

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.

INTRODUCTION

1
2 1. This case arises Glenmark's Carvedilol, which was contaminated
3 with nitrosamine impurities and manufactured in manner that was not compliant
4 with current Good Manufacturing Practices ("cGMPs") in violation of various
5 states' laws. Glenmark's Carvedilol was adulterated, misbranded, unsafe non-
6 merchantable, unfit for intended and ordinary purposes, inherently defective or
7 flawed, and not of the quality that Glenmark represented.
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10 2. Carvedilol is a generic version of the branded drug Coreg® or its
11 extended-release version Coreg ER®, which is a beta-blocker. The drug is a
12 front-line therapy to treat high blood pressure, congestive heart failure, and other
13 heart-related conditions.
14

15 3. Prior to genericization, Coreg was a 'blockbuster' branded drug,
16 with annual sales around \$1 billion at its peak.
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18 4. Once approved, generic versions of Coreg quickly gained market
19 share. Glenmark first obtained approval from the United States Food and Drug
20 Administration ("FDA") to sell its generic Carvedilol in September 2007.
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22 5. The generic carvedilol market grew quickly. As of 2025, the United
23 States carvedilol market was estimated to be valued at nearly \$2 billion annually,
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1 and projected to reach \$3.7 billion by 2035.²

2 6. Glenmark represented and warranted to consumers and TPPs that its
3 Carvedilol was therapeutically equivalent to, and otherwise the same as, the
4 actual FDA-approved brand name drug Coreg. Specifically, Glenmark
5 represented and warranted that its Carvedilol was fit for intended and ordinary
6 uses, merchantable, met the specifications of Glenmark's FDA-approved labeling
7 materials, and that Glenmark manufactured and distributed its Carvedilol in
8 accordance with all applicable laws and regulations, including specifically
9 cGMPs as incorporated by state laws.
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11
12 7. A therapeutic equivalent, among other things, must (i) have the same
13 efficacy *and* safety as an approved drug, (ii) have the same identity, strength,
14 quality, and purity as an approved drug, (iii) be adequately labeled, and (iv) be
15 manufactured in compliance with cGMPs.³
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19 ² [https://www.researchnester.com/reports/carvedilol-drug-](https://www.researchnester.com/reports/carvedilol-drug-market/4019#:~:text=Carvedilol%20Drug%20Market%20Outlook%20assessed%20at%20USD%202%20billion)
20 [market/4019#:~:text=Carvedilol%20Drug%20Market%20Outlook%20assessed%20a](https://www.researchnester.com/reports/carvedilol-drug-market/4019#:~:text=Carvedilol%20Drug%20Market%20Outlook%20assessed%20at%20USD%202%20billion)
21 [t%20USD%202%20billion](https://www.researchnester.com/reports/carvedilol-drug-market/4019#:~:text=Carvedilol%20Drug%20Market%20Outlook%20assessed%20at%20USD%202%20billion)
22

23 ³ Orange Book Preface to 43rd Edition, U.S. FOOD & DRUG ADMIN. (Jan. 24,
24 2023), available at [https://www.fda.gov/drugs/development-approval-process-](https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-)
25 [drugs/orange-book-](https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-)
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1 8. In reality, however, Glenmark's Carvedilol was not therapeutically
2 equivalent to FDA-approved Coreg. Glenmark's Coreg did not have the same
3 safety profile, or same identity, strength, quality and purity, as FDA-approved
4 Coreg because Glenmark's Carvedilol contained a dangerous, undisclosed
5 nitrosamine known as N-Nitroso-Carvedilol I. Glenmark's Carvedilol was not
6 manufactured in a cGMP-compliant manner and therefore without any assurance
7 that Carvedilol was of the appropriate quality and properly labeled.
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9

10 9. When a drug is manufactured in a non-cGMP compliant manner, that
11 means the manufacturer cannot assure that the drug meets the appropriate quality,
12 purity, identity or strength. Because a manufacturing process failure and
13 testing/quality assurance failure lay at the heart of Glenmark's process for making
14 Carvedilol, the Products were not made in a cGMP-compliant manner, which
15 rendered the products adulterated and misbranded, and therefore unsellable and
16 worthless (or alternatively, certainly worth some amount less), whether or not a
17 given pill contained nitrosamines or not. *See, e.g.,* 21 U.S.C. § 351; *see also* 21
18 U.S.C. § 331.
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22 10. As a result, Glenmark's Carvedilol was a dangerous unapproved
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25 [preface#:~:text=Any%20drug%20product%20in%20the,source%20or%20coded](#)
26 [%20as%20non%2D.](#)

1 drug, and was adulterated, misbranded, or both (and thereby rendered worthless,
2 or alternatively, certainly worth some amount less), through contamination with a
3 genotoxic, probable human carcinogenic nitrosamine⁴ and lack of cGMP
4 compliance concerning product testing, manufacture, and quality oversight.
5 Indeed, Glenmark has a documented history of cGMP compliance failures at one,
6 if not more, of its overseas facilities at which it manufactured and tested
7 Carvedilol.
8
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10 11. Glenmark had actual or constructive notice of nitrosamine potential
11 contamination and the dangerousness of these genotoxic, carcinogenic
12 compounds. Nitrosamines and their routes of synthesis have been well known for
13 decades. Scientific literature has long taught about nitrosamines, as well as their
14 detection and avoidance. International scientific guidance endorsed by the FDA,
15 EMA, and other regulatory bodies, identify nitrosamines as dangerous
16 compounds within the “cohort of concern” that require manufacturers to
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20 _____
21 ⁴ As discussed *infra*, the FDA, International Agency for Research on Cancer
22 (“IARC”), European Medicines Agency (“EMA”), World Health Organization
23 (“WHO”), U.S. Environmental Protection Agency (“EPA”), and other reputable
24 agencies around the world consider nitrosamines to be genotoxic and probable
25 human carcinogens.
26

1 characterize and control such impurities.⁵ FDA guidance issued in 2019, in the
2 wake of the 2018 valsartan recalls due to unprecedented nitrosamine
3 contamination, made clear there were *no* acceptable levels of nitrosamines
4 permitted any drugs at that time.⁶ Other nitrosamine-instigated recalls followed in
5 2019, 2020, and 2021. All of the foregoing predated Glenmark's Carvedilol
6 recalls beginning in 2025 (*see infra*).
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9 12. Glenmark willfully disregarded the scientific and industry guidance,
10 and knowingly and fraudulently manufactured, sold, labeled, marketed, or
11 distributed adulterated or misbranded Carvedilol for purchase in the United States
12 by consumers and TPPs.
13

14 13. In or about March 2025, the FDA announced a nationwide recall of
15 more than 732,000 bottles of Glenmark's Carvedilol. The FDA cited cGMP
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19 ⁵ ICH Guidance for Industry, *M7(R1) Assessment and Control of DNA Reactive*
20 *(Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*.
21

22 ⁶ *General Advice Ltr.*, U.S. FOOD & DRUG ADMIN. (2019) ("FDA has determined
23 that there is no acceptable specification for nitrosamines . . . Therefore, FDA
24 advises that nitrosamines should be absent[.]"), *available at*
25 <https://www.fda.gov/media/122643/download>.
26

1 deviations, including the presence of the nitrosamine impurities, as the reasons for
2 the recall.⁷

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

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

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

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

17 18. The N-Nitroso-Carvedilol I contamination in Glenmark's Carvedilol
18 was controllable or avoidable. That other generic manufacturers of carvedilol
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26 ⁷ <https://www.accessdata.fda.gov/scripts/ires/?Event=96861>

1 continue to sell their product to this day with no troubling nitrosamine
2 contamination underscores the feasibility of avoiding the contamination, had
3 Glenmark exercised appropriate care.
4

5 19. Plaintiff and other class members paid for contaminated Carvedilol
6 that was illegally placed into the stream of commerce by Glenmark. Glenmark's
7 willful introduction of its Carvedilol into the market caused many consumers and
8 TPPs to sustain substantial economic damages as a result of paying for VCDs that
9 were falsely represented as approved drugs, but that were not (and which were
10 adulterated and/or misbranded) because of nitrosamine contamination and/or
11 cGMP failures in the manufacture of Carvedilol. Further, Carvedilol was
12 adulterated, misbranded, or otherwise improper because they were not made in a
13 cGMP-compliant manner (whether or not a particular tablet contained a particular
14 amount of nitrosamines or not).
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18 20. Glenmark's Carvedilol was not fit for intended and ordinary use and
19 was not merchantable, and Glenmark has been unjustly enriched through the sale
20 of these knowingly adulterated, misbranded, unapproved, and otherwise flawed
21 drugs. Glenmark's conduct, as detailed in this Complaint, also constitutes
22 actionable common law fraud, consumer fraud, negligence and negligence per se,
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⁸ <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=97370>.

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

3 **PARTIES**

4
5 21. Plaintiff Sharon Carroll is a citizen and/or resident of Washington.
6 During the class period, Plaintiff Carroll purchased Glenmark's Carvedilol in
7 Washington, including but not limited to purchases on or about March 16, 2024,
8 October 4, 2024, March 31, 2025, and July 2, 2025. Each time, the product
9 purchased bore a unique National Drug Code ("NDC"), either NDC 68462-0164-
10 05 (e.g., on March 16, 2024) or NDC 68462-0163-05 (e.g., on October 4, 2024,
11 March 31, 2025, and July 2, 2025), which denoted that it was indeed sold,
12 manufactured, and/or distributed into the United States supply chain by
13 Glenmark.
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17 22. The Carvedilol bearing NDCs 68462-0164-05 and NDC 68462-
18 0163-05 that Plaintiff purchased were within expiry just as the same Carvedilol
19 bearing those same NDCs that were tested and found to contain nitrosamines, and
20 which were subject to Glenmark's recalls, as described *infra*. As Plaintiff's
21 purchases of these NDCs were all within expiry as the same NDCs tested and
22 found to contain nitrosamines as described *infra*, on information and belief all of
23 the Carvedilol purchased by Plaintiff were contaminated with nitrosamines, not
24 cGMP-complaint, not as safe as represented, and otherwise defective or flawed.
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1 23. Glenmark expressly and impliedly warranted and represented to
2 Plaintiff Carroll that the Carvedilol she purchased was FDA approved, the same
3 as FDA-approved brand-named equivalent Coreg product, was safe and
4 merchantable and fit for ordinary and intended purpose, not contaminated with
5 any carcinogenic impurities, was made in a cGMP-compliant manner and was not
6 otherwise defective or flawed.
7

8
9 24. Contrary to these representations, Plaintiff Carroll's Carvedilol was
10 not properly manufactured, was all contaminated with nitrosamines, and was not
11 the same as brand-name Coreg as a result. This is so because (i) Glenmark's
12 uniform manufacturing practices renders all of their Carvedilol defective and
13 contaminated with nitrosamines, and (ii) the prescriptions were filled during the
14 period when the manufacturing defects were in place and/or around the same time
15 as the testing and recalls described *infra*. As a result, the Carvedilol purchased by
16 Plaintiff Carroll was not as safe as represented, and did not perform as expected.
17 Among other things, she has suffered physical impact in the form of exposure to a
18 non-bargained for carcinogenic agent with potent mutagenic properties that
19 operates at the cellular and sub-cellular levels, implicating future potential health
20 consequences.
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25 25. The Carvedilol purchased also was not made in a cGMP-compliant
26 manner (e.g., not made with adequate quality assurances that the product was free

1 from nitrosamine contamination; had been properly tested and evaluated; had the
2 same safety profile as FDA-approved Coreg; etc.). Had Plaintiff Carroll known
3 the product was not as represented because it was contaminated with a
4 nitrosamine and not made in a cGMP-compliant manner, Plaintiff Carroll would
5 not have paid for Glenmark's Carvedilol, or alternatively would have paid some
6 amount less for it, or further alternatively would have sought a different
7 carvedilol product. In fact, Plaintiff Carroll would not have been able to purchase
8 the Carvedilol in the first place because, due to the nitrosamine contamination and
9 non-cGMP compliant manufacture of Carvedilol, Plaintiff Carroll's Carvedilol
10 was adulterated, misbranded, and thus, worthless (or alternatively, certainly worth
11 some amount less).
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15 26. Defendant Glenmark Pharmaceuticals, Inc., USA ("Glenmark") is a
16 Delaware corporation with its principal place of business at 750 Corporate Drive,
17 Mahwah, NJ 07430-2009. Glenmark, on its own or through its subsidiaries or
18 affiliates, regularly conducts business throughout the United States and its
19 territories and possessions. Glenmark is a wholly-owned subsidiary of Glenmark
20 Pharmaceuticals Ltd. based in India. At all times material to this case, Glenmark
21 has been engaged in the manufacturing, sale, or distribution of Carvedilol.
22 Glenmark directly oversees or controls the manufacture of the active
23 pharmaceutical ingredient ("API") for Carvedilol, as well as the finished-dose
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1 Carvedilol. Glenmark has distributed or sold Carvedilol throughout the United
2 States for which persons have paid and reimbursed, to Glenmark's benefit.

3 4 **JURISDICTION AND VENUE**

5 27. This Court has federal subject matter jurisdiction under the Class
6 Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the
7 proposed class is a citizen of a state different from that of Defendant, (b) the
8 amount in controversy exceeds \$5,000,000, exclusive of interest and costs, (c) the
9 proposed class consists of more than 100 class members, and (d) none of the
10 exceptions under the subsection apply to this action.
11

12 28. This Court has personal jurisdiction over Defendant under 28 U.S.C.
13 § 1407, and because Defendant conducts business in in this state and has
14 intentionally availed itself of the markets within this state through their business
15 activities, such that the exercise of jurisdiction by this Court is proper and
16 necessary.
17

18 29. Venue is proper in this District because at least some of the class's
19 claims alleged in this action accrued in this District, Plaintiff resides in this
20 District, Plaintiff purchased Glenmark's Carvedilol in this District, and Defendant
21 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

1 the respective FDA-approved branded drugs. The TPPs permitted carvedilol,
2 including Glenmark's Carvedilol, to be included on their formularies based on the
3 Defendant's misrepresentations that its Carvedilol was bioequivalent,
4 therapeutically and pharmacokinetically equivalent, and the same as FDA-
5 approved branded Coreg, complied with all current Good Manufacturing
6 Practices ("cGMPs"), and were safe for consumption.
7
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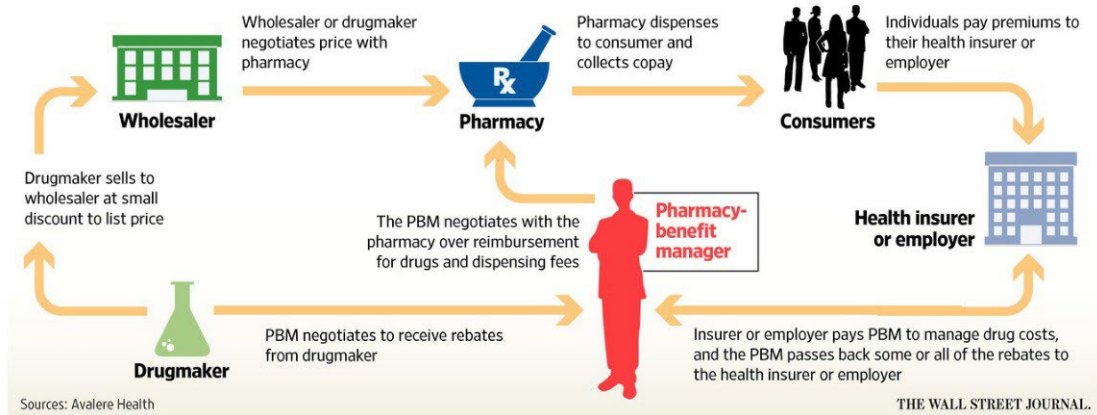
9 34. The formulary placement corresponds with the amount that a plan
10 participant must contribute as a co-payment when purchasing a drug—the higher
11 the placement, the lower the co-payment, and the higher likelihood that plan
12 beneficiaries will purchase the drug instead of a more expensive alternative. As a
13 result, higher formulary placement increases the likelihood that a doctor will
14 prescribe the drug. TPPs provide copies of their PBMs' formularies to providers,
15 pharmacists, and patients in their network to aid prescribers' adherence to the
16 formulary.
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19 35. The following chart, published by the Wall Street Journal,⁹ broadly
20 illustrates the pharmaceutical supply chain:
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23 ⁹ Joseph Walker, *Drugmakers Point Finger at Middlemen for Rising Drug Prices*,
24 WALL ST. J. (Oct. 3, 2016), [https://www.wsj.com/articles/drugmakers-point-](https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336)
25 [finger-at-middlemen-for-rising-drug-prices-1475443336](https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336).
26

How Drug Distribution Works

A complex supply chain determines how prescription drugs are paid for in the U.S.



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

1 type.¹⁰

2 38. The NDC is a critical component of each and every transfer of a
3 prescription drug (from the manufacturer to the wholesaler; from the wholesaler
4 to the retailer; and from the retailer to the consumer) and, therefore, every
5 transaction is accompanied by and labeled with the NDC. This same code is used
6 by TPPs and PBMs in the real-time claims adjudication process to identify the
7 precise dollar amount they will reimburse the pharmacy for a particular
8 prescription drug purchase.
9

10 39. Retail prescription labels display the NDC of the dispensed product,
11 which is part of the electronic dispensing record. In many cases, the “lot” number
12 will also appear on the prescription bottle provided to the consumer and, thus,
13 specifically indicate whether the recall applies to the particular pills in the
14 bottle.¹¹
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20 _____
21 ¹⁰ *National Drug Code Directory*, U.S. FOOD & DRUG ADMIN.,
22 <https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>; *National Drug*
23 *Codes Explained*, DRUGS.COM, <https://www.drugs.com/ndc.html>.
24

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

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

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.

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

3 43. While the DSCSA was enacted in 2013, participants in the
4 pharmaceutical supply chain maintained similar information as a part of their
5 ordinary course of business prior to the enactment of the DSCSA.
6

7 44. The DSCSA generally requires participants in the drug supply
8 manufacturing chain (starting from the manufacturer, through the wholesaler, to
9 the retail pharmacy) to retain, for every pharmaceutical drug transaction, the
10 following information about that transaction: product name; National Drug Code;
11 container size; number of containers; lot number; date of transaction; date of
12 shipment; and name and address of the entity transferring ownership and taking
13 ownership of the product.
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17 45. The DSCSA requires that this data be kept in a manner to allow
18 these authorized participants to respond within 48 hours to requests from
19 appropriate federal or state officials—in the event of a recall or for the purpose of
20 investigating suspect product or an illegitimate product—for the transaction
21
22

23 ¹⁴ Daniel R. Levinson, *Drug Supply Chain Security: Dispensers Received Most*
24 *Tracing Information*, U.S. DEPT. HEALTH & HUM. SERVS., at 2 (Mar. 2018),
25 <https://oig.hhs.gov/oei/reports/oei-05-16-00550.pdf>.
26

1 history of the pharmaceutical product.¹⁵

2 46. The supply chain for distribution of prescription drugs in the United
3 States is highly concentrated. This means that data obtained from a relatively
4 small number of market participants can provide detailed information about the
5 large majority of carvedilol (including Carvedilol) sales, transfers, and
6 prescription fills.
7

8 47. The entire process of reimbursing pharmacies and consumers for
9 end-purchases depends on the ability to know the precise drug and packaging that
10 was dispensed, as well as the manufacturer of that drug. This system has
11 necessarily resulted in very high levels of data standardization in this industry.
12 Although pharmacies maintain their own “pharmacy log” data reflecting
13 dispensing, sales and return activity, the key elements are fundamentally similar.
14

15 48. Because pharmacies require similar information for their own
16 tracking and inventory systems, and wholesalers sell to multiple pharmacy chains,
17 the key elements are fundamentally the same.
18

19 49. Further, all pharmacies must use the basic data fields, definitions and
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21 ¹⁵ *Title II of the Drug Quality and Security Act*, U.S. FOOD & DRUG ADMIN.,
22 [https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-](https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act)
23 [quality-and-security-act](https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act).
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1 formats provided in the Telecommunications Guidelines developed by the
 2 National Council for Prescription Drug Programs, the use of which was made
 3 mandatory in 2003 under regulations implementing the Health Insurance
 4 Portability and Accountability Act (HIPAA).¹⁶ Because of these HIPAA
 5 requirements, all of these inter-related systems (Manufacturers, Wholesalers,
 6 Retailers, and TPPs) use a common language to identify products.
 7

8
 9 50. As a general matter, for Medicare and Medicaid compliance,
 10 pharmacies typically keep prescription records for ten years.¹⁷
 11

12 51. A key part of the DSCSA is the requirement that “product tracing
 13 information should be exchanged” for each transaction and retained for at least
 14 six years,¹⁸ including the following transaction information (“TI”):¹⁹
 15

16 ¹⁶ 45 C.F.R. § 162.1802.
 17

18 ¹⁷ 42 C.F.R. § 423.505(d).
 19

20 ¹⁸ *Protect Your Patients*, U.S. FOOD & DRUG ADMIN.,
 21 <https://www.fda.gov/media/113114/download>; 21 U.S.C. §§ 360eee-

22 1(b)(1)(A)(ii), (c)(bb)(BB)(II)(v)(I), and (d)(1)(A)(iii).
 23

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

- 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>.

1 53. The term “product identifier” “means a standardized graphic that
2 includes, in both human-readable form and on a machine-readable data carrier . . .
3 the standardized numerical identifier, lot number, and expiration date of the
4 product.”²¹

6 54. Publicly available Guidelines published by AmerisourceBergen
7 require that “each Prescription Drug lowest saleable unit” it receives from a
8 manufacturer must have the clearly indicated product identifier on the unit label.²²
9 In addition, case labels and partial case labels must list the lot number and
10 expiration date.²³ The Guidelines illustrate these requirements as reproduced
11 below.
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18 ²¹ 21 U.S.C. § 360eee(14).

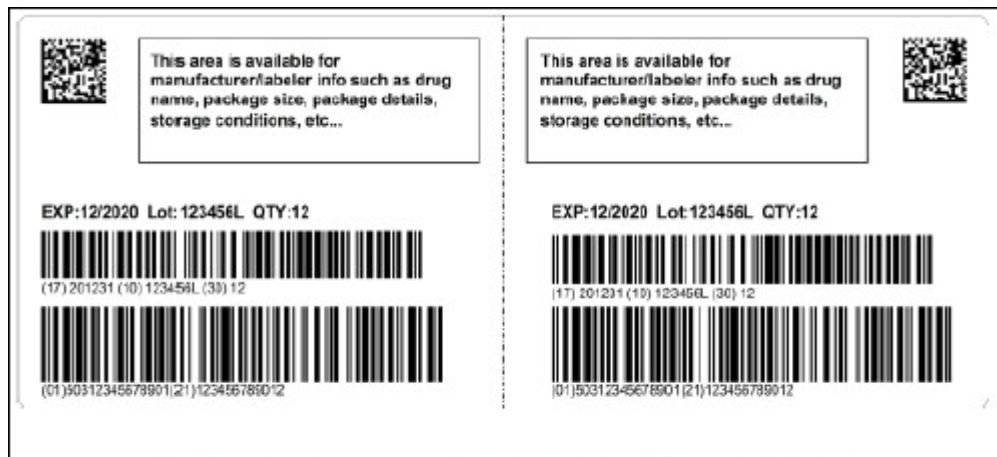
19 ²² *AmerisourceBergen Manufacturer Packaging and Logistics Requirements*

20 *Guide*, AMERISOURCEBERGEN, at 14 (Jan. 2019),

21 <https://www.amerisourcebergen.com/->

22 [/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-](https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf)
23 [final-v14.pdf](https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/manufacturer-logistics-guideline-final-v14.pdf).

24 ²³ *Id.* at 15-16.
25
26

*AmerisourceBergen Manufacturer Labeling Requirements*²⁴DSCSA RX Serialized Unit LabelExample of Rx Serialized Homogenous Case LabelExample Partial Case Labeled with SSCC²⁴ *Id.* at 14-16.

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

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.*

1 59. If a branded drug manufacturer ceases to manufacture a drug that
2 meets all terms of its NDA approval, or in other words, when the drug is not the
3 same as its corresponding brand-name drug, then the manufacturer has created an
4 entirely new and unapproved drug.
5

6 60. If a branded drug manufacturer ceases to manufacture a drug that
7 meets all terms of its NDA approval, or, in other words, when the drug is not the
8 same as its corresponding brand-name drug, the manufacturer may no longer rely
9 on the drug's labeling.
10

11 61. A drug's labeling must "contain a summary of the essential scientific
12 information needed for safe and effective use. . . [It] shall be informative and
13 accurate and neither promotional in tone nor false and misleading[.]" 21 C.F.R.
14 § 201.56.
15
16

17 **E. Approval of the NDA for Coreg**

18 62. Coreg is known generically as carvedilol, which is also the name of
19 the drug's active pharmaceutical ingredient ("API"). Coreg is a beta-blocker
20 prescribed to treat high blood pressure, heart failure, and related conditions. At a
21 very high level, the drug works by blocking β_1 and β^2 adrenergic receptors,
22 thereby lowering blood pressure or heart rate.
23
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1 63. The FDA approved Coreg in 1995, with subsequently approvals to
2 treat other conditions in 1997 and 2001. The FDA approved the extended release
3 (“ER”) formulation of Coreg in October 2006.
4

5 64. Coreg’s FDA-approved labeling specifies the active and inactive
6 ingredients, precautions, warnings, and other use and safety information. Neither
7 N-Nitroso-Carvedilol I specifically, nor nitrosamines generally, are listed on the
8 FDA-approved labeling.
9

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

12 65. Under federal law, pharmaceutical drugs must be manufactured in
13 accordance with cGMPs to ensure they meet safety, quality, purity, identity, and
14 strength standards. *See* 21 U.S.C. § 351(a)(2)(B). States’ laws incorporate these
15 standards.
16

17 66. Moreover, 21 C.F.R. § 210.1(a) states that the cGMPs establish
18 “minimum current good manufacturing practice for methods to be used in, and
19 the facilities or controls to be used for, the manufacture, processing, packing, or
20 holding of a drug to assure that such drug meets the requirements of the act as to
21 safety, and has the identity and strength and meets the quality and purity
22 characteristics that it purports or is represented to possess.” In other words,
23
24
25
26

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

3 67. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and
4 211. These detailed regulations set forth minimum standards for: organization and
5 personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart
6 D); control of components and drug product containers and closures (Subpart E);
7 production and process controls (Subpart F); packaging and label controls
8 (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I);
9 records and reports (Subpart J); and returned and salvaged drug products (Subpart
10 K). The FDA has worldwide jurisdiction to enforce these regulations if the
11 facility is making drugs intended to be distributed in the United States.
12

13 68. Under federal law, cGMPs include "the implementation of oversight
14 and controls over the manufacture of drugs to ensure quality, including managing
15 the risk of and establishing the safety of raw materials, materials used in the
16 manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j).
17 Accordingly, it is a cGMP violation for a manufacturer to contract out
18 prescription drug manufacturing without sufficiently ensuring the continuing
19 quality of the subcontractors' operations.
20

21 69. FDA regulations require a "quality control unit" to independently
22 test drug product manufactured by another company on contract:
23
24
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1 There shall be a quality control unit that shall have the
2 responsibility and authority to approve or reject all
3 components, drug product containers, closures, in-
4 process materials, packaging material, labeling, and
5 drug products, and the authority to review production
6 records to assure that no errors have occurred or, if
7 errors have occurred, that they have been fully
8 investigated. The quality control unit shall be
9 responsible for approving or rejecting drug products
10 manufactured, processed, packed, or held under contract
11 by another company. 21 C.F.R. § 211.22(a).

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

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

22 72. “Laboratory records shall include complete data derived from all
23 tests necessary to assure compliance with established specifications and
24 standards, including examinations and assays” and a “statement of the results of
25 tests and how the results compare with established standards of identity, strength,
26

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

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

14 74. Quality personnel must appropriately review all production records
15 and investigate and explain any discrepancies or failures. *See* 21 C.F.R.
16 § 211.192. Also, as applicable, a quality technical agreement also should be in
17 place as to quality-related aspects of cGMP. *See, e.g.,* 21 C.F.R. §§ 211.80,
18 211.82, 211.86, 211.142, 211.196, 211.63. An overarching goal of these efforts
19 and cGMP is to ensure that a drug is safe and “has the identity and strength and
20 meets the quality and purity characteristics that it purports or is represented to
21 possess.” 21 C.F.R. § 210.1(a).

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

1 Q10 pharmaceutical quality system, that includes proper adherence to cGMPs,
 2 and complements the ICH Q8 pharmaceutical development and ICH Q9 quality
 3 risk management.²⁷
 4

5 **G. Adulterated or Misbranded Drugs Are Illegal to Sell**

6 76. Any drug not manufactured in accordance with cGMPs is deemed
 7 “adulterated and/or misbranded” or “misbranded” and may not be distributed or
 8 sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B); 21 C.F.R. §
 9 210.1(b). States have enacted laws adopting or mirroring these federal standards.
 10

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

- 12 a. “[I]f it has been prepared, packed, or held under unsanitary
 13 conditions whereby it may have been contaminated with filth,
 14 or whereby it may have been rendered injurious to health”;²⁸
 15
 16 b. “[I]f . . . the methods used in, or the facilities or controls used
 17 for, its manufacture, processing, packing, or holding do not
 18 conform to or are not operated or administered in conformity
 19
 20

21 _____
 22 ²⁷ *See, e.g., ICH Guidance for Industry, Q10 Pharmaceutical Quality System, ,*
 23 U.S. FOOD & DRUG. ADMIN. (April 2009),
 24 <https://www.fda.gov/media/71553/download>.
 25

26 ²⁸ 21 U.S.C. § 351(a)(2)(A).

1 with current good manufacturing practice to assure that such
 2 drug meets the requirements . . . as to safety and has the
 3 identity and strength, and meets the quality and purity
 4 characteristics, which it purports or is represented to
 5 possess”;²⁹

7 c. “If it purports to be or is represented as a drug the name of
 8 which is recognized in an official compendium, and . . . its
 9 quality or purity falls below, the standard set forth in such
 10 compendium”;³⁰ or

12 d. “If . . . any substance has been (1) mixed or packed therewith
 13 so as to reduce its quality or strength or (2) substituted wholly
 14 or in part therefor.”³¹

16 78. A drug is misbranded:

18 a. “If its labeling is false or misleading in any particular”;³²

21
 22 ²⁹ 21 U.S.C. § 351(a)(2)(B).

23 ³⁰ 21 U.S.C. § 351(b).

24 ³¹ 21 U.S.C. § 351(d).

25 ³² 21 U.S.C. § 352(a)(1).

- 1 b. “If any word, statement, or other information required . . . to
2 appear on the label or labeling is not prominently placed
3 thereon . . . in such terms as to render it likely to be read and
4 understood by the ordinary individual under customary
5 conditions of purchase and use”;³³
6
7 c. If the labeling does not contain, among other things, “the
8 proportion of each active ingredient”;³⁴
9
10 d. “Unless its labeling bears (1) adequate directions for use; and
11 (2) such adequate warnings . . . against unsafe dosage or
12 methods or duration of administration or application, in such
13 manner and form, as are necessary for the protection of
14 users”;³⁵
15
16 e. “If it purports to be a drug the name of which is recognized in
17 an official compendium, unless it is packaged and labeled as
18 prescribed therein”;³⁶
19
20

21
22 ³³ 21 U.S.C. § 352(c).

23 ³⁴ 21 U.S.C. § 352(e)(1)(A)(ii).

24 ³⁵ 21 U.S.C. § 352(f).

25 ³⁶ 21 U.S.C. § 352(g).

1 f. “[I]f it is an imitation of another drug”;³⁷

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

3 h. “If it is dangerous to health when used in the dosage or
4 manner, or with the frequency or duration prescribed,
5 recommended, or suggested in the labeling thereof”;³⁹

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

7 j. If the drug’s “packaging or labeling is in violation of an
8 applicable regulation.”⁴¹

9
10
11 79. The manufacture and sale of any adulterated or misbranded drug is
12 prohibited under federal law.⁴²

13
14 80. The introduction into commerce of any adulterated or misbranded
15 drug is also prohibited.⁴³

16
17
18 ³⁷ 21 U.S.C. § 352(i)(2).

19 ³⁸ 21 U.S.C. § 352(i)(3).

20 ³⁹ 21 U.S.C. § 352(j).

21 ⁴⁰ 21 U.S.C. § 352(n).

22 ⁴¹ 21 U.S.C. § 352(p).

23 ⁴² 21 U.S.C. § 331(g).

24 ⁴³ 21 U.S.C. § 331(a).

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

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

6 83. Plaintiff references federal law in this Complaint not in any attempt
 7 to enforce it, but to demonstrate that its state-law tort claims do not impose any
 8 additional obligations on Glenmark beyond what is already required of it under
 9 federal law.
 10

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

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

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

⁴⁴ 21 U.S.C. § 331(c).

1 includes components of drugs, such as active
2 pharmaceutical ingredients.⁴⁵

3 85. 21 C.F.R. § 210.3(b)(7) defines an “active ingredient” in a drug as
4 “any component that is intended to furnish pharmacological activity or other
5 direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease,
6 or to affect the structure or any function of the body of man or other animals. The
7 term includes those components that may undergo chemical change in the
8 manufacture of the drug product and be present in the drug product in a modified
9 form intended to furnish the specified activity or effect.”⁴⁶
10
11

12 86. Accordingly, the FDA requires the submission of an NDA by
13 manufacturers whenever a new active ingredient is added to a drug, as the drug
14 has become a new and differing drug from those previously approved by the
15 FDA. Absent such an application, followed by a review and approval by the
16 FDA, the new drug remains a distinct, unapproved product.⁴⁷
17
18

19 87. This new and unapproved drug with additional active ingredients
20 (such as nitrosamines in the subject VCDs) cannot have the same label as the
21

22 ⁴⁵ *Human Drugs*, U.S. FOOD & DRUG ADMIN.,

23 <https://www.fda.gov/industry/regulated-products/human-drugs#drug>.

24
25 ⁴⁶ 21 C.F.R. § 210.3(b)(7).

26 ⁴⁷ *See* 21 C.F.R. § 310.3(h).

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

3 88. At the very least and alternatively, drugs with differing and
4 dangerous ingredients than brand-name counterparts are adulterated or
5 misbranded under federal law, and the sale or introduction into commerce of
6 adulterated or misbranded drugs is illegal.⁴⁸
7

8
9 89. Here, N-Nitroso-Carvedilol I and/or other nitrosamines resulted from
10 the deficient manufacturing process of Carvedilol, rendering Carvedilol different
11 than the FDA-approved versions of Coreg. Importantly, N-Nitroso-Carvedilol I
12 and other nitrosamines can cause cancer by triggering genetic mutations in
13 humans. This mutation affects the structure of the human body, and thus, N-
14 Nitroso-Carvedilol I and other nitrosamines are, by definition, an active
15 ingredient in a drug.
16
17
18
19

20 _____
21 ⁴⁸ See generally *Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees*
22 *to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and*
23 *False Statements to the FDA*, U.S. DEP'T JUST. (May 13, 2013),
24 [https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-](https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false)
25 [and-agrees-pay-500-million-resolve-false.](https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false)
26

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

7 91. The presence of additional active ingredients or components (i.e., N-
8 Nitroso-Carvedilol I and/or other nitrosamines) and potentially other deviations
9 from Coreg rendered Glenmark's Carvedilol of a lesser quality and a different
10 safety profile than FDA-approved Coreg, and indeed, the FDA-approved version
11 of Glenmark's Carvedilol.
12

14 92. Contaminated and adulterated Carvedilol is not a substitute for FDA-
15 approved Coreg and has no value or practically no value to a purchaser of
16 Carvedilol.
17

18 93. Plaintiff and other Class Members paid or reimbursed for an FDA-
19 approved generic version of FDA-approved Coreg, but that is not what was
20 received.
21

22 94. Plainly, Glenmark did not deliver the product paid for by Plaintiff
23 and other Class Members.
24
25
26

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

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.

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

3 100. In addition, by referring to its drugs as “Carvedilol,” Defendant was
4 making false statements. The Carvedilol sold, and which Plaintiff and other Class
5 Members paid for, was a different, new unapproved drug not therapeutically or
6 pharmaceutically equivalent to FDA-approved Coreg, on account of a different
7 undisclosed safety profile, different identity, purity and quality, and not being
8 made in a cGMP-compliant manner.
9

10 101. It is unlawful to introduce a misbranded drug into interstate
11 commerce.⁵⁴ Thus, the Carvedilol paid for by Plaintiff and other Class Members
12 was unlawfully distributed and sold.
13

14
15 **IV. Defendant Misrepresented That Carvedilol Was Manufactured in**
16 **Compliance with Current Good Manufacturing Practices**

17 102. Under federal law, cGMPs include “the implementation of oversight
18 and controls over the manufacture of drugs to ensure quality, including managing
19 the risk of and establishing the safety of raw materials, materials used in the
20 manufacturing of drugs, and finished drug products.” 21 U.S.C. § 351(j).
21 Accordingly, it is a cGMP violation for a manufacturer to make a prescription
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⁵⁴ 21 U.S.C. § 331(a).

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

3 103. FDA regulations require a “quality control unit” to independently
4
5 test drug product manufactured by another company on contract:

6 There shall be a quality control unit that shall have the
7 responsibility and authority to approve or reject all
8 components, drug product containers, closures, in-
9 process materials, packaging material, labeling, and
10 drug products, and the authority to review production
11 records to assure that no errors have occurred or, if
12 errors have occurred, that they have been fully
13 investigated. The quality control unit shall be
14 responsible for approving or rejecting drug products
15 manufactured, processed, packed, or held under contract
16 by another company. 21 C.F.R. § 211.22(a).

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

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

1 106. “Laboratory records shall include complete data derived from all
2 tests necessary to assure compliance with established specifications and
3 standards, including examinations and assays” and a “statement of the results of
4 tests and how the results compare with established standards of identity, strength,
5 quality, and purity for the component, drug product container, closure, in-process
6 material, or drug product tested.” 21 C.F.R. § 211.194.
7
8

9 107. As noted *supra*, a firm must have appropriate systems and personnel
10 in place to assure a drug has the safety, identity, strength, quality, and purity that
11 it purports or is represented to possess. *See, e.g.*, 21 C.F.R. §§ 210.1(a),
12 211.25(a)-(b), 211.34, 211.80, 211.82, 211.86, 211.142, 211.63 211.192 211.196,
13 211.63.
14

15 108. Glenmark’s Carvedilol did not conform to cGMP-required safety
16 and quality parameters, which demonstrates inadequate production, process, and
17 quality oversight by Glenmark.
18

19 109. Glenmark’s failure to conform to cGMPs resulted in the production,
20 and ultimate sale and reimbursement, of a product that was so contaminated and
21 adulterated with high—not merely trace—levels of nitrosamines that it could not
22 be considered the same as FDA-approved Coreg, yet Glenmark still falsely
23 labeled or held out its products as the same as FDA-approved Coreg in all
24 material respects.
25
26

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.

1 control them. Every iteration of the ICH M7 Guidance dating back to 2006
2 similarly classified nitrosamines and warned of the need for “compound-specific
3 toxicity data” beyond that for other substances.⁵⁶
4

5 113. Agencies ranging from IARC and WHO,⁵⁷ to the EPA,⁵⁸ to the
6 American Conference of Governmental Industrial Hygienists,⁵⁹ to the Agency for
7

8 ⁵⁶ See, e.g., *ICH Guidance for Industry, M7(R1) Assessment and Control of DNA*
9

10 *Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential*

11 *Carcinogenic Risk*, EUROPEAN MEDICINES AGENCY, at

12 <https://www.ema.europa.eu/en/ich-m7-assessment-control-dna-reactive->
13

14 [mutagenic-impurities-pharmaceuticals-limit-potential#document-history-section](https://www.ema.europa.eu/en/ich-m7-assessment-control-dna-reactive-mutagenic-impurities-pharmaceuticals-limit-potential#document-history-section)
15

(collecting iterations of guidance back to issuance in 2006).
16

17 ⁵⁷ See, e.g., IARC Scientific Publications, No. 14, Lyon, France: International
18

Agency for Research on Cancer, 1976; *Environmental Aspects of N-Nitroso*
19

Compounds, Vol. 1. (E.A. Walker, M. Castegnaro, L. Griciute, and R.E. Lyle,
20

eds.), IARC Scientific Publications, No. 19, Lyon, France: International Agency
21

for Research on Cancer, 1978; *N-Nitroso Compounds: Analysis, Formation and*
22

Occurrence. (E.A. Walker, M. Castegnaro, L. Griciute, and M. Borzsonyi, eds.),
23

IARC Scientific Publications, No. 31, Lyon, France: International Agency for
24

Research on Cancer, 1980.
25
26

1 Toxic Substances and Disease Registry⁶⁰ to the U.S. Department of Health and
2 Human Services (“DHHS”)⁶¹ classify various nitrosamine compounds as
3 probable human carcinogens.⁶²
4

5 114. Anecdotally, nitrosamines have also been used in intentional
6 poisonings.⁶³
7
8

9
10 ⁵⁸ *Technical Fact Sheet N-Nitroso-dimethylamine (NDMA)*, U.S.

11 ENVIRONMENTAL PROTECTION AGENCY (Nov. 2017), *available at*

12 [https://www.epa.gov/sites/production/files/2017-](https://www.epa.gov/sites/production/files/2017-0/documents/ndma_fact_sheet_update_9-15-17_508.pdf)
13 [0/documents/ndma_fact_sheet_update_9-15-17_508.pdf](https://www.epa.gov/sites/production/files/2017-0/documents/ndma_fact_sheet_update_9-15-17_508.pdf).
14

15 ⁵⁹ *Id.*

16 ⁶⁰ *Id.*

17 ⁶¹ *Id.*

18 ⁶² *Pharmacology and Toxicology Guidance for Industry, Genotoxic and*
19 *Carcinogenic Impurities in Drug Substances and Products: Recommended*
20 *Approaches*, U.S. FOOD & DRUG. ADMIN. (Dec. 2018).
21

22 ⁶³ See Chase Purde, *A common blood-pressure medicine is being recalled because*
23 *of a toxic ingredient*, QUARTZ (July 18, 2018), [https://qz.com/1330936/the-fda-is-](https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/)
24 [recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/](https://qz.com/1330936/the-fda-is-recalling-a-common-blood-pressure-drug-because-it-was-mixed-with-ndma/).
25
26

1 115. Nitrosamines are not new. The scientific community has been aware
2 of nitrosamine formation and carcinogenicity for several decades. The chemical
3 reactions leading to nitrosamine formation have been described as textbook
4 chemistry.⁶⁴ The carcinogenicity of nitrosamines has been well documented since
5 at least the 1950s.⁶⁵
6

7
8
9 ⁶⁴ Sun, Z., Liu Y.D., and Zhong, R.G. (2010) Theoretical Investigation of *N*-
10 Nitrosodimethylamine Formation from Nitrosation of Trimethylamine, *J. Phys.*
11 *Chem. A*.

12 114, 455-465; 29; International Agency for Research on Cancer (1978); Some *N*-
13 nitroso compounds, in *IARC Monogr. Eval. Carcinog. Risk Chem. Hum.* pp 83-
14 175, IARC, Lyon, FR.
15

16 ⁶⁵ Magee, P. N., and Barnes, J. M. (1956) The production of malignant primary
17 hepatic tumors in the rat by feeding dimethylnitrosamine, *Brit J Cancer* 10, 114-
18 122; see also, e.g., De Flora, S. *et al.*, *Cimetidine, Ranitidine and Their*
19

20 *Mutagenic Nitroso Derivatives*, The Lancet,
21

22 Oct. 31, 1981, at 993-94; Maura, *et al.*, *DNA Damage Induced by Nitrosated*

23 *Ranitidine in Cultured Mammalian Cells*, 18 *Tox. Ltr.* 97-102 (1983); De Flora

24 S., *et al.*, *Genotoxicity of Nitrosated Ranitidine*, 4 *Carcinogenesis* 3, 255-60

25 (1983).
26

1 116. The pharmaceutical industry has been aware of the potential for the
2 formation of nitrosamines in pharmaceutical drugs at least as far back as at least
3 2005,⁶⁶ and likely earlier. The scientific literature instructed for decades that
4 companies should evaluate their products for the potential of nitrosamine
5 formation.⁶⁷

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

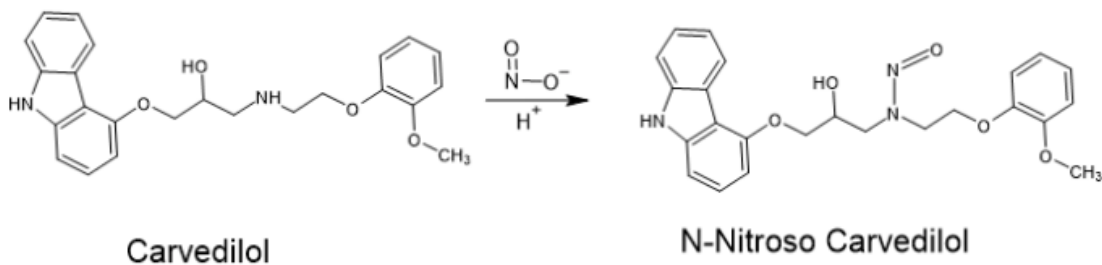
16 ⁶⁶ Lutz Müller et al., *A rationale for determining, testing, and controlling specific*
17 *impurities in pharmaceuticals that possess potential for genotoxicity*, REGUL.

19 TOXICOLOGY & PHARMACOLOGY (Dec. 26, 2005),

20 [https://www.sciencedirect.com/science/article/abs/pii/S0273230005002084?via%](https://www.sciencedirect.com/science/article/abs/pii/S0273230005002084?via%3Dihub)
21 [3Dihub](https://www.sciencedirect.com/science/article/abs/pii/S0273230005002084?via%3Dihub).

23 ⁶⁷ *Id.*

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



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 Angiotensin 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>.

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

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

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

16 ⁷¹ *Id.*

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

23 ⁷³ *See, e.g., Boetzel, et al., A Nitrite Excipient Database: A Useful Tool to Support*
24 *N-Nitrosamine Risk Assessments for Drug Products*, J. of Pharm. Sciences 112
25 (2023) 1615-1624.
26

1 121. Further, it was known prior to Glenmark's recalls that drug products
2 containing an active ingredient like carvedilol with a secondary amine functional
3 group were vulnerable to nitrosating agents from excipients or other ingredients,
4 leading to the formation of nitrosamines.
5

6 122. In fact, FDA guidance explicitly directed drug manufacturers to
7 identify such potential reactions during the manufacture of drug product:
8

9 Drug product manufacturers and applicants should conduct risk
10 assessments to determine the potential for small-molecule
11 nitrosamine impurities and NDSRIs in drug products. A risk
12 assessment should involve collaboration with the API manufacturer
13 to aid in the identification of the API ROS or other process
14 conditions of the API's manufacture that put the drug product at risk
15 for nitrosamine impurities. The risk assessment should also include
16 evaluation of any pathway (e.g., degradation and nitrosamine
17 precursor impurities such as dimethylamine or other secondary
18 amine precursors) that may introduce the risk of nitrosamine
19 formation during drug product manufacture or storage. . . . If a
20 nitrosamine impurity is detected, manufacturers and applicants
21 should investigate the root cause and implement changes in the
22 manufacturing process to prevent or reduce nitrosamine
23 impurities[.]⁷⁴
24

25 123. Moreover, "[m]anufacturers and applicants should also evaluate
26 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>.

1 eliminate the source of nitrosamine impurities.”⁷⁵

2 124. A manufacturer’s obligations to test for nitrosamines is ongoing: “To
3 meet the current good manufacturing practice (CGMP) regulations in 21 CFR part
4 211, subpart E, and be consistent with the ICH guidance for industry *Q10*
5 *Pharmaceutical Quality System* (April 2009), drug product manufacturers and
6 applicants should continue testing each API lot for nitrosamine impurities.”⁷⁶
7
8

9 125. Thus, Glenmark was on actual and constructive notice of the need to
10 have adequate quality systems in place to detect, characterize, analyze, and
11 quantify nitrosamines years before its Carvedilol recalls in 2025. There is no
12 indication that Glenmark ever undertook an appropriate evaluation of its
13 Carvedilol to ascertain the likelihood of nitrosamine formation, let alone develop
14 a cGMP-compliant way to detect, and to avoid or at least to minimize,
15 nitrosamine formation.
16
17

18 126. Because the nitrosamine contamination was a process-related
19 impurity—i.e., it was not isolated, a one-off accident, etc.—it is plausible and,
20 under the weight of industry literature and guidance, reasonably expected that
21 every batch and every lot of finished product manufactured would experience the
22 same cGMP deficiency.
23
24

25
26 ⁷⁵ *Id.*

1 127. Generally speaking, a process impurity is an unintended chemical
2 entity or potential chemical reaction introduced during the manufacturing process.
3 Such impurities generally originate from raw materials, catalysts, reagents,
4 intermediates, environmental conditions, or by-products formed during synthesis.
5 According to ICH Guidance Q3A(R2), process (and degradation) impurities
6 should be evaluated for their potential, characterized, monitored, and controlled
7 or eliminated.
8
9

10 128. Since commercial manufacturing processes are validated for
11 repeatability, process impurities present will be present in all subsequent
12 production batches. This is due in part to pharmaceutical manufacturing aiming to
13 ensure uniform mixing of active ingredients and general content uniformity.
14 Thus, the distribution of any impurity is expected with certain assumptions to be
15 also uniformly distributed in the drug product.
16
17

18 129. Regulatory agencies require drug manufacturers to establish
19 scientifically justified specifications for impurities to ensure batch uniformity.
20 According to 21 CFR Part 211, batch-to-batch consistency must be maintained
21 through validated manufacturing processes, ensuring that any impurity identified
22 persists predictably across all commercial batches.
23
24
25
26

⁷⁶ *Id.*

1 130. The same principles and quality-by-design carry through to drug
2 products. The entire framework of drug product manufacturing is to ensure
3 repeatable consistency and within-specifications uniformity in the product
4 manufacture.
5

6 131. Based on established regulatory guidelines, industry standards, and
7 empirical data, it is reasonable to conclude that a process impurity, once present,
8 will consistently appear in every batch of the finished drug product unless
9 actively removed or degraded during formulation.
10

11 132. In other words, the manufacture of a drug product, such as MCDs,
12 must by design, regulation, and expectation result in the routine, systematic
13 production of like-quality products, such that both desired components as well as
14 unwanted impurities are consistently, uniformly present in each product made
15 during the common-by-design manufacturing process.
16
17

18 133. Therefore, an impurity such as the one in Carvedilol—which as
19 detailed herein resulted from a chemical reaction during a singular manufacturing
20 process that utilizes by design the same components every time—would be
21 widespread and systematically present in every product manufactured.
22
23
24
25
26

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>.

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:

1 In-process materials shall be tested for identity,
2 strength, quality, and purity as appropriate, and
3 approved or rejected by the quality control unit, during
4 the production process, e.g., at commencement or
completion of significant phases or after storage for
long periods.

5 21 C.F.R. § 211.110(c).

6 142. Similarly, 21 C.F.R. § 211.100 and § 211.22(b), among other
7 provisions, requires quality control units to ensure sufficient written and other
8 procedures exist to assure the identity, strength, quality, and purity of the drug
9 product.
10

11 143. And, as discussed above, the quality control units are and were
12 responsible for approving or rejecting drug products manufactured, processed,
13 packed, or held under contract by each API or finished-dose manufacturer that
14 made Glenmark's Carvedilol, whether Glenmark itself or a firm contracted on
15 Glenmark's behalf. As the seller of Carvedilol in the United States, Glenmark
16 bore non-delegable responsibility to ensure Carvedilol was made in a cGMP-
17 compliant manner.
18
19
20

21 144. The quality control units responsible for Glenmark's Carvedilol were
22 grossly deficient in fulfilling their responsibilities.
23

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

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

4
5 146. If the foregoing sampling-related, testing-related, and quality- related
6 cGMPs were properly observed by Glenmark, the nitrosamine contamination in
7 Glenmark's Carvedilol would have been discovered almost immediately, and
8 Defendant was thus (at minimum) on constructive notice from the moment its
9 Carvedilol became contaminated.

10
11 147. Not only did Glenmark fail to eliminate nitrosamines from its
12 Carvedilol, but the amount of nitrosamines found in Carvedilol as reported by the
13 FDA, which would be expected to be the same in all product given the root cause
14 being a process impurity, was above the acceptable intake limit. Notably, that
15 limit should apply only when nitrosamines are not avoidable in a drug product.
16 Here, nitrosamines were avoidable, but Glenmark failed to take appropriate steps
17 to detect, characterize, and eliminate nitrosamines in its Carvedilol.

18
19 148. Glenmark obtained its Carvedilol from a manufacturing facility in
20 India operated by Glenmark's corporate affiliate, Glenmark Pharmaceuticals Ltd.
21 ("Glenmark-India"). The two firms, Glenmark and Glenmark-India, share
22 personnel and other resources. For instance, Glenmark is the United States agent
23 for Glenmark-India's regulatory submissions to the FDA.
24
25
26

1 149. On information and belief, Glenmark-India manufactured Carvedilol
2 for Glenmark at two facilities in India, one in Goa (the “Goa Facility”) and one in
3 Pithampur/Madhya Pradesh (the “Pithampur Facility”). Both facilities have had
4 longstanding, serious cGMP deficiencies.
5

6 150. For instance, after years of reported cGMP failures, the FDA sent
7 Glenmark-India a Warning Letter in November 2022 noting many “significant
8 violations of” cGMPs. These deviations included failures to investigate
9 discrepancies or failures in drug product batches; “to establish adequate written
10 procedures for production and process control designed to assure that the drug
11 products you manufacturer have the identity strength, quality, and purity they
12 purport or are represented to possess”; “to establish and follow required
13 laboratory control mechanisms”; and to prepare maintain proper batch and control
14 records.” “Because [Glenmark-India’s] methods, facilities or controls for
15 manufacturing, processing, packing or holding do not conform to CGMP, your
16 drug products are adulterated[.]”
17
18
19
20

21 151. After years of escaping regulatory inspections, the FDA inspected
22 Glenmark-India’s drug manufacturing facility in Pithampur, Madhya Pradesh,
23 454774 India, in February 2025.
24

25 152. This investigation resulted in an FDA Warning Letter issued in July
26 2025 to Glenmark-India. The FDA Warning Letter summarized numerous

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

14 153. The FDA even noted in the July 2025 Warning Letter that many
15 cGMP violations were similar to those found Glenmark’s “company’s network,”
16 including the Goa Facility, a facility in Himachal Pradesh, and Glenmark’s own
17 facility in North Carolina.

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

26 155. Glenmark knowingly, recklessly, or negligently introduced

1 adulterated or misbranded Carvedilol containing dangerous amounts of
 2 nitrosamines into the U.S. market. Glenmark failed to recall its Carvedilol earlier
 3 because it feared permanently ceding market share to competitors. It did not
 4 institute the recalls until after the FDA's February 2025 inspection of the
 5 Pithampur Facility.
 6

7 **VIII. Defendant's Warranties and Fraudulent and Deceptive Statements to** 8 **Purchasers Regarding Its Carvedilol**

9 156. Defendant made and breached express and implied warranties and
 10 also made affirmative and implied misrepresentations and omissions to
 11 purchasers about its adulterated or misbranded VCDs.
 12

13 157. The FDA maintains a list of "Approved Drug Products with
 14 Therapeutic Equivalence Evaluations" known as the Orange Book.⁷⁹ The Orange
 15 Book is a public document; Defendant sought and received the inclusion of its
 16 Carvedilol in the Orange Book upon approval of its ANDA.
 17

18 158. Defendant's Carvedilol is accompanied by an FDA-approved label.
 19 By presenting purchasers with an FDA-approved Carvedilol label, Defendant
 20

21
 22 ⁷⁹ *Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S.

23 FOOD & DRUG ADMIN., [https://www.fda.gov/drugs/drug-approvals-and-](https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book)
 24 [databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-](https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book)
 25 [book](https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).
 26

1 made representations and express or implied warranties of the “sameness” of its
2 product to the Orange Book listed Carvedilol, and in turn Coreg, and that its
3 products were consistent with the safety, quality, purity, identity, and strength
4 characteristics reflected in the FDA-approved labels or were not adulterated or
5 misbranded or not made in a CMP-compliant manner.
6

7 159. The Carvedilol produced and sold by Defendant were not FDA-
8 approved carvedilol.
9

10 160. By introducing its Carvedilol into the United States marketed as a
11 generic carvedilol drug equivalent to Coreg, Defendant represented and warranted
12 to purchasers that its Carvedilol was in fact the same as the approved version of
13 Carvedilol and, in turn, Coreg. Much of the drug supply chain, including the most
14 critical components of that supply chain (for example, patients and purchasers)
15 rely on these representations and warranties.
16
17

18 161. In addition, Defendant affirmatively misrepresented and warranted to
19 purchasers through its websites, brochures, and other marketing or informational
20 materials that its Carvedilol complied with cGMPs and did not contain (or were
21 not likely to contain) any components or impurities besides those identified on the
22 products’ FDA-approved labels.
23
24

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

1 and in turn Coreg, thus breaching Defendant's express warranties of sameness;
2 (2) was the result of gross deviations from cGMPs rendering Defendant's
3 Carvedilol worthless (or alternatively, certainly worth less), thus breaching
4 Defendant's express warranties of sameness; and (3) results in Defendant's
5 Carvedilol containing an ingredient or component or impurity that is not also
6 contained in the FDA-approved label, also breaching Defendant's express
7 warranty of sameness (and express warranty that the products contained the
8 ingredients or component or impurities listed on Defendant's FDA-approved
9 label). Defendant willfully, recklessly, or negligently failed to ensure its
10 Carvedilol labels and other advertising or marketing statements accurately
11 conveyed information about its products.
12

13
14
15 163. The presence of nitrosamines in Defendant's Carvedilol and serial
16 and willful failures to comply with cGMPs and other shortcomings in
17 Defendant's drug manufacturing processes have resulted in Defendant's
18 Carvedilol being adulterated or misbranded or not compliant with cGMPs.
19
20

21 164. At all relevant times, Defendant also impliedly warranted that its
22 Carvedilol was merchantable and fit for its ordinary purposes.
23

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

1 Defendant's Carvedilol means that Defendant has violated implied warranties to
2 Plaintiffs and other Class Members. The presence of nitrosamines in Defendant's
3 Carvedilol makes the product non-merchantable and not fit for its ordinary
4 purposes, breaching Defendant's implied warranty of merchantability and/or
5 fitness for ordinary purposes.
6

7 166. For these and other reasons, Defendant's Carvedilol are, therefore,
8 adulterated, misbranded, or unapproved, and not compliant with cGMPs, and it
9 was illegal for Defendant to have introduced or sold such Carvedilol in the United
10 States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).
11
12

13 167. Adulterated, misbranded, or unapproved Carvedilol contaminated
14 with cancer- causing compounds, or manufactured in a non-cGMP compliant
15 manner, are essentially worthless (or alternatively, certainly worth less). No
16 reasonable purchaser (including Plaintiff) would purchase (or reimburse for) these
17 nitrosamine-laden Carvedilol. Nor could they, as adulterated, misbranded, or
18 unapproved Carvedilol cannot be legally sold or purchased within the United
19 States. At a minimum, adulterated, misbranded, or unapproved Carvedilol was
20 worth less than their non-contaminated equivalents. Further, adulterated,
21 misbranded, and/or unapproved Carvedilol does not possess the same safety and
22 efficacy profiles as their branded equivalents. As such, the Carvedilol was not
23 what it was supposed to be.
24
25
26

1 168. Because of the seriousness of the impurity—unsafe levels of a
2 carcinogen—all or virtually all purchasers immediately stopped paying for the
3 tainted drug products after receiving notice of the recall; in fact, Glenmark
4 advised the pharmacy supply chain to quarantine the recalled product. Even in the
5 absence of nitrosamines, the cGMP failures at Defendant Glenmark’s
6 manufacturing process meant its products were adulterated for lack of adequate
7 quality assurances.
8
9

10 **IX. Fraudulent Concealment and Tolling**

11 169. Plaintiffs’ and Class Members’ causes of action accrued no earlier
12 than the date(s) the FDA announced the recall of Glenmark’s Carvedilol.
13 Plaintiff exercised reasonable diligence but could not discover the nitrosamine
14 contamination or Glenmark’s cGMP violations, each of which independently
15 rendered its Carvedilol adulterated, misbranded, and a non-approved new drug,
16 because Glenmark’s wrongful acts were concealed from Plaintiff and the public,
17 and facts pertinent to same were within Glenmark’s possession and control.
18 Glenmark’s conduct as alleged herein constitutes a continuing violation of
19 applicable laws.
20
21
22

23 170. Alternatively, any statute of limitation or prescriptive period is
24 equitably tolled because of fraudulent concealment. Glenmark affirmatively
25 concealed from Plaintiff and other Class Members its unlawful conduct.
26

1 Defendant affirmatively strove to avoid disclosing its knowledge of its cGMP
2 violations related to Carvedilol, and of the fact that Carvedilol was adulterated
3 and/or misbranded and contaminated with nitrosamines and were not the same as
4 the FDA-approved generic and Coreg.
5

6 171. For instance, Glenmark did not reveal to the public that its
7 Carvedilol contained nitrosamines or was otherwise adulterated, misbranded,
8 and/or unapproved, or non-therapeutically equivalent to FDA-approved Coreg.
9

10 172. To the contrary, Glenmark continued to represent and warrant that its
11 Carvedilol was the same as Coreg, and continued to sell its Carvedilol in the
12 United States after the 2018 valsartan recalls (when industry focus on
13 nitrosamines became especially acute, even though the industry and literature
14 knew of nitrosamine formation much earlier).
15
16

17 173. Because of this, Plaintiff and other Class Members did not discover,
18 nor could they have discovered through reasonable and ordinary diligence,
19 Defendant's deceptive, fraudulent, and unlawful conduct alleged herein.
20 Defendant's false and misleading explanations, or obfuscations, lulled Plaintiff
21 and Class Members into believing that the prices paid for Defendant's Carvedilol
22 were appropriate for what they believed to be non-adulterated or misbranded
23 drugs despite their exercise of reasonable and ordinary diligence.
24
25

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

1 any applicable statute of limitations affecting the rights of Plaintiff and other
2 Class Members has been tolled. Plaintiff and other Class Members exercised
3 reasonable diligence by, among other things, promptly investigating and bringing
4 the allegations contained herein. Despite these or other efforts, Plaintiff was
5 unable to discover, and could not have discovered, the unlawful conduct alleged
6 herein at the time it occurred or at an earlier time so as to enable any complaint to
7 be filed sooner.
8
9

10 CLASS ACTION ALLEGATIONS

11 175. Plaintiff seeks to represent a Nationwide Class and Washington
12 Subclass under Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) as defined below:
13

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

18 **Washington Subclass:** All individuals and entities who
19 paid any amount of money for Carvedilol (intended for
20 personal or household use) that was purchased or
21 dispensed in Washington that was manufactured,
distributed, or sold by Defendant.

22 176. Plaintiffs allege additional sub-classes for all purchasers in each
23 State, territory, or possession—or combinations of States, territories, or
24 possessions to the extent class members from these jurisdictions can be grouped
25 together for purposes of class treatment—that paid any amount of money out of
26

1 pocket for Carvedilol (intended for personal or household use) that was
2 manufactured, distributed, or sold by Defendant (collectively, with the
3 Washington Subclass above, the “Subclasses”).
4

5 177. Collectively, the foregoing Nationwide Class and the Subclasses are
6 referred to as the “Class.”
7

8 178. Excluded from the Class are: (a) any judge or magistrate presiding
9 over this action, and members of their families; (b) Defendant and affiliated
10 entities, and their employees, officers, directors, and agents; (c) Defendant’s legal
11 representatives, assigns and successors; and (d) all persons who properly execute
12 and file a timely request for exclusion from any Court-approved class.
13

14 179. Plaintiff reserves the right to narrow or expand the foregoing class
15 definition, or to create or modify subclasses as the Court deems necessary.
16

17 180. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on
18 behalf of the Class.
19

20 181. **Numerosity:** While the exact number of Class Members cannot be
21 determined without discovery, they are believed to consist of potentially hundreds
22 of entities nationwide. The Class Members are therefore so numerous that joinder
23 of all members is impracticable.
24

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

1 predominate over any questions affecting individual Class and Subclass members.

2 These common legal and factual questions include, but are not limited to, the
3 following:
4

- 5 a. Whether Defendant made express or implied warranties of
6 “sameness” to Plaintiff and Class Members regarding its
7 Carvedilol;
8
- 9 b. Whether Defendant’s Carvedilol were, in fact, the same as the
10 FDA-approved generic and FDA-approved branded product
11 consistent with such express or implied warranties;
12
- 13 c. Whether Defendant’s Carvedilol was contaminated with
14 nitrosamines or similar contaminants;
15
- 16 d. Whether Defendant’s Carvedilol containing nitrosamines or
17 similar contaminants was adulterated or misbranded;
18
- 19 e. Whether Defendant violated cGMPs regarding the
20 manufacture of its Carvedilol;
21
- 22 f. Whether Defendant falsely claimed that its Carvedilol was the
23 same as Coreg and thus therapeutically interchangeable;
24
- 25 g. Whether Defendant affirmatively misrepresented or omitted
26 facts regarding its compliance with cGMPs;

- 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

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

3 185. The elements of Rule 23(b)(2) are met. Defendant has acted on
4 grounds that apply generally to Class Members so that preliminary or final
5 injunctive relief and corresponding declaratory relief is appropriate respecting the
6 Class as a whole.
7

8
9 186. **Superiority:** A class action is superior to all other available means
10 for the fair and efficient adjudication of this controversy. Although many other
11 Class Members have claims against Defendant, the likelihood that individual
12 Class Members will prosecute separate actions is remote due to the time and
13 expense necessary to conduct such litigation. Serial adjudication in numerous
14 venues would not be efficient, timely or proper. Judicial resources would be
15 unnecessarily depleted by resolution of individual claims. Joinder on an
16 individual basis of thousands of claimants in one suit would be impractical or
17 impossible. In addition, individualized rulings and judgments could result in
18 inconsistent relief for similarly situated plaintiffs. Plaintiffs' counsel, highly
19 experienced in pharmaceutical litigation, consumer fraud litigation, class actions,
20 and federal court litigation, foresee little difficulty in the management of this case
21 as a class action.
22
23
24
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26

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

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

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

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

1 192. Defendant's sale of Carvedilol expressly warranted the products
2 were compliant with compendial standards, USP requirements, Orange Book
3 requirements. These affirmations were false, because Defendant's Carvedilol was
4 not therapeutically equivalent to FDA-approved Coreg, with inter alia a different
5 safety profile, different identity, purity, and quality characteristics, and not made
6 in a cGMP-compliant manner.
7

8
9 193. Defendant expressly warranted that its Carvedilol was merchantable,
10 and fit for ordinary use, as an FDA-approved pharmaceutical that is
11 therapeutically equivalent to and the same as FDA-approved Coreg. In other
12 words, Defendant expressly warranted that its products were the same as FDA-
13 approved Coreg or an FDA-approved generic equivalent, in terms of therapeutic
14 equivalence, safety profile, possessing the same identity, purity, and quality, and
15 assurance of being made in a cGMP-compliant manner.
16
17

18 194. Defendant sold Carvedilol that it expressly warranted was compliant
19 with cGMPs and were not adulterated or misbranded. Indeed, the very fact that
20 Defendant sold Carvedilol in the stream of commerce warranted it was cGMP-
21 compliant and not adulterated because adulterated products are illegal to sell or
22 dispense.
23
24

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

1 compliance with cGMPs, contained nitrosamine contaminants, was not
 2 therapeutically equivalent, lacked the same safety profile as FDA-approved
 3 Coreg, had different identity, purity, and quality characteristics, and was
 4 adulterated and misbranded.
 5

6 196. At all times relevant all fifty States and the District of Columbia and
 7 Puerto Rico have codified and adopted the provisions of the Uniform Commercial
 8 Code: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-
 9 2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-
 10 313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. §
 11 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat.
 12 § 490:2- 313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind.
 13 Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. §
 14 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen.
 15 Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. §
 16 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code
 17 Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-
 18 313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law
 19 § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev.
 20 Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13
 21 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-
 22
 23
 24
 25
 26

1 313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-
2 2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va.
3 Code § 8.2- 313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev.
4 Code § 62A 2-313; Wis. Stat. Ann. § 402.313; and Wyo. Stat. § 34.1-2-313.
5

6 197. At the time that Defendant marketed and sold its Carvedilol, it
7 recognized the purposes for which the products would be used, and expressly
8 warranted the products were the same as FDA-approved Coreg, made in a cGMP-
9 compliant manner, were not contaminated with nitrosamines, and were not
10 adulterated or misbranded. These affirmative representations became part of the
11 basis of the bargain in every purchase or reimbursement by Plaintiff and other
12 Class Members including but not limited to express representations made in
13 referring to its Carvedilol.
14
15

16 198. Plaintiff and each member of the Class were reasonably expected
17 purchasers who would use, consume or be affected by (or whose insureds would
18 use, consume, or be affected by) the adulterated, misbranded, and sub-standard
19 Carvedilol manufactured and sold by Defendant.
20
21

22 199. Defendant breached its express warranties with respect to its
23 Carvedilol as it was not of merchantable quality, was not fit for their ordinary
24 purpose, was contaminated with nitrosamines, did not comply with cGMPs and
25 was adulterated and misbranded.
26

1 200. Plaintiff and each member of the Class would not have (and could
2 not have) paid for the Carvedilol had they known these drugs were not the same
3 as FDA-approved Coreg, did not contain the same ingredients or components or
4 impurities, did not have the same safety and efficacy profile of as FDA-approved
5 Coreg, and contained nitrosamines. They did not receive the expected benefit of
6 the bargain by receiving Carvedilol that contained undisclosed dangerous
7 nitrosamines and/or were made in a non-cGMP compliant manner, either of
8 which rendered the products adulterated, misbranded, illegal to sell, and therefore
9 worthless (or alternatively, certainly worth less).
10
11

12
13 201. Defendant's Carvedilol did not fulfill the intended purpose. Plaintiff
14 and other Class Members bargained for an adequately made, adequately labeled
15 product that did not pose significant undisclosed risks. But Defendant's
16 Carvedilol was not adequately made, was not adequately labeled, and posed
17 significant undisclosed risks, viz., it contained an undisclosed genotoxic
18 carcinogen. While Plaintiff and other Class Members do not seek damages for
19 any physical injuries, each of them (or, in the case of TPPs, each of their
20 insureds) have been exposed to a non-bargained for carcinogenic agent with
21 potent mutagenic properties that operates at the cellular and sub-cellular levels,
22 implicating future potential health consequences.
23
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26

1 202. As a direct and proximate result of Defendant's breach of express
2 warranties, Plaintiff and other Class Members have been injured and suffered
3 damages in the amount of the purchase price of their medications, the purchase
4 price of any replacement medications, the lost value of any non-returned product
5 rendered unusable after the recalls, and any consequential damages resulting from
6 the purchases, in that the Carvedilol they purchased was so inherently flawed,
7 unfit, or unmerchantable as to have little to no market value.
8

9
10 203. While Plaintiff and other Class Members do not seek damages for
11 any physical injuries, each of them (or, in the case of TPPs, each of their
12 insureds) have been exposed to a non-bargained for carcinogenic agent with
13 potent mutagenic properties that operates at the cellular and sub-cellular levels,
14 implicating future potential health consequences. This, combined with being
15 made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class
16 Members (or their insureds) suffering physical harm or impact from ingesting a
17 flawed product.
18

19
20 204. Pre-suit notice is not required, but even if it is, such notice was
21 provided to Defendant.
22

23
24 **COUNT II**
25 **BREACH OF IMPLIED WARRANTIES**

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

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.

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

3 207. Defendant was a merchant within the meaning of the above statutes.
4

5 208. Defendant's Carvedilol constituted "goods" or the equivalent within
6 the meaning of the above statutes. Defendant placed its Carvedilol in sealed
7 packaging or other closed containers and placed it on the market.
8

9 209. Defendant was obligated to provide Plaintiff and other Class
10 Members reasonably fit Carvedilol for the purpose for which the product was
11 sold, and to conform to the standards of the trade in which Defendant is involved
12 such that the product was of fit and merchantable quality.
13

14 210. Defendant knew or should have known that its Carvedilol was being
15 manufactured and sold for the intended purpose of human consumption as a
16 therapeutic equivalent to FDA-approved Coreg or an FDA-approved generic
17 equivalent (or is strictly liable in the event of lack of actual or constructive
18 knowledge), and impliedly warranted that its Carvedilol was of merchantable
19 quality and fit for that purpose.
20
21

22 211. Adulterated and misbranded drugs are illegal to sell. Nitrosamine
23 contamination, and manufacture in a non-cGMP compliant manner, each
24 independently establish a drug's adulteration or misbranding. Defendant's
25 distribution and sale of its Carvedilol was an implied affirmation that its
26

1 Carvedilol was not adulterated, i.e., did not contain any nitrosamine
2 contaminants, and was made in a cGMP-compliant manner. These express and
3 implied affirmations were false.
4

5 212. Further, Defendant impliedly affirmed in its product labeling (e.g.,
6 label, package insert, medication guide) that its Carvedilol was therapeutically
7 equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Coreg
8 and an FDA-approved generic equivalent. These affirmations were false.
9 Defendant's Carvedilol did *not* have the same safety profile as FDA-approved
10 Coreg or an FDA-approved generic equivalent. Defendant failed to disclose the
11 facts of nitrosamine contamination and manufacture in a non-cGMP compliant
12 manner. Defendant's Carvedilol further lacked the appropriate identity, quality,
13 and purity. Defendant's Carvedilol was not safe as warranted, given the lack of
14 appropriate cGMP-compliant manufacture and the presence of an undisclosed
15 contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.
16
17
18

19 213. Defendant's product labeling (e.g., label, package insert, medication
20 guide) were required to be truthful, accurate, and non-deceptive, and to
21 adequately advise of any precautions or safety-related risks. Defendant's
22 Carvedilol product labeling failed to do so, insofar as it did not disclose known or
23 knowable risks relating to nitrosamine contamination and that the Carvedilol was
24
25
26

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

3 214. Defendant's sale of Carvedilol impliedly warranted that the product
4 wase compliant with compendial standards, USP requirements, and Orange Book
5 requirements. These affirmations were false because Defendant's Carvedilol was
6 not therapeutically equivalent to FDA-approved Coreg or an FDA-approved
7 generic equivalent, with, inter alia, a different safety profile, different identity,
8 purity, and quality characteristics, and not made in a cGMP-compliant manner.
9

10
11 215. Defendant impliedly warranted that its Carvedilol was merchantable,
12 and fit for ordinary use, as an FDA-approved pharmaceutical that is
13 therapeutically equivalent to and the same as FDA-approved Coreg or an FDA-
14 approved generic equivalent. In other words, Defendant impliedly warranted that
15 its products were the same as FDA-approved Coreg or an FDA-approved generic
16 equivalent, in terms of therapeutic equivalence, safety profile, possessing the
17 same identity, purity, and quality, and assurance of being made in a cGMP-
18 compliant manner.
19

20
21 216. Defendant sold Carvedilol that it impliedly warranted were
22 compliant with cGMPs and were not adulterated or misbranded. Indeed, the very
23 fact Defendant sold Carvedilol in the stream of commerce warranted they were
24
25
26

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

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

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

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

1 220. Plaintiff and each other Class Member were the intended third-party
2 beneficiary recipients of all arrangements Defendant had with downstream
3 resellers of Defendant's Carvedilol. Plaintiff and each other Class Member were
4 those whose benefit any promises, affirmations, or warranties were made by
5 Defendant concerning Carvedilol, as they were the intended end purchasers and
6 end users (or, in the case of TPPs, their insureds were the intended end users) of
7 Defendant's Carvedilol, which Defendant knew by virtue of its position as
8 manufacturer and seller of the Carvedilol.
9

10
11 221. Defendant knew, or should have known, that its Carvedilol was
12 being manufactured and sold for the intended purpose of human consumption as
13 the therapeutic equivalent to FDA-approved Coreg or an FDA-approved generic
14 equivalent, with the same safety profile, identity, purity, and quality
15 characteristics, and manufactured in a cGMP-compliant manner.
16
17

18 222. Defendant breached its implied warranty because Defendant's
19 Carvedilol was not of merchantable quality, nor fit for the product's ordinary
20 purpose, and did not conform to the standards generally applicable to such goods.
21

22 223. Plaintiff and other Class Members purchased the Carvedilol in
23 reliance on Defendant's skill and judgment and the implied warranties of fitness
24 for the purpose.
25

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

1 Members.

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

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

1 227. As a direct and proximate result of Defendant's breach of implied
2 warranties, Plaintiff and other Class Members have been injured and suffered
3 damages in the amount of the purchase price of their medications, the purchase
4 price of any replacement medications, the lost value of any non-returned product
5 rendered unusable after the recalls, and any consequential damages resulting from
6 the purchases, in that the Carvedilol they paid for were so inherently flawed,
7 unfit, or unmerchantable as to have little to no market value.
8

9
10 228. While Plaintiff and other Class Members do not seek damages for
11 any physical injuries, each of them (or, in the case of TPPs, each of their
12 insureds) have been exposed to a non-bargained for carcinogenic agent with
13 potent mutagenic properties that operates at the cellular and sub-cellular levels,
14 implicating future potential health consequences. This, combined with being
15 made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class
16 Members (or their insureds) suffering physical harm or impact from ingesting a
17 flawed product.
18
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21 229. Pre-suit notice is not required, but even if it is, such notice was
22 provided to Defendant.
23

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

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

1 231. Defendant is a “warrantor” within the meaning of the Magnuson-
2 Moss Warranty Act.

3 232. Plaintiff and other Class Members are “consumers” within the
4 meaning of the Magnuson-Moss Warranty Act.
5

6 233. Defendant expressly or impliedly warranted its Carvedilol as alleged
7 in the First and Second Causes of Action.
8

9 234. Under 15 U.S.C. § 2310(d)(1), Plaintiff and other Class Members
10 were “damaged by the failure of a supplier, warrantor, or service contractor to
11 comply with any obligation under this chapter, or under a written warranty,
12 implied warranty, or service contract, may bring suit for damages and other legal
13 and equitable relief.” 15 U.S.C. § 2310(d)(1). Plaintiff sues pursuant to this
14 section to recover money damages and for legal and equitable relief on behalf of
15 themselves and the Class Members.
16
17

18 235. Defendant has not acted on the opportunity to cure its failure with
19 respect to its warranted Carvedilol.
20

21 236. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this
22 action, Plaintiff is entitled to receive an award of attorneys’ fees and expenses and
23 pray for the same.
24
25
26

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

1 guidance, regulatory guidance, and the scientific literature dating back decades.
2 Defendant certainly knew at least no later than July 2018 about the urgent need to
3 properly evaluate and test products for nitrosamines in the wake of the valsartan
4 recalls, and subsequent nitrosamine-related recalls. Defendant similarly knew or
5 should have known prior to initiating its Carvedilol recalls about that cGMP
6 deviations or failures concerning quality control and risk management may result
7 in the adulteration and misbranding of a drug product.
8
9

10 241. Defendant knew or should have known, or was deliberately
11 indifferent to knowing, the chemistry relevant to its Carvedilol manufacture
12 process. Appropriate, cGMP-compliant evaluation, testing, quality oversight, and
13 risk management would have identified the nitrosamine contaminants in
14 Defendant's Carvedilol, which by virtue of its manufacturing process is
15 reasonably expected to generate such contaminants in every batch or lot of
16 Carvedilol.
17
18

19 242. Adulterated and misbranded drugs are illegal to sell. Nitrosamine
20 contamination, and manufacture in a non-cGMP compliant manner, each
21 independently establish a drug's adulteration or misbranding. Defendant's
22 distribution and sale of its Carvedilol was a direct affirmation that its Carvedilol
23 was not adulterated, i.e., did not contain any nitrosamine contaminants, and was
24 made in a cGMP-compliant manner. These affirmations were false.
25
26

1 243. Further, Defendant affirmed in its product labeling (e.g., label,
2 package insert, medication guide) that its Carvedilol was therapeutically
3 equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Coreg
4 or as an FDA-approved generic equivalent. These affirmations were false.
5 Defendant's Carvedilol did *not* have the same safety profile as FDA-approved
6 Coreg or an FDA-approved generic equivalent. Defendant failed to disclose the
7 facts of nitrosamine contamination and manufacture in a non-cGMP compliant
8 manner. Defendant's Carvedilol further lacked the appropriate identity, quality,
9 and purity. Defendant's Carvedilol was not safe as represented, given the lack of
10 appropriate cGMP-compliant manufacture and the presence of an undisclosed
11 contaminant posed the unreasonable risk of genotoxicity and carcinogenicity.
12

13 244. Defendant's product labeling (e.g., label, package insert, medication
14 guide) were required to be truthful, accurate, and non-deceptive, and to
15 adequately advise of any precautions or safety-related risks. Defendant's
16 Carvedilol product labeling failed to do so, insofar as it did not disclose known or
17 knowable risks relating to nitrosamine contamination and that the Carvedilol was
18 not manufactured in a cGMP-compliant manner, and therefore there was no
19 adequate quality assurance.
20

21 245. Defendant's sale of Carvedilol represented the products were
22 compliant with compendial standards, USP requirements, and Orange Book
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1 requirements. These representations were false, because Defendant's Carvedilol
2 was not therapeutically equivalent to FDA-approved Coreg or an FDA-approved
3 generic equivalent, with inter alia a different safety profile, different identity,
4 purity, and quality characteristics, and not made in a cGMP-compliant manner.
5

6 246. Defendant omitted from its product labeling, other promotional
7 materials, and through its sale of Carvedilol that its Carvedilol contained a
8 dangerous, undisclosed, genotoxic, carcinogenic nitrosamine, and that the
9 Carvedilol was not made in a cGMP-compliant manner.
10

11 247. Defendant's product labeling (e.g., label, package insert, medication
12 guide) and other promotional materials contained, at best, half-truths about the
13 safety and cGMP compliance status of its Carvedilol. Once Defendant
14 voluntarily chose to speak about its Carvedilol, it had a duty to do so truthfully.
15 But it did not, given Defendant's knowledge of nitrosamine formation, its own
16 Carvedilol manufacturing process, and its own cGMP-compliance status. Failure
17 to correct its statements rendered them untruthful.
18
19
20

21 248. Defendant knowingly, or at least recklessly, represented that its
22 Carvedilol was manufactured in a cGMP manner and that its Carvedilol was what
23 it was supposed to be, when that was not the case. Rather, Defendant knew or
24 recklessly disregarded industry and regulatory guidance, and related risks of
25 nitrosamine potential if cGMP deviations or failures occurred (the absence of
26

1 such deviations or failures would mean that the nitrosamine contamination could
2 have and should have been discovered earlier), that were available in the public
3 domain and otherwise well prior to Defendant's recalls.
4

5 249. Defendant's actions had the effect of fraudulently inducing Plaintiffs
6 and other Class Members to pay in whole or in part for Defendant's Carvedilol
7 products that Defendant knew or should have known were not therapeutically
8 equivalent to or the same as FDA-approved Coreg or an FDA-approved generic
9 equivalent, contained undisclosed nitrosamines, were not made in a cGMP-
10 compliant manner, and were adulterated or misbranded. Plaintiff and other Class
11 Members would not have paid for Defendant's Carvedilol had they known the
12 truth. Indeed, Plaintiff and other Class Members could not have paid for
13 Defendant's Carvedilol had they known the truth because Defendant's Carvedilol
14 was illegally manufactured, illegally imported, illegally distributed, and illegally
15 sold to Plaintiff and Class Members based on Defendant's fraudulent
16 misrepresentations and omissions.
17
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21 250. Defendant knew, or reasonably should have known, that its
22 misrepresentations were materially false or misleading, or that the omission of
23 material facts rendered such representations false or misleading.
24

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

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

2 252. Defendant's misrepresentations and omissions were material.

3 253. Defendant actively concealed its misrepresentations and omissions
4 from Plaintiff and other Class Members, government regulators, and the public.
5

6 254. To the extent applicable, Defendant intended its misrepresentations
7 and omissions to induce Plaintiff and other Class Members to pay for Defendant's
8 Carvedilol.
9

10 255. But for these misrepresentations and omissions, Plaintiff and other
11 Class Members would not have paid for Defendant's Carvedilol.
12

13 256. To the extent applicable, Plaintiff and other Class Members were
14 justified in relying on Defendant's misrepresentations and omissions. The same or
15 substantively identical misrepresentations and omissions were communicated to
16 each Class Member, including through product labeling and other statements by
17 Defendant. No reasonable consumer or TPP would have paid what they did for
18 Defendant's Carvedilol but for Defendant's unlawful conduct. To the extent
19 applicable, reliance may be presumed in these circumstances.
20
21

22 257. Plaintiff and each member of the Class would not have (and could
23 not have) purchased the Carvedilol had they known these drugs were not the same
24 as FDA-approved Coreg or an FDA-approved generic equivalent, did not contain
25 the same ingredients, did not have the same safety and efficacy profile of as FDA-
26

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

7
8
9 258. A special relationship existed between Defendant, on the one hand,
10 and each Plaintiff and other Class Member, on the other.

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

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

- 22
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 - Alabama Code §§ 20-1-24 and -27(1);

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

1 Defendant's misrepresentations and omissions as alleged here.

2 263. While Plaintiff and other Class Members do not seek damages for
3 any physical injuries, each of them (or, in the case of TPPs, each of their
4 insureds) have been exposed to a non-bargained for carcinogenic agent with
5 potent mutagenic properties that operates at the cellular and sub-cellular levels,
6 implicating future potential health consequences. This, combined with being
7 made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class
8 Members (or their insureds) suffering physical harm or impact from ingesting a
9 flawed product.
10

11
12
13 **COUNT V**
14 **NEGLIGENT MISREPRESENTATION AND OMISSION**

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

17 265. Defendant had or undertook a duty to represent the quality, nature,
18 and characteristics of its Carvedilol accurately and truthfully.
19

20 266. Defendant failed to exercise ordinary care in making representations
21 (or in failing to disclose facts) concerning the quality, nature, and characteristics
22 of its Carvedilol, namely representing that its Carvedilol was therapeutically
23 equivalent to FDA-approved Coreg or an FDA-approved generic equivalent
24 despite nitrosamine contamination and failure to manufacture the Carvedilol in
25 compliance with cGMPs, rendering such representations false.
26

1 267. Defendant negligently misrepresented or omitted facts regarding the
2 quality, nature, and characteristics of its Carvedilol, namely failing to disclose
3 that its Carvedilol was not therapeutically equivalent to FDA-approved Coreg or
4 an FDA-approved generic equivalent as result of nitrosamine contamination and
5 failure to manufacture the Carvedilol in compliance with cGMPs.
6

7 268. Defendant's statements were false at the time the misrepresentations
8 were made (or at the time omissions were not made).
9

10 269. Defendant knew, or reasonably should have known, that its
11 representations alleged herein were materially false or misleading, or that its
12 omission of material facts rendered such representations false or misleading.
13 Defendant also knew, or had reason to know, that its misrepresentations and
14 omissions would induce Class members to pay for (directly or through
15 reimbursement) for Defendant's Carvedilol.
16
17

18 270. Defendant knew or should have known prior to initiating recalls in
19 the United States about the risks posed by nitrosamines as a result of industry and
20 regulatory guidance dating back decades, and the related risks of nitrosamine
21 potential in the event of cGMP deviations of failures concerning quality control
22 and risk management.
23
24

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

1 they were supposed to be, when that was not the case. Rather, Defendant knew or
2 recklessly disregarded industry and regulatory guidance, and related risks of
3 nitrosamine potential if cGMP deviations or failures occurred (the absence of
4 such deviations or failures would mean that the nitrosamine contamination could
5 have and should have been discovered earlier), that was available in the public
6 domain and otherwise well prior to Defendant's recalls.
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8

9 272. Defendant had direct or constructive knowledge of the risks of
10 nitrosamine contamination at least as early as 2018 (and likely much sooner)
11 because of other nitrosamine-related recalls. At that time, Defendant knew, and
12 certainly should have known, of the possibility of nitrosamine formation in its
13 Carvedilol, particularly because regulators including the FDA issued guidance in
14 the second half of 2018 and throughout 2019 that warned of the specific risk of
15 nitrosamine formation in chemical syntheses similar to those used by Defendant
16 to make its Carvedilol. Yet, Defendant sat by idly and did nothing until 2025.
17
18

19 273. The scientific literature warned of the need to test for nitrosamines at
20 least as early as 2006, if not earlier. Additionally, the literature suggests that
21 nitrosamine contamination occurred in Carvedilol potentially due to the similar
22 route of contamination that resulted in nitrosamine contamination of other recalls
23 years before Defendant's recalls.
24
25

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

1 or constructive knowledge about the risks posed by nitrosamines as a result of
2 industry and regulatory guidance dating back decades, the newer guidance in
3 2018 and 2019, other product recalls relating to nitrosamines, and the related risks
4 of nitrosamine potential in the event of cGMP deviations or failures concerning
5 quality control and risk management. But Defendant intentionally, recklessly, or
6 negligently disregarded that knowledge in making its representations that were
7 false or deceptive about its Carvedilol, namely, that it was not contaminated with
8 nitrosamines and/or was manufactured in a cGMP compliant manner, each of
9 which was false and either of which rendered the Carvedilol adulterated and
10 misbranded.
11
12
13

14 275. Defendant's specific statements and omissions go beyond simply
15 naming its product "Carvedilol." Defendant's representations and labeling carried
16 with it the assurance, as required by state laws incorporating federal law, that the
17 product did not contain any undisclosed contaminants, that Carvedilol had the
18 same efficacy *and* safety profile as FDA-approved Coreg or an FDA-approved
19 generic equivalent, and that the Carvedilol was not made in a non-cGMP
20 compliant manner. Defendant omitted the material information that Carvedilol
21 was not what it purported to be, insofar as it contained undisclosed dangerous
22 nitrosamine contaminants, was not as safe as FDA-approved Coreg or an FDA-
23 approved generic equivalent, and was not made in a cGMP-compliant manner.
24
25
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1 As such, the Carvedilol was adulterated and misbranded, which is illegal to sell.
2 Plaintiff or Class Members could never buy an adulterated drug; thus,
3 Defendant's distribution and sale of its Carvedilol in the first instance was a
4 representation that the drugs were not adulterated.
5

6 276. A special relationship existed between Defendant, on the one hand,
7 and each Plaintiff and other Class Member, on the other.
8

9 277. This relationship arose because Defendant, as a pharmaceutical drug
10 manufacturer owes a distinct duty to consumers of its highly-regulated
11 pharmaceutical products, to be ingested by Plaintiffs and other Class Members
12 (or, in the case of TPPs, their insureds). Defendant's superior knowledge and
13 economic position vis-à-vis the true nature of its Carvedilol further bolstered the
14 special relationship and distinct duty.
15
16

17 278. In addition, state drug regulation laws impose an independent duty
18 on drug manufacturers to ensure that end purchasers (or their insureds) receive
19 drugs that are made in accordance with cGMPs. This duty emanates from each
20 state's adoption or adherence to federal cGMP and adulteration standards,
21 including but not limited to the following parallel state statutes:
22

- 23 • Alabama Code §§ 20-1-24 and -27(1);
- 24 • Alaska Statutes § 17.20.290(a)(1);
- 25 • Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- 26

- 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);

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

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19 279. Defendant failed to comply with federal cGMPs and federal
20 adulteration standards, as incorporated by state law, which created independent
21 state-law duties beyond any contractual relationship between the parties.
22

23 280. As a direct and proximate result of Defendant's acts and omissions
24 described herein, Plaintiff and other Class Members have suffered harm and will
25 continue to do so.
26

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

3 282. Defendant intended its misrepresentations or omissions to induce
4 Plaintiff and Class Members to make purchases or reimbursements of Carvedilol
5 or had reckless disregard for same.
6

7 283. But for these misrepresentations (or omissions), Plaintiff and other
8 Class Members would not have made purchases of Defendant's Carvedilol.
9

10 284. Plaintiff and other Class Members were justified in relying on
11 Defendant's misrepresentations or omissions. The same or substantively identical
12 misrepresentations were communicated, or the same or substantively identical
13 omissions were not communicated, to each Class Member.
14

15 285. Plaintiff and other Class Members were damaged by reason of
16 Defendant's misrepresentations or omissions alleged here.
17

18 286. While Plaintiff and other Class Members do not seek damages for
19 any physical injuries, each of them (or, in the case of TPPs, each of their
20 insureds) have been exposed to a non-bargained for carcinogenic agent with
21 potent mutagenic properties that operates at the cellular and sub-cellular levels,
22 implicating future potential health consequences. This, combined with being
23 made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class
24 Members (or their insureds) suffering physical harm or impact from ingesting a
25
26

1 flawed product.

2 **COUNT VI**
3 **VIOLATION OF STATE CONSUMER PROTECTION LAWS**

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

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

- 7
- 8 a. Defendant has engaged in unfair competition or unfair or
9 deceptive acts or practices in violation of Ala. Code § 8-19-1,
10 *et seq.*;
11
- 12 b. Defendant has engaged in unfair competition or unfair or
13 deceptive acts or practices in violation of Alaska Stat. §
14 45.50.471, *et seq.*;
15
- 16 c. Defendant has engaged in unfair competition or unfair or
17 deceptive acts or practices in violation of Arizona Rev. Stat. §
18 44-1522, *et seq.*;
19
- 20 d. Defendant has engaged in unfair competition or unfair or
21 deceptive acts or practices in violation of Ark. Code § 4-88-
22 101, *et seq.*;
23
- 24 e. Defendant has violated the California Unfair Competition Law
25 by engaging in unfair or deceptive acts or practices in
26 violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

- 1 f. Defendant has violated the California Consumers Legal
2 Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;
- 3 g. Defendant has violated the California False Advertising Law,
4 Cal. Bus. & Prof. Code §§ 17500, *et seq.*;
- 5
6 h. Defendant has engaged in unfair competition or unfair or
7 deceptive acts or practices in violation of Colo. Rev. Stat. § 6-
8 1-105, *et seq.*;
- 9
10 i. Defendant has engaged in unfair competition or unfair or
11 deceptive acts or practices in violation of Conn. Gen. Stat. §
12 42-110b, *et seq.*;
- 13
14 j. Defendant has engaged in unfair competition or unfair or
15 deceptive acts or practices in violation of 6 Del. Code § 2511,
16 *et seq.*;
- 17
18 k. Defendant has engaged in unfair competition or unfair or
19 deceptive acts or practices in violation of D.C. Code § 28-
20 3901, *et seq.*;
- 21
22 l. Defendant has engaged in unfair competition or unfair or
23 deceptive acts or practices in violation of Fla. Stat. § 501.201,
24 *et seq.*;
- 25
26

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

4
5 n. Defendant has engaged in unfair competition or unfair or
6 deceptive acts or practices in violation of Haw. Rev. Stat. §
7 480, *et seq.*;

8
9 o. Defendant has engaged in unfair competition or unfair or
10 deceptive acts or practices in violation of Idaho Code § 48-
11 601, *et seq.*;

12
13 p. Defendant has engaged in unfair competition or unfair or
14 deceptive acts or practices in violation 815 ILCS 505/1, *et*
15 *seq.*;

16
17 q. Defendant has engaged in unfair competition or unfair or
18 deceptive acts or practices in violation of Ind. Code Ann. § 24-
19 5-0.5.1, *et seq.*;

20
21 r. Defendant has engaged in unfair competition or unfair or
22 deceptive acts or practices in violation of Iowa Code Ann. §
23 714H, *et seq.*;

24
25 s. Defendant has engaged in unfair competition or unfair or
26 deceptive acts or practices in violation of Kan. Stat. § 50-623,

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.*;

1 z. Defendant has engaged in unfair competition or unfair or
2 deceptive acts or practices in violation of Minn. Stat. §
3 325F.67, *et seq.*;

4
5 aa. Defendant has engaged in unfair competition or unfair or
6 deceptive acts or practices in violation of Miss. Code Ann. §
7 75-24-1, *et seq.*;

8
9 bb. Defendant has engaged in unfair competition or unfair or
10 deceptive acts or practices in violation of Vernon's Mo. Rev.
11 Stat. § 407.0 10, *et seq.*;

12
13 cc. Defendant has engaged in unfair competition or unfair or
14 deceptive acts or practices in violation of Mont. Code § 30-14-
15 101, *et seq.*;

16
17 dd. Defendant has engaged in unfair competition or unfair or
18 deceptive acts or practices in violation of Neb. Rev. Stat. § 59-
19 1601, *et seq.*;

20
21 ee. Defendant has engaged in unfair competition or unfair or
22 deceptive acts or practices in violation of Nev. Rev. Stat. §
23 598.0903, *et seq.*;

24
25 ff. Defendant has engaged in unfair competition or unfair or
26 deceptive acts or practices in violation of N.H. Rev. Stat. §

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.*;

1 mm. Defendant has engaged in unfair competition or unfair
2 or deceptive acts or practices in violation of Ohio Rev. Stat. §
3 1345.01, *et seq.*;

4
5 nn. Defendant has engaged in unfair competition or unfair or
6 deceptive acts or practices in violation of Okla. Stat. tit. 15 §
7 751, *et seq.*;

8
9 oo. Defendant has engaged in unfair competition or unfair or
10 deceptive acts or practices in violation of Or. Rev. Stat. §
11 646.605, *et seq.*;

12
13 pp. Defendant has engaged in unfair competition or unfair or
14 deceptive acts or practices in violation of 73 Pa. Stat. § 201-1,
15 *et seq.*;

16
17 qq. Defendant has engaged in unfair competition or unfair or
18 deceptive acts or practices in violation of R.I. Gen. Laws § 6-
19 13.1-1, *et seq.*;

20
21 rr. Defendant has engaged in unfair competition or unfair or
22 deceptive acts or practices in violation of S.C. Code Laws §
23 39-5-10, *et seq.*;

24
25 ss. Defendant has engaged in unfair competition or unfair or
26 deceptive acts or practices in violation of S.D. Code Laws §

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

1 deceptive acts or practices in violation of W. Va. Code § 46A-
2 6-101, *et seq.*;

3 aaa. Defendant has engaged in unfair competition or unfair
4 or deceptive acts or practices in violation of Wis. Stat. §
5 100.20, *et seq.*;

6 bbb. Defendant has engaged in unfair competition or unfair
7 or deceptive acts or practices in violation of Wyo. Stat. § 40-
8 12-100, *et seq.*; and

9 ccc. Defendant has engaged in unfair competition or unfair
10 or deceptive acts or practices in violation of 23 L.P.R.A. §
11 1001, *et seq.*, the applicable statute for the Commonwealth of
12 Puerto Rico.

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

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

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

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

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

2 293. Defendant, through a pervasive pattern of unfair, false, misleading,
3 and deceptive statements and omissions, manufactured and sold Carvedilol
4 without revealing to Plaintiff and other Class Members that the products were not
5 FDA-approved drugs, were not therapeutically equivalent to FDA-approved
6 Coreg or an FDA-approved generic equivalent, were contaminated with
7 nitrosamines, were not manufactured in accordance with cGMPs, posed
8 significant undisclosed safety risks, and were adulterated and misbranded.
9

10 294. In addition to these material omissions, Defendant affirmatively and
11 unfairly or deceptively misrepresented material facts including, that its Carvedilol
12 was not a new unapproved drug, was therapeutically equivalent to FDA-approved
13 Coreg or an FDA-approved generic equivalent, did not contain nitrosamines, was
14 manufactured in accordance with cGMPs, did not carry any significant
15 undisclosed safety risks, and was neither adulterated nor misbranded.
16

17 295. Defendant knew or should have known, prior to initiating its recalls,
18 about the risks posed by nitrosamine as a result of industry guidance, regulatory
19 guidance, and scientific literature dating back decades. Defendant certainly knew
20 at least no later than July 2018 about the urgent need to properly evaluate and test
21 products for nitrosamines in the wake of other product recalls related to
22 nitrosamines. Defendant similarly knew or should have known prior to initiating
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1 its Carvedilol recalls that cGMP deviations or failures concerning quality control
2 and risk management may result in the adulteration and misbranding of a drug
3 product.
4

5 296. Defendant knew or should have known, or was deliberately
6 indifferent to knowing, the chemistry relevant to its Carvedilol manufacture
7 process. Appropriate, cGMP-compliant evaluation, testing, quality oversight, and
8 risk management would have identified the nitrosamine contaminants in
9 Defendant's Carvedilol, which by virtue of its manufacturing process is
10 reasonably expected to generate such contaminants in every batch or lot of VCDs.
11
12

13 297. Adulterated and misbranded drugs are illegal to sell. Nitrosamine
14 contamination, and manufacture in a non-cGMP compliant manner, each
15 independently establish a drug's adulteration or misbranding. Defendant's
16 distribution and sale of its Carvedilol was a direct affirmation that its Carvedilol
17 was not adulterated, i.e., did not contain any nitrosamine contaminants, and was
18 made in a cGMP-compliant manner. These affirmations were false.
19
20

21 298. Further, Defendant affirmed in its product labeling (e.g., label,
22 package insert, medication guide) that its Carvedilol was therapeutically
23 equivalent (i.e., had the same efficacy *and* safety profile) as FDA-approved Coreg
24 or an FDA-approved generic equivalent. These affirmations were false.
25 Defendant's Carvedilol did *not* have the same safety profile as FDA-approved
26

1 Coreg or an FDA-approved generic equivalent. Defendant failed to disclose the
2 facts of nitrosamine contamination and manufacture in a non-cGMP compliant
3 manner. Defendant's Carvedilol further lacked the appropriate identity, quality,
4 and purity. Defendant's Carvedilol was not safe as represented, given the lack of
5 appropriate cGMP-compliant manufacture and the presence of an undisclosed
6 contaminant that posed the unreasonable risk of genotoxicity and carcinogenicity.
7
8

9 299. Defendant's product labeling (e.g., label, package insert, medication
10 guide) was required to be truthful, accurate, and non-deceptive, and to adequately
11 advise of any precautions or safety-related risks. Defendant's Carvedilol product
12 labeling failed to do so, insofar as it did not disclose known or knowable risks
13 relating to nitrosamine contamination or that the Carvedilol was not manufactured
14 in a cGMP-compliant manner, and therefore there was no adequate quality
15 assurance.
16
17

18 300. Defendant's sale of Carvedilol represented that the products were
19 compliant with compendial standards, USP requirements, and Orange Book
20 requirements. These representations were false because Defendant's Carvedilol
21 was not therapeutically equivalent to FDA-approved Coreg or an FDA-approved
22 generic equivalent with inter alia a different safety profile, different identity,
23 purity, and quality characteristics, and was not made in a cGMP-compliant
24 manner.
25
26

1 301. Defendant omitted from its representations and product labeling that
2 its Carvedilol contained a dangerous, undisclosed, genotoxic, carcinogenic
3 nitrosamine, and that the Carvedilol was not made in a cGMP-compliant manner.
4

5 302. Defendant's representations and product labeling (e.g., label,
6 package insert, medication guide) contained, at best, half-truths about the safety
7 and cGMP compliance status of its Carvedilol. Once Defendant voluntarily chose
8 to speak about its Carvedilol, it had a duty to do so truthfully. But it did not,
9 given Defendant's knowledge of nitrosamine formation, its own Carvedilol
10 manufacturing process, and its own cGMP-compliance status. Failure to correct
11 its statements rendered them untruthful.
12
13

14 303. Defendant knowingly, or at least recklessly, represented that its
15 Carvedilol was manufactured in a cGMP manner and that its Carvedilol was what
16 it was supposed to be, when that was not the case. Rather, Defendant knew or
17 recklessly disregarded industry and regulatory guidance, and related risks of
18 nitrosamine formation if cGMP deviations or failures occurred (the absence of
19 such deviations or failures would mean that the nitrosamine contamination could
20 have and should have been discovered earlier), that was available in the public
21 domain and otherwise well prior to Defendant's recalls.
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23
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25 304. Defendant's actions had the effect of fraudulently inducing Plaintiff
26 and other Class Members to pay in whole or in part for Defendant's Carvedilol—

1 products which Defendant knew or should have known were not therapeutically
2 equivalent to or the same as FDA-approved Coreg or an FDA-approved generic
3 equivalent, contained undisclosed nitrosamines, were not made in a cGMP-
4 compliant manner, and were adulterated or misbranded. Plaintiff and other Class
5 Members would not have paid for Defendant's Carvedilol had they known the
6 truth. Indeed, Plaintiff and other Class Members could not have paid for
7 Defendant's Carvedilol had they known the truth because Defendant's Carvedilol
8 was illegally manufactured, illegally imported, illegally distributed, and illegally
9 sold to Plaintiff and Class Members based on Defendant's fraudulent
10 misrepresentations and omissions.
11
12
13

14 305. Defendant's conduct was unfair, deceptive, and unconscionable in
15 that it included (i) the manufacture and sale of products with a heightened
16 propensity to cause physical injuries and (ii) misrepresentations and omissions of
17 material facts concerning the characteristics and safety of Carvedilol that
18 offended public policy; was immoral, unethical, oppressive, outrageous,
19 unscrupulous, and substantially injurious; and caused substantial harm that
20 greatly outweighs any possible utility from the conduct.
21
22
23

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

1 adulterated. Despite the risks to Plaintiff and other Class Members, Defendant
2 elected not to conduct risk assessment, quality analysis, and testing that would
3 have prevented the Plaintiff's exposure. The failure to ensure the safety of
4 prescription drugs sold to consumers offends established public policy and
5 constitutes immoral, unethical, oppressive, outrageous, unscrupulous, and
6 substantially injurious conduct. The failure to test causes substantial harm to
7 consumers that greatly outweighs any possible utility. The act of sale of the
8 Carvedilol by Defendant constituted an affirmative act in conjunction with the
9 accompanying labels and other documents, representing that the Carvedilol was
10 safe, of the specified quality, and met all applicable standards, including but not
11 limited to USP, Orange Book, and other applicable regulations.
12

13
14
15 307. Defendant engaged in deceptive conduct because the affirmative and
16 implied misrepresentations and omissions at issue were likely to, and in fact did,
17 mislead, deceive, or cheat reasonable purchasers including Plaintiff and other
18 Class Members, who relied on these misrepresentations and omissions. In
19 addition, the misrepresentations and omissions were the type that tend to create a
20 false impression. Reasonable consumers, including Plaintiff and other Class
21 Members, would have found it material to their purchasing or reimbursing
22 decisions that the Carvedilol was not therapeutically equivalent to FDA-approved
23 Coreg or an FDA-approved generic equivalent, was an unapproved new drug,
24
25
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1 contained undisclosed safety risks, was contaminated with nitrosamines, was not
2 made in accordance with cGMPs, and was adulterated, misbranded, and illegal to
3 sell. Knowledge of these facts would have been a substantial factor in Plaintiff's
4 and other Class Members' decisions to pay for Carvedilol, and they would not
5 have made these payments in the absence of Defendant's wrongful conduct.
6

7 308. Defendant's advertising and statements in the conduct of business
8 were deceptive because the misrepresentations and omissions had the capacity,
9 tendency, and effect of deceiving reasonable consumers, including the Plaintiff.
10 Reasonable consumers, including Plaintiff and other Class Members, would have
11 found it material to their purchasing decisions that the Carvedilol was not
12 therapeutically equivalent to FDA-approved Coreg or an FDA-approved
13 equivalent, was an unapproved new drug, contained undisclosed safety risks,
14 was contaminated with nitrosamines, were not made in accordance with cGMPs,
15 and were adulterated, misbranded, and illegal to sell. Knowledge of these facts
16 would have been a substantial factor in Plaintiff's and other Class Members'
17 decisions to pay for Carvedilol, and they would not have made these payments in
18 the absence of Defendant's wrongful conduct.
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23 309. To the extent applicable, Defendant knew, intended, or should have
24 known that its fraudulent and deceptive acts, omissions, or concealment would
25 and did induce reliance and that reliance can be presumed under the
26

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

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

22 311. Defendant engaged in unfair and deceptive conduct by misleading,
23 through affirmative misrepresentation and omission, consumers and TPPs as to
24 the content of the Carvedilol. In fact, the products never should have been offered
25 to consumers in the first place, and could not have been in the absence of the
26

1 stated wrongful conduct.

2 312. As demonstrated herein, Defendant engaged in patently unlawful
3 conduct through their manufacturing, receipt, and sale of contaminated,
4 adulterated and misbranded prescription drugs. *See, e.g.*, 21 U.S.C. §§ 331(a)-(c),
5 (g) (as incorporated by states' laws).
6

7 313. Defendant's conduct actually and proximately caused actual
8 damages to Plaintiff and other Class Members. Absent Defendant's unfair and
9 deceptive conduct, Plaintiff and other Class Members would have behaved
10 differently and would not have purchased the Carvedilol.
11
12

13 314. Defendant's misrepresentations and omissions induced Plaintiff and
14 other Class Members to purchase the Carvedilol they would not otherwise have
15 purchased, economically harming and damaging each of them.
16

17 315. As a direct and proximate result of Defendant's unfair methods of
18 competition and unfair or deceptive acts or practices, Plaintiff and other Class
19 Members have suffered damages—an ascertainable loss—in an amount to be
20 proved at trial.
21

22 316. While Plaintiff and other Class Members do not seek damages for
23 any physical injuries, each of them (or, in the case of TPPs, each of their
24 insureds) have been exposed to a non-bargained for carcinogenic agent with
25 potent mutagenic properties that operates at the cellular and sub-cellular levels,
26

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

5
6 317. Pre-suit notice is not required, but even if it is, such notice was
7 provided to Defendant.
8

9 **COUNT VII**
10 **NEGLIGENCE**

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

13 319. Defendant owed a duty to Plaintiffs and the Class to use and exercise
14 reasonable and due care in the manufacturing, distribution, and sale of its
15 Carvedilol.
16

17 320. Defendant owed a duty to Plaintiff and the Class to ensure that the
18 Carvedilol it sold in the United States was therapeutically and pharmaceutically
19 equivalent to FDA-approved Coreg or an FDA-approved generic equivalent,
20 complied with cGMPs, and was not adulterated or misbranded.
21

22 321. Defendant owed a duty of care to Plaintiff and the Class because
23 they were the foreseeable, reasonable, and probable user of Carvedilol and
24 victims of Defendant's fraudulent and deceptive activities. Defendant knew, or
25 should have known, that its Carvedilol was not therapeutically or
26

1 pharmaceutically equivalent to FDA-approved Carvedilol or an FDA-approved
2 generic equivalent, did not comply with cGMPs, and was adulterated and
3 misbranded, and Defendant was in the best position to uncover and remedy these
4 shortcomings.
5

6 322. Defendant failed to do this. Defendant inadequately oversaw the
7 manufacture and sale of its own Carvedilol. Defendant knew that ignoring the
8 manufacturing issues surrounding its Carvedilol would damage Plaintiff and the
9 Class and increase its own profits.
10

11 323. Defendant maintained or should have maintained a special
12 relationship with Plaintiff and the Class, as they were obligated to ensure that its
13 Carvedilol complied with cGMPs and was not adulterated or misbranded.
14

15 324. Defendant had a duty to exercise reasonable care in the manufacture,
16 quality control, and distribution of Carvedilol. Defendant's failure to exercise
17 this duty, in spite of knowing or recklessly disregarding the risks of nitrosamine
18 contamination and cGMP deviations or failures that meant Defendant could not
19 assure that its Carvedilol was of appropriate quality, identity, purity, or strength,
20 was a breach of Defendant's duty.
21

22 325. Defendant's own actions and inactions created a foreseeable risk of
23 harm to Plaintiff and the Class. Defendant's misconduct included, but was not
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25
26

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

3 326. Defendant knew, or reasonably should have known, that its
4 representations alleged herein were materially false or misleading, or that
5 omission of material facts rendered such representations false or misleading.
6 Defendant also knew, or had reason to know, that its misrepresentations and
7 omissions would induce Plaintiff and Class members to pay or reimburse for
8 Defendant's Carvedilol.
9

10 327. Defendant knew or should have known prior to initiating recalls
11 about the risks posed by nitrosamines as a result of industry and regulatory
12 guidance dating back decades, and the related risks of nitrosamine potential in the
13 event of cGMP deviations or failures concerning quality control and risk
14 management.
15

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

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

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

22 331. Thus, prior to initiating recalls of Carvedilol, Defendant had actual
23 or constructive knowledge about the risks posed by nitrosamines as a result of
24 industry and regulatory guidance dating back decades, the newer guidance in
25 2018 and 2019, and the related risks of nitrosamine potential in the event of
26

1 cGMP deviations or failures concerning quality control and risk management.
2 But Defendant intentionally, recklessly, or negligently disregarded that
3 knowledge in making its representations that were false or deceptive about its
4 Carvedilol, namely, that its Carvedilol was not contaminated with nitrosamines
5 and/or was manufactured in a cGMP compliant manner, each of which was false
6 and either of which rendered the Carvedilol adulterated and misbranded.
7
8

9 332. Defendant's specific statements and omissions go beyond simply
10 naming their drug "Carvedilol." Defendant's marketing and labeling carried with
11 it the assurance, as required by state laws incorporating federal law, that the
12 product did not contain any undisclosed contaminants, that Carvedilol had the
13 same efficacy *and* safety profile as FDA-approved Coreg or an FDA-approved
14 generic equivalent, and that the Carvedilol was not made in a non-cGMP
15 compliant manner. Defendant omitted the material information that Carvedilol
16 was not what it purported to be, insofar as it contained undisclosed dangerous
17 nitrosamine contaminants, was not as safe as FDA-approved Coreg or an FDA-
18 approved generic equivalent, and was not made in a cGMP-compliant manner. As
19 such, the Carvedilol was adulterated and misbranded, which is illegal to sell. No
20 Plaintiff or Class Member could ever buy an adulterated drug; thus, Defendant's
21 distribution and sale of its Carvedilol in the first instance was a representation that
22 the drugs were not adulterated.
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1 333. A special relationship existed between Defendant, on the one hand,
2 and each Plaintiff and other Class Member, on the other. This relationship arose
3 because Defendant, as a pharmaceutical drug manufacturer, owes a distinct duty
4 to consumers of its highly regulated pharmaceutical products, to be ingested by
5 Plaintiff and other Class Members (or, in the case of TPPs, their insureds).
6 Defendant's superior knowledge and economic position vis-à-vis the true nature
7 of its Carvedilol further bolstered the special relationship and distinct duty.
8
9

10 334. In addition, state drug regulation laws impose an independent duty
11 on drug manufacturers to ensure that end purchasers (or their insureds) receive
12 drugs that are made in accordance with cGMPs. This duty emanates from each
13 state's adoption or adherence to federal cGMP and adulteration standards,
14 including but not limited to the following parallel state statutes:
15
16

- 17 • Alabama Code §§ 20-1-24 and -27(1);
- 18 • Alaska Statutes § 17.20.290(a)(1);
- 19 • Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- 20 • Arkansas Code § 20-56-215(1);
- 21 • California Health and Safety Code §§ 111295 and 111400;
- 22 • Colorado Statutes §§ 25-5-403(1)(a),(b) and -414(1)(c);
- 23 • Title 16, Delaware Code §§ 3302 and 3303(2);
- 24 • District of Columbia Code § 48-702(2);
- 25
- 26

- 1 • Florida Statutes §§ 499.005(1) and .006(3);
- 2 • Georgia Code § 26-3-3(1);
- 3 • Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- 4 • Idaho Code § 37-115(a);
- 5 • Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- 6 • Iowa Code §§ 126.3(1) and .9(1)(c);
- 7 • Kentucky Statutes § 217.175(1);
- 8 • Maryland Code, Health–General §§ 21-216(c)(5)(2) and -256(1);
- 9 • Massachusetts General Laws chapter 94 §§ 186 and 190;
- 10 • Minnesota Statutes §§ 151.34(1) and .35(1);
- 11 • Missouri Statutes § 196.015(1);
- 12 • Montana Code §§ § 50-31-305(3) and -501(1);
- 13 • Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- 14 • Nevada Statutes § 585.520(1);
- 15 • New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- 16 • New Mexico Statutes §§ 26-1-3(A) and -10(A);
- 17 • New York Education Law § 6811;
- 18 • North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- 19 • Ohio Code § 3715.52(A)(1);
- 20 • 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.

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

1 insureds) have been exposed to a non-bargained for carcinogenic agent with
2 potent mutagenic properties that operates at the cellular and sub-cellular levels,
3 implicating future potential health consequences. This, combined with being
4 made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class
5 Members (or their insureds) suffering physical harm or impact from ingesting a
6 flawed product.
7

8
9 **COUNT VIII**
10 **NEGLIGENCE PER SE**

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

13 340. Defendant owed a duty to Plaintiff and the Class to use and exercise
14 reasonable and due care in the manufacture, distribution, and sale of its
15 Carvedilol.
16

17 341. Defendant's statements were false at the time the misrepresentations
18 were made (or at the time omissions were not made).
19

20 342. Defendant knew, or reasonably should have known, that its
21 representations alleged herein were materially false or misleading, or that
22 omission of material facts rendered such representations false or misleading.
23 Defendant also knew, or had reason to know, that its misrepresentations and
24 omissions would induce Class Members to pay (directly or through
25 reimbursement) for Defendant's Carvedilol.
26

1 343. Defendant knew or should have known prior to initiating recalls
2 about the risks posed by nitrosamines as a result of industry and regulatory
3 guidance dating back decades, and the related risks of nitrosamine potential in the
4 event of cGMP deviations or failures concerning quality control and risk
5 management.
6

7 344. Defendant knowingly, recklessly, or negligently represented that its
8 VCDs were manufactured in a cGMP manner and that its VCDs were what they
9 were supposed to be, when that was not the case. Rather, Defendant knew or
10 recklessly disregarded industry and regulatory guidance, and related risks of
11 nitrosamine potential if cGMP deviations or failures occurred (the absence of
12 such deviations or failures would mean that the nitrosamine contamination could
13 have and should have been discovered earlier), that was available in the public
14 domain and otherwise well prior to Defendant's recalls.
15
16

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

3 346. The scientific literature warned of the need to test for nitrosamines at
4
5 least as early as 2006, if not earlier. Additionally, the literature suggests that
6 nitrosamine contamination occurred in Carvedilol potentially due to the similar
7 route of contamination that resulted in nitrosamine contamination of other drugs
8 recalled in 2018, 2019, and thereafter, years before Defendant's own recalls.

9
10 347. Thus, prior to initiating recalls of Carvedilol, Defendant had actual
11 or constructive knowledge about the risks posed by nitrosamines as a result of
12 industry and regulatory guidance dating back decades, the newer guidance in
13 2018 and 2019 and thereafter, and the related risks of nitrosamine potential in the
14 event of cGMP deviations or failures concerning quality control and risk
15 management. But Defendant intentionally, recklessly, or negligently disregarded
16 that knowledge in making its representations that were false or deceptive about its
17 Carvedilol, namely, that its Carvedilol was not contaminated with nitrosamines
18 and/or was manufactured in a cGMP compliant manner, each of which was false
19 and either of which rendered the Carvedilol adulterated and misbranded.

20
21 348. Defendant's specific statements and omissions go beyond simply
22 naming their drug "Carvedilol." Defendant's representations and labeling carried
23 with it the assurance, as required by state laws incorporating federal law, that the
24
25
26

1 product did not contain any undisclosed contaminants, that Carvedilol had the
2 same efficacy *and* safety profile as FDA-approved Coreg or an FDA-approved
3 generic equivalent, and that Carvedilol was not made in a non-cGMP compliant
4 manner. Defendant omitted the material information that Carvedilol was not
5 what it purported to be, insofar as its Carvedilol contained undisclosed dangerous
6 nitrosamine contaminants, was not as safe as FDA-approved Coreg or an FDA-
7 approved generic equivalent, and was not made in a cGMP-compliant manner.
8
9 As such, Carvedilol was adulterated and misbranded, which is illegal to sell. No
10 Plaintiff or Class Member could ever buy an adulterated drug; thus, Defendant's
11 distribution and sale of its Carvedilol in the first instance was a representation that
12 the drug was not adulterated.

13
14
15 349. A special relationship existed between Defendant, on the one hand,
16 and each Plaintiff and other Class Member, on the other.

17
18 350. This relationship arose because Defendant, as a pharmaceutical drug
19 manufacturer owes a distinct duty to consumers of its highly regulated
20 pharmaceutical products, to be ingested by Plaintiff and other Class Members (or,
21 in the case of TPPs, their insureds). Defendant's superior knowledge and
22 economic position vis-à-vis the true nature of its Carvedilol further bolstered the
23 special relationship and distinct duty.

24
25
26 351. In addition, state drug regulation laws impose an independent duty

1 on drug manufacturers to ensure that end purchasers (or their insureds) receive
2 drugs that are made in accordance with cGMPs. This duty emanates from each
3 state's adoption or adherence to federal cGMP and adulteration standards,
4 including but not limited to the following parallel state statutes:
5

- 6 a. Alabama Code §§ 20-1-24 and -27(1);
- 7 b. Alaska Statutes § 17.20.290(a)(1);
- 8 c. Arizona Statutes §§ 32-1965(1), (2) and -1966(3);
- 9 d. Arkansas Code § 20-56-215(1);
- 10 e. California Health and Safety Code §§ 111295 and 111400;
- 11 f. Colorado Statutes §§ 25-5-403(1)(a), (b) and -414(1)(c);
- 12 g. Title 16, Delaware Code §§ 3302 and 3303(2);
- 13 h. District of Columbia Code § 48-702(2);
- 14 i. Florida Statutes §§ 499.005(1) and .006(3);
- 15 j. Georgia Code § 26-3-3(1);
- 16 k. Hawaii Revised Statutes §§ 328-6(1) and -14(1)(B)(ii);
- 17 l. Idaho Code § 37-115(a);
- 18 m. Chapter 410, Illinois Statutes §§ 620/3.1 and /14(a)(2)(B);
- 19 n. Iowa Code §§ 126.3(1) and .9(1)(c);
- 20 o. Kentucky Statutes § 217.175(1);
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- 1 p. Maryland Code, Health-General §§ 21-216(c)(5)(2) and -
2 256(1);
- 3 q. Massachusetts General Laws chapter 94 §§ 186 and 190;
- 4 r. Minnesota Statutes §§ 151.34(1) and .35(1);
- 5 s. Missouri Statutes § 196.015(1);
- 6 t. Montana Code §§ 50-31-305(3) and -501(1);
- 7 u. Nebraska Revised Statutes §§ 71-2461(2) and -2481;
- 8 v. Nevada Statutes § 585.520(1);
- 9 w. New Hampshire Revised Statutes §§ 146:1(I) and :4(V);
- 10 x. New Mexico Statutes §§ 26-1-3(A) and -10(A);
- 11 y. New York Education Law § 6811;
- 12 z. North Dakota Century Code §§ 19-02.1-02(1) and .1-13(3);
- 13 aa. Ohio Code § 3715.52(A)(1);
- 14 bb. Oklahoma Statutes title 63 § 1-1402(a);
- 15 cc. Title 35, Pennsylvania Statutes § 780-113(a)(1);
- 16 dd. Title 21, Rhode Island General Laws § 21-3-3(1);
- 17 ee. South Carolina Code §§ 39-23-30(a)(2)(B) and -80(A)(1);
- 18 ff. South Dakota Code §§ 39-15-3 and -10;
- 19 gg. Title 18, Vermont Statutes § 4052(1);
- 20 hh. Virginia Code § 54.1-3457(1);
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1 ii. Revised Code of Washington §§ 69.04.040, 69.04.430;

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

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

4
5 352. Defendant failed to comply with federal cGMPs and federal
6 adulteration standards, as incorporated by state law, which created independent
7 state-law duties beyond any contractual relationship between the parties.
8

9 353. As a result of Defendant's failures to do so, Defendant's own actions
10 and inactions created a foreseeable risk of harm to Plaintiff and the Class.
11

12 354. As a direct and proximate result of Defendant's negligent conduct,
13 Plaintiff and the Class have suffered injury and are entitled to damages in an
14 amount to be proven at trial.
15

16 355. While Plaintiff and other Class Members do not seek damages for
17 any physical injuries, each of them (or, in the case of TPPs, each of their
18 insureds) have been exposed to a non-bargained for carcinogenic agent with
19 potent mutagenic properties that operates at the cellular and sub-cellular levels,
20 implicating future potential health consequences. This, combined with being
21 made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class
22 Members (or their insureds) suffering physical harm or impact from ingesting a
23 flawed product.
24
25
26

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.

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

3 361. Plaintiff and other Class Members are entitled to seek and do seek
4 restitution from Defendant as well as an order from this Court requiring
5 disgorgement of all profits, benefits, and other compensation obtained by
6 Defendant by virtue of its wrongful conduct.
7

8 362. While Plaintiff and other Class Members do not seek damages for
9 any physical injuries, each of them (or, in the case of TPPs, each of their
10 insureds) have been exposed to a non-bargained for carcinogenic agent with
11 potent mutagenic properties that operates at the cellular and sub-cellular levels,
12 implicating future potential health consequences. This, combined with being
13 made in a manner not compliant with cGMPs, resulted in Plaintiff and other Class
14 Members (or their insureds) suffering physical harm or impact from ingesting a
15 flawed product.
16
17
18

19
20 **PRAYER FOR RELIEF**

21 For these reasons, Plaintiff prays for the following judgment:

- 22 a. An order certifying this action as a class action;
23 b. An order appointing Plaintiff as Class Representative, and
24 appointing undersigned counsel as Class Counsel to represent
25 the Class;
26

- 1 c. A declaration that Defendant is liable under each and every
2 one of the above-enumerated causes of action;
- 3 d. An order awarding appropriate preliminary and/or final
4 injunctive relief against the conduct of Defendant described
5 above;
6
- 7 e. Payment to Plaintiff and Class Members of all damages,
8 exemplary or punitive damages, and/or restitution associated
9 with the conduct for all causes of action in an amount to be
10 proven at trial, including but not limited to the full amounts
11 paid or reimbursed for the Carvedilol; the costs to replace or
12 return Carvedilol because of recalls; and the increases in the
13 amounts paid for non-adulterated, non-misbranded, Carvedilol
14 in the wake of the recalls;
15
- 16 f. An award of attorneys' fees, expert witness fees, and costs, as
17 provided by applicable law or as would be reasonable from
18 any recovery of monies recovered for or benefits bestowed on
19 the Class Members;
20
- 21 g. An award of statutory penalties to the extent available;
22
- 23 h. Interest as provided by law, including but not limited to pre-
24 judgment and post-judgment interest as provided by rule or
25
26

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.

TOUSLEY BRAIN STEPHENS PLLC

/s/Kim D. Stephens, P.S.

Kim D. Stephens, P.S., WSBA #11984

/s/Cecily C. Jordan

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This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Glenmark's Carvedilol Blood Pressure Drug Contaminated with Probable Carcinogen, Class Action Lawsuit Alleges](#)
