labeled, and posed significant undisclosed risks, viz., it contained an undisclosed genotoxic carcinogen. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences.

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202. As a direct and proximate result of Defendant's breach of express warranties, Plaintiff and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, the lost value of any non-returned product rendered unusable after the recalls, and any consequential damages resulting from the purchases, in that the Carvedilol they purchased was so inherently flawed, unfit, or unmerchantable as to have little to no market value.

203. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences. This, combined with being made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class Members (or their insureds) suffering physical harm or impact from ingesting a flawed product.

204. Pre-suit notice is not required, but even if it is, such notice was provided to Defendant.

COUNT II
BREACH OF IMPLIED WARRANTIES

205. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

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206. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2- 314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va.

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Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314; and Wyo. Stat. § 34.1-2-314.

207. Defendant was a merchant within the meaning of the above statutes.

208. Defendant's Carvedilol constituted "goods" or the equivalent within the meaning of the above statutes. Defendant placed its Carvedilol in sealed packaging or other closed containers and placed it on the market.

209. Defendant was obligated to provide Plaintiff and other Class Members reasonably fit Carvedilol for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendant is involved such that the product was of fit and merchantable quality.

210. Defendant knew or should have known that its Carvedilol was being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to FDA-approved Coreg or an FDA-approved generic equivalent (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that its Carvedilol was of merchantable quality and fit for that purpose.

211. Adulterated and misbranded drugs are illegal to sell. Nitrosamine contamination, and manufacture in a non-cGMP compliant manner, each independently establish a drug's adulteration or misbranding. Defendant's distribution and sale of its Carvedilol was an implied affirmation that its

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Carvedilol was not adulterated, i.e., did not contain any nitrosamine contaminants, and was made in a cGMP-compliant manner. These express and implied affirmations were false.

212. Further, Defendant impliedly affirmed in its product labeling (e.g., label, package insert, medication guide) that its Carvedilol was therapeutically equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Coreg and an FDA-approved generic equivalent. These affirmations were false. Defendant's Carvedilol did *not* have the same safety profile as FDA-approved Coreg or an FDA-approved generic equivalent. Defendant failed to disclose the facts of nitrosamine contamination and manufacture in a non-cGMP compliant manner. Defendant's Carvedilol further lacked the appropriate identity, quality, and purity. Defendant's Carvedilol was not safe as warranted, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.

213. Defendant's product labeling (e.g., label, package insert, medication guide) were required to be truthful, accurate, and non-deceptive, and to adequately advise of any precautions or safety-related risks. Defendant's Carvedilol product labeling failed to do so, insofar as it did not disclose known or knowable risks relating to nitrosamine contamination and that the Carvedilol was

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not manufactured in a cGMP-compliant manner, and therefore there was no adequate quality assurance.

214. Defendant's sale of Carvedilol impliedly warranted that the product wase compliant with compendial standards, USP requirements, and Orange Book requirements. These affirmations were false because Defendant's Carvedilol was not therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent, with, inter alia, a different safety profile, different identity, purity, and quality characteristics, and not made in a cGMP-compliant manner.

215. Defendant impliedly warranted that its Carvedilol was merchantable, and fit for ordinary use, as an FDA-approved pharmaceutical that is therapeutically equivalent to and the same as FDA-approved Coreg or an FDA-approved generic equivalent. In other words, Defendant impliedly warranted that its products were the same as FDA-approved Coreg or an FDA-approved generic equivalent, in terms of therapeutic equivalence, safety profile, possessing the same identity, purity, and quality, and assurance of being made in a cGMP-compliant manner.

216. Defendant sold Carvedilol that it impliedly warranted were compliant with cGMPs and were not adulterated or misbranded. Indeed, the very fact Defendant sold Carvedilol in the stream of commerce warranted they were

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cGMP-compliant and not adulterated, because adulterated products are illegal to sell or dispense.

217. Defendant's Carvedilol did not conform to Defendant's implied representations and warranties because the product was not manufactured in compliance with cGMPs, contained nitrosamine contaminants, was not therapeutically equivalent, lacked the same safety profile as FDA-approved Coreg, had different identity, purity, and quality characteristics, and was adulterated and misbranded.

218. At the time that Defendant marketed and sold its Carvedilol, it recognized the purposes for which the products would be used, and impliedly warranted the products were the same as FDA-approved Carvedilol, made in a cGMP-compliant manner, were not contaminated with nitrosamines, and were not adulterated or misbranded. These implied representations became part of the basis of the bargain in every purchase or reimbursement by Plaintiff and other Class Members including but not limited to implied representations made in referring to its VCDs.

219. Plaintiff and each member of the Class were reasonably expected purchasers who would use, consume or be affected by (or whose insureds would use, consume, or be affected by) the adulterated, misbranded, and sub-standard Carvedilol manufactured and sold by Defendant.

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220. Plaintiff and each other Class Member were the intended third-party beneficiary recipients of all arrangements Defendant had with downstream resellers of Defendant's Carvedilol. Plaintiff and each other Class Member were those whose benefit any promises, affirmations, or warranties were made by Defendant concerning Carvedilol, as they were the intended end purchasers and end users (or, in the case of TPPs, their insureds were the intended end users) of Defendant's Carvedilol, which Defendant knew by virtue of its position as manufacturer and seller of the Carvedilol.

221. Defendant knew, or should have known, that its Carvedilol was being manufactured and sold for the intended purpose of human consumption as the therapeutic equivalent to FDA-approved Coreg or an FDA-approved generic equivalent, with the same safety profile, identity, purity, and quality characteristics, and manufactured in a cGMP-compliant manner.

222. Defendant breached its implied warranty because Defendant's Carvedilol was not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

223. Plaintiff and other Class Members purchased the Carvedilol in reliance on Defendant's skill and judgment and the implied warranties of fitness for the purpose.

224. The Carvedilol was not altered by Plaintiff or any other Class

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Members.

225. Plaintiff and each member of the Class would not have (and could not have) purchased the Carvedilol had they known these drugs were not the same as FDA-approved Coreg or an FDA-approved generic equivalent, did not contain the same ingredients or components or impurities, did not have the same safety and efficacy profile as FDA-approved Coreg, and contained nitrosamines. They did not receive the expected benefit of the bargain by receiving Carvedilol that contained undisclosed dangerous nitrosamines and/or was made in a non-cGMP compliant manner, either of which rendered the products adulterated, misbranded, illegal to sell, and therefore worthless (or alternatively, certainly worth less).

226. Defendant's Carvedilol did not fulfill the intended purpose. Plaintiff and other Class Members bargained for an adequately made, adequately labeled product that did not pose significant undisclosed risks. But Defendant's Carvedilol was not adequately made, was not adequately labeled, and posed significant undisclosed risks, viz., contained an undisclosed genotoxic carcinogen. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences.

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227. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, the lost value of any non-returned product rendered unusable after the recalls, and any consequential damages resulting from the purchases, in that the Carvedilol they paid for were so inherently flawed, unfit, or unmerchantable as to have little to no market value.

228. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences. This, combined with being made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class Members (or their insureds) suffering physical harm or impact from ingesting a flawed product.

229. Pre-suit notice is not required, but even if it is, such notice was provided to Defendant.

COUNT III
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301 *et seq.*

230. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

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231. Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

232. Plaintiff and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

233. Defendant expressly or impliedly warranted its Carvedilol as alleged in the First and Second Causes of Action.

234. Under 15 U.S.C. § 2310(d)(1), Plaintiff and other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiff sues pursuant to this section to recover money damages and for legal and equitable relief on behalf of themselves and the Class Members.

235. Defendant has not acted on the opportunity to cure its failure with respect to its warranted Carvedilol.

236. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiff is entitled to receive an award of attorneys' fees and expenses and pray for the same.

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COUNT IV
FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)

237. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

238. Defendant affirmatively misrepresented material facts including, among other things, that its Carvedilol was therapeutically equivalent and the same as FDA-approved Coreg or an FDA-approved generic equivalent including per the Orange Book, that its Carvedilol was not a new unapproved drug, that its Carvedilol did not contain any undisclosed contaminants or risks, that its Carvedilol was manufactured in a cGMP-compliant manner, and that its Carvedilol was saleable and was not adulterated or misbranded.

239. Defendant omitted and/or affirmatively concealed material facts including, among other things, that its Carvedilol was not therapeutically equivalent or the same as FDA-approved Coreg or an FDA-approved generic equivalent including per the Orange Book, that its Carvedilol was a new unapproved drug, that its Carvedilol contained undisclosed contaminants or risks, that its Carvedilol was not manufactured in a cGMP-compliant manner, and that its Carvedilol was not saleable and was adulterated or misbranded.

240. Defendant knew or should have known, prior to initiating its Carvedilol recalls about the risks posed by nitrosamine as a result of industry

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guidance, regulatory guidance, and the scientific literature dating back decades. Defendant certainly knew at least no later than July 2018 about the urgent need to properly evaluate and test products for nitrosamines in the wake of the valsartan recalls, and subsequent nitrosamine-related recalls. Defendant similarly knew or should have known prior to initiating its Carvedilol recalls about that cGMP deviations or failures concerning quality control and risk management may result in the adulteration and misbranding of a drug product.

241. Defendant knew or should have known, or was deliberately indifferent to knowing, the chemistry relevant to its Carvedilol manufacture process. Appropriate, cGMP-compliant evaluation, testing, quality oversight, and risk management would have identified the nitrosamine contaminants in Defendant's Carvedilol, which by virtue of its manufacturing process is reasonably expected to generate such contaminants in every batch or lot of Carvedilol.

242. Adulterated and misbranded drugs are illegal to sell. Nitrosamine contamination, and manufacture in a non-cGMP compliant manner, each independently establish a drug's adulteration or misbranding. Defendant's distribution and sale of its Carvedilol was a direct affirmation that its Carvedilol was not adulterated, i.e., did not contain any nitrosamine contaminants, and was made in a cGMP-compliant manner. These affirmations were false.

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243. Further, Defendant affirmed in its product labeling (e.g., label, package insert, medication guide) that its Carvedilol was therapeutically equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Coreg or as an FDA-approved generic equivalent. These affirmations were false. Defendant's Carvedilol did *not* have the same safety profile as FDA-approved Coreg or an FDA-approved generic equivalent. Defendant failed to disclose the facts of nitrosamine contamination and manufacture in a non-cGMP compliant manner. Defendant's Carvedilol further lacked the appropriate identity, quality, and purity. Defendant's Carvedilol was not safe as represented, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.

244. Defendant's product labeling (e.g., label, package insert, medication guide) were required to be truthful, accurate, and non-deceptive, and to adequately advise of any precautions or safety-related risks. Defendant's Carvedilol product labeling failed to do so, insofar as it did not disclose known or knowable risks relating to nitrosamine contamination and that the Carvedilol was not manufactured in a cGMP-compliant manner, and therefore there was no adequate quality assurance.

245. Defendant's sale of Carvedilol represented the products were compliant with compendial standards, USP requirements, and Orange Book

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requirements. These representations were false, because Defendant's Carvedilol was not therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent, with inter alia a different safety profile, different identity, purity, and quality characteristics, and not made in a cGMP-compliant manner.

246. Defendant omitted from its product labeling, other promotional materials, and through its sale of Carvedilol that its Carvedilol contained a dangerous, undisclosed, genotoxic, carcinogenic nitrosamine, and that the Carvedilol was not made in a cGMP-compliant manner.

247. Defendant's product labeling (e.g., label, package insert, medication guide) and other promotional materials contained, at best, half-truths about the safety and cGMP compliance status of its Carvedilol. Once Defendant voluntarily chose to speak about its Carvedilol, it had a duty to do so truthfully. But it did not, given Defendant's knowledge of nitrosamine formation, its own Carvedilol manufacturing process, and its own cGMP-compliance status. Failure to correct its statements rendered them untruthful.

248. Defendant knowingly, or at least recklessly, represented that its Carvedilol was manufactured in a cGMP manner and that its Carvedilol was what it was supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of

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such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that were available in the public domain and otherwise well prior to Defendant's recalls.

249. Defendant's actions had the effect of fraudulently inducing Plaintiffs and other Class Members to pay in whole or in part for Defendant's Carvedilol products that Defendant knew or should have known were not therapeutically equivalent to or the same as FDA-approved Coreg or an FDA-approved generic equivalent, contained undisclosed nitrosamines, were not made in a cGMP-compliant manner, and were adulterated or misbranded. Plaintiff and other Class Members would not have paid for Defendant's Carvedilol had they known the truth. Indeed, Plaintiff and other Class Members could not have paid for Defendant's Carvedilol had they known the truth because Defendant's Carvedilol was illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiff and Class Members based on Defendant's fraudulent misrepresentations and omissions.

250. Defendant knew, or reasonably should have known, that its misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

251. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Plaintiff and other Class

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Members to pay for some or all of the cost of Defendant's Carvedilol.

252. Defendant's misrepresentations and omissions were material.

253. Defendant actively concealed its misrepresentations and omissions from Plaintiff and other Class Members, government regulators, and the public.

254. To the extent applicable, Defendant intended its misrepresentations and omissions to induce Plaintiff and other Class Members to pay for Defendant's Carvedilol.

255. But for these misrepresentations and omissions, Plaintiff and other Class Members would not have paid for Defendant's Carvedilol.

256. To the extent applicable, Plaintiff and other Class Members were justified in relying on Defendant's misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated to each Class Member, including through product labeling and other statements by Defendant. No reasonable consumer or TPP would have paid what they did for Defendant's Carvedilol but for Defendant's unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

257. Plaintiff and each member of the Class would not have (and could not have) purchased the Carvedilol had they known these drugs were not the same as FDA-approved Coreg or an FDA-approved generic equivalent, did not contain the same ingredients, did not have the same safety and efficacy profile of as FDA-

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approved Carvedilol or an FDA-approved generic equivalent, and contained nitrosamines. They did not receive the expected benefit of the bargain by receiving Carvedilol that contained undisclosed dangerous nitrosamines and/or were made in a non-cGMP compliant manner, either of which rendered the products adulterated, misbranded, illegal to sell, and therefore worthless (or alternatively, certainly worth less).

258. A special relationship existed between Defendant, on the one hand, and each Plaintiff and other Class Member, on the other.

259. This relationship arose because Defendant, as a pharmaceutical drug manufacturer, owes a distinct duty to consumers of its highly-regulated pharmaceutical products, to be ingested by Plaintiff and other Class Members (or, in the case of TPPs, their insureds). Defendant's superior knowledge and economic position vis-à-vis the true nature of its Carvedilol further bolstered the special relationship and distinct duty.

260. In addition, state drug regulation laws impose an independent duty on drug manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);

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- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;

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- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- Revised Code of Washington §§ 69.04.040, 69.04.430;
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

261. Defendant failed to comply with federal cGMPs and federal adulteration standards, as incorporated by state law, which created independent state-law duties beyond any contractual relationship between the parties.

262. Plaintiff and other Class Members were damaged by reason of

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Defendant's misrepresentations and omissions as alleged here.

263. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences. This, combined with being made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class Members (or their insureds) suffering physical harm or impact from ingesting a flawed product.

COUNT V
NEGLIGENT MISREPRESENTATION AND OMISSION

264. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

265. Defendant had or undertook a duty to represent the quality, nature, and characteristics of its Carvedilol accurately and truthfully.

266. Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its Carvedilol, namely representing that its Carvedilol was therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent despite nitrosamine contamination and failure to manufacture the Carvedilol in compliance with cGMPs, rendering such representations false.

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267. Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its Carvedilol, namely failing to disclose that its Carvedilol was not therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent as result of nitrosamine contamination and failure to manufacture the Carvedilol in compliance with cGMPs.

268. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

269. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that its omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to pay for (directly or through reimbursement) for Defendant's Carvedilol.

270. Defendant knew or should have known prior to initiating recalls in the United States about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations of failures concerning quality control and risk management.

271. Defendant knowingly, recklessly, or negligently represented that its Carvedilol was manufactured in a cGMP manner and that its Carvedilol was what

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they were supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

272. Defendant had direct or constructive knowledge of the risks of nitrosamine contamination at least as early as 2018 (and likely much sooner) because of other nitrosamine-related recalls. At that time, Defendant knew, and certainly should have known, of the possibility of nitrosamine formation in its Carvedilol, particularly because regulators including the FDA issued guidance in the second half of 2018 and throughout 2019 that warned of the specific risk of nitrosamine formation in chemical syntheses similar to those used by Defendant to make its Carvedilol. Yet, Defendant sat by idly and did nothing until 2025.

273. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that nitrosamine contamination occurred in Carvedilol potentially due to the similar route of contamination that resulted in nitrosamine contamination of other recalls years before Defendant's recalls.

274. Thus, prior to initiating recalls of Carvedilol, Defendant had actual

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or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, other product recalls relating to nitrosamines, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But Defendant intentionally, recklessly, or negligently disregarded that knowledge in making its representations that were false or deceptive about its Carvedilol, namely, that it was not contaminated with nitrosamines and/or was manufactured in a cGMP compliant manner, each of which was false and either of which rendered the Carvedilol adulterated and misbranded.

275. Defendant's specific statements and omissions go beyond simply naming its product "Carvedilol." Defendant's representations and labeling carried with it the assurance, as required by state laws incorporating federal law, that the product did not contain any undisclosed contaminants, that Carvedilol had the same efficacy *and* safety profile as FDA-approved Coreg or an FDA-approved generic equivalent, and that the Carvedilol was not made in a non-cGMP compliant manner. Defendant omitted the material information that Carvedilol was not what it purported to be, insofar as it contained undisclosed dangerous nitrosamine contaminants, was not as safe as FDA-approved Coreg or an FDA-approved generic equivalent, and was not made in a cGMP-compliant manner.

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As such, the Carvedilol was adulterated and misbranded, which is illegal to sell. Plaintiff or Class Members could never buy an adulterated drug; thus, Defendant's distribution and sale of its Carvedilol in the first instance was a representation that the drugs were not adulterated.

276. A special relationship existed between Defendant, on the one hand, and each Plaintiff and other Class Member, on the other.

277. This relationship arose because Defendant, as a pharmaceutical drug manufacturer owes a distinct duty to consumers of its highly-regulated pharmaceutical products, to be ingested by Plaintiffs and other Class Members (or, in the case of TPPs, their insureds). Defendant's superior knowledge and economic position vis-à-vis the true nature of its Carvedilol further bolstered the special relationship and distinct duty.

278. In addition, state drug regulation laws impose an independent duty on drug manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);

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- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);
- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);

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- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);
- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- Revised Code of Washington §§ 69.04.040, 69.04.430;
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

279. Defendant failed to comply with federal cGMPs and federal adulteration standards, as incorporated by state law, which created independent state-law duties beyond any contractual relationship between the parties.

280. As a direct and proximate result of Defendant's acts and omissions described herein, Plaintiff and other Class Members have suffered harm and will continue to do so.

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281. Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for Carvedilol.

282. Defendant intended its misrepresentations or omissions to induce Plaintiff and Class Members to make purchases or reimbursements of Carvedilol or had reckless disregard for same.

283. But for these misrepresentations (or omissions), Plaintiff and other Class Members would not have made purchases of Defendant's Carvedilol.

284. Plaintiff and other Class Members were justified in relying on Defendant's misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, or the same or substantively identical omissions were not communicated, to each Class Member.

285. Plaintiff and other Class Members were damaged by reason of Defendant's misrepresentations or omissions alleged here.

286. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences. This, combined with being made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class Members (or their insureds) suffering physical harm or impact from ingesting a

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flawed product.

COUNT VI
VIOLATION OF STATE CONSUMER PROTECTION LAWS

287. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

288. Defendant has violated the consumer protection statutes as follows:

a. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendant has violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

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f. Defendant has violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendant has violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*;

h. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq*.;

i. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq*.;

j. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq*.;

k. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq*.;

l. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.;

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m. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-390, *et seq.* and §10-1-370, *et seq.*;

n. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

p. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623,

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et seq.;

t. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

w. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

x. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

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z. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

aa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

bb. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

cc. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

dd. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

ff. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. §

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358-A:1, *et seq.*;

gg. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

hh. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ii. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

jj. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, *et seq.*;

kk. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ll. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

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mm. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

nn. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

oo. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

pp. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

qq. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq.*;

rr. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

ss. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws §

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37-24-1, *et seq.*;

tt. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

uu. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

vv. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ww. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

xx. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

yy. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

zz. Defendant has engaged in unfair competition or unfair or

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deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

aaa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

bbb. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

ccc. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

289. To the extent applicable, Plaintiff alleges each violation of the foregoing through the respective products liability statute of each state.

290. Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

291. Defendant's Carvedilol constitutes goods under the foregoing statutes, and Defendant is a merchant or seller.

292. Plaintiff and other Class Members paid for Carvedilol for personal, household, or non-resale purposes, and each was an aggrieved person by virtue of

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Defendant's misconduct within the meaning of the above statutes.

293. Defendant, through a pervasive pattern of unfair, false, misleading, and deceptive statements and omissions, manufactured and sold Carvedilol without revealing to Plaintiff and other Class Members that the products were not FDA-approved drugs, were not therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent, were contaminated with nitrosamines, were not manufactured in accordance with cGMPs, posed significant undisclosed safety risks, and were adulterated and misbranded.

294. In addition to these material omissions, Defendant affirmatively and unfairly or deceptively misrepresented material facts including, that its Carvedilol was not a new unapproved drug, was therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent, did not contain nitrosamines, was manufactured in accordance with cGMPs, did not carry any significant undisclosed safety risks, and was neither adulterated nor misbranded.

295. Defendant knew or should have known, prior to initiating its recalls, about the risks posed by nitrosamine as a result of industry guidance, regulatory guidance, and scientific literature dating back decades. Defendant certainly knew at least no later than July 2018 about the urgent need to properly evaluate and test products for nitrosamines in the wake of other product recalls related to nitrosamines. Defendant similarly knew or should have known prior to initiating

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its Carvedilol recalls that cGMP deviations or failures concerning quality control and risk management may result in the adulteration and misbranding of a drug product.

296. Defendant knew or should have known, or was deliberately indifferent to knowing, the chemistry relevant to its Carvedilol manufacture process. Appropriate, cGMP-compliant evaluation, testing, quality oversight, and risk management would have identified the nitrosamine contaminants in Defendant's Carvedilol, which by virtue of its manufacturing process is reasonably expected to generate such contaminants in every batch or lot of VCDs.

297. Adulterated and misbranded drugs are illegal to sell. Nitrosamine contamination, and manufacture in a non-cGMP compliant manner, each independently establish a drug's adulteration or misbranding. Defendant's distribution and sale of its Carvedilol was a direct affirmation that its Carvedilol was not adulterated, i.e., did not contain any nitrosamine contaminants, and was made in a cGMP-compliant manner. These affirmations were false.

298. Further, Defendant affirmed in its product labeling (e.g., label, package insert, medication guide) that its Carvedilol was therapeutically equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Coreg or an FDA-approved generic equivalent. These affirmations were false. Defendant's Carvedilol did *not* have the same safety profile as FDA-approved

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Coreg or an FDA-approved generic equivalent. Defendant failed to disclose the facts of nitrosamine contamination and manufacture in a non-cGMP compliant manner. Defendant's Carvedilol further lacked the appropriate identity, quality, and purity. Defendant's Carvedilol was not safe as represented, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant that posed the unreasonable risk of genotoxicity and carcinogenicity.

299. Defendant's product labeling (e.g., label, package insert, medication guide) was required to be truthful, accurate, and non-deceptive, and to adequately advise of any precautions or safety-related risks. Defendant's Carvedilol product labeling failed to do so, insofar as it did not disclose known or knowable risks relating to nitrosamine contamination or that the Carvedilol was not manufactured in a cGMP-compliant manner, and therefore there was no adequate quality assurance.

300. Defendant's sale of Carvedilol represented that the products were compliant with compendial standards, USP requirements, and Orange Book requirements. These representations were false because Defendant's Carvedilol was not therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent with inter alia a different safety profile, different identity, purity, and quality characteristics, and was not made in a cGMP-compliant manner.

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301. Defendant omitted from its representations and product labeling that its Carvedilol contained a dangerous, undisclosed, genotoxic, carcinogenic nitrosamine, and that the Carvedilol was not made in a cGMP-compliant manner.

302. Defendant's representations and product labeling (e.g., label, package insert, medication guide) contained, at best, half-truths about the safety and cGMP compliance status of its Carvedilol. Once Defendant voluntarily chose to speak about its Carvedilol, it had a duty to do so truthfully. But it did not, given Defendant's knowledge of nitrosamine formation, its own Carvedilol manufacturing process, and its own cGMP-compliance status. Failure to correct its statements rendered them untruthful.

303. Defendant knowingly, or at least recklessly, represented that its Carvedilol was manufactured in a cGMP manner and that its Carvedilol was what it was supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine formation if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

304. Defendant's actions had the effect of fraudulently inducing Plaintiff and other Class Members to pay in whole or in part for Defendant's Carvedilol—

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products which Defendant knew or should have known were not therapeutically equivalent to or the same as FDA-approved Coreg or an FDA-approved generic equivalent, contained undisclosed nitrosamines, were not made in a cGMP-compliant manner, and were adulterated or misbranded. Plaintiff and other Class Members would not have paid for Defendant's Carvedilol had they known the truth. Indeed, Plaintiff and other Class Members could not have paid for Defendant's Carvedilol had they known the truth because Defendant's Carvedilol was illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiff and Class Members based on Defendant's fraudulent misrepresentations and omissions.

305. Defendant's conduct was unfair, deceptive, and unconscionable in that it included (i) the manufacture and sale of products with a heightened propensity to cause physical injuries and (ii) misrepresentations and omissions of material facts concerning the characteristics and safety of Carvedilol that offended public policy; was immoral, unethical, oppressive, outrageous, unscrupulous, and substantially injurious; and caused substantial harm that greatly outweighs any possible utility from the conduct.

306. Defendant's deliberate decision not to test the Carvedilol further constitutes unfair and unconscionable conduct. As set forth herein, the Defendant was aware of the risks that the Carvedilol was contaminated, misbranded and

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adulterated. Despite the risks to Plaintiff and other Class Members, Defendant elected not to conduct risk assessment, quality analysis, and testing that would have prevented the Plaintiff's exposure. The failure to ensure the safety of prescription drugs sold to consumers offends established public policy and constitutes immoral, unethical, oppressive, outrageous, unscrupulous, and substantially injurious conduct. The failure to test causes substantial harm to consumers that greatly outweighs any possible utility. The act of sale of the Carvedilol by Defendant constituted an affirmative act in conjunction with the accompanying labels and other documents, representing that the Carvedilol was safe, of the specified quality, and met all applicable standards, including but not limited to USP, Orange Book, and other applicable regulations.

307. Defendant engaged in deceptive conduct because the affirmative and implied misrepresentations and omissions at issue were likely to, and in fact did, mislead, deceive, or cheat reasonable purchasers including Plaintiff and other Class Members, who relied on these misrepresentations and omissions. In addition, the misrepresentations and omissions were the type that tend to create a false impression. Reasonable consumers, including Plaintiff and other Class Members, would have found it material to their purchasing or reimbursing decisions that the Carvedilol was not therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent, was an unapproved new drug,

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contained undisclosed safety risks, was contaminated with nitrosamines, was not made in accordance with cGMPs, and was adulterated, misbranded, and illegal to sell. Knowledge of these facts would have been a substantial factor in Plaintiff's and other Class Members' decisions to pay for Carvedilol, and they would not have made these payments in the absence of Defendant's wrongful conduct.

308. Defendant's advertising and statements in the conduct of business were deceptive because the misrepresentations and omissions had the capacity, tendency, and effect of deceiving reasonable consumers, including the Plaintiff. Reasonable consumers, including Plaintiff and other Class Members, would have found it material to their purchasing decisions that the Carvedilol was not therapeutically equivalent to FDA-approved Coreg or an FDA-approved equivalent, was an unapproved new drug, contained undisclosed safety risks, weas contaminated with nitrosamines, were not made in accordance with cGMPs, and were adulterated, misbranded, and illegal to sell. Knowledge of these facts would have been a substantial factor in Plaintiff's and other Class Members' decisions to pay for Carvedilol, and they would not have made these payments in the absence of Defendant's wrongful conduct.

309. To the extent applicable, Defendant knew, intended, or should have known that its fraudulent and deceptive acts, omissions, or concealment would and did induce reliance and that reliance can be presumed under the

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circumstances. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

310. Plaintiff and other Class Members justifiably relied on Defendant's representations that the Carvedilol they were purchasing was safe, therapeutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent, was not a new unapproved drug, did not contain any undisclosed risks, was not contaminated with nitrosamines, was made in accordance with cGMPs, and was not adulterated or misbranded. Plaintiff and other Class Members further relied on the Defendant's express and implied representations that they exercised the highest degree of care to ensure safety and quality at all times, along with Defendant's failure to disclose the contamination of Carvedilol and manufacturing and quality control problems, and the Defendant's affirmative and implied assurances that its Carvedilol was safe for human consumption and/or ingestion.

311. Defendant engaged in unfair and deceptive conduct by misleading, through affirmative misrepresentation and omission, consumers and TPPs as to the content of the Carvedilol. In fact, the products never should have been offered to consumers in the first place, and could not have been in the absence of the

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stated wrongful conduct.

312. As demonstrated herein, Defendant engaged in patently unlawful conduct through their manufacturing, receipt, and sale of contaminated, adulterated and misbranded prescription drugs. *See, e.g.*, 21 U.S.C. §§ 331(a)-(c), (g) (as incorporated by states' laws).

313. Defendant's conduct actually and proximately caused actual damages to Plaintiff and other Class Members. Absent Defendant's unfair and deceptive conduct, Plaintiff and other Class Members would have behaved differently and would not have purchased the Carvedilol.

314. Defendant's misrepresentations and omissions induced Plaintiff and other Class Members to purchase the Carvedilol they would not otherwise have purchased, economically harming and damaging each of them.

315. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and other Class Members have suffered damages—an ascertainable loss—in an amount to be proved at trial.

316. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels,

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implicating future potential health consequences. This, combined with being made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class Members (or their insureds) suffering physical harm or impact from ingesting a flawed product.

317. Pre-suit notice is not required, but even if it is, such notice was provided to Defendant.

COUNT VII
NEGLIGENCE

318. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

319. Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing, distribution, and sale of its Carvedilol.

320. Defendant owed a duty to Plaintiff and the Class to ensure that the Carvedilol it sold in the United States was therapeutically and pharmaceutically equivalent to FDA-approved Coreg or an FDA-approved generic equivalent, complied with cGMPs, and was not adulterated or misbranded.

321. Defendant owed a duty of care to Plaintiff and the Class because they were the foreseeable, reasonable, and probable user of Carvedilol and victims of Defendant's fraudulent and deceptive activities. Defendant knew, or should have known, that its Carvedilol was not therapeutically or

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pharmaceutically equivalent to FDA-approved Carvedilol or an FDA-approved generic equivalent, did not comply with cGMPs, and was adulterated and misbranded, and Defendant was in the best position to uncover and remedy these shortcomings.

322. Defendant failed to do this. Defendant inadequately oversaw the manufacture and sale of its own Carvedilol. Defendant knew that ignoring the manufacturing issues surrounding its Carvedilol would damage Plaintiff and the Class and increase its own profits.

323. Defendant maintained or should have maintained a special relationship with Plaintiff and the Class, as they were obligated to ensure that its Carvedilol complied with cGMPs and was not adulterated or misbranded.

324. Defendant had a duty to exercise reasonable care in the manufacture, quality control, and distribution of Carvedilol. Defendant's failure to exercise this duty, in spite of knowing or recklessly disregarding the risks of nitrosamine contamination and cGMP deviations or failures that meant Defendant could not assure that its Carvedilol was of appropriate quality, identity, purity, or strength, was a breach of Defendant's duty.

325. Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class. Defendant's misconduct included, but was not

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limited to, failing to oversee actions taken in the manufacture and sale of its Carvedilol.

326. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Plaintiff and Class members to pay or reimburse for Defendant's Carvedilol.

327. Defendant knew or should have known prior to initiating recalls about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations of failures concerning quality control and risk management.

328. Defendant knowingly, recklessly, or negligently represented that its Carvedilol was manufactured in a cGMP manner and that its Carvedilol was what it was supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public

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domain and otherwise well prior to Defendant's recalls.

329. Defendant had direct or constructive knowledge of the risks of nitrosamine contamination at least as early as 2018 (and likely much sooner) because of other recalls related to nitrosamine contamination. At that time, Defendant knew, and certainly should have known, of the possibility of nitrosamine formation in its Carvedilol, particularly because regulators including the FDA issued guidance in the second half of 2018 and throughout 2019 and thereafter, that warned of the specific risk of nitrosamine formation in chemical syntheses similar to those used by Defendant to make its Carvedilol. Yet, Defendant sat by idly and did nothing until 2025.

330. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that nitrosamine contamination occurred in Carvedilol potentially due to the similar route of contamination that resulted in nitrosamine contamination of other drugs recalled due to nitrosamine issues that started years before Defendant's own recalls.

331. Thus, prior to initiating recalls of Carvedilol, Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019, and the related risks of nitrosamine potential in the event of

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cGMP deviations or failures concerning quality control and risk management. But Defendant intentionally, recklessly, or negligently disregarded that knowledge in making its representations that were false or deceptive about its Carvedilol, namely, that its Carvedilol was not contaminated with nitrosamines and/or was manufactured in a cGMP compliant manner, each of which was false and either of which rendered the Carvedilol adulterated and misbranded.

332. Defendant's specific statements and omissions go beyond simply naming their drug "Carvedilol." Defendant's marketing and labeling carried with it the assurance, as required by state laws incorporating federal law, that the product did not contain any undisclosed contaminants, that Carvedilol had the same efficacy *and* safety profile as FDA-approved Coreg or an FDA-approved generic equivalent, and that the Carvedilol was not made in a non-cGMP compliant manner. Defendant omitted the material information that Carvedilol was not what it purported to be, insofar as it contained undisclosed dangerous nitrosamine contaminants, was not as safe as FDA-approved Coreg or an FDA-approved generic equivalent, and was not made in a cGMP-compliant manner. As such, the Carvedilol was adulterated and misbranded, which is illegal to sell. No Plaintiff or Class Member could ever buy an adulterated drug; thus, Defendant's distribution and sale of its Carvedilol in the first instance was a representation that the drugs were not adulterated.

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333. A special relationship existed between Defendant, on the one hand, and each Plaintiff and other Class Member, on the other. This relationship arose because Defendant, as a pharmaceutical drug manufacturer, owes a distinct duty to consumers of its highly regulated pharmaceutical products, to be ingested by Plaintiff and other Class Members (or, in the case of TPPs, their insureds). Defendant's superior knowledge and economic position vis-à-vis the true nature of its Carvedilol further bolstered the special relationship and distinct duty.

334. In addition, state drug regulation laws impose an independent duty on drug manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

- Alabama Code §§ 20-1-24 and -27(1);
- Alaska Statutes § 17.20.290(a)(1);
- Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- Arkansas Code § 20-56-215(1);
- California Health and Safety Code §§ 111295 and 111400;
- Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- Title 16, Delaware Code §§ 3302 and 3303(2);
- District of Columbia Code § 48-702(2);

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- Florida Statutes §§ 499.005(1) and .006(3);
- Georgia Code § 26-3-3(1);
- Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- Idaho Code § 37-115(a);
- Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- Iowa Code §§ 126.3(1) and .9(1)(c);
- Kentucky Statutes § 217.175(1);
- Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- Massachusetts General Laws chapter 94 §§ 186 and 190;
- Minnesota Statutes §§ 151.34(1) and .35(1);
- Missouri Statutes § 196.015(1);
- Montana Code §§ § 50-31-305(3) and -501(1);
- Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- Nevada Statutes § 585.520(1);
- New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- New Mexico Statutes §§ 26-1-3(A) and -10(A);
- New York Education Law § 6811;
- North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- Ohio Code § 3715.52(A)(1);
- Oklahoma Statutes title 63 § 1-1402(a);

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- Title 35, Pennsylvania Statutes § 780-113(a)(1);
- Title 21, Rhode Island General Laws § 21-3-3(1);
- South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- South Dakota Code §§ 39-15-3 and -10;
- Title 18, Vermont Statutes § 4052(1);
- Virginia Code § 54.1-3457(1);
- Revised Code of Washington §§ 69.04.040, 69.04.430;
- West Virginia Code §§ 16-7-1 and -2(a)(3); and
- Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

335. Defendant failed to comply with federal cGMPs and federal adulteration standards, as incorporated by state law, which created independent state-law duties beyond any contractual relationship between the parties.

336. Defendant breached duties owed to Plaintiff and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

337. As a direct and proximate result of Defendant's negligent conduct, Plaintiff and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

338. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their

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insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences. This, combined with being made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class Members (or their insureds) suffering physical harm or impact from ingesting a flawed product.

COUNT VIII
NEGLIGENCE PER SE

339. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

340. Defendant owed a duty to Plaintiff and the Class to use and exercise reasonable and due care in the manufacture, distribution, and sale of its Carvedilol.

341. Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

342. Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class Members to pay (directly or through reimbursement) for Defendant's Carvedilol.

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343. Defendant knew or should have known prior to initiating recalls about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, and the related risks of nitrosamine potential in the event of cGMP deviations of failures concerning quality control and risk management.

344. Defendant knowingly, recklessly, or negligently represented that its VCDs were manufactured in a cGMP manner and that its VCDs were what they were supposed to be, when that was not the case. Rather, Defendant knew or recklessly disregarded industry and regulatory guidance, and related risks of nitrosamine potential if cGMP deviations or failures occurred (the absence of such deviations or failures would mean that the nitrosamine contamination could have and should have been discovered earlier), that was available in the public domain and otherwise well prior to Defendant's recalls.

345. Defendant had direct or constructive knowledge of the risks of nitrosamine contamination at least as early as 2018 (and likely much sooner) because of other recalls related to nitrosamine contamination. At that time, Defendant knew, and certainly should have known, of the possibility of nitrosamine formation in its Carvedilol, particularly because regulators including the FDA issued guidance in the second half of 2018 and throughout 2019 and thereafter, that warned of the specific risk of nitrosamine formation in chemical

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syntheses similar to those used by Defendant to make its Carvedilol. Yet, Defendant sat by idly and did nothing until 2025.

346. The scientific literature warned of the need to test for nitrosamines at least as early as 2006, if not earlier. Additionally, the literature suggests that nitrosamine contamination occurred in Carvedilol potentially due to the similar route of contamination that resulted in nitrosamine contamination of other drugs recalled in 2018, 2019, and thereafter, years before Defendant's own recalls.

347. Thus, prior to initiating recalls of Carvedilol, Defendant had actual or constructive knowledge about the risks posed by nitrosamines as a result of industry and regulatory guidance dating back decades, the newer guidance in 2018 and 2019 and thereafter, and the related risks of nitrosamine potential in the event of cGMP deviations or failures concerning quality control and risk management. But Defendant intentionally, recklessly, or negligently disregarded that knowledge in making its representations that were false or deceptive about its Carvedilol, namely, that its Carvedilol was not contaminated with nitrosamines and/or was manufactured in a cGMP compliant manner, each of which was false and either of which rendered the Carvedilol adulterated and misbranded.

348. Defendant's specific statements and omissions go beyond simply naming their drug "Carvedilol." Defendant's representations and labeling carried with it the assurance, as required by state laws incorporating federal law, that the

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product did not contain any undisclosed contaminants, that Carvedilol had the same efficacy *and* safety profile as FDA-approved Coreg or an FDA-approved generic equivalent, and that Carvedilol was not made in a non-cGMP compliant manner. Defendant omitted the material information that Carvedilol was not what it purported to be, insofar as its Carvedilol contained undisclosed dangerous nitrosamine contaminants, was not as safe as FDA-approved Coreg or an FDA-approved generic equivalent, and was not made in a cGMP-compliant manner. As such, Carvedilol was adulterated and misbranded, which is illegal to sell. No Plaintiff or Class Member could ever buy an adulterated drug; thus, Defendant's distribution and sale of its Carvedilol in the first instance was a representation that the drug was not adulterated.

349. A special relationship existed between Defendant, on the one hand, and each Plaintiff and other Class Member, on the other.

350. This relationship arose because Defendant, as a pharmaceutical drug manufacturer owes a distinct duty to consumers of its highly regulated pharmaceutical products, to be ingested by Plaintiff and other Class Members (or, in the case of TPPs, their insureds). Defendant's superior knowledge and economic position vis-à-vis the true nature of its Carvedilol further bolstered the special relationship and distinct duty.

351. In addition, state drug regulation laws impose an independent duty

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on drug manufacturers to ensure that end purchasers (or their insureds) receive drugs that are made in accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including but not limited to the following parallel state statutes:

a. Alabama Code §§ 20-1-24 and -27(1);

b. Alaska Statutes § 17.20.290(a)(1);

c. Arizona Statutes §§ 32-1965(1), (2) and -1966(3);

d. Arkansas Code § 20-56-215(1);

e. California Health and Safety Code §§ 111295 and 111400;

f. Colorado Statutes §§ 25-5-403(1)(a), (b) and -414(1)(c);

g. Title 16, Delaware Code §§ 3302 and 3303(2);

h. District of Columbia Code § 48-702(2);

i. Florida Statutes §§ 499.005(1) and .006(3);

j. Georgia Code § 26-3-3(1);

k. Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);

l. Idaho Code § 37-115(a);

m. Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);

n. Iowa Code §§ 126.3(1) and .9(1)(c);

o. Kentucky Statutes § 217.175(1);

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p. Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);

q. Massachusetts General Laws chapter 94 §§ 186 and 190;

r. Minnesota Statutes §§ 151.34(1) and .35(1);

s. Missouri Statutes § 196.015(1);

t. Montana Code §§ § 50-31-305(3) and -501(1);

u. Nebraska Revised Statutes §§ 71-2461(2) and -2481;

v. Nevada Statutes § 585.520(1);

w. New Hampshire Revised Statutes §§ 146:1(I) and :4(V);

x. New Mexico Statutes §§ 26-1-3(A) and -10(A);

y. New York Education Law § 6811;

z. North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);

aa. Ohio Code § 3715.52(A)(1);

bb. Oklahoma Statutes title 63 § 1-1402(a);

cc. Title 35, Pennsylvania Statutes § 780-113(a)(1);

dd. Title 21, Rhode Island General Laws § 21-3-3(1);

ee. South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);

ff. South Dakota Code §§ 39-15-3 and -10;

gg. Title 18, Vermont Statutes § 4052(1);

hh. Virginia Code § 54.1-3457(1);

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ii. Revised Code of Washington §§ 69.04.040, 69.04.430;

jj. West Virginia Code §§ 16-7-1 and -2(a)(3); and

kk. Wyoming Statutes §§ 35-7-111(a)(i)–(iv), (vi) and -116.

352. Defendant failed to comply with federal cGMPs and federal adulteration standards, as incorporated by state law, which created independent state-law duties beyond any contractual relationship between the parties.

353. As a result of Defendant's failures to do so, Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiff and the Class.

354. As a direct and proximate result of Defendant's negligent conduct, Plaintiff and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

355. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences. This, combined with being made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class Members (or their insureds) suffering physical harm or impact from ingesting a flawed product.

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COUNT IX
UNJUST ENRICHMENT

356. Plaintiff repeats each and every allegation contained in the paragraphs above and incorporates such allegations by reference herein.

357. As alleged herein, Defendant was unjustly enriched at the expense of Plaintiff and other Class Members by virtue of the latter's paying for Defendant's Carvedilol.

358. Defendant profited immensely from introducing a carcinogen into the United States for human consumption, and an unapproved drug that was not made in a cGMP-compliant manner. On top of that, because Defendant's Carvedilol was adulterated and misbranded, the distribution and sale of which in the United States was illegal. Defendant's Carvedilol was not safe as warranted, given the lack of appropriate cGMP-compliant manufacture and the presence of an undisclosed contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.

359. Plaintiff and other Class Members were unjustly deprived of money obtained by Defendant as a result of the improper amounts paid for Defendant's Carvedilol. It would be inequitable and unconscionable for Defendant to retain the profit, benefit, and other compensation obtained from Plaintiff and other Class Members as a result of its wrongful conduct alleged in this Complaint.

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360. In the alternative to the other causes of actions alleged herein, Plaintiff and each other class member have no adequate remedy at law.

361. Plaintiff and other Class Members are entitled to seek and do seek restitution from Defendant as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendant by virtue of its wrongful conduct.

362. While Plaintiff and other Class Members do not seek damages for any physical injuries, each of them (or, in the case of TPPs, each of their insureds) have been exposed to a non-bargained for carcinogenic agent with potent mutagenic properties that operates at the cellular and sub-cellular levels, implicating future potential health consequences. This, combined with being made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class Members (or their insureds) suffering physical harm or impact from ingesting a flawed product.

PRAYER FOR RELIEF

For these reasons, Plaintiff prays for the following judgment:

a. An order certifying this action as a class action;

b. An order appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

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c. A declaration that Defendant is liable under each and every one of the above-enumerated causes of action;

d. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendant described above;

e. Payment to Plaintiff and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the Carvedilol; the costs to replace or return Carvedilol because of recalls; and the increases in the amounts paid for non-adulterated, non-misbranded, Carvedilol in the wake of the recalls;

f. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

g. An award of statutory penalties to the extent available;

h. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or

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statute; and

i. Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiff respectfully requests a trial by jury on all causes of action so triable.

DATED this 4th day of August, 2026.

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