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DOTTIE DODSON,

Plaintiffs,

v.

NOVARTIS INTERNATIONAL AG, NOVARTIS PHARMA AG, NOVARTIS PHARMA PRODUKTIONS GmbH, NOVARTIS PHARMACEUTICALS CORP.

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION –MORRIS COUNTY

CIVIL ACTION
MRSL-957-13

COMPLAINT & JURY TRIAL DEMAND

Plaintiff DOTTIE DODSON (hereinafter "Plaintiff") by and through her attorneys Napoli Bern Ripka Shkolnik & Associates, LLP, by way of complaint against the above-named defendants (hereinafter "Defendants"), hereby allege as follows:

I. INTRODUCTION

1. This is an action for personal injuries suffered as a proximate result of Plaintiff being prescribed and ingesting the defective and unreasonably dangerous drug Valturna® (aliskiren and valsartan), a prescription medication used to treat high blood pressure or hypertension in adult patients, which at all times relevant hereto,

was manufactured, designed, tested, packaged, labeled, marketed, advertised and distributed and sold by Defendants identified herein.

II. PARTIES

2. At all times relevant hereto, Plaintiff was and is a resident of the state of Ohio.

3. Defendant Novartis International AG is a foreign corporation headquartered in Basel, Switzerland.

4. Defendant Novartis Pharma AG, an affiliate of Novartis International AG, is a foreign corporation with its principle place of business in Stein, Switzerland.

5. Defendant Novartis Pharmaceuticals Corp., an affiliate of Novartis International AG, is a New Jersey corporation, which has its principle place of business in East Hanover New Jersey.

6. Novartis International AG, Novartis Pharma AG and Novartis Pharmaceuticals Corp. shall hereinafter be referred to as "Defendants."

7. Defendants, at all times relevant to the claims herein asserted against them, were and are pharmaceutical companies involved in research, design, development, testing, manufacture, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public throughout the United States and the State of New Jersey.

8. Defendants are or have been, at all times relevant to the claims herein asserted against them, engaged in designing, developing, testing, manufacturing, promoting, marketing, distributing, selling and/or introducing into or delivering in interstate commerce, throughout the United States, and in the state of New Jersey,

either directly or indirectly through third-parties, subsidiaries, or related entities, the drug Tekturna® (known generically as aliskiren).

III. JURISDICTION

9. Plaintiffs incorporate by reference all of the above paragraphs.

10. This Court has jurisdiction over Defendant Novartis Pharmaceuticals Corp. because it is a corporation duly existing under and by virtue of the laws of New Jersey and having its principal place of business at One Health Plaza, East Hanover, New Jersey.

11. This court has jurisdiction over all Defendants because at all times relevant hereto, Defendants designed, developed, tested, manufactured, packaged, labeled, marketed, advertised, distributed and sold Tekturna® in the state of New Jersey, with a reasonable expectation that the product would be used or consumed in this State, and thus have regularly and solicited and/or transacted business in this state.

IV. FACTUAL ALLEGATIONS

12. Defendants, directly or through their agents, apparent agents, servants or employees, designed, developed, tested, manufactured, marketed, advertised, distributed, promoted and sold Tekturna® (sol in Europe under the name Rasilez® and known generically as aliskiren), a prescription medication for adults intended to treat high blood pressure, or hypertension.

13. Aliskiren, the active component of Tekturna®, is an orally active, nonpeptide potent renin inhibitor.

14. Taken in tablet form, Tekturna® regulates blood pressure by inhibiting renin, an enzyme secreted by the kidney that narrows blood vessels.

15. By lowering blood pressure through action on the renin-angiotensin-aldosterone system (RAAS), Tekturna® is comparable to two classes of drugs known as angiotensin converting enzyme inhibitors (ACEIs or ACE inhibitors) and angiotensin receptor blockers (ARBs).

16. In March 2007, the U.S. Food and Drug Administration (FDA) approved Tekturna®, classified as a new molecular entity (NME), for the treatment of high blood pressure or hypertension either as monotherapy or in combination with other drugs.

17. Defendants promoted Tekturna® as having potential advantages over ACEIs and ARBs due to its unique direct inhibition of renin.

18. Defendants also promoted Tekturna® for combined use with ACEIs and ARBs.

19. Prior to FDA approval, Defendants studied the effectiveness and safety of Tekturna® in clinical trials of short duration.

20. Tekturna®'s effectiveness in lowering blood pressure was tested in six placebo-controlled eight-week clinical trials involving patients with mild to moderate hypertension.[1]

21. In studies of Tekturna®'s safety involving 6,460 patients, only 1,740 patients were treated for longer than six months and only 1,250 for over one year.[2]

22. Until 2011, warnings included on Tekturna® labeling were limited to the drug's potential to cause fetal toxicity; head and neck angioedema,

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[1] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108862.html.
[2] *Id.*

23. In July 2007, a Therapeutic Class Review of Tekturna® by RegenceRX Pharmacy Benefit Management found that there was no evidence that the drug was better at lowering blood pressure than optimal doses of other antihypertensive agents, or than ACEIs or ARBs.[3]

24. The same review concluded that there was no evidence that combining Tekturka with an ACEI or ARB is superior to maximizing the dose of the ACEI or ARB and that Tekturna® had not demonstrated improved safety or tolerability over ACEIs or ARBs.

25. In November 2007, Defendants issued a statement regarding a 12-week trial, known as the ALOFT (Aliskiren Observation of Heart Failure Treatment) Study in which Tekturna® 150 mg was added to existing standard therapies for heart failure, including ACEIs, ARBs, beta blockers or aldersterone antagonists.

26. According to Defendants, "The ALOFT study [wa]s one in a series of trials in ASPIRE HIGHER, an extensive ongoing clinical trials program investigating the effects of Tekturna® on markers of heart and kidney damage, indicators of disease progression."[4]

27. The ASPIRE trials were intended to evaluate Tekturna®'s potential benefit beyond blood pressure reduction.

28. Defendants announced that "Tekturna® achieved its primary endpoint and demonstrated an acceptable safety and tolerability profile in these hard-to-treat patients."[5]

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[3] http://www.regencerx.com/docs/physicianRx/cardiovascular-Tekturna®®-aliskiren-0707.pdf.
[4] http://www.drugs.com/clinical_trials/study-shows-Tekturna®-first-only-approved-direct-renin-inhibitor-reduces-key-marker-heart-failure-2642.html.
[5] *Id.*

29. By aggressively promoting Tekturna® for both independent and combined use and pushing to broaden its approved indications beyond blood pressure control, Defendants sought to sustain their franchise of blood pressure therapies and supplant the market share loss they suffered due to increasing production of generic versions of Defendants' highly profitable anti-hypertensive drug Diovan®, an ARB.

30. Throughout 2009 and 2010, Defendants relied upon Tekturna® to offset declining Diovan sales.[6]

31. Defendants, directly or through their agents, apparent agents, servants or employees, designed, developed, tested, manufactured, marketed, advertised, distributed, promoted and sold Valturna®, a prescription medication for adults intended to treat high blood pressure, or hypertension.

32. Valturna® is a combination drug containing both alskiren, the active component of the drug Tekturna®, and valsartan, an ARB and the active component in the prescription drug Diovan®.

33. Diovan® is manufactured, marketed, distributed and sold by Defendants.

34. In September 2009, the FDA approved Valturna®, Defendants' single-pill combination of aliskiren (Tekturna®) and valsartan (Diovan®).

35. The FDA's approval of Valturna®, was based on an eight-week clinical trial of 1,800 patients.

36. At the time of Valturna's release in 2009, its label contained the following "Warnings and Precautions":

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[6] "Innovation Drives Novartis to Double-Digit Growth for 2010," *available at* http://www.novartis.com/newsroom/media-releases/en/2011/1482782.shtml.

•Avoid fetal or neonatal exposure. (5.1)
•Head and neck angioedema: Discontinue Valturna and monitor until signs and symptoms resolve. (5.2)
•Hypotension in volume- or salt-depleted Patients: Correct imbalances before initiating therapy with Valturna. (5.3)
•Patients with renal impairment: Decreases in renal function may be anticipated in susceptible individuals. (5.4)
•Patients with hepatic impairment: Slower clearance may occur. (5.5)
•Hyperkalemia: Consider periodic determinations of serum electrolytes to detect possible electrolyte imbalances, particularly in patients at risk. (5.7)

37. By 2011, Defendants were engaged in the placebo-controlled Phase II ALTITUDE study, the first trial to investigate Tekturna® for more than one year in a specific population of patients with Type II diabetes and renal impairment.

38. In the multinational study, Tekturna® was administered to patients in addition to optimal cardiovascular treatment including ACEIs or ARBs.

39. An independent Data Monitoring Committee (the DMC) overseeing the trial concluded that patients were not only unlikely to benefit from the addition of Tekturna® to standard anti-hypertensives, but were at risk of higher adverse events.

40. Specifically, the DMC found that there was an increased incidence after 18 to 24 months of non-fatal stroke, renal complications, hyperlakemia and hypotension.

41. On November 20, 2011, Defendants announced that following the seventh interim review of data from the ALTITUDE study, the trial would be terminated in accordance with the recommendation of the DMC.[7]

[7] http://www.novartis.com/newsroom/media-releases/en/2011/1572562.shtml

42. Defendants stated that "as a cautionary measure Novartis will cease promotion of Rasilez/Tekturna®-based products for use in combination with an ACE-inhibitor or ARB."[8]

43. In March 2012, after years of actively promoting Tekturna® for concomitant use with ACEIs and ARBs, Defendants revised the labeling information for Tekturna® to add warnings to "[a]void concomitant use with ARBs or ACEI in patients with renal impairment" and contraindications stating "Do not use with angiotensin receptor blockers (ARBs) or ACE inhibitors (ACEI) in patients with diabetes."

44. Prior to March 2012, Defendants provided no contraindications for Tekturna® and provided no warnings whatsoever against the combined use of Tekturna® and ARBs.

45. Prior to March 2012, the only warning Defendants provided with regard to combined used of Tekturna® and ACEIs were the following: "Hyperlakemia: Caution should be exercised when co-administered with ACEI, potassium-sparing diuretics, potassium supplements or other potassium containing salt substitutes."

46. On April 20, 2012 the FDA announced that it was "warning of possible risks when using blood pressure medicines containing aliskiren with other drugs containing angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) in patients with diabetes or kidney (renal) impairment."

47. The FDA stated that "[i]n ALTITUDE, the risks of kidney (renal) impairment, low blood pressure (hypotension), and high potassium blood levels (hyperlakemia) in a group of patients taking aliskiren plus an ARB or ACEI

[8] *Id.*

increased relative to a group of patients taking placebo plus an ARB or ACEI. The preliminary data from ALTITUDE also demonstrated a slight excess of cardiovascular events (death or stroke) in the aliskiren group."

48. The FDA identified the following as approved ACEIs that should not be taken in conjunction with Tekturna®:

a. Aceon (perindopril erbumine)
b. Accupril (quinapril hydrochloride)
c. Accuretic (quinapril hydrochloride and hydrochlorothiazide)
d. Altace (ramipril)
e. Capoten (captopril)
f. Capozide (captopril and hydrochlorothiazide)
g. Lotensin (benazepril hydrochloride)
h. Lotensin HCT (benzapril hydropchloride and hydrochlorothiazide)
i. Lotrel (benzapril hydrochloride and amlodipine besylate)
j. Mavik (trandolapril)
k. Prinivil (lisinopril)
l. Prinzide (lisinopril and hydrochlorothiazide)
m. Tarka (trandolapril and verapamil hydrochloride)
n. Univasc (moexipril hydrochloride)
o. Uniretic (moexipril hydrochloride and hydrochlorothiazide)
p. Zestril (lisinopril)
q. Zestoretic (lisinopril and hydrochlorothiazide)

49. The FDA identified the following as approved ARBs that should not be taken in conjunction with Tekturna®:

a. Atacand (candesartan cilexitil)
b. Atacand HCT (candesartan cilexetil and hydrochlorothiazide)
c. Avalide (irbesartan and hydrochlorothiazide)
d. Avapro (irbesartan)
e. Benicar (olmesartan medoxomil)
f. Benicar HCT (olmesartan medoxomil and hydrochlorothiazide)
g. Cozaar (losartan potassium)
h. Diovan (valsartan)
i. Diovan HCT (valsartan and hydrochlorothiazide)
j. Edarbi (azilsartan kamedoxomil)
k. Hyzaar (losartan potassium and hydrochlorothiazide)
l. Micardis (telmisartan)
m. Micardis HTC (telmisartan and hydrochlorithiazide)
n. Teveten (eprosartan mesylate)

o. Teveten HCT (eprosartan mesylate and hydrochlorothiazide)
p. Twynsta (telmisartan and amlodipine besylate)

50. In light of these findings regarding combined used of Tekturna (aliskiren) and ARBs/ACEIs, Defendants announced their intent to pull their combination product, Valturna®, from U.S. Markets.

51. Defendants never provided any warnings whatsoever regarding the risk of cardiovascular events such as death or stroke associated with combined used of aliskiren and ARBs and ACEIs, despite the results of its own ALTITUDE study as well as the FDA's announcement citing that study.

52. With total disregard for the health and safety of patients like Plaintiff and the general public, Defendants rushed Tekturna® to market as a treatment for high blood pressure or hypertension without having adequately tested the drug in clinical trials for a sufficient period of time to assess the risks of long-term aliskiren therapy. Defendants' pre-market clinical trials of the drug's ability to lower blood pressure were limited to a mere 8 weeks. In Defendants' most extensive pre-market trial to determine the drug's safety, *the vast majority of participants – nearly 75 percent (4,720/6,460) – were only studied for 6 months or less*.

53. With total disregard for the health and safety of patients like Plaintiff and the general public, Defendants rushed Valturna® to market as treatments for high blood pressure or hypertension without having adequately tested the drugs in clinical trials for a sufficient period of time to assess the risks of combined aliskiren-valsartan therapy.

54. With total disregard for the health and safety of patients like Plaintiff and the general public, Defendants aggressively promoted Tekturna® for use with ARBs

and ACEIs despite lacking sufficient data regarding the potential risks of this combinative therapy.

55. With total disregard for the health and safety of patients like Plaintiff and the general public, Defendants aggressively promoted Valturna® despite lacking sufficient data regarding the potential risks of combining aliskiren with valsartan.

56. Defendants failed to provide adequate warnings or contraindications that sufficiently apprise prescribing physicians, patients like Plaintiff and the general public of the grievous risks associated with Valturna®'s combination of aliskiren and valsartan.

57. As manufacturers and distributors of Tekturna®, Defendants knew or should have known that the drug was not safe for combined use with ARBs and ACEIs and, in fact, presented serious risks to patients when used in conjunction with those classes of drugs.

58. Even with knowledge that Tekturna® presented serious dangers to patients when taken in conjunction with ARBs and ACEIs derived from its own study, Defendants failed to pull Tekturna® from the market or provide strong warnings about the risks of combination therapy.

59. As a result of the defective nature of Tekturna® and the unreasonable risk posed by the drug's combined use with ARBs and ACEIs, persons who were prescribed and ingested Tekturna® in conjunction with an ARB and/or ACEI, like Plaintiff herein, were at an increased risk for developing serious bodily injuries, including renal impairment/chronic kidney disease as well as cardiovascular events including stroke.

60. Consumers, including Plaintiff herein, who have used Tekturna® in conjunction with an ARB or ACEI, had several alternative safer products available to treat their high blood pressure/hypertension and have not been adequately warned about the significant risks and lack of benefits associated with such combination therapy.

61. As manufacturers and distributors of Valturna®, Defendants knew or should have known that combining aliskiren and valsartan was not safe and, in fact, presented serious risks to patients.

62. As a result of the defective nature of Valturna® and the unreasonable risk posed by the drug's use, persons who were prescribed and ingested Valturna®, like Plaintiff herein, were at an increased risk for developing serious bodily injuries, including renal impairment/chronic kidney disease as well as cardiovascular events including stroke.

63. Consumers, including Plaintiff herein, who have used Valturna® had several alternative safer products available to treat their high blood pressure/hypertension and have not been adequately warned about the significant risks and lack of benefits associated with such combination therapy.

64. Defendants, through their affirmative representations and omissions, actively misled Plaintiff and Plaintiff's prescribing physicians about the true and significant risks associated with combined use of Tekturna and ARBs/ACEIs and of the significant risks of Valturna®.

65. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not reasonably have been aware, that Plaintiff would be exposed to the risks identified in this Complaint.

66. Before 2010, Plaintiff was prescribed and ingested both Tekturna® and Benicar®, an ARB, for combined therapy.

67. Plaintiff was prescribed and began taking Valturna® in 2010.

68. Plaintiff ingested Tekturna® and Valturna® as directed by Plaintiff's prescribing physician.

69. The Tekturna® and Valturna® that Plaintiff ingested reached Plaintiff with no substantial change in condition from the time it was manufactured and distributed by Defendants.

70. Plaintiff's prescribing physicians would not have prescribed Tekturna® in combined use with Benicar® and would not have prescribed Valturna® had Defendants properly disclosed the significant risks associated with combinative aliskiren-valsartan therapy.

71. Plaintiff would not have ingested Tekturna® with Benicar® and would not have ingested Valturna® had defendant properly disclosed the significant risks associated with combinative aliskiren-valsartan therapy.

72. As a direct and proximate result of Defendants' acts and omissions, which led to Plaintiff's simultaneous use of Tekturna® and Benicar®, and subsequently to Plaintiff's use of Valturna®, Plaintiff developed chronic kidney disease/end stage renal failure in 2011.

73. These personal injuries were permanent and lasting in nature, causing Plaintiff to suffer severe physical pain, mental anguish, diminished enjoyment of life and the continued need for medical treatment and monitoring and/or medications.

74. In addition to this mental pain and suffering, Plaintiff has suffered significant economic losses as a direct and proximate result of Plaintiff's ingestion of Tekturna® and Benicar®, and subsequently of Valturna®, which were the direct and proximate results of Defendants' acts and omissions.

75. Plaintiff accordingly seeks damages associated with these injuries.

COUNT I – NEGLIGENCE

(New Jersey and/or Ohio Law)

76. Plaintiffs incorporate by reference each of the paragraphs above.

77. Defendants had a duty to exercise reasonable care in design, development testing, manufacturing, labeling, promotion, marketing, sale and distribution of Tekturna® including a duty to assure that the product did not cause unreasonable and dangerous side-effects to users like Plaintiff.

78. Defendants breached that duty by failing to exercise ordinary care in the manufacture, sale, marketing, testing, labeling, sale and distribution of Tekturna® in that Defendants knew or should have known that Tekturna® created an unreasonable risk of harm to patients like Plaintiff.

79. Defendants negligent acts or omissions include, *inter alia*:

a. Designing, developing, manufacturing, promoting, labeling, marketing, selling and distributing Tekturna® as a treatment for high blood pressure or hyptertension without thorough and adequate pre-market testing to assess the risks of long-term aliskiren therapy

b. Failing to undertake sufficient studies and conduct necessary tests to determine whether Tekturna® was safe for combined use with ARBs and ACEIs;

c. Promoting, marketing, selling and distributing Tekturna® as effective and safe for combined use with ARBs and ACEIs despite having failed to undertake sufficient clinical testing to assess the drug's safety in combination therapy;

d. Failing to conduct adequate post-marketing surveillance of Tekturna® to determine the safety of the drug when used, as promoted by Defendants, in conjunction with ARBs and ACEIs;

e. Misrepresenting and overstating the efficacy and benefits of using Tekturna® and/or adding Tekturna® to a regimen of ARBs or ACEIs, versus use of ARBs and ACEIs alone;

f. Failing to adequately warn of the risk of renal impairment and stroke associated associated with combined use of Tekturna® and ARBs and/or ACEIs on labeling and/or prescribing information for Tekturna®;

g. Continuing to manufacture and sell Tekturna® with knowledge that it was unreasonably dangerous.

80. Defendants had the means and the resources to fulfill their general duty of care for the entire that Tekturna® has been on the market in the United States and yet persisted in their failure to provide adequate disclosures to consumers and the medical community.

81. As a result of Defendants' negligent acts and omissions, Plaintiff suffered grievous and lasting personal injuries including end stage renal failure and stroke, physical pain and mental anguish, permanently diminished enjoyment of life and potential death, as well as the need for lifelong medical treatment, monitoring and/or medications.

82. Plaintiff has required and will require health care and services, and has incurred medical, health care, incidental, and related expenses. Plaintiff is informed and

further alleges that he will in the future be required to obtain further medical care and/or hospital care and medical services.

83. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives, safety and well-being of the consumers and Tekturna® users, including Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for any and all damages, (including, but not limited to severe physical pain and suffering; mental anguish; pecuniary losses, out-of-pocket expenses, medical treatment and monitoring and loss of future earning capacity, future earnings and income), past, present and future, together with interest, cost of suit counsel fees and any other awards deemed due, just and owing.

COUNT II -- STRICT LIABILITY

(N.J. Product Liability Act-N.J.S.A. 2A:58C-1 *et seq.* and/or Ohio Law)

84. Plaintiffs incorporate by reference each of the paragraphs above.

85. At all times relevant hereto, Defendants were engaged in the business of designing, manufacturing, testing, marketing, distributing, selling and placing into the stream of commerce pharmaceuticals, including Tekturna® and Valturna®, for sale to, and for use by, members of the public.

86. The Tekturna® and Valturna® designed, developed, tested, manufactured, marketed, distributed and sold by Defendants reached Plaintiff without substantial change and was ingested by Plaintiff as directed.

87. The Tekturna® and Valturna® prescribed to Plaintiff was defective and unreasonably dangerous for its intended use when it entered the stream of commerce and when used by Plaintiff.

88. Plaintiff could not have discovered any defect in Tekturna® and/or Valturna® through the exercise of reasonable care.

89. Defendants knew or should have known that Tekturna® and Valturna® caused unreasonably dangerous side effects when ingested for their intended purpose.

90. Defendants knew or should have known that warnings and other clinically relevant information data that they distributed regarding the risk of injuries and death associated with the use of Tekturna® and Valturna® were incomplete and inadequate, if not intentionally void of criminal information about Tekturna®'s and Valturna® serious side effects.

91. Defendants failed to provide timely and adequate warnings to physicians, pharmacies and consumers, including Plaintiff and Plaintiff's physicians, in at least the following ways:

a. Defendants aggressively promoted and sold Tekturna®, both as a blood pressure control treatment and for indications beyond blood pressure control, for use in conjunction with ARBs and ACEIs despite lacking sufficient clinical data regarding the safety of the drug when used with ARBs and ACEIs.

b. Defendants significantly overstated the benefits of using Tekturna® independently and/or adding Tekturna® to a regimen including ARBs or ACEIs as an alternative to using ARBs or ACEIs alone.

c. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Tekturna® when used in

conjunction with an ARB or ACEI, including its tendency to increase the risk of and/or cause renal impairment and stroke; and

d. Defendants failed to provide adequate post-marketing warnings and instructions after Defendants knew or should of known of the unreasonable risk of developing renal impairment and stroke as a result of taking Tekturna® in conjunction with an ARB or ACEI.

e. Defendants aggressively promoted and sold Valturna® despite lacking sufficient clinical data regarding the combined use of aliskiren and valsartan.

f. Defendants significantly overstated the benefits of using Valturna®.

g. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Valturna®.

92. As a result of Defendants' foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including renal failure. These injures have cause Plaintiff to suffer severe physical pain and mental anguish, permanently diminished enjoyment of life, potential death, as well as the need for lifelong medical treatment, monitoring and/or medications. Defendants' conduct, as described above, was extreme and outrageous.

93. Defendants made conscious decisions not to conduct necessary pre-marketing testing, not to redesign or adequately re-label their defective product, and not to sufficiently warn or inform the unsuspecting consuming public of the unreasonable risks of Tekturna® and Valturna®.

94. Defendants acted willfully, intentionally and with reckless disregard for the life and safety of Plaintiff and the safety of the general public.

95. Defendants knew or should have known that consumers, Plaintiff specifically, would needlessly suffer injury as a result of Defendants' actions.

96. As a direct, foreseeable and proximate result of Defendants' defective Tekturna® product, Plaintiff suffered grievous bodily injuries, including renal failure and stroke, pain, suffering, consequent economic damages and other losses, when his physicians, lacking adequate warnings and other appropriate facts that were omitted from information provided by Defendants to physicians, prescribed for Plaintiff the use of Tekturna® for a prolonged and unwarranted period of time.

97. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, mental anguish, medical expenses, lost income and disability and diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

98. For the foregoing reasons, Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for any and all damages, (including, but not limited to severe physical pain and suffering; mental anguish; pecuniary losses, out-of-pocket expenses, medical treatment and monitoring and loss of future earning capacity, future earnings and income), past, present and future, together with interest, cost of suit counsel fees and any other awards deemed due, just and owing.

COUNT III - BREACH OF EXPRESS WARRANTY

(N.J. Product Liability Act-N.J.S.A. 2A:58C-1 *et seq.* and/or Ohio Law)

99. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

100. At all times herein mentioned, Defendants, by directly and indirectly advertising, marketing, and promoting Tekturna® for the treatment of high blood pressure in monotherapy or in combination with other drugs, expressly warranted to all foreseeable users of the drug, including Plaintiff, that Tekturna® was safe and effective when used in combination with other classes of drugs, including ARBs and ACEIs.

101. At all times herein mentioned, Defendants, by directly and indirectly advertising, marketing, and promoting Valturna® as a single-pill combined aliskiren-valsartan therapy for the treatment of high blood pressure expressly warranted to all foreseeable users of the drug, including Plaintiff, that Valturna® was safe and effective for its intended use.

102. Plaintiff and her physicians relied upon the aforesaid express warranties by Defendants.

103. Plaintiff's use of Tekturna® and Valturna® was consistent with the purposes for which Defendants directly and indirectly advertised, marketed and promoted Tekturna® and Valturna®, and Plaintiff's use of Tekturna® and Valturna® was reasonably contemplated, intended, and foreseen by Defendants at the time of the distribution and sale of both drugs by Defendants, and, therefore, Plaintiff's use of Tekturna® and Valturna® was within the scope of the above-described express warranties.

104. Defendants breached the aforesaid express warranties because Tekturna® was not safe for combined use with ARBs and ACEIs. Instead, such combined therapy exposed individuals who were prescribed both Tekturna® and an ARB or

ACEI to significant risk of grievous injury, including, among other things, stroke and renal failure.

105. Concomitantly, Defendants breached the aforesaid express warranties because Valturna® was not safe. Instead, Valturna® exposed individuals significant risk of grievous injury, including, among other things, stroke and renal failure.

106. As a direct and proximate result of the aforesaid conduct of Defendants, Plaintiff suffered serious person injuries, including renal failure.

WHEREFORE, Plaintiff demands judgment against Defendants for any and all damages, (including, but not limited to severe physical pain and suffering; mental anguish; pecuniary losses, out-of-pocket expenses, medical treatment and monitoring and loss of future earning capacity, future earnings and income), past, present and future, together with interest, cost of suit counsel fees and any other awards deemed due, just and owing.

COUNT IV -- BREACH OF IMPLIED WARRANTY

(N.J. Product Liability Act-N.J.S.A. 2A:58C-1 *et seq.* and/or Ohio Law)

107. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein.

108. Defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Tekturna® to all foreseeable users, including Plaintiff, that Tekturna® was safe and effective for the purposes for which it had been placed in the stream of commerce by Defendants, including for combined therapy with ARBs and ACEIs, and that Tekturna® was reasonably safe, proper, merchantable and fit for its intended purpose.

109. Defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Valturna® to all foreseeable users, including Plaintiff, that Valturna® was safe and effective for the purposes for which it had been placed in the stream of commerce by Defendants.

110. Plaintiff and Plaintiff's physicians relied upon the aforesaid implied warranties by Defendants.

111. Plaintiff's use of Tekturna® and Valturna® was consistent with the purposes for which Defendants directly and indirectly advertised, marketed and promoted Tekturna® and Valturna®, and Plaintiff's use of the drugs was reasonably contemplated, intended, and foreseen by Defendants at the time of the distribution and sale of Tekturna® by Defendants. Therefore, Plaintiff's use of Tekturna® and Valturna® was within the scope of the above-described implied warranties.

112. Defendants breached the aforesaid implied warranties because Tekturna® was not safe for use in combined therapy with ARBs and/or ACEIs. Instead, Tekturna® exposed individuals who were prescribed both Tekturna® and an ARB or ACEI to significant risk of grievous injury, including, among other things, stroke and renal failure.

113. Concomittantly, Defendants breached the aforesaid implied warranties because Valturna® was not safe for use. Instead, Valturna® exposed individuals to significant risk of grievous injury, including, among other things, stroke and renal failure.

WHEREFORE, Plaintiff demand judgment against Defendants for any and all damages, (including, but not limited to severe physical pain and suffering; mental anguish;

pecuniary losses, out-of-pocket expenses, medical treatment and monitoring and loss of future earning capacity, future earnings and income), past, present and future, together with interest, cost of suit counsel fees and any other awards deemed due, just and owing.

COUNT V – FRAUDULENT CONCEALMENT

(New Jersey and Ohio Law)

114. Plaintiffs reallege each and every allegation of this Complaint contained herein as if each were set forth fully and completely herein

115. Throughout the relevant time period, Defendants knew that Tekturna® and Valturna® was or were defective and unreasonably unsafe for their intended purpose.

116. In deciding whether to prescribe a drug, doctors do a risk/benefit assessment in determining which drug to prescribe. Doctors, such as Plaintiff's doctor(s) and healthcare providers, rely on the information received about Tekturna® and Valturna® from various sources, such as journal articles, company literature and discussions with Defendants' sales people.

117. Such information must be accurate and provide an unbiased picture of a drug's safety and efficacy in treating a condition. If the information is false or misleading, the physician, such as Plaintiff's doctor(s) and healthcare providers, cannot accurately assess the crucial risk/benefit balance for the patient or exercise professional judgment that is independent.

118. Consequently, the physician, including Plaintiff's doctor(s) and health care providers, cannot act in accordance with the professional and fiduciary obligations

owed to the patient nor can the patient, or in this instance plaintiffs, give informed consent to the treatment.

119. Concealing adverse information and providing inaccurate or biased information that is material to a prescribing decision misleads the physician and the patient who relies on that physician's professional judgment, as was the case with Plaintiff and Plaintiff's doctor(s) and healthcare providers. This misleading information, along with omissions of material facts related to Tekturna®'s and Valturna®'s safety, causes health care providers, patients and the general public to be misled about Tekturna®'s and Valturna® 's risks and benefits and prevent doctors from making a proper risk/benefit assessment as to the use of Tekturna® in in combined use with other drugs and as to the use of Valturna® as a single-pill combinative therapy.

120. In flagrant and conscious disregard and indifference, Defendants failed utterly to take adequate measures to alert the public, prescribing physicians, and the patients who take it, of the incipient dangers associated with Tekturna® and its combined use with ARBs and ACEIs.

121. In flagrant and conscious disregard and indifference, Defendants failed utterly to take adequate measures to alert the public, prescribing physicians, and the patients who take it, of the incipient dangers associated with Valturna®.

122. Defendants' advertising program, by affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that Tekturna® was safe for use in combined therapy; had no, or no unacceptable, side

effects; had fewer side effects than other treatment regimens for high blood pressure/hypertension; and would not interfere with daily life.

123. Defendants' advertising program, by affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that Valturna® was safe for; had no, or no unacceptable, side effects; had fewer side effects than other treatment regimens for high blood pressure/hypertension; and would not interfere with daily life.

124. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of Tekturna® in combined therapy with ARBs and ACEIs. Defendants, through promotional literature, deceived potential users and prescribers of said drug by relying on only allegedly positive information, including testimonials from allegedly satisfied users, and manipulating statistics to suggest widespread acceptability, while concealing, misstating and downplaying the known adverse and serious health effects.

125. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of Valturna®. Defendants, through promotional literature, deceived potential users and prescribers of said drug by relying on only allegedly positive information, including testimonials from allegedly satisfied users, and manipulating statistics to suggest widespread acceptability, while concealing, misstating and downplaying the known adverse and serious health effects

126. Defendants falsely and deceptively kept relevant information from potential Tekturna® users and minimized prescriber concerns regarding the safety and efficacy of Tekturna®.

127. Defendants falsely and deceptively kept relevant information from potential Valturna® users and minimized prescriber concerns regarding the safety and efficacy of Valturna®.

128. In particular, in the materials disseminated by Defendants falsely and deceptively misrepresented or omitted a number of material facts regarding the previously stated allegations.

129. When said representations and/or omissions were made by Defendants, Defendants knew those representations and/or omissions to be false, or willfully, wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Defendants with the intent of defrauding and deceiving the public in general and the medical community, and with the intent of inducing the public to take Tekturna® and the medical community to recommend, prescribe, and dispense Tekturna® for use in combined therapy with ARBs and ACEIs.

130. These representations and/or omissions were made by Defendants with the intent of defrauding and deceiving the public in general and the medical community, and with the intent of inducing the public to take Valturna® and the medical community to recommend, prescribe, and dispense Valturna®

131. The aforementioned misrepresentations by Defendants were reasonably relied upon by Plaintiff and/or his prescribing physicians to their detriment.

132. As a direct and proximate result of the aforesaid conduct of Defendants, Plaintiff developed end stage renal failure, resulting in physical and mental pain and suffering, as well as general, special and medical damages and related expenses, and will continue to suffer these damages in the future, in an amount in excess of the jurisdictional minimum of this Court.

WHEREFORE, Plaintiff demands judgment against Defendants for any and all damages, (including, but not limited to severe physical pain and suffering; mental anguish; pecuniary losses, out-of-pocket expenses, medical treatment and monitoring and loss of future earning capacity, future earnings and income), past, present and future, together with interest, cost of suit counsel fees and any other awards deemed due, just and owing.

COUNT VI—VIOLATION OF CONSUMER PROTECTION LAW

(Ohio Rev. Code Ann. §§ 1345.01 *et seq.*)

133. Defendants are suppliers, manufacturers, advertisers, and sellers, who are subject to liability under the above legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

134. Defendants violated the above-named consumer protection statute, designed to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Tekturna® and Valturna® were fit to be used for the purpose for which they were intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

135. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

136. Defendants had actual knowledge of the defective and dangerous condition of Tekturna® and Valturna® and failed to take any action to cure such defective and dangerous conditions.

137. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which products to use and prescribe.

138. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

139. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

140. As a direct and proximate result of Defendants' violations of the states' consumer protection laws Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of

profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

PUNITIVE DAMAGES

141. Plaintiffs reallege each and every allegation of this Complaint contained herein.

142. At all times relevant hereto, Defendants knew or should have known that Tekturna® was inherently dangerous with respect to use in combined therapy with ARBs and ACEIs.

143. At all times relevant hereto, Defendants knew or should have known that Valturna®, as a product combining aliskiren (Tekturna) and valsartan (Diovan), an ARB, was inherently dangerous.

144. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Tekturna® in combined therapy with ARBs and ACEIs and of Valturna®.

145. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff concerning the safety of Tekturna® for use in combined therapy with ARBs and ACEIs.

146. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff concerning the safety of Valturna®.

147. At all times material hereto, Defendants knew and recklessly disregarded the fact that use of Tekturna® in combined therapy with ARBs and ACEIs poses a significant risk of grievous personal injury, including renal failure and stroke.

148. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the significance of the risks of Tekturna® in combined therapy with ARBs and ACEIs.

149. At all times material hereto, Defendants knew and recklessly disregarded the fact that use of Valturna poses a significant risk of grievous personal injury, including renal failure and stroke.

150. Defendants knew of Valturna®'s defective and unreasonably dangerous nature, but continue to manufacture, produce, assemble, market, distribute, and sell Valturna® so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiffs, in conscious and/or negligent disregard of the foreseeable harm caused by the product.

151. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiffs, the significant risks of use of Tekturna® in combined therapy with ARBs and ACEIs in order to ensure continued and increased sales.

152. Defendants' intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using Tekturna® with ARBs and/or ACEIs against its benefits.

153. Defendants' intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using Valturna® against its benefits.

154. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

Dated this 3rd Day of April, 2013 BY: 

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DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, W. Steven Berman, Esq., and Hunter Shkolnik, Esquire, are hereby designated as trial counsel in this matter.

CERTIFICATION PURSUANT TO RULE 4:5-1

I certify that the matter in controversy is not the subject of any other court action or arbitration proceeding now pending or contemplated and that no other parties should be joined in this action. I further certify that the matter in controversy is one of several actions being contemporaneously filed or contemplated by different plaintiffs against the same defendants based upon similar or identical causes of action. I further certify that the foregoing statements are true and that if knowingly false when made may subject me to punishment.

Dated this 3rd Day of April, 2013

BY: W. Steve Berman

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