IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

Kimberly Durham and Morris Durham,	
Plaintiffs,	CA: 2:12-1935
v.	
American Medical Systems, Inc, and Caldera Medical, Inc.	**MDL # 2325**
Defendants.	

COMPLAINT FOR DAMAGES
Jury Trial Requested

The Plaintiffs Kimberly Durham ("Plaintiff Durham") and Morris Durham, by and through their undersigned counsel, file this Complaint against the Defendants and allege:

PARTIES

1. Plaintiffs are citizens and residents of Noble County, Indiana.

2. Defendant American Medical Systems, Inc. ("AMS") is a Delaware Corporation with its principal place of business in Minnesota.

3. Defendant Caldera Medical, Inc. ("Caldera") is a California Corporation with its principal place of business in California.

JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, because Plaintiffs' alleged damages exceed $75,000.00, exclusive of interest and costs, and because the parties are citizens of different states.

5. Venue is proper pursuant to 28 U.S.C. § 1391 and pursuant to the Judicial Panel on Multidistrict Litigation's Order that all cases filed in United States Federal District Courts involving allegations of defects in pelvic surgical mesh products where American Medical Systems is a named defendant should be centralized in the Southern District of West Virginia.

6. Personal jurisdiction over Defendants is appropriate because at all times relevant to this Complaint, Defendants conducted regular business in Plaintiffs' home state and the state of West Virginia by selling and distributing their products. Further, Defendants placed products into the stream of commerce which caused personal injuries to Plaintiffs.

FACTUAL ALLEGATIONS

7. Defendants manufactured, designed, and distributed the Desara Sling System ("The Product"). Defendants marketed the Product to the medical community and to Plaintiff as a safe, effective, and reliable medical device; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions such as pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures.

8. In 2006 Caldera and AMS entered into a royalty bearing cross-license agreement, which allowed Caldera to market the Desara Sling System. The Desara Sling System utilized design elements and technology designed and owned by AMS. In exchange for the use of their critical

design elements and technology, AMS receives royalties from Caldera based on sales of the products included in the 2006 agreement, including the Desara Sling System.

9. Contrary to the Defendants' representations regarding the Product, the Product and the mesh used to manufacture the Product are defective and unreasonably dangerous, and have high failure, injury, and complication rates. They fail to perform as intended, require frequent and often debilitating re-operations, and can cause severe and irreversible injuries. These defects include, but are not limited to:

a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring bodily functions in ways that adversely affect patient health;

b. The mesh harbors infections that adversely affect human tissues and patient health;

c. The Product and the mesh migrate from the location of their implantation adversely affecting tissues and patient health;

d. The mesh scratches and rubs tissues adversely affecting patient health;

e. The Product and the mesh regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery;

f. The Product and the mesh injure patients such that the Product must be removed, resulting in additional surgery;

g. The Product and the mesh become embedded in human tissue over time such that upon removal damage is caused to organs and tissues, adversely affecting patient health; and

h. The Product is defective in shape, composition, weight, as well as physical, chemical, and mechanical properties, and is inappropriately engineered for use in the female pelvis.

10. The Product creates an unreasonable risk of injury and other adverse health consequences for patients, including, but not limited to vaginal erosion, infection, extrusion, perforation, chronic pain, and/or abscesses.

11. Prior to the time the product was implanted into Plaintiff Durham, Defendant was aware of the defects in the mesh, including those outlined above. Despite Defendants' awareness of the

defects and unreasonable risks of the Product and mesh, Defendants manufactured, marketed, and distributed the Product for implantation in patients, even though they knew the Product might injure and harm those patients. Alternatively, Defendants failed to exercise reasonable care in determining the risks and potential consequences of implanting the Product into patients.

12. Defendants made public statements that the Product was safe and would not cause harm to patients intending that medical professionals and members of the public would rely upon them and purchase the product for implantation to Patients. When Defendants made these public statements, Defendants knew or should have known that they were inaccurate.

13. Defendants and their representatives also directly made statements to medical professionals that implanting the Product into patients was safe and would cause not harm. When Defendants and their representatives made these statements they knew or should have known the statements were inaccurate.

14. Defendants made statements to the Food and Drug Administration during the 510(k) approval process for the Product that inadequately relied on predicate devices and not clinical testing or other design verifications and process.

15. Defendants also knowingly made material misrepresentations to the federal Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the product.

16. Even though the Defendants knew or should have known that the Product created an unreasonable risk of harm to the woman into whom it was implanted, they continued to market the Product in the United States.

17. Further, Defendants have never provided adequate warnings or information of the risks associated with the Product to the physicians who implanted the Product or the women implanted with the device.

18. On October 15, 2007, the Product was implanted into Plaintiff Durham at Dupont Hospital in Ft. Wayne, Indiana and as a result Plaintiff Durham has suffered serious bodily injuries, mental and physical pain and suffering, including, but not limited to vaginal pain and painful intercourse.

19. In July 2011, the FDA issued a safety bulletin saying that complications related to the use of transvaginal mesh such as the Product are not rare and it is not clear that the use of transvaginal mesh to repair pelvic organ prolapse is more effective than traditional methods of repair. Plaintiff was not on notice that she had an actionable claim until that time.

COUNT I: NEGLIGENCE

20. Plaintiffs reiterate paragraphs 1-19 above as if set forth verbatim herein

21. The Defendants had a duty to exercise reasonable and ordinary care in the manufacturer, design, labeling, instructions for use, warnings, sale, marketing, and distribution of the Product.

22. The Defendants breached their duty of care to Plaintiff Durham in the manufacture, design, labeling, warnings, instructions, sale, marketing, and distribution of the Product.

23. As a proximate result of the Mesh Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Product, Plaintiff Durham has sustained severe and permanent injuries, including pain, suffering, loss of care, comfort, and consortium, and economic damages.

COUNT II: STRICT LIABILITY- MANUFACTURING DEFECT

24. Plaintiffs reiterate paragraphs 1-23 above as if set forth verbatim herein.

25. The Defendants' Product is defectively and improperly manufactured, rendering the Product unreasonably dangerous and hazardous to Plaintiff Durham and is defective as a matter of law with respect to its manufacture.

26. The Defendants' Product is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers.

27. The Defendants' Product creates risks to the health and safety of Plaintiff Durham that are far more significant and devastating than the risks posed by other products and procedures available to treat her corresponding medical conditions, and which far outweigh the utility of the Product.

28. As a direct and proximate result of the Product's defects, Plaintiff Durham was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, emotional distress, economic loss including, but not limited to medical services and expenses.

29. The Defendants are strictly liable to Plaintiff Durham for manufacturing and selling a defective product.

COUNT III: STRICT LIABILITY- DESIGN DEFECT

30. Plaintiffs reiterate paragraphs 1-29 above as if set forth verbatim herein.

31. The Defendants' Product is defectively and improperly designed, rendering the Product unreasonably dangerous and hazardous to Plaintiff Durham.

32. The Defendants' Product is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers.

33. The Defendants' Product creates risks to the health and safety of Plaintiff Durham that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Product.

34. As a direct and proximate result of the Product's defects, Plaintiff Durham was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, emotional distress, economic loss including, but not limited to medical services and expenses.

35. The Defendants are strictly liable to Plaintiff Durham for design and sale of a defective product.

COUNT IV: STRICT LIABILITY- FAIURE TO WARN

36. Plaintiffs reiterate paragraphs 1-35 above as if set forth verbatim herein.

37. The Defendants' Product was unreasonably dangerous and not safe for its intended use and was defective as a matter of law with respect to its lack of appropriate and necessary warnings.

38. The reasonably foreseeable use of the Product involved significant dangers not obvious to the ordinary users of the Product.

39. The Defendants failed to warn properly and adequately Plaintiff Durham and her health care providers as to the proper candidates and safest and most effective methods of implantation and use of the Product.

40. The Defendants failed to warn properly and adequately Plaintiff Durham and her health care providers as to the risks and benefits of the Product, given Plaintiff Durham's condition and need for information.

41. The Defendants failed to warn properly and adequately Plaintiff Durham and her health care providers with regard to the inadequate research and testing of the Product and the complete lack of a safe, effective procedure for the removal of the Product.

42. The Defendants misrepresented the safety, risks, and benefits of the Product, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for Plaintiff Durham's rights and health.

43. As a direct and proximate result of the Defendants' failure to warn Plaintiff Durham of the risks described above, Plaintiff Durham was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, emotional distress, economic loss including, but not limited to medical services and expenses.

44. The Defendants are strictly liable to Plaintiff Durham for failure to warn, design, manufacture, and sale of a defective product.

COUNT V: BREACH OF EXPRESS WARRANTY

45. Plaintiffs reiterate paragraphs 1-44 above as if set forth verbatim herein.

46. The Defendants manufactured, distributed, advertised, promoted, and sold the Product.

47. The Defendants intended that the Product be used in the manner that Plaintiff Durham in fact used it and expressly warranted that the product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other mesh products, and that it was adequately tested and fit for its intended use.

48. At the time the Defendants made these express warranties, they knew or should have known that the Product did not conform to the express warranties because the Product was unreasonably dangerous and defective and had numerous serious side effects, many of which Defendants did not accurately warn about.

49. Plaintiff Durham and/or her health care provider chose the Product based upon the Defendants' warranties and representations regarding the safety and fitness of the Product.

50. Plaintiff Durham, individually and/or by and through her physicians, reasonably relied upon the Defendants' express warranties that the Product was safe, merchantable, and fit for its intended use.

51. The Defendants breached these express warranties because the Product implanted in Plaintiff Durham was unreasonably dangerous and defective, contrary to the Defendants' representations and warranties.

52. As a proximate result of the Defendants' conduct, Plaintiff Durham has sustained severe and permanent injuries, including pain, suffering, loss of care, comfort, and consortium, and economic damages.

COUNT VI: BREACH OF EXPRESS WARRANTY

53. Plaintiffs reiterate paragraphs 1-52 above as if set forth verbatim herein.

54. The Defendants manufactured, distributed, advertised, promoted, and sold the Product.

55. The Defendants intended that the Product be used for the purposes and manner that Plaintiff Durham or Plaintiff Durham's implanting physician in fact used them and impliedly warranted that the Product was of a merchantable quality, safe and fit for such use, and adequately tested.

56. Plaintiff Durham and her physician were foreseeable users of the Defendants' Product.

57. Plaintiff Durham, individually and/or through her physician, relied upon the Defendants' implied warranty of merchantability and fitness for a particular purpose when she consented to have the Product implanted in her.

58. The Defendants breached the implied warranty, because the product was neither merchantable nor suited for its intended purpose.

59. The Defendants breached their implied warranties because the Product implanted in Plaintiff Durham was unreasonably dangerous and defective, contrary to the Mesh Defendants' representations and warranties.

60. As a proximate result of the Defendants' conduct, Plaintiff Durham has sustained severe and permanent injuries, including pain, suffering, loss of care, comfort, and consortium, and economic damages.

COUNT VII: LOSS OF CONSORTIUM

61. Plaintiff reiterates paragraphs 1-61 above as if set forth verbatim herein.

62. Plaintiff Morris Durham is the spouse of Plaintiff Kimberly Durham, and as a direct and proximate result of Defendants' conduct, Plaintiff Morris Durham has suffered the loss of his wife's affection, companionship, services, society, and other damages.

63. As a direct and proximate result of Defendant's conduct, Plaintiff Morris Durham is entitled to and seeks all compensatory damages, punitive damages, attorney's fees, and any and all other damages allowed by law in an amount to be determined at the trial of this action.

COUNT VIII: PUNITIVE DAMAGES

64. Plaintiffs reiterate paragraphs 1-63 above as if set forth verbatim herein.

65. Defendants knew or should have known that the Product was defective and presented an unreasonable risk of harm.

66. Defendants' conduct in designing, manufacturing, labeling, packing, and selling a defective product that Defendant knew presented an unreasonable risk of harm demonstrates reckless indifference to and conscious disregard for the foreseeable users of the product, which justifies a punitive damage award.

WHEREFORE, Plaintiffs respectfully pray for judgment against the Defendants for actual damages, special damages, consequential damages, and punitive damages in an amount to be determined by the jury at the trial of this action, for the costs and disbursements of this action and for such other and further relief as this court deems just and proper.

Respectfully submitted,

s/ Chad A. McGowan

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Attorneys for Plaintiffs

June 8, 2012

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CHARLESTON DIVISION

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design elements and technology, AMS receives royalties from Caldera based on sales of the products included in the 2006 agreement, including the Desara Sling System.

9. Contrary to the Defendants' representations regarding the Product, the Product and the mesh used to manufacture the Product are defective and unreasonably dangerous, and have high failure, injury, and complication rates. They fail to perform as intended, require frequent and often debilitating re-operations, and can cause severe and irreversible injuries. These defects include, but are not limited to:

a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring bodily functions in ways that adversely affect patient health;

b. The mesh harbors infections that adversely affect human tissues and patient health;

c. The Product and the mesh migrate from the location of their implantation adversely affecting tissues and patient health;

d. The mesh scratches and rubs tissues adversely affecting patient health;

e. The Product and the mesh regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery;

f. The Product and the mesh injure patients such that the Product must be removed, resulting in additional surgery;

g. The Product and the mesh become embedded in human tissue over time such that upon removal damage is caused to organs and tissues, adversely affecting patient health; and

h. The Product is defective in shape, composition, weight, as well as physical, chemical, and mechanical properties, and is inappropriately engineered for use in the female pelvis.

10. The Product creates an unreasonable risk of injury and other adverse health consequences for patients, including, but not limited to vaginal erosion, infection, extrusion, perforation, chronic pain, and/or abscesses.

11. Prior to the time the product was implanted into Plaintiff Durham, Defendant was aware of the defects in the mesh, including those outlined above. Despite Defendants' awareness of the

defects and unreasonable risks of the Product and mesh, Defendants manufactured, marketed, and distributed the Product for implantation in patients, even though they knew the Product might injure and harm those patients. Alternatively, Defendants failed to exercise reasonable care in determining the risks and potential consequences of implanting the Product into patients.

12. Defendants made public statements that the Product was safe and would not cause harm to patients intending that medical professionals and members of the public would rely upon them and purchase the product for implantation to Patients. When Defendants made these public statements, Defendants knew or should have known that they were inaccurate.

13. Defendants and their representatives also directly made statements to medical professionals that implanting the Product into patients was safe and would cause not harm. When Defendants and their representatives made these statements they knew or should have known the statements were inaccurate.

14. Defendants made statements to the Food and Drug Administration during the 510(k) approval process for the Product that inadequately relied on predicate devices and not clinical testing or other design verifications and process.

15. Defendants also knowingly made material misrepresentations to the federal Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the product.

16. Even though the Defendants knew or should have known that the Product created an unreasonable risk of harm to the woman into whom it was implanted, they continued to market the Product in the United States.

17. Further, Defendants have never provided adequate warnings or information of the risks associated with the Product to the physicians who implanted the Product or the women implanted with the device.

18. On October 15, 2007, the Product was implanted into Plaintiff Durham at Dupont Hospital in Ft. Wayne, Indiana and as a result Plaintiff Durham has suffered serious bodily injuries, mental and physical pain and suffering, including, but not limited to vaginal pain and painful intercourse.

19. In July 2011, the FDA issued a safety bulletin saying that complications related to the use of transvaginal mesh such as the Product are not rare and it is not clear that the use of transvaginal mesh to repair pelvic organ prolapse is more effective than traditional methods of repair. Plaintiff was not on notice that she had an actionable claim until that time.

COUNT I: NEGLIGENCE

20. Plaintiffs reiterate paragraphs 1-19 above as if set forth verbatim herein

21. The Defendants had a duty to exercise reasonable and ordinary care in the manufacturer, design, labeling, instructions for use, warnings, sale, marketing, and distribution of the Product.

22. The Defendants breached their duty of care to Plaintiff Durham in the manufacture, design, labeling, warnings, instructions, sale, marketing, and distribution of the Product.

23. As a proximate result of the Mesh Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Product, Plaintiff Durham has sustained severe and permanent injuries, including pain, suffering, loss of care, comfort, and consortium, and economic damages.

COUNT II: STRICT LIABILITY- MANUFACTURING DEFECT

24. Plaintiffs reiterate paragraphs 1-23 above as if set forth verbatim herein.

25. The Defendants' Product is defectively and improperly manufactured, rendering the Product unreasonably dangerous and hazardous to Plaintiff Durham and is defective as a matter of law with respect to its manufacture.

26. The Defendants' Product is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers.

27. The Defendants' Product creates risks to the health and safety of Plaintiff Durham that are far more significant and devastating than the risks posed by other products and procedures available to treat her corresponding medical conditions, and which far outweigh the utility of the Product.

28. As a direct and proximate result of the Product's defects, Plaintiff Durham was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, emotional distress, economic loss including, but not limited to medical services and expenses.

29. The Defendants are strictly liable to Plaintiff Durham for manufacturing and selling a defective product.

COUNT III: STRICT LIABILITY- DESIGN DEFECT

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32. The Defendants' Product is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers.

33. The Defendants' Product creates risks to the health and safety of Plaintiff Durham that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Product.

34. As a direct and proximate result of the Product's defects, Plaintiff Durham was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, emotional distress, economic loss including, but not limited to medical services and expenses.

35. The Defendants are strictly liable to Plaintiff Durham for design and sale of a defective product.

COUNT IV: STRICT LIABILITY- FAIURE TO WARN

36. Plaintiffs reiterate paragraphs 1-35 above as if set forth verbatim herein.

37. The Defendants' Product was unreasonably dangerous and not safe for its intended use and was defective as a matter of law with respect to its lack of appropriate and necessary warnings.

38. The reasonably foreseeable use of the Product involved significant dangers not obvious to the ordinary users of the Product.

39. The Defendants failed to warn properly and adequately Plaintiff Durham and her health care providers as to the proper candidates and safest and most effective methods of implantation and use of the Product.

40. The Defendants failed to warn properly and adequately Plaintiff Durham and her health care providers as to the risks and benefits of the Product, given Plaintiff Durham's condition and need for information.

41. The Defendants failed to warn properly and adequately Plaintiff Durham and her health care providers with regard to the inadequate research and testing of the Product and the complete lack of a safe, effective procedure for the removal of the Product.

42. The Defendants misrepresented the safety, risks, and benefits of the Product, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for Plaintiff Durham's rights and health.

43. As a direct and proximate result of the Defendants' failure to warn Plaintiff Durham of the risks described above, Plaintiff Durham was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, emotional distress, economic loss including, but not limited to medical services and expenses.

44. The Defendants are strictly liable to Plaintiff Durham for failure to warn, design, manufacture, and sale of a defective product.

COUNT V: BREACH OF EXPRESS WARRANTY

45. Plaintiffs reiterate paragraphs 1-44 above as if set forth verbatim herein.

46. The Defendants manufactured, distributed, advertised, promoted, and sold the Product.

47. The Defendants intended that the Product be used in the manner that Plaintiff Durham in fact used it and expressly warranted that the product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other mesh products, and that it was adequately tested and fit for its intended use.

48. At the time the Defendants made these express warranties, they knew or should have known that the Product did not conform to the express warranties because the Product was unreasonably dangerous and defective and had numerous serious side effects, many of which Defendants did not accurately warn about.

49. Plaintiff Durham and/or her health care provider chose the Product based upon the Defendants' warranties and representations regarding the safety and fitness of the Product.

50. Plaintiff Durham, individually and/or by and through her physicians, reasonably relied upon the Defendants' express warranties that the Product was safe, merchantable, and fit for its intended use.

51. The Defendants breached these express warranties because the Product implanted in Plaintiff Durham was unreasonably dangerous and defective, contrary to the Defendants' representations and warranties.

52. As a proximate result of the Defendants' conduct, Plaintiff Durham has sustained severe and permanent injuries, including pain, suffering, loss of care, comfort, and consortium, and economic damages.

COUNT VI: BREACH OF EXPRESS WARRANTY

53. Plaintiffs reiterate paragraphs 1-52 above as if set forth verbatim herein.

54. The Defendants manufactured, distributed, advertised, promoted, and sold the Product.

55. The Defendants intended that the Product be used for the purposes and manner that Plaintiff Durham or Plaintiff Durham's implanting physician in fact used them and impliedly warranted that the Product was of a merchantable quality, safe and fit for such use, and adequately tested.

56. Plaintiff Durham and her physician were foreseeable users of the Defendants' Product.

57. Plaintiff Durham, individually and/or through her physician, relied upon the Defendants' implied warranty of merchantability and fitness for a particular purpose when she consented to have the Product implanted in her.

58. The Defendants breached the implied warranty, because the product was neither merchantable nor suited for its intended purpose.

59. The Defendants breached their implied warranties because the Product implanted in Plaintiff Durham was unreasonably dangerous and defective, contrary to the Mesh Defendants' representations and warranties.

60. As a proximate result of the Defendants' conduct, Plaintiff Durham has sustained severe and permanent injuries, including pain, suffering, loss of care, comfort, and consortium, and economic damages.

COUNT VII: LOSS OF CONSORTIUM

61. Plaintiff reiterates paragraphs 1-61 above as if set forth verbatim herein.

62. Plaintiff Morris Durham is the spouse of Plaintiff Kimberly Durham, and as a direct and proximate result of Defendants' conduct, Plaintiff Morris Durham has suffered the loss of his wife's affection, companionship, services, society, and other damages.

63. As a direct and proximate result of Defendant's conduct, Plaintiff Morris Durham is entitled to and seeks all compensatory damages, punitive damages, attorney's fees, and any and all other damages allowed by law in an amount to be determined at the trial of this action.

COUNT VIII: PUNITIVE DAMAGES

64. Plaintiffs reiterate paragraphs 1-63 above as if set forth verbatim herein.

65. Defendants knew or should have known that the Product was defective and presented an unreasonable risk of harm.

66. Defendants' conduct in designing, manufacturing, labeling, packing, and selling a defective product that Defendant knew presented an unreasonable risk of harm demonstrates reckless indifference to and conscious disregard for the foreseeable users of the product, which justifies a punitive damage award.

WHEREFORE, Plaintiffs respectfully pray for judgment against the Defendants for actual damages, special damages, consequential damages, and punitive damages in an amount to be determined by the jury at the trial of this action, for the costs and disbursements of this action and for such other and further relief as this court deems just and proper.

Respectfully submitted,

s/ Chad A. McGowan

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June 8, 2012