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**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT OF CALIFORNIA**

RAYMOND J. COLLETTE,

Plaintiff,

v.

WYETH PHARMACEUTICALS, INC.; SANDOZ PHARMACEUTICALS CORPORATION d/b/a SANDOZ, INC.; NOVARTIS PHARMACEUTICALS CORPORATION; and EON LABS, INC., f/k/a EON LABS MANUFACTURING, INC.

Defendants.

Case No.

**COMPLAINT FOR DAMAGES:**

1. STRICT PRODUCTS LIABILITY – FAILURE TO WARN;
2. NEGLIGENCE – FAILURE TO WARN;
3. NEGLIGENCE –MARKETING AND SALE;
4. NEGLIGENCE *PER SE*;
5. FRAUD AND DECEIT;
6. VIOLATION OF CAL. BUS. & PROF. CODE § 17200, *et seq.*;
7. VIOLAION OF CAL. CIVIL CODE § 1750, *et seq.* (Injunctive Relief Only)

JURY TRIAL DEMANDED

Plaintiff Raymond J. Collette, by and through Plaintiff's attorneys listed above, for Plaintiff's Complaint and Demand for Jury against Defendants, alleges as follows, all on information and belief, which facts are likely to have evidentiary support after a reasonable opportunity for investigation and discovery, except as to the allegations of Plaintiff's personal experiences, which are alleged on personal knowledge:

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## PARTIES, JURISDICTION AND VENUE

**Plaintiff**

1. On personal knowledge, Plaintiff RAYMOND J. COLLETTE (hereinafter "Plaintiff" or Mr. Collette") is an individual who resides in Glenn County, California. Plaintiff was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and, as a proximate cause thereof, developed amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In December of 2011, Plaintiff was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. Plaintiff was subsequently prescribed a "rhythm medication" by his cardiologist in January 2012, which turned out to be Amiodarone. Plaintiff received no warning about the potential life threatening complications, nor did any Medication Guide accompany the purchase of Amiodarone.

2. On personal knowledge, at the time Amiodarone was prescribed to him, Plaintiff was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did Plaintiff receive the FDA-mandated Medication Guide to be distributed with each prescription of Amiodarone that warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

3. Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff Raymond Collette consumed Amiodarone; more particularly, Amiodarone manufactured by SANDOZ PHARMACEUTICALS CORPORATION and EON LABS, INC. and actively promoted for "off-label" use by Defendants.

**Defendants**

4. Defendant Wyeth Pharmaceuticals, Inc. (hereinafter "Wyeth") is a Delaware corporation maintaining its principal place of business in Madison, New Jersey. This Defendant conducts substantial, systemic, continuous, and regular business in California and was involved in the distribution, marketing, promotion, sale, labeling, and design, of Amiodarone (sold under

brand names Cordarone®, Nexterone and Pacerone) in the State of California and the United States, as detailed below.

5. Defendant Sandoz Pharmaceuticals Corporation (hereinafter "Sandoz"), was a New Jersey corporation with its principal place of business in New Jersey. Defendant Sandoz Pharmaceuticals Corporation was acquired by Defendant Novartis Pharmaceuticals Corporation on October 30, 2009 and is a wholly-owned subsidiary Novartis Pharmaceuticals Corporation. Defendant Sandoz Pharmaceuticals Corporation, currently doing business as Sandoz, Inc., regularly conducts business in California and throughout the United States and is involved in the manufacture, distribution, marketing, sale, labeling, and design of Amiodarone, including the Amiodarone ingested by Plaintiff.

6. Defendant Novartis Pharmaceuticals Corporation (hereinafter "Novartis"), formerly known as Sandoz Pharmaceuticals Corporation, is a Delaware corporation maintaining its principal place of business in East Hanover, New Jersey, and incorporated in and authorized to do business in the State of California. This Defendant conducts substantial, systemic, continuous, and regular business in California and the United States.

7. Defendant Eon Labs, Inc. (hereinafter "Eon"), f/k/a Eon Labs Manufacturing, Inc., is a Delaware corporation with its principal place of business in Laurelton, New York. Eon Labs, Inc. was purchased by Novartis in 2005, who then merged it as a subsidiary of Sandoz, Inc. Eon Labs manufactures many generic products, including the Amiodarone ingested by Plaintiff. Eon Labs regularly conducts business in California and the United States.

8. At all times relevant to this Complaint, the Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing in interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Amiodarone throughout the State of California, and Amiodarone ingested by the Plaintiff. Defendants have engaged in a calculated and coordinated campaign of silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the use of Cordarone®/Amiodarone,

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and did so because the prospect of significant future profits outweighed their concern regarding health and safety issues, all to the significant detriment of the public and Plaintiff Collette.

9. Each of the above named Defendants acted in concert and both aided and abetted and conspired with each other not to disclose the material facts stated herein, with such conduct authorized and/or acted on by and through its officers, employees, agents, servants, and/or representatives, including those actively engaged in the legal defense of Defendants.

10. Each reference made in this Complaint to any corporate Defendant includes its predecessors, successors, parents, subsidiaries, affiliates, and divisions of the corporation for the corresponding time period they were in any way involved in the design testing, manufacture, distribution, sale or use of Amiodarone.

11. Jurisdiction is proper in this District because the Plaintiff and Defendants reside in different states and the amount in controversy exceeds $75,000. *See* 28 U.S.C. § 1332(a). Venue is proper in this District because the Amiodarone ingested by Plaintiff and provided without the required Medication Guide was likely distributed to Plaintiff from this District. *See* 28 U.S.C. § 1391(b).

12. Defendants conduct business in the State of California and this District. Defendants' commercial activities in the State of California and this District include, but are not limited to, the marketing, sale and distribution of Cordarone®, and its generic bioequivalent, Amiodarone.

## FACTUAL BACKGROUND

13. All prescription drugs require approval by the Food and Drug Administration (hereinafter "FDA") before the drug may be marketed for a specific designated use. Manufacturers of new drugs must submit a new drug application (hereinafter "NDA") to the FDA. An NDA must include information about the drug's safety and efficiency, gleaned from clinical trials for a specific designated use.[1] It must also propose a label reflecting appropriate

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[1] 21 U.S.C. § 355(a)-(b).

use, warnings, precautions, and adverse reactions.[2]

14. For generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the federal Food, Drug, and Cosmetic Act (hereinafter "FDCA") and is referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an "abbreviated new drug application" (hereinafter "ANDA") procedure for generic manufacturers.[3] Generic manufacturers are not required to repeat the clinical trials conducted by name brand manufacturers.[4] ANDAs are approved based on the initial safety profile of the name brand drug and are subject to all post-marketing events and post-sales events, including, but not limited to, collecting, tracking, and reporting adverse incident reports regarding the drug.

15. Amiodarone, as the drug is commonly known, was developed in Belgium in the 1960's as a drug for treating a common heart condition known as angina. At that time, Amiodarone was released for marketing in most countries OTHER than the United States.

16. The misunderstanding and use of Amiodarone as a drug "with little side effects" became widespread except in the United States. In the 1970's American physicians began obtaining Amiodarone from Canada and Europe for use in their patients with life-threatening arrhythmias who did not respond to other drugs. This activity was sanctioned by the FDA but only on a limited basis. Initial results were promising; by the mid-1980's literally tens of thousands of Americans were taking the drug without FDA approval or testing. Physicians in the United States apparently monitored the conditions of their patients more rigorously than their colleagues around the world, because they found the drug produced a bizarre series of side effects that doctors around the world seemed to have missed and that were not caught because of the lack of testing or randomized trials.

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[2] 21 C.F.R. § 201.56.

[3] 21 U.S.C. § 355(j).

[4] Although clinical trials were not completed by the brand manufacturer of Amiodarone.

17. The FDA was essentially forced to release Amiodarone for marketing in the United States by the mid-1980's when foreign manufacturers of the drug threatened to cut off the supply to American patients after having supplied the drug for free to thousands of Americans for over five years.

18. In 1985, Defendant Wyeth received FDA approval[5] to market and sell the anti-arrhythmic heart medication Cordarone® (Amiodarone hydrochloride is the generic formulation) under a "special needs" approval without the usually mandated rigorous and FDA-approved double-blind randomized clinical trials. Although the FDA has urged Wyeth to conduct randomized clinical trials, such trials have never been conducted. The FDA approval for Cordarone® thus remains a special and unusual "special needs" approval, as the customary and rigorous randomized clinical trials now required by the FDA for all NDAs or ANDAs have never been conducted for Amiodarone. Defendant Wyeth was the initial manufacturer, promoter and distributor or "brand manufacturer" of Cordarone® in the United States.

19. Wyeth's Cordarone® was approved by the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies. It was not approved for the treatment of the atrial fibrillation that Plaintiff suffers from. In addition, the FDA required any person who was prescribed this medication to first receive a "Medication Guide."[6] Distributing this Medication Guide was the responsibility of all Defendants. However, Defendant Wyeth aggressively and successfully marketed Cordarone® for inappropriate "off-label" uses as a "first line anti-arrhythmic therapy" and the Defendants did not arrange for distribution of the Medication Guide.

20. Defendant Wyeth instituted and maintained an active promotional campaign to physicians touting the anti-arrhythmic benefits of Amiodarone. The campaigns were aggressive

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[5] *See* NDA 18-972, Approval Letter, December 24, 1985.

[6] Medication Guide for Amiodarone HCI. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf.

and in many situations focused on the use of the drug for atrial fibrillation, even though such general use was not approved by the FDA, and failed to warn prescribing physicians of the potential dangers associated with Amiodarone toxicity and dangers to atrial fibrillation patients. Defendant Wyeth's campaigns were so pervasive and effective that for an entire generation of physicians, the drug wrongfully became a first-line therapy for atrial fibrillation because physicians were not warned of many of the potential dangers of the drug or that it had never been approved for such use by the FDA. Defendant Wyeth's fraudulent and misleading marketing campaigns resulted in warning letters from the FDA to stop the false and misleading promotion of the drug, where such promotion downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy.[7] The FDA letters noted that it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug.[8] The purpose of this federal requirement is to protect patients by ensuring drug manufacturers test prospective uses of their drugs in randomized and well-controlled clinical trials to determine whether the drug is safe and effective for such specific designated uses. These requirements are meant to ensure that drug companies such as Defendants would give physicians and medical personnel trustworthy information so that medications are appropriately prescribed.

21. Any specifically prescribed uses beyond those approved by the FDA are deemed "off-label" because they have not been approved by the FDA. While a pharmaceutical company is permitted to disseminate certain information about off-label uses, such dissemination must adhere to strict requirements. For instance, the manufacturer must submit an application to the FDA seeking approval of the drug for off-label use; the manufacturer must provide its marketing materials to the FDA prior to dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically sound

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[7] Warnings by the FDA to Wyeth began as early as 1988. http://www.mcclatchydc.com/2003/11/04/28118/fda-oversight-of-off-label-drug.html.

[8] *See* 21 U.S.C. §§ 331(d), 352(f), and 355.

information . . . necessary to provide objectivity and balance."[9] Defendants failed to do so. The dissemination of information in violation of these provisions violates the FDCA and state law.[10] This law also requires pharmaceutical companies to furnish federal regulators with advance copies of the information they disseminate.[11] Any deviation from these requirements violates FDA regulations.

22. Defendants Sandoz, Eon and Novartis ("Sandoz/Novartis") received approval for the manufacture, marketing, sale and distribution of the generic formulation of Amiodarone hydrochloride in 1998.[12] As with all generic bioequivalent approvals, Sandoz/Novartis were required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA. [13]

23. Defendants Sandoz/Novartis took advantage of the pervasive brand innovation promotional activities of Defendant Wyeth, and the Sandoz/Novartis' version of the drug directly benefited from the decades of marketing of the drug for "off-label" uses by Defendant Wyeth. The version of the drug produced by Sandoz/Novartis was also subject to the same advertising, marketing, and promotional requirements and restrictions set forth by the FDA for Defendant Wyeth in their advertising, marketing, and promotion of the drug Cordarone®. Sandoz/Novartis were required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings, and medication guides with information exactly as required of the original brand formulation manufacturer, Wyeth, as updated as directed by the FDA.[14]

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[9] 21 U.S.C. § 360aaa, *et seq.*

[10] 21 U.S.C. § 331(z); Cal. Health & Safety Code §§ 109875 *et. seq.*

[11] 21 U.S.C. § 360aaa.

[12] The approval letter noted on the FDA database is addressed to Eon Labs Manufacturing, Inc. and dated December 23, 1998. http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/75315ltr.pdf.

[13] *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

[14] *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

24. As with all generic bioequivalent approvals, Defendants Sandoz/Novartis were required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand formulation manufacturer, Defendant Wyeth, and as updated as directed by the FDA.[15] The Sandoz/Novartis generic version of the drug directly benefited from the decades of marketing of the drug for "off-label" uses by Defendant Wyeth as well as their own promotional activities.[16] Sandoz/Novartis promotes and advertises Amiodarone on its own website and in its product catalog.

25. Prior to being prescribed Amiodarone, Plaintiff Raymond Collette was diagnosed with mild atrial fibrillation that was not deemed life threatening. He was not in a medical situation of "last resort" as to the management of his atrial fibrillation, which was the only approved use of Amiodarone. Correction or treatment of atrial fibrillation was never an FDA approved use of Cordarone® or Amiodarone.

26. In January of 2012, as a result of the long-term and pervasive promotional activities of brand innovator Defendant Wyeth to an entire generation of physicians, along with the continuing sales efforts of Defendants Sandoz/Novartis, Dr. James Yhip prescribed Mr. Collette a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were of the generic brand version of Amiodarone manufactured by Sandoz. Mr. Collette filled the prescription and ingested the drug Amiodarone according to the instructions. Dr. Yhip was apparently a victim of Defendant Wyeth's long term and successful brand innovator promotional efforts, as well as Defendants Sandoz/Novartis' sales efforts that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

27. Mr. Collette was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. More

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[15] *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

[16] *See* Application 75-188 Approval Letter to Robert A. Fermia dated February 24, 1999.

important, Mr. Collette did not receive the required Medication Guide from Defendants for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by the Defendants to the pharmacists for distribution to Plaintiff with his prescription. Because he did not receive the Medication Guide that Defendants were required by law to provide him, Plaintiff received and ingested a mislabeled drug. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including Amiodarone, and Mr. Collette's prescription was for an "off-label" use and was also provided without the benefit of the FDA-mandated Medication Guide. Plaintiff was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

28. In addition to not receiving the Medication Guide, Mr. Collette was not provided up-to-date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. The Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to persons such as Mr. Collette. Had he been provided the Medication Guide, Mr. Collette would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

29. This off-label prescription and distribution of the drug to control a non-life threatening atrial fibrillation, which also is a direct result of the long-term promotional efforts of Defendant Wyeth and the continuing sales efforts of Defendants Sandoz/Novartis and without the required Medication Guide, was a producing and proximate cause of Plaintiff's injuries from Amiodarone toxicity. Each manufacturer who ships a container of an FDA-approved drug product that also requires distribution of a Medication Guide is responsible for ensuring that Medication Guides are available in quantity for distribution to all patients with each prescription. Defendants are manufacturers as defined by the FDA. The FDA has recognized that "it is important that patients receive appropriate risk information in the form of Medication Guides in order to make informed decisions about certain prescribed medications." The Medication Guides are to specifically provide information directly to the patient outside of the interaction with the physician. It is important to note that the FDA has mandated that the warnings included in the Medication Guides go directly to the distributor and via the distributor and pharmacists

directly to the patient as an important notification distributed outside and in addition to any warning or information that is provided by the physician. Failure by Defendants to provide the Medication Guide results in the distribution of a mislabeled and illegal drug.

30. The serious side effects outlined in the Medication Guide, all of which Mr. Collette experienced after taking Amiodarone, included lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression.[17]

31. Amiodarone causes additional horrific side effects that have resulted in its restricted use in the United States, including causing blindness as it causes deposits to form on the cornea of the eyes. Amiodarone causes a very disfiguring blue-grey discoloration of the skin, generally in areas of exposure to the sun. Amiodarone often sensitizes the skin to sunlight so that even trivial exposure results in severe sunburns. Amiodarone causes hypothyroidism-low thyroidism. Some patients develop hyperthyroidism-high thyroid, which is more dangerous and more difficult to treat. Amiodarone can cause liver toxicity; therefore, liver enzymes need to be periodically monitored. Amiodarone can cause severe gastric reflux, caused by a paralysis of the sphincter at the end of the esophagus.

32. The most serious side effect of Amiodarone and the one requiring the patient Medication Guide is pulmonary toxicity-lung disease. Amiodarone produces two types of lung disease -- first, acute pulmonary syndrome, which looks and acts like typical pneumonia, with a sudden onset of cough and shortness of breath, a condition that improves once Amiodarone is stopped. The second type is more dangerous and life-threatening. This condition involves a gradual, almost unnoticeable, stiffening of the lungs that both the doctor and patient can overlook until finally severe irreversible lung damage has been done. This condition can occur quickly after taking the drug or can occur years after the drug has begun. Lung toxicity has been found by the FDA to be in 17% of those taking the drug, and fatalities from pulmonary toxicity have

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[17] Medication Guide for Amiodarone HCI. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf.

been found to be 10% of those taking the drug. These statistics come from those taking the drug for conditions the drug is not approved for-atrial fibrillation, as well as the ventricular condition it is approved for as a drug of last resort after other treatments have been tried and have failed.

33. Because Plaintiff was not provided a Medication Guide he did not know that Amiodarone "should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias" and even then only after "other treatments did not work or were not tolerated."[18] Mr. Collette did not know that any other use such as the use for his atrial fibrillation was considered to be "off-label" or of the corresponding dangers associated with such uses.

34. Because his pharmacist was not provided a Medication Guide to give directly to him outside of his doctor's office or as required by FDA regulations by the Defendants, Mr. Collette did not know "the medicine stays in your body for months after treatment is stopped."[19] However, the effects of Amiodarone are extremely long lasting. Amiodarone is fat-soluble, and tends to concentrate in tissues including fat, muscle, liver, lungs, and skin. It confers a high volume of distribution and a long half-life; the amount of time it takes for one-half of an administered drug to be lost through biological processes (metabolism and elimination). Because of this long half-life, Amiodarone's dangerous properties continue to cause injuries in patients such as Plaintiff long after he ceased using the drug, including serious pulmonary injuries. This information was unknown to Mr. Collette due to the failure of the Defendants to provide the Medication Guide, an illegal act that has been continuous and on-going.

35. The National Consumer Pharmacy Association has identified the failure of manufacturers to ensure the distribution of Medication Guides as a significant safety issue, and has called on the FDA to "enforce current FDA MedGuide regulations holding manufacturers accountable for providing Medication Guides in sufficient number or the means to produce

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[18] Medication Guide for Amiodarone HCI. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf.

[19] Medication Guide for Amiodarone HCI. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf.

Medication Guides in sufficient number, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product."[20]

36. The need for the Medication Guide was so great the FDA not only replaced package inserts, but "all" other means of providing information to consumers of the dangers of the drug. According to the FDA, the Medication Guide replaces the previous "package inserts" or any other means by which the manufacturers may attempt to warn consumers of the effects of the drugs Cordarone or Amiodarone. Without distributing the guides, these drugs are "mislabeled," "misbranded," "adulterated" and illegally sold. Defendants are responsible for the consumer receiving the FDA-approved Medication Guide with each Amiodarone prescription. Strict liability is imposed on the sellers of "mislabeled," "misbranded," "adulterated" and illegal drugs. This is a "non-delegable" duty that cannot be accomplished by other means.

**Plaintiff's Use of Amiodarone and Resulting Injuries**

37. As a result of Defendants' illegal, off-label promotion and distribution of Amiodarone as a viable treatment for atrial defibrillation without the required Medication Guide and as a "first line" arrhythmia drug, Plaintiff and Plaintiff's physician were unaware that Mr. Collette would be exposed to the risks of pulmonary fibrosis and other injuries. Beginning in approximately August of 2012, Plaintiff began to experience many of the symptoms outlined in the Medication Guide, which include shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. Mr. Collette was admitted to the hospital with an initial diagnosis of interstitial pneumonia, and the pulmonologist treating him discontinued his use of Amiodarone. Eventually as Plaintiff's condition worsened, a high definition CT scan was performed, which revealed lung changes not typical of pneumonia. After spending almost a month in the hospital, including a large amount of time in DCU on a ventilator, Mr. Collette was discharged with a diagnosis of amiodarone-induced pulmonary fibrosis.

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[20] Use of Medication Guides to Distribute Drug Risk Information to Patients, Colleen Brennan, R.Ph.; Bryan Ziegler, Pharm.D., MBA.

38. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened making it difficult for lungs to work properly.

39. Prior to developing amiodarone-induced pulmonary fibrosis, Mr. Collette was a remarkably healthy and active 72 year-old. He spent a great deal of time gardening and tending to livestock. Shortly before this injury, Mr. Collette had gone on a vacation to New Mexico and Colorado, which involved lengthy, high altitude hikes that Plaintiff easily completed. Mr. Collette is now a shadow of his former self. After developing amiodarone-induced pulmonary fibrosis, Mr. Collette could not walk across the room on 100% oxygen. Mr. Collette also lost almost 40 pounds of weight and suffers from a litany of other health problems related to his use of Amiodarone, including hyperthyroidism and diabetes caused by the massive amounts of prednisone used to treat his amiodarone-induced pulmonary fibrosis.

40. The link between Plaintiff's injuries and Defendants' wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Mr. Collette did not learn that by law he was supposed to receive the Medication Guide with his prescription of Amiodarone until then. Additionally, it was not until then that Mr. Collette learned that Amiodarone was not FDA approved for the treatment of atrial fibrillation and that it was used on him solely on an "off label" basis. It was not until then that Plaintiff knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

41. For the reasons detailed below, the running of any applicable statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' conspiracy to fraudulently conceal the true facts detailed herein through the use of affirmative misrepresentations and omissions of material fact from Plaintiff and Plaintiff's physician of the true risks associated with Amiodarone. As a result

of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physician were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those injuries were the direct and proximate result of the wrongful acts and omissions of material facts by Defendants.

**A. Cordarone®, Concealment, and the Off-Label Promotional Scheme By Defendant Wyeth**

42. As noted above, on or about December 24, 1985, Defendant drug manufacturer Wyeth introduced Cordarone® into the United States' stream of commerce. Wyeth received approval for Cordarone® from the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies and was accompanied by a Medication Guide. The bioequivalent manufactured by Defendants Sandoz/Novartis received approval from the FDA in 1998 under the same approval guidelines by the FDA as for Cordarone®, including the requirement that Sandoz/Novartis provide patients with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.[21]

43. The FDA's early specific enforcement actions regarding the marketing and labeling of the drug Cordarone®, include:

a. On or about October 7, 1986: label revision;

b. On or about May 15, 1987: label revision;

c. On or about August 7, 1987: package change;

d. On or about October 28, 1987: manufacturing changes;

e. On or about June 29, 1988: label revision;

f. On or about September 14, 1988: label revision;

g. On or about December 13, 1988: package change;

[21] *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

h. On or about February 2, 1989: label revision;

i. On or about July 28, 1989: formulation revision;

j. On or about August 9, 1990: label revision;

k. On or about August 9, 1990: manufacturing change;

l. On or about April 14, 1994: label revision;

m. On or about October 15, 1995: label revision;

n. On or about June 15, 1998: label revision;

o. On or about January 5, 1999: label revision;

p. On or about October 8, 1999: label revision;

q. On or about December 18, 1999: label revision;

r. On or about September 20, 2002: control supplement;

s. On or about December 18, 2002: label revision;

t. On or about April 30, 2003: label revision;

u. On or about May 6, 2003: label revision; and

v. On or about May 21, 2004: label revision.

44. On or about December 15, 1989, and subsequently in 1992, 1998, and thereafter, the FDA sent violation communications to Wyeth regarding the FDA's determination that Wyeth had violated the FDCA and its implementing regulation by, *inter alia*, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Cordarone®. Wyeth misrepresented Cordarone's® indications and usage, efficacy, risks, and benefits. Further, Wyeth failed to submit marketing materials to the FDA, in violation of the FDCA.

45. In May of 1995, the Australian Government's Therapeutic Goods Administration ("TGA") (that country's counterpart to the U.S. FDA), issued an Australian Adverse Drug Reactions Bulletin, emphasizing that Amiodarone was appropriate only for use in the treatment of ventricular and supraventricular arrhythmias. Notably, this Bulletin highlighted that "the drug [Amiodarone] is known to have multiple adverse effects, which can involve most organ systems," and again stressed that "Amiodarone is only to be used in patients with serious

arrhythmias where there is no safer drug therapy." Defendants were aware of this finding and thus that any off-label promotion was improper and unsafe for patients.

46. On or about April 29, 1996, the FDA required Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Carcinogenesis;

b. Mutagenesis;

c. Impairment of fertility, pregnancy; and

d. Neonatal hypo- or hyperthyroidism.

47. The severity of catastrophic adverse reactions, including death, led Wyeth to discontinue production and distribution of Cordarone® in Canada on or about September 10, 1996.

48. On or about February 11, 1997, the FDA issued a warning letter to Wyeth regarding Cordarone's® understated or incorrect labeling and warnings based on the FDA's medical research. Thereafter, on or about April 16, 1997, Wyeth changed its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Loss of vision;

b. Impairment of vision, including optic neuritis, optic neuropathy, corneal lesions, lens opacities, optic disk damage, papilledema, retinal hemorrhage and degeneration, photophobia;

c. Liver injury;

d. Pregnancy;

e. Adult Respiratory Distress Syndrome;

f. Angioedema; and

g. Mortality.

49. In 1998, the FDA issued a Written Request for Pediatric Studies under Section 505A of the Act to Wyeth regarding Cordarone®. The apparent basis for this request was that insufficient tests, surveys, and studies had been conducted regarding Cordarone® consumption

by pediatric patients, although there was knowledge by Defendants and other drug manufacturers and in the medical community that off-label use of Cordarone® in pediatric patients was becoming more and more common.

50. Also in 1998, the FDA issued a letter to Wyeth requiring that company to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Mortality (based upon the European Infarct Amiodarone Trial and Canadian Myocardial Infarct Trial);

b. Precautions regarding volatile anesthetic agents for Amiodarone users undergoing surgery;

c. Carcinogenesis;

d. Mutagenesis;

e. Impairment of fertility, pregnancy; and

f. Neonatal hypo- or hyperthyroidism.

51. On or about December 6-10, 1998, Wyeth sponsored a CME for the 33rd Midyear Clinical Meeting of the American Society of Health-System Pharmacists. This CME was for healthcare providers, including pharmacists, as part of the on-going promotion of Cordarone® for off-label purposes. As part of the CME, Wyeth produced and distributed to attendees, a 68-page official looking, "peer review appearing" magazine, "The Pharmacist Reporter (July 1999, Vol. 4, No. 5)." This publication was actually a promotional bulletin highlighting Wyeth's goal for Cordarone®: increased off-label use. Among the topics addressed in various articles in "The Pharmacist Reporter," several of which appear to soften, downplay, and/or minimize Cordarone's® devastating side effects, were the following:

a. "An Aggressive Treatment Strategy for Atrial Fibrillation";

b. "Use of Amiodarone in Patients Undergoing Cardiothoracic Surgery"; and

c. "A Possible New Standard of Care for Prehospital Cardiac Arrest."

52. On or about October 8, 1999, the FDA issued a letter to Wyeth requiring Defendant Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Clinical pharmacology and pharmokinetics, in that food consumption increases Cordarone's® absorption rate;

b. Geriatric use, whereby clinical studies of Cordarone® in persons 65 and older had not been conducted; and

c. Dosage and administration, in that food consumption must be addressed in dosing and loading doses are to be used.

53. On or about January 12, 1999, the FDA issued a letter to Wyeth requiring Defendant Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding geriatric use, whereby clinical studies of Amiodarone in persons 65 and older had not been conducted.

54. On or about February 12, 1999, the FDA issued a letter to Wyeth requiring Defendant Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the effects of food consumption on dosage and administration.

55. In February of 2002, the Australian Government's TGA issued an Australian Adverse Drug Reactions Bulletin, alerting healthcare professionals in that country that numerous adverse medical events associated with Cordarone® had been reported to the TGA in 2002 and 2001, including Cordarone® induced pulmonary toxicity and deaths. The TGA warning contained the following important information for healthcare professionals, which Defendants concealed from patients and healthcare professionals in the United States:

> "Although commonly insidious in onset, amiodarone—induced pulmonary toxicity may develop rapidly. The lowest effective dose should be used, and patients should be instructed to report any dysponea or non-productive cough. Amiodarone also has other toxicities including hepatotoxicity which can cause cirrhosis and hepatic failure, cardiovascular effects including bradycardia and tachycardia, skin reactions including photosensitivity and discolouration, neurotoxicity including ataxia and peripheral neuropathy, as well as both corneal deposits and hyper- and hypothyroidism."

56. On or about December 18, 2002, the FDA issued a letter to Wyeth requiring Defendant Wyeth to change its labeling, warnings, and packaging for Cordarone®, specifically,

adding new warnings or revising minimalist warnings regarding adverse drug interactions with immunosuppressant static drugs, resulting in rhabdomyolysis.

57. On or about December 19, 2002, the FDA issued a warning letter to Wyeth requiring Defendant to correct understated warnings and/or issue new warnings regarding the following:

a. Acute onset (days to weeks) of pulmonary toxicity;

b. Patients having preexisting pulmonary disease have poorer prognosis if pulmonary toxicity develops; and

c. Post-marketing reports include possible fatal respiratory disorders (including distress, failure, arrest, ARDS, fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, and pulmonary infiltrates).

58. In 2003, the FDA issued a warning letter to Wyeth, requiring Defendant Wyeth to change its labeling, warnings, and packaging for Cordarone®, specifically, adding new warnings or revising minimalist warnings regarding the following:

a. worsened arrhythmia;

b. thyroid abnormalities;

c. drug interactions (protease inhibitors, histamine antagonists, immunosuppressives, antibiotics, cardiovasculars, anti-arrhythmics, anti-hypertensives, anticoagulants);

d. other substance (grapefruit juice, herbal supplements) interactions;

e. electrolyte disturbances; and

f. nursing mothers passing the drug to newborns through breast milk.

59. In 2003, the FDA sent violation communications to Defendant Wyeth regarding the FDA's determination that Defendant had violated the FDCA and its implementing regulation by, *inter alia*, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Cordarone® by children and pregnant women. Thereafter, Defendant notified physicians to stop prescribing Cordarone® to children and pregnant women because of the serious risk of permanent injuries.

60. Despite all this information in its exclusive possession, Defendant Wyeth's pharmaceutical sales and marketing directors encouraged their respective sales representatives to

visit physicians' offices throughout the United States to over-promote the drug for off-label use, such as atrial fibrillation. It is publicly estimated that Defendant Wyeth ultimately realized more than Three Billion Dollars ($3,000,000,000) in sales for "off-label" uses of Cordarone®.

61. Defendant Wyeth was on notice, by no later than 1998, that severe damage to the lungs were side effects of the ingestion of Cordarone®, which can cause permanent injury and death.

62. Defendant Wyeth misrepresented Cordarone's® indications and usage, efficacy, risks, and benefits. Further, Defendant Wyeth intentionally failed to submit marketing materials to the FDA in violation of the FDCA.

63. At all material times, Defendant Wyeth failed and refused to actively and affirmatively monitor Cordarone's® "off-label" unapproved uses insofar that such uses caused catastrophic injuries and death. Defendant Wyeth, however, continued to promote Cordarone® for unapproved uses. Such promotion had direct beneficial results for the generic manufacturer Defendants Sandoz/Novartis as well.

**B. Facts Common to All Defendants**

64. As a result of the above, to date, despite changing the warnings and labeling for Cordarone® multiple times over the past 25 years and the requirement for the distribution of Medication Guides to all patients, and knowing of numerous catastrophic injuries caused by Cordarone® and Amiodarone, all Defendants, acting in concert, continued to actively conceal and understate the drug's nature and adverse risks of catastrophic injury, pulmonary injury and death, thereby tolling any applicable statutes of limitation.

65. At all material times, Defendants, jointly and severally, have had actual or constructive knowledge that Cordarone® and Amiodarone cause and contribute to severe and disabling medical conditions such as experienced by Plaintiff as set forth above, which include, without limitation, the following: pulmonary toxicity, pulmonary fibrosis, hepatic damage and failure, neurotoxicity, neonatal hypothyroidism, birth defects, optic neuritis, toxic optic neuropathy, blindness, peripheral neuropathy, heart damage and failure, hypotension, serious exacerbation of arrhythmias, and congestive heart failure.

66. Defendants, jointly and severally, have received information concerning more than one thousand deaths resulting from the use of Cordarone®/Amiodarone.

67. Defendants, jointly and severally, have received information concerning cases of severe medical conditions resulting from the use of Cordarone®/Amiodarone such as some of those experienced by Plaintiff, including, without limitation, pulmonary toxicity, pulmonary fibrosis, lung damage, hepatic damage and failure, neurotoxicity, peripheral neuropathy, neonatal hypothyroidism, optic neuritis, toxic optic neuropathy, blindness, serious exacerbation of arrhythmias, and congestive heart failure.

68. Defendants, jointly and severally, have concealed information about catastrophic injuries and death attributable to this drug, and thousands of serious adverse medical events in their exclusive possession from the FDA, health care professionals, and consumers, including Plaintiff Collette.

69. Healthcare providers as well as patient-consumers reported these events directly to Defendants. Yet none of the Defendants publicly distributed this information, and in fact continued to encourage such "off label" use, and refused to ensure the required Medication Guide was disseminated, which was a pre-condition of the sale of this drug to consumers, including to Mr. Collette.

70. In addition to these direct notices of adverse events, the FDA had, and continues to have, in effect an adverse reaction surveillance system for all regulated drugs, including Cordarone®/Amiodarone, called the Adverse Event Reporting System (AERS).

71. AERS has placed these Defendants on notice of numerous instances of catastrophic injuries caused by ingestion of Cordarone®/Amiodarone.

72. At all material times since these Defendants promoted these products for "off-label" use from 1999 to the present date, Defendants failed to disclose to the FDA, healthcare professionals, consumers, and Plaintiff the material adverse information they possessed concerning the incidents and actual adverse medical events, injuries, and deaths suffered by Cordarone®/Amiodarone users. Instead, Defendants actively concealed such material facts and instead actively promoted, or piggy-backed the promotional efforts of innovator brand drug

manufacturer Wyeth, for "off-label," unapproved uses as described herein through various means, including, but not limited to, the following:

a. Direct-to-physician and direct-to-pharmacist promotion through sales representatives;

b. Promotion through funding and manipulation of so-called "educators" who organize and arrange continuing medical education (CME) courses for physicians and pharmacists;

c. Formulation of unlawful conspiracies with certain medical marketing and medical "education" entities to promote – without appearing to promote – such off-label uses;

d. Sponsorship and funding of the production of CME materials;

e. Cultivation and development of so-called "opinion leaders" in local medical communities and support for the careers and research of those physicians, pharmacists, and researchers who advocate off-label uses;

f. Sponsorship of journal supplements and symposia on off-label uses for Cordarone®;

g. Placing (through sponsorship of limited trials, studies, and surveys) of medical literature databases showing positive effects (already established) on risk factors with the twin purposes of overwhelming any independent study showing negative effects on different risk factors, and causing earnest but time-crunched physicians to be impressed with the sheer quantity of favorable (but redundant) studies on MedLine, or medical library, search;

h. Media advertisements and brochures, some of which were disguised as "educational materials"; and

i. Various other forms of marketing and promotion including websites and catalogs promoting Amiodarone.

73. In accepting the benefits of brand innovator Wyeth's efforts in promoting "off-label" uses of Cordarone® by sponsoring CME conferences and materials, journal supplements, redundant trials, and the work and careers of favorably disposed opinion leaders, Defendants could escape disclosure of their role in the presentation of their desired view. At other times, Defendants would be disclosed merely as having provided an "unrestricted educational grant" for seminars, when in fact the grant was premised on an understanding about the content or Defendants otherwise exercised influence over it.

74. Additionally, Sandoz/Novartis and/or its agents' pharmaceutical sales representatives, materials and sources actively promoted their generic Amiodarone in the stream of commerce for the "off-label" uses openly promoted by Defendant Wyeth.

75. At all materials times, despite FDA warnings and thousands of adverse patient experiences, Defendants continued their fraudulent marketing, promotional, and sales practices from 1999 through the present date, and have continued in their acts of conspiracy as detailed above.

76. At all material times, the Cordarone®/Amiodarone manufactured and/or supplied by Defendants was and is unaccompanied by proper warnings regarding all possible adverse side effects and comparative severity and duration of such adverse effects and the required Medication Guides. The warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. This is particularly so with regard to "off-label" use.

77. At all material times, Defendants failed to warn the public and Plaintiff of material facts regarding the safety and efficacy of Cordarone®/Amiodarone, such that this drug would likely have never been approved, and no physician would have been able to prescribe this drug for all but the most limited use in the United States.

78. At all material times, Defendant Wyeth failed to perform adequate testing. Based on the thousands of complaints it has received, adequate testing would have shown that Cordarone® possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope, and severity should have been made with respect to the use of Cordarone®, particularly for "off-label" use.

79. For example, although Defendants should have known, and currently know that the majority of patients consuming Cordarone®/Amiodarone are older, including those aged 55 and over such as Plaintiff, Defendant Wyeth has failed and refused to conduct testing, studies, surveys, and/or report the results of same regarding Cordarone® use in this age group.

80. At all material times, the Cordarone®/Amiodarone manufactured, distributed, and/or supplied by Defendants was defective due to inadequate post-marketing warning and instruction. Once Defendants knew or should have known of the risk of injury from Cordarone®/Amiodarone, especially for "off-label" use, Defendants failed to provide adequate and required warnings to physicians, users or consumers of Cordarone®/Amiodarone, including the Plaintiff, and continued to aggressively sell Cordarone®/Amiodarone, including for "off-label" use and including the required Medication Guide.

81. At all material times, while Defendants, jointly and severally, concealed this adverse information, they simultaneously engaged in a massive and illegal marketing and promotional scheme in which they aggressively and illegally promoted Cordarone®/Amiodarone for uses never authorized by the FDA. In fact, Defendants marketed, promoted, and "pushed" Cordarone®/Amiodarone, not as a drug of last resort, but as a drug suitable as an initial therapy and to treat non-life-threatening heart conditions.

82. At all material times, Defendants, jointly and severally, also promoted Cordarone®/Amiodarone for heart conditions less severe than life-threatening ventricular arrhythmia (the only purpose for which the drug originally received FDA approval).

83. Defendants thus engaged in a conspiracy of silence regarding "off-label" use, choosing to market and promote the drug for "off-label" use, and then feigning ignorance before the FDA, health care providers, and consumers, which continues to date. They failed and refused to conduct thorough testing on the side effects, despite knowing that their scheme to promote the drug for "off-label" uses had been, and continues to be, successful.

84. At all material times, Defendants' affirmative misrepresentations and omissions of material fact have so infected the market in the United States that physicians and consumers relied on Defendants' statements and omitted material facts, to their detriment.

85. Under increased FDA scrutiny and mandates, Wyeth and Sandoz/Novartis have been forced to correct and change their warning labels, and add new warnings, for Cordarone®/Amiodarone for adverse side effects about which they knew long before being required to make such changes.

86. Nevertheless, at all material times, the warnings for Cordarone®/Amiodarone in effect during the relevant time period were vague, incomplete, and/or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians, pharmacists, consumer patients and Plaintiff of the actual risks associated with this drug.

87. At all material times, Defendants' deception, concealment, and illegal marketing and promotion has been so pervasive throughout the United States, that prescribing physicians and consumer patients have during the relevant time period still believe that Cordarone®/Amiodarone is an acceptable initial, secondary, or otherwise early-stage anti-arrhythmic intervention. This deceptive marketing served (and continues to serve) Defendants in several ways, including: (1) instilling Defendants' desired view about the drug's "off-label" uses among health care providers; (2) by concealing its agency in these activities, they would escape the legal ramifications of its unlawful promotional activities; and (3) boost Defendants' profits for the drug.

88. At all material times, Defendants, jointly, and severally, owed a duty to the health care providers, consumer patients, and Plaintiff herein, to engage in honest and non-deceptive practices; exercise due care under the circumstances to exercise due care in the design, manufacture, marketing, promotion, sale, and distribution of Cordarone®/Amiodarone and the required Medication Guide; to provide a reasonably safe and non-defective drug; to provide adequate and appropriate warnings for said drug; to comply with federal guidelines, rules, and regulations; and/or to sell and distribute the drug in accordance with FDA restrictions.

89. At all material times, Defendants marketed Cordarone®/Amiodarone as having approval, characteristics, uses, and benefits that the drug did not have, and as being legal to sell for its "off-label" use when it was not.

90. At all material times, Defendants, jointly and severally, did design, create, test, develop, label, sterilize, package, manufacture, market, promote, advertise, distribute, sell, warn, and/or otherwise caused the product to be placed into the stream of commerce, and ultimately to be ingested by Plaintiff.

91. At all material times, Defendants failed and refused to actively and affirmatively monitor Cordarone®/Amiodarone's "off-label" unapproved uses insofar that such uses caused catastrophic injuries and death. Defendants, however, continued to illegally sell Cordarone®/Amiodarone for unapproved uses.

92. Based on the above facts, at all material times, Defendants, jointly and severally, engaged in a continuing course of misstatements, illegal conduct concealment and material nondisclosure upon Plaintiff, which prevented Plaintiff from knowing or having reason to know of Defendants' illegal misconduct.

**C. Amiodarone Did Not Undergo the Rigorous FDA Approval Process Required For Federal Preemption**

93. As noted above, on or about December 24, 1985, Defendant drug manufacturer Wyeth introduced Cordarone® into the United States' stream of commerce. Wyeth received approval for Cordarone® from the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies and only if provided along with the required Medication Guide. Furthermore, despite repeated requests by the FDA at the outset of the review process and throughout the history of the drug, neither Wyeth, Sandoz/Novartis or other generic drug manufacturers of the product have submitted the drug to the rigorous randomized clinical trials required for FDA drug approval.

94. Unlike any other drug in modern history, Amiodarone became FDA approved without rigorous, FDA sanctioned randomized clinical trials. The legal reasons for preemption applied to drug litigation for FDA-approved drugs are not present in Amiodarone because Amiodarone has never been subjected to double blind testing as mandated by the FDA.

95. Amiodarone has been determined to affect many different organs in many ways. First, the drug takes many weeks to achieve the maximum effectiveness. Amiodarone is literally "stored" in most of the tissues of the body and as a result, to "load" the body with the drug all the tissues need to be saturated. Therefore, the typical loading regimen of Amiodarone is to use

extremely large dosages of the drug for the first week to two weeks then to taper the dosage over the next month. It is not unusual to give a patient 1200 to 1600 mg a day when starting the drug and to maintain the patient on 100 to 200 mg per day on a chronic basis.

96. Amiodarone leaves the body very slowly. The drug is not excreted like most drugs through the liver or kidney, but is only lost when Amiodarone containing cells such as skin cells or cells from the gastrointestinal tract are lost. Therefore, even when it is decided that the patient needs to stop taking Amiodarone, the drug remains in the system in measurable quantities for months and even years.

97. More important, because the drug is stored in many different types of tissues it can cause side effects that affect many different types of organs. Some of the side effects take months and years to develop. Constant diligence is needed.

98. Amiodarone never underwent the rigorous clinical randomized trials all other FDA approved drugs other than a few "grandfathered" drugs with long market histories have undergone. Despite repeated requests, demands and even threats from the FDA, the manufacturers of Amiodarone and its FDA labeled "brand-names" including Wyeth's Cordarone® have never undergone the type of clinical trials that would show its defects or the benefits verses the risks associated with the drug's use. Despite the economic argument that the patent has expired, or that the costs of testing is too high to justify the investment, Amiodarone continues to generate enormous revenues and profits for the drug manufacturers without the public having the protection of FDA randomized clinical trials.

99. The only trials Amiodarone underwent were non-scientific, reporting a combination of various patient results to obtain statistical data that is neither randomized nor reliable. Defendants did not even provide the statistical data that has been determined by the FDA to be accurate for the drug and required in the black box labeling of the product. This combination of reporting of various patients was non-scientific and cannot serve as the basis for a claim of preemption.

100. Without rigorous, scientific, clinical trials and randomized testing approved by the FDA, the reasons for FDA preemption do not exist and cannot be sustained. Neither the so-

called "brand names" nor the generic versions of the drug offer any protection to the public from the FDA approval process. Since the manufacturers will not undergo FDA-approved testing they cannot use the FDA approval process as a shield from liability when sued. None of the reasons articulated by the United States Supreme Court for the protection preemption provides are present with Amiodarone. None of the cost-benefit analysis is present. In addition, none of the regulatory analysis argument and thus no argument about the need to protect any interests of "Federalism" is present to support preemption.

101. This is not to say the FDA completely disregarded its regulatory or enforcement powers regarding Amiodarone. While no testing justifying preemption was ever performed, when the statistical evidence of the dangers of Amiodarone and its many side effects became known, the FDA repeatedly amended the labeling requirements for Amiodarone, and enacted a requirement that the drug manufacturers directly provide the patient the Medication Guide by ensuring distribution of the Medication Guides to the distributors and then to the patient along with the drug.

102. Due to the failure to conduct required randomized clinical testing by the Defendants, and Defendants' failure to provide the Medication Guide, Plaintiff's claims are not preempted from claiming Defendants illegally marketed the product for off-label use, and Plaintiff is not preempted from claiming that the product itself is unreasonably dangerous as it was packaged, marketed, designed, manufactured and sold. Plaintiff is also not preempted from claiming Defendants failed to warn of the dangers of the product by failing to provide the FDA required Medication Guide that consists of language the FDA approved go directly to the patient. The failure to provide the FDA Medication Guide is a different claim than merely alleging the package insert or labeling fails to inform or warn patients or consumers of the dangers of the product. The failure to provide each patient the Medication Guide as required by the FDA by failing to provide the Medication Guides to the distributor for ultimate distribution to the patient with the drug is a direct violation of the FDA's mandate to the manufacturers of the drug that is intended to warn patients directly outside the communication with the prescribing physician.

**FIRST CAUSE OF ACTION**

**(Strict Products Liability – Failure to Warn)**

**(Against All Defendants)**

103. Plaintiff incorporates by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further alleges as follows:

104. At all times relevant to this action, Defendants, and each of them, engaged in the business of designing, manufacturing, testing, marketing, labeling, distributing and placing into the stream of commerce Amiodarone for sale to, and use by, members of the public including Plaintiff.

105. Amiodarone posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of Amiodarone. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with the "off-label" use of Amiodarone; and continuing to market, promote, sell and defend such use of Amiodarone without requiring the concurrent dissemination of the Medication Guide.

106. Amiodarone that was manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably and substantially dangerous to any users or ordinary consumers of the device, such as Plaintiff. Such ordinary consumers, including Plaintiff, would not and could not have recognized or discovered the potential risks and side effects of Amiodarone as set forth herein.

107. The warnings and directions provided with Amiodarone by Defendants failed adequately to warn of the potential risks and side effects of Amiodarone and the dangerous propensities of said medication, which risks were known or were reasonably scientifically knowable to Defendants when, among other things, they failed to ensure the Medication Guide was provided to all consumers, including Plaintiff.

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108. Defendant Wyeth, as the brand-name manufacturer, designer and marketer of Amiodarone, owed a duty of care to Plaintiff and other consumers of Amiodarone, to ensure they receive proper warnings regarding the risks of use of Amiodarone. Dr. Yhip reasonably relied upon Defendants' representations that Amiodarone was not only appropriate (FDA approved) for the treatment of atrial fibrillation but that it was an appropriate "first line" drug used in the treatment of this condition. Further, Dr. Yhip reasonably relied upon Defendants to disclose all serious side effects in the use of Amiodarone so they may be considered by the physicians in their prescribing choices.

109. Defendants' Amiodarone products were expected to and did reach Plaintiff and his physician and pharmacist without substantial change in their condition as manufactured, distributed, and sold by Defendants. Additionally, Plaintiff's physician prescribed and Plaintiff used Amiodarone in the manner in which Amiodarone was intended to be used by Defendants, making such use reasonably foreseeable to Defendants.

110. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct and proximate result, Plaintiff expended money and will continue to expend money for medical bills and expenses. Plaintiff is entitled to compensatory and equitable damages in an amount to be proven at trial.

111. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date of Plaintiff's initial use of Amiodarone, including but not limited to failing to ensure he was timely provided the Medication Guide, was a substantial factor in causing Plaintiff's injuries, losses and damages, as described herein.

**SECOND CAUSE OF ACTION**

**(Negligence – Failure to Warn)**

112. Plaintiff incorporates by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further alleges as follows:

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113. At all relevant times, Defendants, and each of them, engaged in the business of designing, manufacturing, testing, marketing, labeling, distributing and placing into the stream of commerce Amiodarone for sale to, and use by, members of the public.

114. Amiodarone posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of Amiodarone. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein. Defendants negligently disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with the "off-label" use of Amiodarone; and continuing to market, promote, sell and defend such use of Amiodarone.

115. The warnings and directions provided with Amiodarone by Defendants failed adequately to warn of the potential risks and side effects of Amiodarone and the dangerous propensities of said medication, which risks were known or were reasonably scientifically knowable to Defendants by, among other things, not providing the Medication Guide as required by law. All Defendants owed a duty to Plaintiff to ensure Plaintiff and his physician were adequately and completely warned of all potential serious complications regarding the use of Amiodarone and received the Medication Guide. As alleged above, Defendants knew and had reason to know that Amiodarone caused increased risk of harm to the Plaintiff and other consumers like him. Defendants disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with the use of Amiodarone; and continuing to market, promote, sell and defend Amiodarone.

116. Defendant Wyeth, as the original brand-name manufacturer, designer and marketer of Amiodarone, and Defendants Sandoz/Novartis, as the manufacturer of the medication ingested by Plaintiff, owed a duty of care to Plaintiff and other consumers of Amiodarone, to ensure they receive proper warnings regarding the risks of use of Amiodarone. Plaintiff and/or his physician reasonably relied upon Defendants' representations that Amiodarone was not only appropriate (FDA approved) for the treatment of atrial fibrillation but also was an appropriate "first line" drug used in the treatment of this condition. Further, Plaintiff

and/or his physician reasonably relied upon Defendants to disclose all serious side effects in the use of Amiodarone so those may be considered by the physician in his prescribing choices.

117. Amiodarone drugs ingested by Plaintiff were expected to and did reach Plaintiff and his physician and pharmacist without substantial change in their condition as manufactured, distributed, and sold by Defendants. Additionally, Plaintiff used Amiodarone in the manner in which Amiodarone was intended to be used by Defendants, making such use reasonably foreseeable to Defendants.

118. As a direct and proximate result of Defendants' manufacture, distribution, and sale of Amiodarone, Plaintiff suffered the injuries, losses and damages herein described.

119. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct and proximate result, Plaintiff expended money and will continue to expend money for medical bills and expenses. Plaintiff is entitled to compensatory and equitable damages in an amount to be proven at trial.

**THIRD CAUSE OF ACTION**

**(Negligence – Marketing and Sale)**

120. Plaintiff incorporates by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further alleges as follows.

121. Prior to, on, and after the date of Plaintiff's use of Amiodarone, Defendants were aware that Amiodarone had not been approved by the FDA for the treatment of atrial fibrillation. To the contrary, because of its dangers, Amiodarone was only FDA approved for the treatment of ventricular fibrillation as a drug of last resort after all other treatments had failed. Despite this Wyeth, and the other Defendants, marketed and sold Amiodarone for the treatment of atrial fibrillation. Not only was it marketed by Defendants in an "off-label" manner, it was marketed and sold as a "first line" drug to be used in the treatment of atrial fibrillation. All Defendants owed a duty to Plaintiff to market and sell Amiodarone only for uses approved by the FDA and for uses for which it has been established as efficacious and safe. As alleged above, Defendants either knew or reasonably had reason to know that Amiodarone was not approved for

the treatment of atrial fibrillation and was most certainly not an appropriate first line treatment. Defendants disregarded the risk of harm created by the marketing and sale of Amiodarone for these "off-label" uses.

122. Defendant Wyeth, as the brand-name manufacturer, designer and marketer of Amiodarone, owed a duty of care to Plaintiff and other consumers of Amiodarone to ensure it marketed and sold it only for approved uses. Instead, Wyeth engaged in a massive campaign to market the drug for "off-label" uses, in particular for the treatment of atrial fibrillation. This concerted and systemic effort to persuade physicians Amiodarone was not only safe and efficacious for the treatment of atrial fibrillation but also approved for that use, has led a generation of cardiologists and other cardiac specialists to incorrectly believe Amiodarone is appropriate for the treatment of atrial fibrillation.

123. Defendants' Amiodarone drug products were expected to and did reach Plaintiff and his physician and pharmacist without substantial change in their condition as manufactured, marketed, and sold by Defendants. Additionally, Plaintiff's physician prescribed, and Plaintiff used, Amiodarone in the manner in which Amiodarone was marketed and sold by Defendants, making such use reasonably foreseeable to Defendants.

124. As a direct and proximate result of Defendants' manufacture, marketing, and sale of Amiodarone, Plaintiff suffered the injuries, losses and damages herein described.

125. Defendants' negligent marketing and sale of Amiodarone was a substantial factor in causing Plaintiff's injuries, losses and damages, as described herein.

126. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct and proximate result, Plaintiff expended money and will continue to expend money for medical bills and expenses. Plaintiff is entitled to compensatory and equitable damages in an amount to be proven at trial.

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**FOURTH CAUSE OF ACTION**

**(Negligence *Per Se*)**

127. Plaintiff incorporates by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further alleges as follows.

128. All Defendants owed a duty to Plaintiff to market and sale Amiodarone only for uses approved by the FDA and for uses for which it has been established as efficacious and safe.

129. Defendants violated this duty by marketing, promoting and selling Amiodarone for uses not approved by the FDA. Defendants violated this duty by selling Amiodarone without supplying the Medication Guide required by the FDA. This concerted and systemic effort to persuade physicians Amiodarone was not only safe and efficacious for the treatment of atrial fibrillation but also approved for that use, has led a generation of cardiologists and other cardiac specialists to incorrectly believe Amiodarone is appropriate for the treatment of atrial fibrillation.

130. Under California law negligence is presumed if the defendant has violated a statute, ordinance or regulation of a public entity. Defendants' acts and omissions, as alleged in detail above, are violations of the Sherman Food, Drug and Cosmetic Act as well as various FDA regulations.

131. The Sherman Food, Drug and Cosmetic Act forbids the sale of misbranded or adulterated drugs. Cal. Health & Safety Code § 111225, *et. seq*. The Sherman Food, Drug and Cosmetic Act also notes a drug is misbranded if: (1) the labeling is false or misleading; (2) it fails to include a warning required by law; or (3) it fails to include adequate warnings or directions for use. Defendants' failure to provide the required Medication Guide with prescriptions of Amiodarone violates these provisions of the California Sherman Food, Drug and Cosmetic Act.

132. As a direct and proximate result of Defendants' violations of the Sherman Food, Drug and Cosmetic Act and various FDA regulations regarding the marketing and sale of Amiodarone, Plaintiff suffered the injuries, losses and damages herein described.

133. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental

anguish, economic losses and other damages. As a direct and proximate result, Plaintiff expended money and will continue to expend money for medical bills and expenses. Plaintiff is entitled to compensatory and equitable damages in an amount to be proven at trial.

**FIFTH CAUSE OF ACTION**

**(Fraud and Deceit)**

134. Plaintiff incorporates by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further alleges as follows.

135. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell Amiodarone, owed a duty to provide accurate and complete information to Plaintiff, his physician, and the public regarding Amiodarone, including mandatory distribution of the Medication Guide.

136. However, Defendants misled Plaintiff, Plaintiff's physician, and the public into believing that Amiodarone was safe and effective for use in the treatment of atrial fibrillation, and engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals and patients to use Amiodarone as set forth above, even though Defendants knew or should have known that Amiodarone was unreasonably unsafe. Defendants also failed to warn health care professionals and the public about the safety risks of Amiodarone they designed, marketed and sold.

137. Defendants' advertising program and promotional items, by containing affirmative misrepresentations and omitting material facts, falsely and deceptively sought to create the image and impression that Amiodarone was safe for human use, had no unacceptable side effects, and would not interfere with daily life.

138. Defendants actively concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of Amiodarone. Defendants, through their promotional practices, deceived potential treating physicians, Plaintiff, other patients, and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiff, regarding the safety of Amiodarone in terms of its "off-label" use.

139. Defendants expressly denied that Amiodarone created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from Amiodarone in terms of its "off-label" use.

140. Defendants did not accurately report the results of adverse events by withholding from the FDA, physicians, Plaintiff, and the public, the truth regarding Amiodarone failures for years, all the while undertaking a major advertising campaign to sell Amiodarone. Defendants received reports of Amiodarone's side effects attributable to "off-label" use from various sources, and withheld this information and maintained it in their possession, while continuing to sell Amiodarone to individuals such as Plaintiff.

141. Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of Amiodarone. Defendants failed to fully inform physicians, patients, including Plaintiff, and the public of the true defects in Amiodarone, which were known to Defendants, and continued to assure physicians and patients that Amiodarone was adequate and reliable for the purpose intended and continued and continue to sell Amiodarone.

142. Through the materials they disseminated, Defendants falsely and deceptively misrepresented or omitted a number of material facts regarding Amiodarone as set forth in detail above.

143. Defendants possessed evidence demonstrating Amiodarone caused serious adverse side effects. Nevertheless, Defendants continued to market Amiodarone by providing false and misleading information with regard to its safety to Plaintiff and Plaintiff's treating physician.

144. Among Defendants' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's physician and the general public are Defendants' assurances to that Amiodarone was a safe and effective drug for the treatment of atrial fibrillation. Defendants made such statements even after they became aware of numerous and serious complications with Amiodarone. Defendants did not reveal (and instead actively concealed) their knowledge of numerous and serious complications with Amiodarone. Despite their knowledge of serious problems with Amiodarone, Defendants continued and continue to market Amiodarone.

145. Defendants also concealed from Plaintiff and Plaintiff's physician the material facts they were obligated to disclose, including that Amiodarone was not FDA approved for the treatment of atrial fibrillation, was not an appropriate "first line of treatment" for atrial fibrillation, is required to be accompanied by a Medication Guide intended to warn the consumer of the serious, life-threatening complications from the use of Amiodarone and was approved by the FDA for limited use without any associated clinical trials establishing the safety and efficacy of the drug.

146. Defendants engaged in all the acts and omissions described above with the intent that Plaintiff and his physician reasonably would rely on the misrepresentation, deception and concealment of material facts in deciding to use Amiodarone rather than another product.

147. Plaintiff and/or Plaintiff's physician justifiably relied to their detriment on Defendants' misrepresentations as set out above. This reliance proximately caused the injuries and damages described in this Complaint.

148. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, economic losses and other damages. As a direct result, Plaintiff expended money and will continue to expend money for medical bills and expenses. Plaintiff is entitled to compensatory and exemplary damages in an amount to be proven at trial.

**SIXTH CAUSE OF ACTION**

**(Violation of Cal. Bus. & Prof. Code §§ 17200, *et seq*.)**

149. Plaintiff incorporates by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further alleges as follows.

150. Plaintiff brings this cause of action pursuant to California Business & Professions Code § 17204 ("UCL").

151. California Business & Professions Code § 17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

/ / /

152. The acts and practices described above were and are likely to mislead Plaintiff and the general public, were conducted in California, and therefore constitute acts of unlawful and unfair competition within the meaning of Business & Professions Code § 17200. This conduct includes, but is not limited to:

a. Representing to Plaintiff, Plaintiff's physician and the general public that Amiodarone was safe, fit and effective for its intended purposes, knowing that said representations were false, and concealing from the Plaintiff, Plaintiff's physician and the general public that said Amiodarone had a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians and others that Amiodarone was safe for human use, even though Defendants knew or should have known this to be misleading, and even though Defendants had no reasonable grounds to believe this to be true;

c. Purposely downplaying and understating the health hazards and risks associated with Amiodarone;

d. Marketing the use of Amiodarone for the non-FDA approved treatment of atrial fibrillation in violation of the federal and state laws set forth above;

e. Failing to disclose that the most serious form of warning, a Medication Guide, should be provided to patients prescribed Amiodarone;

f. Failing to provide the FDA-mandated Medication Guide to Plaintiff and other users of Amiodarone in violation of the federal and state laws set forth above;

g. Failing to provide adequate warnings regarding the dangerous defects in Amiodarone;

h. Selling an adulterated and misbranded drug in violation of the FDCA, the Sherman Food, Drug and Cosmetic Law and Cal. Civ. Code § 1750, *et seq*.

153. Defendants, and each of them, have made numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's physician and the general public. Among Defendants' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's

physician and the general public are Defendants' representations that Amiodarone was a safe and effective drug and approved for the treatment of atrial fibrillation. Defendants did not reveal (and instead actively concealed) their knowledge of numerous and serious complications with Amiodarone. Despite their knowledge of serious problems with Amiodarone, Defendants continued and continue to market Amiodarone.

154. Despite their knowledge of serious problems with Amiodarone set forth in detail above, Defendants did not warn the medical community, patients, or the general public about Amiodarone's risks, and continued to promote, market, sell and defend Amiodarone.

155. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California Business & Professions Code § 17200.

156. As a result of their conduct described above, Defendants have been and will be unjustly enriched. By illegally marketing Amiodarone for the treatment of atrial fibrillation, Defendants gained access to a much larger market share than they would have if limited to the FDA-approved use for the treatment of ventricular fibrillation. There number of individuals diagnosed with atrial fibrillation is exponentially greater than the number diagnosed with ventricular fibrillation. Defendants then exacerbated this unjust enrichment by marketing Amiodarone as a "first line" treatment for atrial fibrillation. Defendants have been unjustly enriched by their receipt of millions of dollars in ill-gotten gains in the form of revenues and profits from the illegal sale of Amiodarone in California, sold in large part as a result of the acts and omissions described herein.

157. Plaintiff, pursuant to California Business & Professions Code § 17203, seeks an order compelling Defendants pay equitable monetary relief, including to disgorge the monies collected and profits realized by them as a result of their violations of the UCL, and injunctive relief, including an order prohibiting Defendants from selling Amiodarone without also providing the required Medication Guide to all patients.

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**SEVENTH CAUSE OF ACTION**

**(Violation of Cal. Civil Code § 1750, *et seq.*)**

158. Plaintiff incorporates by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action (except as to any claims for payment of damages) and further alleges as follows.

159. Plaintiff brings this cause of action pursuant to California Civil Code § 1750, *et. seq.*

160. California Civil Code § 1750 – Consumer Legal Remedies Act – protects consumers against unfair and deceptive business practices. The CLRA applies to Defendant's acts and practices because it covers transactions involving the sale of goods to consumers.

161. Defendants engaged in unfair and deceptive practices by:

a. Representing to Plaintiff, Plaintiff's physician and the general public that Amiodarone was safe, fit and effective for its intended purposes, knowing or not reasonably believing that said representations were false, and concealing from the Plaintiff, Plaintiff's physician and the general public that Amiodarone had a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians and others that Amiodarone was safe for the treatment of atrial fibrillation, even though Defendants knew or reasonably should have known this to be false, and even though Defendants had no reasonable grounds to believe them to be true;

c. Representing that Amiodarone was a safe and effective drug and approved for the treatment of atrial fibrillation;

d. Concealing that Amiodarone was not FDA approved for the treatment of atrial fibrillation;

e. Concealing the serious complications associated with Amiodarone from Plaintiff and the Plaintiffs' physician;

/ / /

f. Failing to provide Plaintiff and other consumers with the FDA-required Medication Guide;

g. Purposely downplaying and understating the health hazards and risks associated with Amiodarone; and

h. Continuing to promote the use of Amiodarone to physicians and the public despite being aware there were severe problems associated with its use.

162. Defendants' acts and omissions are in violation of at least the following provisions of the Consumers Legal Remedies Act:

a. In violation of § 1770 (a)(2) misrepresenting the source, sponsorship, approval, or certification of Amiodarone;

b. In violation of § 1770 (a)(5) representing that Amiodarone has sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have;

c. In violation of § 1770 (a)(7) representing that Amiodarone is of a particular standard, quality or grade when it is of another; and

d. In violation of § 1770 (a)(14) representing a transaction involves rights, remedies or obligations that are prohibited by law.

163. The foregoing practices constitute unfair and deceptive practices within the meaning of California Civil Code § 1750.

164. At this time, Plaintiff only seeks injunctive relief pursuant to the Consumers Legal Remedies Act. Plaintiff will amend this Cause of Action to include monetary, statutory and other damages under this claim at the appropriate time.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against the Defendants as follows, as appropriate for the particular cause of action:

1. For general (non-economic) damages according to proof at the time of trial;

2. For special (economic) damages according to proof at the time of trial;

/ / /

3. For disgorgement of all revenues that Defendants have obtained through design, promotion, marketing, manufacture, sale and administration of Amiodarone;

4. For pre-judgment interest as permitted by law;

5. For costs of suit incurred herein as permitted by law;

6. For injunctive relief pursuant to the UCL and the Consumers Legal Remedies Act, including, but not limited to, requiring Defendants to not sell Amiodarone without also distributing the Medication Guide;

6. For such other and further relief as this Court may deem proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all claims so triable.

DATED: March 1, 2016

CONSUMER LAW GROUP OF CALIFORNIA

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Attorneys for Plaintiff

JS 44 (Rev. 12/12) cand rev (1/15/13)

# CIVIL COVER SHEET

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

**I. (a) PLAINTIFFS**
RAYMOND J. COLLETTE

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Alan M. Mansfield/THE CONSUMER LAW GROUP OF CALIFORNIA
16870 W. Bernardo Dr., Ste 400, San Diego, CA 92127
Tel: (619) 308-5034/FAX: (855) 274-1888/Email: alan@clgca.com

**DEFENDANTS**
WYETH PHARMACEUTICALS, INC.; SANDOZ PHARMACEUTICALS CORPORATION d/b/a SANDOZ, INC.; NOVARTIS PHARMACEUTICALS CORPORATION; (Cont'd)

County of Residence of First Listed Defendant
*(IN U.S. PLAINTIFF CASES ONLY)*
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

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

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

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

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

**TORTS**

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

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

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

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

**PRISONER PETITIONS**

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

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

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

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

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

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

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

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

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

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

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

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

**VI. CAUSE OF ACTION**
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. section 1332(a)
Brief description of cause:
Personal injury attributable to Amiodarone

**VII. REQUESTED IN COMPLAINT:**
☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.
**DEMAND $** In excess of $75,000
CHECK YES only if demanded in complaint:
**JURY DEMAND:** ☒ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY** *(See instructions)*:
JUDGE _____ DOCKET NUMBER _____

DATE 2-29-16
SIGNATURE OF ATTORNEY OF RECORD

**IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)**

(Place an "X" in One Box Only) ☐ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA

JS 44 Reverse (Rev. 12/12)

## INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

**I.(a)** **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

**(b)** **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

**(c)** **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

**II.** **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

**III.** **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

**IV.** **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

**V.** **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

**VI.** **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

**VII.** **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

**VIII.** **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.

**ATTACHMENT TO CIVIL COVER SHEET**

**DEFENDANTS** (Cont'd):

and EON LABS, INC., f/k/a EON LABS MANUFACTURING, INC.