

Charfoos & Christensen attorney J. Douglas Peters filed a lawsuit against Actavis Totowa, LLC and other pharmaceutical companies in the Federal Court of the Eastern District of Michigan on July 8, 2008.

Digitek, the brand name for the heart drug digitalis, was wrongfully manufactured by a number of pharmaceutical companies which inadvertently, and without FDA approval, doubled the dosage of the pills it was supplying to consumers in Michigan. Pills sold as .125 and .250 milligrams were in reality .250 and .500 milligrams. This excess dosage, the result of a manufacturing error, prompted the FDA to order a recall of Digitek. Digitek was widely prescribed and used by millions of Americans to treat various heart conditions, including atrial fibrillation, atrial flutter, and congestive heart failure. In August of 2006 the FDA sent a warning letter to Actavis and the other defendants advising them that they had violated the FDA's adverse event reporting obligations. In the letter, the FDA reported that its inspection between January and February of 2006 revealed that there were 6 potentially serious and unexpected adverse events dating back to 1999 that were not reported to the agency. The FDA warning letter also warned Actavis defendants about not properly investigating serious and unexpected adverse events and failing to file periodic safety reports which resulted in at least 26 Adverse Drug Events which were never reported.

In February of 2007, the FDA issued a revised warning letter to the Actavis defendants noting deviations from good manufacturing practices which resulted in the adulteration of products manufactured by the Actavis defendants which the FDA observed during an inspection between July 10 and August 10, 2006.

On April 25, 2008, the FDA announced a "Class I Recall" of all lots of Bertek and UDL Laboratories Digitek. Class I recalls are only instituted when there is a reasonable probability that the product will cause serious injury or death. Up to that point, the serious nature and the fact of the recall had not been communicated to the medical community or the public.

Digitek overdose and digitalis toxicity can cause side effects including ventricular tachycardia (rapid heartbeat) or ventricular fibrillation (irregular heartbeat) or bradycardia (slow heartbeat) or heart block (interrupted heartbeat), and, possibly, cardiac arrest (death).

Charfoos & Christensen is accepting Digitek cases directly or on referral from other attorneys in spite of Michigan's Statute that grants immunity from lawsuits to drug manufacturers. Peters contends that manufacturing errors should not be

covered by the Michigan Statute and he is willing to file these cases and challenge Michigan's Statute on this issue.

Peters is willing to accept cases where the patient had at least a hospitalization, or more serious complications, including death. To prove usage of misbranded pills, Peters requires either 3 or more pills from the prescription the patient was taking at the time of the injury or hospitalization, or, a blood test upon hospitalization showing digitalis intoxication.

If you would like to discuss a Digitek case with Mr. Peters, please feel free to call 1 800 247 5974.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ANTHONY HARRIS and STEPHEN B. LOVE, individually and
on behalf of all others similarly situated,
Plaintiffs,

Case No.

v.

Hon.

ACTAVIS TOTOWA, LLC (formerly known as
Amide Pharmaceutical, Inc.), ACTAVIS INC.,
ACTAVIS ELIZABETH, LLC, ACTAVIS US,
MYLAN, INC., MYLANPHARMACEUTICALS,
INC., MYLAN LABORATORIES, INC.,
MYLAN BERTEK PHARMACEUTICALS INC.,
and UDL LABORATORIES, INC.,

Defendants.

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Ann K. Mandt (P46314)
David R. Parker (P39024)
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CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

I. **INTRODUCTION**

Plaintiffs Anthony Harris and Stephen B. Love, on behalf of themselves and all
others similarly situated, alleges as follows:

1. Plaintiffs bring this Class Action against the Defendants for manufacturing,
producing, supplying, inadequately inspecting, testing, selling and distributing

dangerous, defective, misbranded and adulterated Digitek® (digoxin tablets, USP) (hereinafter referred to as “Digitek®”) containing an amount of the drug’s active ingredient, digoxin, exceeding the dose set forth on the label and in some cases exceeding the dose approved for medical treatment in humans. Because of the wrongful conduct of the Defendants, and the dangers posed by the potential for overdoses of the drug, a massive, national recall of Digitek® tablets has been initiated in the United States.

II. STATEMENT OF JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 (Diversity) as Plaintiff and Defendants are from different states and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs and pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d)(2).

3. Plaintiff alleges an amount in controversy in excess of \$75,000.00 exclusive of interest and costs, as to himself and each member of the proposed Class.

4. Federal jurisdiction is proper under the *Class Action Fairness Act*, 28 U.S.C. §1332(d), as the amount exceeds \$5,000,000 and diversity of citizenship exists between the representative Plaintiff and the Defendants.

5. Venue is proper pursuant to 28 U.S.C. § 1391. The Defendants have sufficient minimum contacts with Michigan or otherwise intentionally avail themselves of the consumer markets within Michigan through the promotion, sale, marketing and/or distribution of their products in the state to render the exercise of jurisdiction by Michigan courts permissible under traditional notions of fair play and substantial justice.

III. PARTIES

A. PARTY PLAINTIFFS

6. Plaintiff Anthony Harris, at all times relevant herein, was a citizen of the City of Redford, County of Wayne, State of Michigan, who ingested Digitek® pursuant to a physician's prescription and subsequent to the ingestion of the dangerous drug suffered serious personal injuries as a result of his ingestion of Digitek®.

7. Plaintiff, Stephen B. Love, at all times relevant herein, was a citizen of the State of Michigan, who ingested Digitek® pursuant to a physician's prescription and subsequent to the ingestion of the dangerous drug suffered serious personal injuries including stroke, kidney damage and heart attack, among other symptoms, as a result of his ingestion of Digitek®.

8. Plaintiffs Anthony Harris and, Stephen B. Love, bring this action on behalf of themselves and all other similarly situated persons in the United States who were prescribed and ingested the Recalled Digitek®, who claim personal injuries or who assert wrongful death, and/or who claim the high likelihood of undetected or latent personal injuries and assert medical monitoring claims arising from the ingestion of the Recalled Digitek®.

B. THE "ACTAVIS DEFENDANTS"

9. The "Actavis Defendants", including Actavis, Inc., Actavis Totowa, LLC (formerly known as Amide Pharmaceutical, Inc.), Actavis Elizabeth, LLC, US, are involved in the development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®.

10. Defendant Actavis Totowa, LLC (formerly known as Amide Pharmaceutical, Inc.) is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey, at 101 East Main Street, Little Falls, NJ 07424-5608 and is a wholly owned subsidiary, agent, and alter ego of Actavis Group hf.

11. Defendant Actavis Elizabeth, LLC is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey at 200 Elmora Avenue, Elizabeth, NJ 07202 and is a wholly owned subsidiary, agent and alter ego of Actavis Group hf.

12. Defendant, Actavis, Inc. is a corporation organized under the laws of Delaware with its principal place of business in New Jersey, at 14 Commerce Drive, Suite 301, Cranford, NJ and is a wholly owned subsidiary, agent, and alter ego of Actavis Group hf.

13. Defendant Actavis, US is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey, at 60 Columbia Road, Bldg. B, Morristown, NJ 07960-4535 and is a wholly owned subsidiary, agent, and alter ego of Actavis Group hf.

14. Defendants Actavis Totowa, LLC (formerly known as Amide Pharmaceutical, Inc.), Actavis, Inc., Actavis Elizabeth, LLC and Actavis US are referred to hereinafter collectively as "Actavis" or "Actavis Defendants" unless otherwise stated.

15. At all material times hereto, the Actavis Defendants:
a. were, and are, engaged in the business of the development, manufacture, production, processing, compounding, formulating, testing, sale,

marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek® in the United States and Michigan either directly or indirectly through third-parties or related entities.

b. were, and are, in the business of profiting from the development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®.

c. conducted continuous and substantial business in the state of Michigan, and,

d. acted and gained knowledge themselves and by and through their various agents, servants, employees, and/or ostensible agents.

C. THE “MYLAN DEFENDANTS”

16. Defendant Mylan, Inc., is a corporation organized and existing under the laws of Pennsylvania with its principal place of business in New Jersey, at 530 Main Street, Chester, NJ 07930.

17. Defendant, Mylan Laboratories, Inc. (“Mylan Laboratories”) is a corporation organized and existing under the laws of Pennsylvania with its principal place of business in New Jersey, at One Woodbridge Center, 9th Floor, Suite 920, Woodbridge, NJ 07095.

18. Defendant Mylan Pharmaceuticals, Inc. (“Mylan Pharmaceuticals”) is a corporation organized and existing under the laws of West Virginia with its principal place of business in New Jersey, at 1405/1425 Route 206, South Bedminster, NJ 07921 and is a wholly owned subsidiary, agent and alter ego of Defendant Mylan, Inc.

19. Defendant Mylan Bertek Pharmaceuticals, Inc. ("Mylan Bertek") is a corporation organized and existing under the laws of Texas with its principal place of business at 12720 Dairy Ashford Rd., Sugarland, TX and is a wholly owned subsidiary, agent and alter ego of Defendant Mylan, Inc.

20. Defendant UDL Laboratories, Inc. ("UDL") is a corporation organized and existing under the laws of West Virginia with its principal place of business in Illinois, at 1718 Northrock Court, Rockford, IL 61103 and is a wholly owned subsidiary, agent and alter ego of Defendant Mylan, Inc.

21. Defendants Mylan, Inc., Mylan Laboratories, Mylan Pharmaceuticals, Mylan Bertek and UDL, are referred to hereinafter collective as "Mylan" or the "Mylan Defendants", unless otherwise stated.

22. At all material times, the Mylan Defendants:

a. were, and are, engaged in the business of the development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek® in the United States and Michigan either directly or indirectly through third-parties or related entities.

b. were, and are, in the business of profiting from the development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek®.

c. conducted continuous and substantial business in the state of Michigan, and,

d. acted and gained knowledge themselves and by and through their various agents, servants, employees, and/or ostensible agents.

IV FACTUAL ALLEGATIONS

A. The Drug - Digitek® (digoxin tablets, USP)

23. Digitek® is the brand-name of one of the cardiac glycosides, a closely related group of drugs having in common specific effects on the myocardium of the heart.

24. Digitek® is a registered trademark of Defendant Bertek Pharmaceuticals.

25. Digitek® is widely prescribed and used by millions of Americans to treat various heart conditions, including atrial fibrillation, atrial flutter and congestive heart failure.

26. Digitek® and digoxin are metabolized in the liver but excreted by the kidney.

27. Digitek® is approved only for sale and distribution in the United States in the following dosages:

- a. Digitek® (digoxin tablets, USP) 0.125 mg, and,
- b. Digitek® (digoxin tablets, USP) 0.250 mg.

(collectively referred to hereinafter as the "approved dose").

28. Each Digitek® tablet is approved by the United States food and Drug Administration ("FDA") only for sale and distribution if it contains the labeled amount of digoxin.

29. Digitek® tablets manufactured and produced with an amount of digoxin in excess of the labeled dose are not approved for sale or distribution in the United States (hereinafter “unapproved excessive dose”).

B. The FDA Warning Letter

30. Upon information and belief, some of the recalled Digitek® was designed, manufactured, produced, processed, compounded, formulated, tested, sold, marketed, packaged, labeled, released, sold and/or distributed from a plant in Little Falls, New Jersey owned by one or more of the Actavis defendants.

31. On or about August 15, 2006, the FDA issued a warning letter to the Actavis defendants through Actavis Totowa for failing to file periodic safety reports at its facility in Little Falls, New Jersey (hereinafter referred to as the 8/06 Warning Letter)

32. In the 8/06 Warning Letter the FDA warned the Actavis defendants that it had violated its adverse event reporting obligations. According to the letter, an FDA inspection between January and February, 2006 revealed there were six potentially serious and unexpected adverse events dating back to 1999 that were not reported to the agency.

33. The FDA warning Letter also warned the Actavis defendants about not properly investigating serious and unexpected adverse events and failing to file periodic safety reports which resulted in at least 26 Adverse Drug Events (“ADEs”) which were never reported.

34. The FDA also warned the Actavis defendants that it had not developed procedures for the surveillance, receipt, evaluation and report of adverse events.

C. The Revised Warning Letter

35. In or around February, 2007, the FDA issued a Revised Warning Letter to the Actavis defendants through Actavis Totowa (hereinafter "Revised Warning Letter") citing "significant deviations from the current Good Manufacturing Practice Regulations". The Revised Warning noted several deviations from good manufacturing practices which resulted in the adulteration of products manufactured by the Actavis defendants which the FDA observed during an inspection between July 10, 2006 and August 10, 2006. Among other things, the letter stated:

"...there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess."

36. The deviations were presented to Actavis Totowa on an FDA-483 on August 10, 2006. The FDA's Revised Warning Letter cited multiple deficiencies including, but not limited to, deficiencies in quality control, preparation and testing, including failure to recognize that some tablets did not meet in-process specifications.

37. The FDA gave Actavis defendants through Actavis Totowa 15 working days to provide written documentation of any drugs associated with any out of specification test results during manufacture and to provide a description of the actions taken to ensure the lots were suitable for release.

D. Dangerous Digitek® tablets Containing Excessive Active Ingredient Digoxin, Including Some With A Dose Exceeding That Approved For Medical Treatment in Humans are Manufactured, Labeled, Distributed and Sold by Defendants

38. Defendants are drug companies that, upon information and belief, manufactured, labeled, produced, formulated, packaged, distributed and sold Digitek® tablets containing an excessive amount of the active ingredient Digoxin.

39. At all pertinent times, defendants knew or should have known that that the Digitek® it produced and sold was not safe for human consumption because of the excessive digoxin in the pills.

E. The Class I Recall and Defendants Failure to Provide Full Information About the Recall

40. On or about April 25, 2008, the FDA announced a “Class I Recall of all lots of Bertek and UDL Laboratories Digitek®.

41. Class I Recalls are only instituted when there is a reasonable probability that the product will cause serious injury or death. The recalled Digitek® is an adulterated, misbranded, dangerous drug which can and has caused serious injury and death.

42. Despite the serious nature of this recall, the Defendants, upon information and belief, have still not informed the medical community or the public, including the Plaintiff and the Class:

- a. how many and which lots of Digitek® contained unapproved amounts of Digoxin;
- b. How long the defendants manufactured and distributed the adulterated drug into the market;
- c. How many reports of injuries and illnesses have been received and,
- d. The nature and severity of the reports of illnesses it received.

F. Digitalis Toxicity

43. Digoxin overdose and digitalis toxicity are life threatening conditions which are identified on the drug label. Among the side effects are ventricular tachycardia (rapid heartbeat), or ventricular fibrillation (irregular heartbeat) or bradycardia (slow heartbeat) or heart block (interrupted heartbeat) and can cause cardiac arrest (death).

44. The recalled Digitek® was adulterated, misbranded and dangerously and improperly manufactured and unfit for human use and defendants knew or should have known this.

45. Defendants had a duty to manufacture, label, distribute and sell Digitek® in a manner which was consistent with good manufacturing practices. It had a duty to label this dangerous drug accurately and only in approved doses.

46. Defendants knew that they had breached their duties and they failed to implement safeguards to protect Plaintiff and class members from serious injury caused by their defective, adulterated drug.

47. Plaintiffs Anthony Harris and Stephen Love were prescribed an approved drug but were given the recalled Digitek® as were the members of the class.

48. As a direct and proximate result of the defendants' negligent conduct in manufacturing, labeling, selling and distributing the defective Digitek®, Plaintiffs Anthony Harris and Stephen Love and members of the class suffered serious personal injury,

49. As a direct and proximate result of the defendants' negligent conduct in manufacturing, labeling, selling and distributing the defective Digitek®, Plaintiffs and the class require medical monitoring.

50. As a direct and proximate result of the defendants' negligent conduct in manufacturing, labeling, selling and distributing the defective Digitek®, Plaintiffs and the class incurred financial injuries purchasing defective Digitek®.

51. As a direct and proximate result of the defendants' negligent conduct in manufacturing, labeling, selling and distributing the defective Digitek®, Plaintiffs and the class have suffered serious physical injury, pain and suffering, loss of ability to work, loss of income loss of social and family relationships and have incurred and will continue to incur significant medical expenses.

52. Based on the information set forth, the Defendants had actual knowledge of the defects in its product and of the high risk of serious personal injury to patients who might ingest adulterated Digitek® and deliberately decided to proceed with the sale of these products anyway. Under such circumstances, an award of punitive damages is warranted.

IV. CLASS ACTION ALLEGATIONS

53. Under Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs bring this action on behalf of themselves and a Class, defined as:

All persons residing in the United States who were prescribed and ingested the recalled Digitek® during the time period when the recalled Digitek® was manufactured, produced, distributed, sold or otherwise made available, who suffered or may have suffered personal injuries or assert wrongful death claims as a result of ingesting the recalled Digitek®.

Excluded from the Class are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from the class are any judge or justice to whom this action is assigned, together with any relative of such judge or justice within the third degree of relationship, and the spouse of any such person.

54. The members of the Class are so numerous that joinder is impractical and would involve thousands of individual actions. The disposition of the claims of the Class in a single class action will provide substantial benefits to all parties and to the Court.

55. The claims of the representative Plaintiffs are typical of the claims of the Class as required by Rule 23(a)(3), in that the representative Plaintiffs are persons who,

like all Class members, purchased and ingested Digitek® and suffered serious physical illness as a result.

56. The factual and legal bases of Defendants' misconduct are common to all members of the Class and represent common misconduct resulting in injury to Plaintiffs and all members of the Class.

57. There are many questions of law and fact common to Plaintiffs and the Class, and those questions predominate over any questions that may affect individual Class members, within the meaning of Rule 23(a)(2) and 23(b)(3). Common questions of law and fact include, but are not limited to, the following:

- Whether Defendants manufacturing and production safety system exists and, if so, whether it was reasonably designed and implemented;
- Whether recalled Digitek® was safe for human consumption;
- Whether Defendants manufactured, produced, packaged, labeled, promoted, distributed and/or sold Digitek® knowing that it contained excessive amounts of digoxin and was a dangerous product;
- Whether Defendants intentionally, recklessly and/or negligently manufactured, produced, labeled, packaged, distributed or sold the recalled Digitek®;
- Whether Defendants had adequate safety measures in place to ensure that Digitek® was manufactured, labeled, packaged and distributed in a manner which was safe and reflected an accurate dose of the drug;
- Whether Defendants conducted adequate quality control measures and/or inspection and/or testing prior to labeling, packaging, distributing and selling Digitek®;

- When Defendants recognized that it had produced, distributed and sold defective Digitek® tablets which were not fit for human consumption and when the FDA and the public were notified of the potentially deadly problems associated with its drug;
- Whether Defendants continued to manufacture Digitek® in the same manner as the defective Digitek® and/or whether Defendants instituted any new safety policies and procedures and if so when they were instituted;
- Whether persons who ingested the recalled Digitek® are at increased risk of personal injury and/or death;
- Whether Defendants negligently monitored, tested and/or inspected the recalled Digitek® prior to its being placed in the stream of commerce;
- Whether Defendants conduct was intentional and/or reckless and warrants punitive damages;
- Whether Defendants breached their duty to warn about the adulterated Digitek®;
- Whether Defendants conduct was negligent under the doctrine of negligence per se or res ipsa loquitur;
- Whether Defendants breached express or implied warranties;
- Whether Defendants conduct constituted fraudulent or negligent misrepresentation;
- Whether Defendants are liable to the Class Members for conduct actionable under the Michigan Consumer Protection Act;
- Whether Defendants are liable to Class Members for damages for conduct actionable under the RICO statute;
- Whether Defendants are liable to Class Members for damages for conduct actionable as common law fraud;

- Whether Defendants unjustly enriched themselves at the expense of Class Members
- Whether Defendants engaged in a pattern and practice that directly caused Plaintiffs and Class Members, to pay for Digitek® prescriptions that were ineffective and that were harmful; and
- Whether Defendants engaged in a pattern of deceptive and/or fraudulent activity with the intent to defraud Plaintiffs and Class Members.

58. Plaintiffs will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience in the prosecution of nationwide class actions. Plaintiffs and their counsel are committed to the vigorous prosecution of this action on behalf of the Class and have the financial resources to do so. Neither Plaintiffs nor counsel have any interests adverse to those of the Class.

59. Plaintiffs and members of the Class have suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication.

60. Class Certification is appropriate pursuant to Fed. R. Civ. P. 23(b)(2) because Defendants acted on grounds generally applicable to the Class, making

appropriate equitable injunctive relief in the form of a Court ordered and supervised Medical Monitoring Program funded by Defendants, to assist Plaintiffs and Class members in early detection and treatment of illnesses caused by ingestion of the recalled Digitek®. Such a program would include:

- a. A method to notify individuals who ingested the recalled Digitek® of their increased risk of harm as a result of their ingestion;
- b. Provision for the accumulation and analysis of relevant demographic and medical information from Class members;
- c. Provision for the creation, maintenance and operation of a medical registry in which relevant demographic and medical information concerning all Class Members is preserved

VI. CLAIMS FOR RELIEF

COUNT I PRODUCT LIABILITY – NEGLIGENCE

61. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

62. Defendants, directly or indirectly, negligently developed, manufactured, tested, produced, labeled, inspected, packaged, dosed, distributed, promoted, marketed, advertised, released, or sold the Recalled Digitek® in the stream of commerce, when they knew, or in the exercise of ordinary care, should have known that the drug posed a significant risk to the health, well-being and safety of the Plaintiffs and the Class, which risks were not known to Plaintiffs, the Class, or their prescribers.

63. At all times material hereto, Defendants had a duty to the Plaintiffs and the Class to exercise reasonable care in the development, manufacturer, production,

inspection, testing, labeling, packaging, distribution, promotion, marketing, supplying, advertising, distributing or sale of Recalled Digitek®.

64. Defendants breached their duty and were negligent in their actions, misrepresentations and omissions toward Plaintiffs, the Class and their prescribers, in that the Defendants:

a. failed to use reasonable care to develop, manufacture, produce, test, inspect, label, package, dose, promote, market, advertise, distribute, release or sell Recalled Digitek® that was safe for its intended and foreseeable uses, not defective and not unreasonably dangerous;

b. sold, released, produced and distributed Digitek® without making proper and sufficient tests to determine the drug's strength dose;

c. failed to use reasonable care to adequately warn foreseeable users such as Plaintiff and the Class of the dangers of ingesting Recalled Digitek®;

d. failed to use reasonable care to make reasonable tests, inspections and/or evaluations necessary to discover such defects and unreasonably dangerous conditions associated with the Recalled Digitek®;

e. failed to comply with and/or to use reasonable care to comply with standards of good manufacturing, production, inspection and testing practices, as well as failed to comply with government regulations and statutes, in the development, manufacture, testing, inspecting, dosing, labeling and otherwise production, distribution and release of Recalled Digitek®;

f. failed to use reasonable care to timely remove and/or recall from the market the unreasonably dangerous drug, the Recalled Digitek®;

g. failed to use reasonable care to investigate and/or use known and/or knowable reasonable alternative manufacturing, production, testing and inspection processes for the Recalled Digitek®;

h. failed to use reasonable care to warn Plaintiffs and the Class of dangers known and/or reasonable suspected to Defendants to be associated with the Recalled Digitek®;

i. failed to use reasonable care to make the Recalled Digitek® safe.

j. negligently representing that the Recalled Digitek® was safe for use for its intended purpose when, in fact, it was not;

k. failed to use reasonable care to make reasonable tests, inspections and/or evaluations necessary to discover such defects and unreasonably dangerous conditions associated with the Recalled Digitek®;

l. failed to timely use reasonable care to discover the dangerous conditions or characteristics of the Recalled Digitek® and recall it; and,

m. failed to use reasonable care to timely conduct a Recall of the Recalled Digitek®, and when the recall was implemented, failed to use reasonable care to implement the recall and inform the medical community and the public, including the Plaintiffs and the Class, of all relevant information such that the chance of harm was minimized to the fullest extent possible.

65. Defendants knew or should have known that the Recalled Digitek® caused unreasonably dangerous risks and serious side-effects, including death, of which Plaintiffs and the Class would not be aware. Defendants nevertheless advertised,

marketed, supplied, released, sold and distributed the drug knowing that there were safer products.

66. As a direct and proximate result of the negligence and breach of Defendants, Plaintiffs and the Class may have sustained serious injury. Defendants owed a duty to Plaintiffs and the Class to use reasonable care in their actions. Defendants' failure to use reasonable care proximately may have caused Plaintiffs' and the Class' injuries.

67. As a direct and proximate result of Defendants' negligence, Plaintiffs and the Class were harmed as aforesaid.

COUNT II
RES IPSA LOQUITUR

68. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

69. The development, manufacture, production, misbranding, adulteration, distribution, supply, testing, inspection, release or sale of a pharmaceutical with doses of the drug's active ingredient that were in excess of the dose on the label and sometimes in excess of the dose approved for human ingestion, *to wit*, the Recalled Digitek®, is in and of itself an act that ordinarily bespeaks negligence.

70. During the time when it was being developed, manufactured and produced, the instrumentality, the Recalled Digitek®, was within the Defendants' exclusive control before being released, supplied, distributed or sold to the public including the Plaintiffs and the Class.

71. There is no indication in the circumstances set forth herein that the injuries that result from an overdose of digoxin, *to wit*, the Recalled Digitek®, was the result of Plaintiffs' or the Class' own voluntary act or neglect.

72. The acts and omissions set forth herein are the type that ordinarily bespeaks negligence and thus liability is established under the doctrine *res ipsa loquitor*.

73. Defendants had a duty to exercise reasonable care in the development, testing, manufacture, production, inspection, labeling, packaging, supply, distribution, marketing, promotion, sale and release of the Recalled Digitek®, including a duty to not manufacture, produce, label, package, supply, distribute, market, promote, release or sell a pharmaceutical with doses of the drug's active ingredient that were in excess of the dose on the label and sometimes in excess of the dose approved for human ingestion, *to wit*, the Recalled Digitek®.

74. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs and the Class were harmed as aforesaid.

COUNT III
NEGLIGENCE PER SE

75. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

76. At all times mentioned herein, Defendants had an obligation not to violate the law, in the development, manufacture, production, formulation, compounding, testing, inspecting, processing, assembling, distribution, marketing, labeling, packaging,

preparation for use, release, sale and warning of the risks and dangers of the aforementioned product.

77. At all times mentioned herein, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S. C. § 301, *et seq*, related amendments and codes and federal regulations provided thereunder, and other applicable laws, statutes and regulations.

78. Plaintiffs and the Class, as purchasers and consumers of the Recalled Digitek®, are within the class of persons the statutes and regulations described above are designed to protect, and the injuries alleged herein are the type of harm these states are designed to prevent.

79. Defendants' acts constitute an adulteration and misbranding as defined by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331 and the regulations promulgated therefrom and constitutes a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under the theories of negligence *per se*.

80. Defendants' manufacture, production, testing and inspection processes are not good manufacturing, production, testing and inspection processes as defined by the Federal Food, Drug and Cosmetics Act 21 U.S. C. § 331 and the regulations therefrom and constitutes a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se*.

81. The acts and omissions as set forth herein, demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as the Plaintiffs and the Class, making Defendants negligent *per se*.

82. As a direct and proximate result of the acts and omissions of Defendants as aforesaid, the Plaintiffs and the Class were harmed as aforesaid.

COUNT IV
PRODUCT LIABILITY – MANUFACTURING DEFECT

83. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

84. At all times material to this action, Defendants were engaged in the business of developing, manufacturing, producing, testing, packaging, inspecting, promoting, marketing, distributing, supplying, labeling, releasing and/or selling the Recalled Digitek®.

85. At all times material to this action, the Recalled Digitek® was expected to reach, and did reach, consumers in the State of Michigan and throughout the United States, including the Plaintiffs and the Class without substantial change in the condition in which it was sold.

86. At all times material to this action, the Recalled Digitek® was developed, manufactured, produced, tested, packaged, inspected, promoted, marketed, supplied, distributed, labeled, released and/or sold by Defendants in an unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Recalled Digitek® contained manufacturing defects, including excessive amounts of its active ingredient which rendered the product unreasonably dangerous;

b. The manufacturing defects of the Recalled Digitek® occurred while the product was in the possession and control of the Defendants;

c. The Recalled Digitek® was not made in accordance with the Defendants' specifications or performance standards and/or those specifications and standards approved by the FDA; and,

d. The manufacturing defects of the Recalled Digitek® existed before it left the control of the Defendants.

87. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs and the class were harmed as aforesaid.

COUNT V
PRODUCT LIABILITY – FAILURE TO WARN

88. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

89. The Recalled Digitek® was defective and unreasonably dangerous when it left the possession of the Defendants in that labeling, packaging and warnings were insufficient to alert consumers, including the Plaintiffs and the Class, of the dangerous risks and reactions associated with the Recalled Digitek®, including but not limited to, failing to warn that the Recalled Digitek® contained a dose of digoxin inconsistent with the dose on the label and sometimes a dose exceeding the approved dose for use by humans.

90. The Plaintiffs and the Class were prescribed and used the subject product for its intended purpose.

91. The Plaintiffs and the Class could not have discovered any defect in the subject product through the exercise of reasonable care.

92. The Defendants, as the developers, manufacturers, producers, suppliers, inspectors, testers, distributors, releasers and/or sellers of the subject Recalled Digitek®, a prescription drug, are held to the level of knowledge of an expert in the field.

93. The label, warnings and dosing information that were given by the Defendants with the Recalled Digitek® were not accurate, clear and/or were ambiguous.

94. The label, warnings and dosing information that were given by the Defendants failed to properly warn physicians, the Plaintiffs, the Class and the public that the Recalled Digitek® contained amounts of digoxin that were inconsistent with the amount on the label and sometimes contained a dose not approved for use in humans and, thus, Plaintiffs, the Class and consumers risked serious injuries, side effects and/or death with the ingestion of the Recalled Digitek®.

95. The Plaintiffs, and the Class, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

96. The Defendants had a continuing duty to warn the Plaintiffs and the Class of the dangers associated with the Recalled Digitek®.

97. Had the Plaintiffs and the Class received adequate warnings or information regarding the dose of digoxin the Recalled Digitek® and/or information regarding the risks of ingesting the subject product, they would not have used it.

98. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs and the class were harmed as aforesaid.

COUNT VI
STRICT PRODUCTS LIABILITY

99. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

100. At all relevant times, Defendants were the developers, manufacturers, producers, makers, dosers, processors, compounders, formulators, labelers, packagers, testers, inspectors, distributors, marketers, promoters, suppliers, releasers and sellers of the Recalled Digitek®, which, at all relevant times, was defective and unreasonably dangerous to consumers.

101. At all relevant times, the Recalled Digitek® was defective in its manufacture and production in that it was not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceeded the benefits. The Recalled Digitek® was defective in manufacture and production in that it posed a greater likelihood of injury than other properly-dosed digoxin medicines and similar drugs on the market, including properly dosed Digitek.® and was more dangerous than ordinary consumers could reasonably foresee.

102. At all relevant times, the defective condition of the Recalled Digitek® rendered it unreasonably dangerous, and the Recalled Digitek® was in this defective condition at the time it left the hands of the Defendants. The Recalled Digitek® was expect to, and did, reach consumers, including the Plaintiff and the Class, without substantial change in the condition in which it was developed, manufactured, labeled, dosed, produced, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

103. At all relevant times, Plaintiffs and the Class were unaware of the significant hazards and defects in the Recalled Digitek®. The Recalled Digitek® was unreasonably dangerous and such danger could not reasonably be contemplated by the ordinary user. During the period that Plaintiffs and the Class were taking the Recalled Digitek®, the medication was being utilized in a manner that was intended by the Defendants. At the time Plaintiffs and the Class received and consumed the Recalled Digitek®, it was represented to be safe and free from latent defects and was to have an approved dose of digoxin consistent with the dose set forth on the label.

104. At all relevant times, Defendants knew or should have known of the danger associated with the use of the Recalled Digitek®, as well as the defective nature of the Recalled Digitek®, but continued to manufacture, sell, distribute, label, package, market, promote, release and/or supply the Recalled Digitek® so as to maximize sales and profits at the expense of the public health and safety and to maintain Digitek® brand integrity, in conscious disregard for the foreseeable harm caused by the Recalled Digitek®.

105. At all relevant times, the Recalled Digitek® was in a defective and unreasonably dangerous condition which would not be recognized or contemplated by a reasonable person among the expected users and consumers at the time it left the control of the Defendants.

106. At all relevant times, the Recalled Digitek® was defective and unreasonably dangerous when used in reasonably expected ways of handling and/or consumption.

107. At all relevant times, the Recalled Digitek® was expected to reach, and did reach, the ultimate user or consumer without substantial change in the condition in which it was sold, supplied, manufactured, produced and/or distributed by Defendants.

108. At all relevant times, the Recalled Digitek® was defective and unreasonably dangerous under § 402(A) *Restatement (Second) of Torts*, and the Product Liability laws of Michigan.

109. Defendants are strictly liable to Plaintiffs and the Class for manufacturing, producing and placing a product into the stream of commerce which was defective and unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of the Defendants.

110. As a direct and proximate result of the acts and omissions of the Defendants as aforesaid, the Plaintiffs and the class were harmed as aforesaid.

COUNT VII
BREACH OF EXPRESS WARRANTY

111. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

112. At all relevant times, Defendants warranted that the Recalled Digitek® was safe and not defective and/or unreasonably dangerous as stated above and warranted that it contained a dose of digoxin that was consistent with the dose set forth on its label and was otherwise safe for human ingestion.

113. At all relevant times, Defendants placed the Recalled Digitek® into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including

Plaintiffs and members of the Class, of the risks associated with the use of the Recalled Digitek® and that it contained an amount of digoxin exceeding labeled dose and sometimes exceeding the approved dose for human ingestion.

114. At all relevant times, Defendants had a duty to exercise reasonable care in the development, testing, manufacture, production, formulation, processing, compounding, labeling, packaging, inspection, supply, distribution, marketing, promotion, sale and release of the Recalled Digitek®, including a duty to:

- a. ensure that the production did not cause the user unreasonably dangerous side-effects;
- b. ensure that the product was labeled accurately;
- c. ensure that the amount, strength and dose of the digoxin in the product was consistent with that set forth on the label and to ensure that the dose was approved by the FDA as a dose safe for use in humans;
- d. warn of the dangerous and potentially fatal side-effects; and,
- e. disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiff and the Class.

115. When the Plaintiffs' and the Class' physicians prescribed the Recalled Digitek® and the Plaintiff and the Class decided to use the Recalled Digitek®, Plaintiffs, the Class and their physicians reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers and side-effects of the Recalled Digitek® and whether the Recalled Digitek® contained a dose of digoxin consistent with its label and not in excess of the dose approved for ingestion by humans.

116. Plaintiffs' and the Class' physicians, the FDA and/or Plaintiffs and the Class had no knowledge of the falsity or incompleteness of the Defendants' statements

and representations concerning the Recalled Digitek® when Plaintiff's and the Class' physicians prescribed and/or otherwise provided the Recalled Digitek® and Plaintiff and the class purchased and used the Recalled Digitek® as developed, tested, manufactured, produced, dosed, inspected, labeled, packaged, distributed, supplied, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants. Plaintiffs and the Class justifiably and detrimentally relied on the warranties and representations of Defendants in the purchase and use of the Recalled Digitek®.

117. At all relevant times, Defendants were under a duty to disclose the defective and unsafe nature of the Recalled Digitek® to physicians, the FDA, consumers and users, such as the Plaintiffs and the Class. Defendants had sole access to material facts concerning the defects and Defendants knew that physicians, the FDA and users, such as Plaintiffs and the Class, could not have reasonably discovered such defects.

118. By the conduct alleged, Defendants, their agents and employees expressly warranted to Plaintiffs, the class and their physicians that the Recalled Digitek® was packaged and labeled accurately, that it contained the approved dose of digoxin and that the drug was safe, merchantable and fit for the purpose intended.

119. This warranty was breached because the Recalled Digitek® was misbranded, adulterated and did not contain the amount of digoxin as stated in the label and sometimes the approved dose for ingestion by humans, nor was it safe and effective as Defendants represented, and Plaintiffs and the Class were harmed as aforesaid.

120. As a direct and proximate result of Defendants' defective and unreasonably dangerous Recalled Digitek® and their breach of express warranty, Plaintiffs and the class were harmed as aforesaid.

COUNT VIII
BREACH OF IMPLIED WARRANTY

121. Plaintiffs and the class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

122. The Defendants developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold the Recalled Digitek® for the treatment of certain cardiac (heart) problems.

123. At the time that the Defendants developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold the Recalled Digitek®, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

124. The Plaintiffs and the Class, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

125. The Plaintiffs and the class were prescribed, purchased and used the Recalled Digitek® for its intended purpose.

126. Due to the Defendants' wrongful conduct as alleged herein, the Plaintiffs and the class could not have known about the mislabeling, misbranding, excessive dose

of digoxin or the risks and side-effects associated with the Recalled Digitek® until after they used it.

127. Contrary to the implied warranty for the subject product, the Recalled Digitek® was not of merchantable quality and was not safe or fit for its intended uses and purposes as alleged herein.

128. As a direct and proximate result of the acts and omissions of Defendants and the defective and unreasonably dangerous Recalled Digitek® and their breach of implied warranty, Plaintiffs and the Class were harmed as aforesaid and Plaintiffs and the class may have suffered injuries and damages including death.

COUNT XI

MISREPRESENTATION AND SUPPRESSION BY DEFENDANTS

129. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

130. Defendants misrepresented to Plaintiffs, the Class and the medical community the safety and effectiveness of the Recalled Digitek® and/or fraudulently, intentionally and/or negligent concealed material information, including adverse information regarding the safety and effectiveness of the Recalled Digitek® and the dose of digoxin contained therein.

131. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that the Recalled Digitek® had defects, dangers and characteristics that were other than what the Defendants had represented to Plaintiffs, the class, the public, the FDA and the

medical community generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiffs, the Class, the public, the FDA and the medical community that:

- a. some doses of digoxin in the Recalled Digitek® were not a dose that was approved by the FDA;
- b. the dose of digoxin in the Recalled Digitek® was not what the label represented the dose to be;
- c. some doses of digoxin in the Recalled Digitek® exceeded the dose approved for use in humans;
- d. the dose of digoxin in the Recalled Digitek® was unsafe, hazardous and dangerous; and
- e. ingesting the Recalled Digitek® would result in an overdose.

132. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

133. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that Plaintiffs and the Class would rely on them, leading to the use of the Recalled Digitek®.

134. At the time of Defendants' fraudulent misrepresentations, Plaintiffs and the Class were unaware of the falsity of the statements being made and believed them to be true. Plaintiffs and the Class had no knowledge of the information concealed and/or suppressed by Defendants.

135. Plaintiffs and the Class justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to the detriment of the Plaintiffs and the Class.

136. Defendants had a duty to warn Plaintiffs, the Class, the public, the FDA and the medical community about the misbranding, adulteration and potential risks and complications associated with the Recalled Digitek® in a timely manner but failed to do so.

137. The misrepresentations and active fraudulent concealment by the Defendants constitute a continuing tort against the Plaintiffs and the class who ingested the Recalled Digitek®.

138. Defendants made the misrepresentations and actively concealed information about the defects and dangers of the Recalled Digitek® with the intention and specific desire that the healthcare professionals treating the Plaintiffs and the Class, the Plaintiffs and the Class themselves and the consuming public would rely on such or the absence of information in selecting and using the Recalled Digitek® as a medical treatment.

139. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiffs and the Class may have suffered injuries and damages including death.

COUNT XII
FRAUD

140. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

141. Defendants fraudulently intentionally, willfully and wantonly, purposefully, knowingly, recklessly, negligently and/or in fact materially misrepresented both affirmatively and by omission that the Recalled Digitek® was of good quality, non-defective, safe for its intended use, merchantable and fit for its particular purposes.

142. Defendants intended, knew and/or should have known that Plaintiffs and the Class would be induced, by the aforesaid misrepresentations, to use the Recalled Digitek®.

143. In using the Recalled Digitek®, Plaintiffs and the class justifiably relied on Defendants' representations that their Recalled Digitek® was of good quality, non-defective, labeled accurately, not adulterated and was safe for its intended use, merchantable and fit for its particular purposes.

144. The Recalled Digitek® was, in fact, misbranded, adulterated, defective and unreasonably dangerous as recited above.

145. As a direct and proximate result of the defective and unreasonably dangerous Recalled Digitek®, as well as Defendants' affirmative misrepresentations and omissions, Plaintiffs and the Class were harmed as aforesaid.

COUNT XIII
NEGLIGENT MISREPRESENTATION

146. Plaintiffs and the class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

147. Defendants, in addition to knowing misrepresentations, made misrepresentations without any reasonable grounds for believing their statements to be true, to Plaintiffs and the Class, other patients and the medical community.

148. Defendants, through their misrepresentations, intended to induce justifiable reliance by Plaintiffs, the Class, other patients and the medical community.

149. Defendants, through their labeling, marketing campaign and communications with treating physicians, were in a relationship so close to that of Plaintiffs, the Class and other patients, that it approaches and resembles privity.

150. Defendants owe a duty to the medical community, Plaintiffs, the Class and other consumers, to conduct appropriate and adequate inspections and tests for all of their products, including the Recalled Digitek®, and to use safe and good manufacturing and production practices, to provide appropriate and adequate information and warnings, but they failed to do so.

151. Defendants failed to conduct appropriate or adequate inspections and/or tests on the Recalled Digitek®.

152. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs and the Class were harmed as aforesaid.

COUNT XIV

VIOLATIONS OF MICHIGAN'S CONSUMER PROTECTION ACT

MCL 445.901 et seq.

153. Plaintiffs and the Class incorporate by reference each preceding and

succeeding paragraph as though set forth fully at length herein.

154. The Recalled Digitek® is considered “goods” within the definition of “trade or commerce” as defined by MCL 445.902(d)

155. At all relevant times, Defendants knew or should have known that the use of the Recalled Digitek® caused serious and life-threatening injuries, but failed to warn the public, including the Plaintiffs and the Class, of the same.

156. At all relevant times, Defendants made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from Plaintiffs, the Class, the FDA, the public and the medical community in the product packaging, labeling, advertising, direct-to-consumer advertising, promotional campaigns and other materials, among other ways, regarding the safety and amount of digoxin in the Recalled Digitek®. Moreover, Defendants downplayed and/or understated the serious nature of the risks associated with Recalled Digitek® in order to increase the sales of the Recalled Digitek® and maintain their share of the digoxin market and maintain the integrity of the Digitek® brand.

157. At all relevant times, Defendants’ statements and omissions were undertaken with the intent that the FDA, physicians and consumers, including Plaintiffs and the Class, would rely on the Defendants’ statements and/or omissions.

158. Plaintiffs and the class were prescribed and/or otherwise provided with, and ingested, the Recalled Digitek® and have or may have suffered ascertainable

losses of money as a result of the Defendants' use or employment of the methods, acts or practices or failure to act alleged herein.

159. The aforesaid misbranding, adulteration, supply, distribution, sale and release of the Recalled Digitek® into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation and/or the knowing concealment, suppression or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connection with the sale or advertisement of such merchandise or services by the Defendants.

160. At all relevant times, Defendants concealed, omitted or minimized the fact that the Recalled Digitek® had an amount of digoxin inconsistent with the stated dose on the label and sometimes exceeding the approved dose for use in humans, or provided misinformation about adverse reactions, risks and potential harms from the Recalled Digitek® and succeeded in persuading consumers, including Plaintiffs and the Class, to purchase and ingest the Recalled Digitek® despite the lack of safety and the risk of adverse medical reactions, including but not limited to those set forth in the Digitek® label.

161. At all relevant times, Defendants' practice of promoting and marketing the Recalled Digitek® created and reinforced a false impression as to the safety of the Recalled Digitek®, thereby placing consumers, including Plaintiffs and the Class, at risk of serious and potentially lethal effects.

162. At all relevant times, the Recalled Digitek® lacked appropriate warnings and information about the dose of digoxin, and the packaging and labels used by Defendants were misleading, inaccurate, incomplete and/or untimely.

163. Defendants violated their post-manufacture duty to warn, which arose when they knew, or with reasonable care should have known, that the Recalled Digitek® was injurious and sometimes fatal.

164. At the times when consumers, including Plaintiffs and the class, purchased and ingested the Recalled Digitek®, Defendants intended that others would rely upon the concealment, suppression or omission of the risks of ingesting the Recalled Digitek®.

165. Defendants' actions in connection with development, manufacture, production, labeling, packaging, supplying, testing, inspecting, distributing, marketing, release and sale of the Recalled Digitek® as set forth herein, evidence a lack of good faith, honesty in fact and were not observant of fair dealing so as to constitute unconscionable commercial practices.

166. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

167. As a proximate result of the acts of consumer fraud set forth above, Plaintiffs and the class purchased and ingested an unsafe, misbranded and adulterated product and incurred monetary expense and the risk to themselves and members of

their households that they would consume the Recalled Digitek® and thereby suffer an increased risk of harm as previously set forth herein.

168. The conduct of the Defendants, as set forth above, constitutes unfair, deceptive, unlawful and/or unconscionable acts and/or practices prohibited under the Michigan Consumer Protection Act MCL 445.901 et seq. and the Consumer Protection Statutes of various states.

169. As a direct and proximate result of Defendants' unfair, deceptive, unlawful and/or unconscionable acts or practices in violation of the aforesaid Consumer Protection Laws, Plaintiffs and the class were harmed as aforesaid.

COUNT XV
MEDICAL MONITORING

170. Plaintiffs and the class incorporate by reference each preceding and succeeding paragraph as though set forth fully herein.

171. Plaintiffs and the Class had significant and extensive exposure to the Recalled Digitek® with their ingestion of the same.

172. The ingestion of the Recalled Digitek® caused toxicity to Plaintiffs and the Class from the chemical drug ingested.

173. The ingestion of the Recalled Digitek® exposed Plaintiffs and the class to serious personal injuries for which Plaintiffs and the Class were at risk.

174. The ingestion of the Recalled Digitek® significantly increased the chance of onset of personal injuries to Plaintiffs and the Class because of their exposure.

175. There is a significant value for Plaintiffs and the Class in the early diagnosis, detection and treatment of the personal injuries from their ingestion of the Recalled Digitek®.

176. During all times relevant hereto, the Defendants knew, or should have known, of the dangers that ingestion of the Recalled Digitek® would cause Plaintiffs and the class because of its defects, which were known or should have been known by Defendants to cause a significantly increased risk of developing personal injuries and potential death from a digoxin overdose or digitalis toxicity.

177. During all times relevant hereto, the Defendants knew or should have known that the dangers of ingestion of the Recalled Digitek® enhanced the risk of contracting serious medical conditions in Plaintiffs and the Class, which would make it necessary for them to undergo medical surveillance and testing in order to monitor them for the development of such injuries and permit early diagnosis and/or treatment of same.

178. During all relevant times hereto, Defendants knew or should have known that the dangers of ingestion of the Recalled Digitek® would make it necessary for Plaintiffs and the Class to undergo medical surveillance in order to monitor them for the development of injuries related to digoxin overdose and digitalis toxicity and permit early medical diagnosis and/or treatment of any such condition.

179. The Defendants' failure to provide Plaintiffs and the class with adequate warnings of the dangers from ingesting the Recalled Digitek® has made it necessary for Plaintiffs and the Class to undergo regular medical surveillance and testing in order to monitor them for the development of injuries related to digoxin overdose and digitalis

toxicity and permit early medical diagnosis and/or treatment of any such conditions. Such conduct by Defendants was reckless, wanton and willful and in conscious disregard for the safety and health of Plaintiffs and the Class.

180. Equity dictates that this court provide Plaintiffs and the class a remedy that provides them with sufficient information and medical monitoring appropriate for them to make informed decisions related to their physical well-being. Absent such notice, the individual members of the Class will be irreparably harmed.

181. Plaintiffs and the class are also entitled to any procedural protections deemed necessary and appropriate to protect their legal interests.

COUNT XVI
UNJUST ENRICHMENT

182. Plaintiffs and the Class incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

183. Defendants accepted payment from Plaintiffs and the class for the purchase of the Recalled Digitek®.

184. Plaintiffs and the class did not receive a safe and effective drug for which they paid and as aforesaid, received a dangerous and defective drug.

185. It would be inequitable for Defendants to retain this money because Plaintiffs and the Class did not in fact receive a safe and effective drug.

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the class demand judgment against Defendants for damages including exemplary damages if applicable to which they are entitled by law, as well as all costs of this action, to the full extent of the law including:

1. An Order certifying the Plaintiff Class and any appropriate sub-class thereof under Fed.R.Civ.P. 23, and appointing Plaintiffs and their counsel to represent the Plaintiff Class.

2. A preliminary injunction (to be made permanent) or other order providing for equitable notice to all members of the Class advising them of *inter alia* Defendants' misconduct; their increased risk of latent injury as a result of their ingestion of the Recalled Digitek®; the potential of developing digitalis toxicity and other injuries by members of the class that may be related to their ingestion of the Recalled Digitek®; and their need to take legal action to preserve their rights with respect to any damages they may have suffered as a result of their ingestion of the Recalled Digitek®.

3. An Order establishing a court-administered Medical Screening Program, to be funded by Defendants to provide for and/or reimburse the cost of medical and diagnostic tests for each member of the class to detect damage and injuries from an overdose of digoxin, digitalis toxicity and other latent or unrecognized injuries and, if such injuries are detected, reimbursement for the cost of treatment and compensation for such injuries.

4. An award of pre- and post-judgment interest at the lawful rate.

5. Any and all damages available by statute or common law available under any of the Counts of this Class Action Complaint.

6. Awarding Plaintiffs and the class punitive damages to deter Defendants' outrageous and wanton, willful conduct and flagrant disregard for the health, welfare and lives of Plaintiffs and the Class.

7. An award of reasonable attorneys' fees and costs and expert fees.

8. A trial by jury on all issues of the case.

9. Any other relief as this court may deem equitable and just.\

VI. JURY TRIAL DEMAND

Plaintiffs and the class hereby demand that all issues of fact of this case be tried to a properly impaneled jury.

CHARFOOS & CHRISTENSEN, P.C.

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Dated: July 8, 2008