IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TEAGUE CONWAY, by and through his parents and natural guardians, Chris and Kristen Conway, 628 Wallace Drive Wayne, PA 19087 and MOLLY GUINAN, by and through her parents and natural guardians, Kevin and Judith Guinan, 40 Glenn Terrace Vineland, NJ 08360 and MARK AARON HESS, by and through his parents and natural guardians, Mark and Angela Hess, 9 George Street Bridgeton, NJ 08302, Plaintiffs, vs. A.I. duPONT HOSPITAL FOR CHILDREN 1600 Rockland Road Wilmington, DE 19803 and NEMOURS FOUNDATION 1600 Rockland Road Wilmington, DE 19803 and NEMOURS CARDIAC CENTER 1600 Rockland road Wilmington, DE 19803 and JOHN T. WALSH 5104 Randall Lane Bethesda, MD 20816 and WILLIAM I. NORWOOD, M.D., Ph.D. 528 S. Longview Place Longwood, FL 32779 and JOHN MURPHY, M.D. 115 Adams Dam Road Centerville, DE 19807	:	Civil Action No. _____ CLASS ACTION ***JURY TRIAL DEMANDED***

and :
NuMED, INC. :
2880 Main Street :
Hopkinton, NY 12965 :
and :
ALLAN J. TOWER :
2880 Main Street :
Hopkinton, NY 12965 :
and :
JOHN P. CHEATHAM, M.D. :
7000 Children's Drive :
Columbus, OH 43205 :
and :
KENNETH A. MURDISON, M.D. :
1600 Rockland Road :
Wilmington, DE 19803 :
and :
NEMOURS DE INSTITUTIONAL REVIEW BOARD :
1600 Rockland Road :
Wilmington, DE 19803 :
_____ :

CLASS ACTION COMPLAINT

Plaintiffs, Teague Conway, Molly Guinan, and Mark Aaron Hess, through their undersigned counsel, on behalf of themselves and on behalf of all others similarly situated, institute this Class Action Complaint against the defendants, A.I. duPont Hospital for Children, Nemours Foundation, Nemours Cardiac Center, John T. Walsh, William I. Norwood, M.D., John Murphy, M.D., NuMED, Inc., Allan Tower, John P. Cheatham, M.D., Kenneth A. Murdison, M.D. , and the Nemours DE Institutional Review Board. In support thereof, the plaintiffs aver:

NATURE OF THE CASE

1. This is a class action filed on behalf of putative classes constituting all persons who have received the NuMED Cheatham Platinum Stent at the Nemours/A.I. duPont Hospital for Children.

2. Defendant, NuMED, Inc. (NuMED), designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or used the NuMED Cheatham Platinum Stent (hereinafter NuMED CP Stent) for the treatment of cardiovascular conditions in children.

3. Defendants designed, researched, created, tests, advertised, marketed, sold and/or promoted the implantation procedure for implantation of the NuMED CP Stent in children (hereafter Implantation Procedure).

4. Plaintiffs and all Plaintiff Class members seek compensatory damages as a result of their exposure to the NuMED CP Stent and Implantation Procedure, which has caused and will continue to cause Plaintiffs to suffer physical pain, mental anguish, medical and other related personal injuries and/or expenses.

5. Further, Plaintiffs and all Plaintiff Class members seek equitable and other relief for themselves, and all others similarly situated to compensate them in whole or in part for the following medical, health, and economic issues which confront them as a result of their injuries:

a. Medical expenses, including, but not limited to, those costs unreimbursed by insurance policies, those expenses to uninsured, those reimbursements to insurers, and/or the payment of higher insurance rates due to their use of the NuMED CP Stent and/or the Implantation Procedure, and lifelong health disorders resulting therefrom;

b. The costs of counseling to alleviate the emotional distress and related injuries imposed by the knowledge that they are at a high risk for suffering and/or have already suffered severe and permanent health consequences and injuries;

c. Additional medical monitoring above and beyond that which was needed prior to Plaintiffs' and Plaintiffs Class members' receipt of the NuMED CP Stent and/or Implantation Procedure, including, but not limited to, examinations, evaluations and diagnostic testing and medications, and other necessary and related materials;

d. The costs of creation and maintenance of networks to share vital medical information about the dangers and harms caused by NuMED CP Stent or Implantation Procedure;

e. The costs necessary to medically evaluate and monitor persons presently and formerly implanted with a NuMED CP Stent; and,

f. Whatever further relief the Court deems just and proper under the circumstances.

JURISDICTION AND PARTIES

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy as to Plaintiffs and each member of the Plaintiff Class exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in state or countries other than the state in which the named individuals and representative Plaintiffs reside.

7. Venue is proper pursuant to 28 U.S.C. §1391(a)(3) as defendants maintained systematic and continuous contacts with the district so as to be subject to personal jurisdiction herein.

8. The damages recoverable in this action exceed the sum of one hundred fifty thousand dollars ($150,000.00); thus, this case is not appropriate for compulsory arbitration under Local Civil Rule 53.2.

9. Defendants obtained the benefits of the laws of the Commonwealth and profited from commerce within the Commonwealth as a result of their design, development, research, testing, manufacture, promotion, and use of the NuMED CP Stent and Implantation Procedure, either directly or indirectly through third parties or related entities, to citizens of the Commonwealth of Pennsylvania.

10. Plaintiffs, Chris and Kristen Conway, are the parents and natural guardians of Teague Conway, the minor plaintiff upon whom the defendants conducted their experimental medical and surgical procedures at issue in this lawsuit.

11. Plaintiffs, Chris and Kristen Conway, are residents and citizens of the United States and the Commonwealth of Pennsylvania.

12. Plaintiffs, Kevin and Judy Guinan, are the parents of Molly Guinan, the minor plaintiff upon whom the defendants conducted their experimental medical and surgical procedures at issue in this lawsuit.

13. Plaintiffs, Kevin and Judy Guinan, are residents and citizens of the United States and the State of New Jersey.

14. Plaintiffs, Mark and Angela Hess, are the parents and natural guardians of Mark Aaron Hess, the minor plaintiff upon whom the defendants conducted their experimental medical and surgical procedures at issue in this lawsuit.

15. Plaintiffs, Mark and Angela Hess, are residents and citizens of the United States and the State of New Jersey.

16. Defendant, A.I. duPont Hospital for Children ("Hospital"), is a hospital for the treatment and care of pediatric patients, and had incorporated into its health care services the Nemours Cardiac Center, and employed and/or had as agents, servants and/or employees, co-defendants Norwood, Murphy, Walsh, Cheatham and Murdison. Defendants A.I. duPont Hospital for Children and Nemours Cardiac Center are located at 1600 Rockland Road, Wilmington, DE 19803, and does business in Philadelphia County.

17. Defendant, Nemours Foundation, is a Florida entity that maintains a place of business

at the A.I. duPont Hospital for Children located at 1600 Rockland Road, Wilmington, DE 19803.

18. Defendant Nemours Cardiac Center is a duly authorized corporation, organized and existing under and by virtue of the laws of the State of Delaware with medical offices and its principal place of business located at 1600 Rockland Road, Wilmington, Delaware 19803.

19. Defendant, John Walsh, at all times pertinent hereto, was acting as Chief Administrator of the Nemours Cardiac Center, and acted in concert with the co-defendants to perform the improper activities and wrongful conduct regarding the NuMED CP Stent as more fully described herein.

20. Defendant, William I. Norwood, M.D., Ph.D., is a cardiac surgeon who, at all times pertinent hereto, was the Director of the Nemours Cardiac Center and acted in concert with the co-defendants to perform the improper activities and wrongful conduct regarding the NuMED CP Stent as more fully described herein.

21. Defendant, John D. Murphy, M.D., is a pediatric cardiologist who, at all times pertinent hereto, was an employee, agent and/or servant of the co-defendants, and was intimately involved in the improper activities and wrongful conduct regarding the NuMED CP Stent as more full described herein.

22. Defendant, NuMED, Inc., is an entity which maintains a principal place of business in Hopkinton, NY. At all times relevant hereto, defendant NuMED, Inc., has designed, developed, researched, tested, manufactured, promoted, marketed, and distributed the NuMED CP Stent as more fully described herein.

23. Defendant, Allan Tower, is averred to be the responsible individual at NuMED, Inc., who, at all times relevant hereto, acted on behalf of NuMED, Inc., and/or was an agent and/or

employee of NuMED, Inc., who engaged in the wrongful conduct with regard to the CP Stent at issue in this lawsuit.

24. Defendant, John P. Cheatham, M.D., (Dr. Cheatham), is a pediatric cardiologist practicing at the Columbus Children's Hospital in Columbus, OH, and was part of the Nemours entity. At all times pertinent hereto, Dr. Cheatham worked directly or indirectly with the co-defendants in the design, development, research, testing, manufacture, promotion, use, and inducement of the Plaintiffs' Class members to have the CP Stent inserted into their children.

25. Defendant, Kenneth A. Murdison, M.D., is a pediatric cardiologist at the Nemours/A.I. duPont Hospital for Children, and is averred to have been part of the health care providers involved in the improper activities and wrongful conduct regarding the NuMED CP Stent as more fully described herein.

26. Defendant, the Nemours DE Institutional Review Board (IRB), is an entity run by employees, agents and/or servants of the defendants duPont and Nemours, and is charged with ensuring the safety, oversight, and monitoring of clinical trials and non-conventional treatments, such as experimental or (alleged) "compassionate use" treatments, such as the NuMED CP Stent procedures at issue in this lawsuit.

FACTUAL BACKGROUND

27. Defendant, NuMED, Inc., was formed by Allan Tower, and claims to be "[T]he Leader in Adult/Pediatric Catheterization."

28. The purpose of NuMED is to, in part, create catheter delivered stent for adults and children with cardiovascular conditions; the stent at issue, the "Cheatham Platinum Stent" (NuMED CP Stent) is averred to have been created, in part, by John P. Cheatham, M.D. and NuMED and used on patients through the co-defendants.

29. According to defendant Tower, the NuMED CP Stent at issue has not received FDA approval in spite of five (5) years of attempts to get the stent approved.

30. All named defendants knew that there was a potential danger in the stent implantation procedure, that it had not been done before, and the consequences were unknown, yet misled the families into a false sense of security that the proposed, experimental procedure was safer and less risky than the standard surgical approach.

31. It is believed and averred that the same stent at issue in this lawsuit, and used on the children at duPont Hospital, was used by Dr. Cheatham, for which the Food and Drug Administration issued a June 1, 2004 Warning Letter (Exhibit "A") demanding Dr. Cheatham stop using the stent.

32. The intended recipients of the NuMED CP Stent are those children who have congenital cardiac defects which require some form of the "Fontan" or "Norwood" procedure; that is, a series of surgical procedures designed, in part, to shift the burden of cardiac output from a deficient ventricle to the more functional one.

33. The standard "non-stent" surgical approach to these complex cardiovascular conditions is known, tested, and provides good long-term function and survival to children born with these cardiac conditions.

34. It is believed and averred that the co-defendants intended to conduct a research study on the patients at Nemours/A.I. duPont Hospital through the Nemours Cardiac Center individually and in conjunction with the research at Columbus Children's Hospital, spearheaded by co-defendant Cheatham.

35. The informed consent form that the participants are alleged to have signed, and the individual discussions of the defendants, their agents, servants and/or employees, minimized the

risks of this experimental stent, and did not describe, as required, the true nature of the history, knowledge and significant risks of complications, requirements for revision surgery, and made it sound as if the stent procedure was much less risky and safer than the third surgical approach.

36. The defendants did have knowledge of the stent's risks and long-term consequences, and, indeed, failed to disclose the true risks of the stent; they also failed to inform the families that the FDA had for five years failed to approve the stent.

37. Defendants, Nemours Foundation and the Hospital, have specifically stated that defendants Norwood, Murphy and Walsh put patients at risk and intentionally withheld information from patients and parents.

38. Defendants, Nemours Foundation and the Hospital, have specifically stated that defendants Norwood, Murphy and Walsh violated hospital policies and procedures, including the acquisition and use of a medical device not approved by the FDA, and failing to follow policies and procedures for obtaining informed consent.

39. Defendants, Nemours Foundation and the Hospital, have accused defendant Murphy of failing to obtain consent from the parent of a minor child for treatment by using the NuMED CP Stent, which had not been approved by the FDA, without informing the parent of the fact that the stent was not approved by the FDA, and failing to obtain the signature of the parent on the required consent form.

40. Defendants, Nemours Foundation and the Hospital, have specifically stated to the Delaware Hospital Licensing agency that defendant Norwood was involved in the decision to use the NuMED CP Stent, that defendants Norwood and Murphy were involved in the use of the unapproved stent in patients without prior notification to and approval of the defendant, Nemours DE Institutional Review Board.

41. Defendants, Nemours Foundation and the Hospital, have specifically stated that, "No parents knew that the doctors were performing procedures without hospital approval," and "The doctors were involved in decisions to place unapproved medical devices in patients without prior notification to, and approval by our Institutional Review Board and [the doctors] implemented an experimental device in 14 babies without obtaining full consent from their parents."

42. Defendants Norwood, Murphy and Walsh have specifically stated that defendants, Nemours Foundation and the Hospital, lied, committed fraud, and covertly denied defendants Norwood, Murphy and Walsh the right to provide information to state agencies.

43. Defendants Norwood, Murphy and Walsh have specifically stated that defendants Nemours Foundation and the Hospital covered up their misconduct by terminating defendants Murphy, Norwood and Walsh.

44. Defendants Norwood, Murphy and Walsh have specifically stated that defendant Nemours Foundation deprived patients of needed care, and acted in reckless disregard of patient safety.

45. Defendants Norwood, Murphy and Walsh have specifically stated that defendant Nemours Foundation ordered Norwood, Murphy and Walsh not to seek FDA approval for use of the NuMED CP Stent.

46. Defendants Norwood, Murphy and Walsh have specifically stated that defendants Nemours Foundation and the Hospital were fully aware of the clinical use of the NuMED CP Stent.

47. Defendants Norwood, Murphy and Walsh have specifically stated that defendant IRB approved presentation on the use of the NuMED CP Stent in March, 2003, and that defendant Nemours DE Institutional Review Board confirmed that use of the stent did not require prior approval. Nemours and the Hospital deny this.

48. Defendants Norwood, Murphy and Walsh have specifically stated that defendant Nemours Foundation was aware of the use of the NuMED CP Stent, and displayed the stent on its website.

49. Defendants Norwood, Murphy and Walsh have specifically stated that defendant Nemours Foundation encouraged them not to interview with Delaware State officials and imposed a "gag order" on fellow employees "forbidding them the right to express their support of [Norwood, Murphy and Walsh] and condemnation of [Nemours Foundation's] wrongful conduct under threat of termination, while paying a public relations agency to improperly mold public opinion."

50. Defendants Norwood, Murphy and Walsh have specifically stated that the behavior of defendant Nemours Foundation "induced [them] to forgo the opportunity to provide truthful information to the investigators for the state licensing agency and as a result, that state licensing agency concluded its investigation based solely upon the false and misleading statements provided by the [Nemours Foundation]."

51. The defendants also failed to inform the families of these children, prior to the second stage of the Fontan procedure, occurring months before the stent implantation, that a collar may be placed in the heart in order to prepare the child's heart to receive the stent during the third procedure; this is a clear violation of the rights and safety of the plaintiffs' children, and demonstrates a reckless disregard on behalf of the defendants to inform and obtain consent from the parents for this experimental procedure.

Facts Relating to Representative Plaintiff, Molly Guinan

52. Molly Guinan was born with a congenital heart defect; defendant Dr. Norwood performed the first and second stages of the surgical corrective procedure, and without informing Molly's parents of the intention to insert the stent during the third procedure, installed the collar in Molly's heart during the second stage in preparation for receiving the experimental NuMED CP Stent in the upcoming third procedure.

53. On October 14, 2002, Molly Guinan underwent the third aspect of the cardiac repair and was told by the defendants and their agents, servants and/or employees (such as Dr. Murdison) prior to the stent implantation procedure that the stent was something that was done "all the time" and was much safer than the standard surgical approach; this statement was, and is, willfully false and deceptive; the false and misleading statements were made with the specific intent to induce parents to have their children receive the stent for research purposes, and not for the best interests of the children.

54. During the January to March, 2003 time period, Molly Guinan developed at least two serious medical conditions known as Protein Losing Enteropathy (PLE) and plastic bronchitis; these conditions were a direct result of the stent placement and its resulting physiologic effects on Molly's body.

55. In spite of the attempts of Molly's parents to get the physicians at the Nemours Cardiac Center to provide proper and necessary care to Molly, including consultations with pulmonary medicine, intensive care, anesthesiology, etc., the physicians at the Nemours Cardiac Center refused to permit Molly to be seen by anyone outside of their small world; in fact, the Guinans had to have Molly discharged from the hospital, and then readmitted to the non-cardiac portion of the hospital, in order to get the intensive care Molly needed, but was deprived of, by the Nemours Cardiac Center physicians.

56. It is averred, upon information and belief, that the defendants made a conscious decision to shield these stent patients from other physicians outside of the Nemours Cardiac Center so as to hide their improper behavior as outlined herein.

57. As a result of the failures of the defendant outlined herein, Molly Guinan was caused to suffer severe and permanent damages, including cardiac arrest requiring resuscitation, dangerous medicines and emergent treatments, which would have been unnecessary had the defendants acted properly.

58. On or about October 6, 2003, the Guinan family received a phone call, and ultimately a facsimile, from the defendants attempting to have them "back date" and sign a NuMED consent form, as it was necessary for the data collection and research purposes; the Guinans told Dr. Murdison that they had not seen that form, and would not sign and backdate it. This was the first time the Guinans were aware of the issues regarding the NuMED Stent. Had the family been properly informed, they would have never agreed to the stent implantation.

59. It was only after the family sought counsel that the "lost" NuMED Stent consent form was "found." However, the signature, allegedly of Mr. Guinan, is an obvious forgery and not that of Mr. Guinan.

60. Immediately after this contact, the Guinans made various complaints to the defendants, and the defendant Institutional Review Board ("IRB"), which claimed it had no knowledge of the experimental stent procedures being performed at the hospital; these claims were made by approximately the middle of November, 2003.

61. In spite of the allegations of the IRB that they had no knowledge of the stent experimentation, information regarding the stent appeared on the hospital's website, and they are alleged to have known that defendant Dr. Murphy intended to present on the stent issue; detailed

allegations of what the hospital and its IRB knew are outlined in Exhibit "B," a lawsuit filed by defendants Norwood, Murphy and Walsh against the co-defendants.

Facts Relating to Representative Plaintiff, Teague Conway

62. In spite of widespread exposure of the improper, illegal and unethical practices of the defendants regarding the cardiac stent practices, on December 4, 2003, after this information was known to all defendants, another stent implantation procedure was performed on plaintiff, Teague Conway.

63. The parents of Teague Conway were not informed of the complaints made by the Guinans, and were misled, as were other parents, as to their child's actual condition, need for the stent, and the true experimental and unknown nature and future risks of the experimental NuMED stent.

64. In order to fraudulently induce the Conways to permit the stent to be used, defendants claimed "compassionate use," and did not inform the family that the stent was experimental.

65. Shortly after Teague Conway's stent was inserted, it clotted, made him significantly sicker than he was prior to the stent placement, and required emergent cardiac surgery to remove the clotted stent; as a result of the emergency surgery, Teague Conway's heart had to be redone to a temporary surgical condition – a major setback – and he will require future cardiac surgery – none of which would have been necessary had the defendants given the family the truth regarding the stent, its true experimental nature, and the accompanying research plans and future developments desires for this stent. For the family would never have agreed to the stent implantation procedure had they been told the full truth.

66. At no time prior to the plaintiffs' participation in this stent placement procedure were they informed of the true nature of the stent, and its attendant risks, unknown nature, or the possible serious and life-threatening complications as described herein.

Facts Relating to Representative Plaintiff, Mark Aaron Hess

67. On January 12, 2003, Mark Aaron Hess, Jr., underwent the experimental implantation of the NuMED stent; this was done in lieu of performing the traditional surgical completion of his heart surgeries. During this procedure, two experimental NuMED CP Stents were used. Mark suffered from pleural effusions right after this surgery. He was monitored and treated, then discharged to home on January 25, 2003.

68. After the last surgery when the stents were implanted, Mark continued to have breathing problems and, on January 27, 2003, Mark was admitted to the hospital again for cardiac complications and vomiting. Mark was treated with heart medications and discharged to home on January 31, 2003.

69. On February 14, 2003, Mark was again admitted to the hospital for evaluation and management of his serious complications after the surgery involving the placement of the stents.

70. Mark Hess continues to have cardiopulmonary complications after the stent placement surgery, and will need ongoing care for these complications for the rest of his life.

71. At no time prior to the plaintiffs' participation in this stent placement procedure were they informed of the true nature of the stent and its attendant risks, unknown in nature, and possible serious and life-threatening complications as described herein.

CLASS DEFINITIONS

72. Plaintiffs bring this action as a class action pursuant to the provisions of Federal Rules of Civil Procedure Rule 23 on behalf of themselves and all others similarly situated, including the classes defined as follows:

> **CLASS I** – All persons in the United States, its possessions and territories, or their estates, administrators or other legal representatives, heirs or beneficiaries, who participated in the NuMED Cheatham Platinum Stent procedures at the Nemours/A.I. duPont Hospital for Children. This class seeks, among other relief, medical monitoring to enable people who have been implanted with the NuMED CP Stent to be monitored for the existence of dangerous side effects, normal heart growth, normal heart function, proper stent positioning, and proper stent function. The monitoring devices to be utilized and provided for the monitoring class shall include, but not be limited to, cardiac catheterizations, echocardiograms, MRIs, CT Scans, X-Rays, blood tests, uranalysis, other surgery or any other testing deemed necessary by class members' treating physicians to determine the cardiovascular health of class members. Additionally members of the class seek necessary procedures, including but not limited to procedures to prevent myocardial infarction, blood clots, pulmonary embolisms, restricted blood flow, to ensure adequate oxygenation of the bolls and overall oxygenation and proper blood flow... Excluded from this class are all persons and entities with claims for personal injury. Also excluded from this class are the defendants, and entities in which the defendants have a controlling interest, and all of its legal representatives, heirs and successors.
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> **CLASS II** – All persons in the Commonwealth of Pennsylvania, its possessions and territories, or their estates, administrators or other legal representatives, heirs or beneficiaries, who participated in the NuMED Cheatham Platinum Stent procedures at the Nemours/A.I. duPont Hospital for Children. This class represents all individuals who have suffered personal injury as a result of the NuMED stent procedures, as well as requiring medical monitoring as described above. Included in this class are others entitled to loss of consortium, as well as dependents and others entitled to recovery or Wrongful Death or Survival Statutes. This class seeks damages for the personal injury damages outlined herein.

73. Plaintiffs bring this action individually and as class representatives to recover damages against the defendants who created, took part in and formulated the protocol to insert the NuMED CP Stent into the plaintiffs or any Plaintiffs Class member.

74. Research subjects have suffered personal injury and death as a direct and proximate result of defendants' actions described herein. In addition, the Derivative Claimants have suffered damages as a direct and proximate result of the defendants' actions, for which an award of damages is appropriate.

CLASS ACTION ALLEGATIONS

75. Plaintiffs bring this action as a class action pursuant to the provisions of Federal Rules of Civil Procedure Rule 23 on behalf of themselves, individually, and Classes of persons similarly situated. This action satisfies the numerosity, commonality, typicality, adequacy, predominance and superiority requirements of those provisions.

76. Upon information and belief, it is averred that there are numerous members of the class set forth above. The proposed members are so numerous that joinder of all members is impractical.

77. The claims of the named plaintiffs are typical of the claims of the class they seek to represent, in that the named plaintiffs and all members of the proposed class were induced to receive the NuMED CP Stent, and assert rights and claims as a plaintiff, member of Class I or member of Class II, as these terms are defined in the proposed class definitions.

78. The proposed classes seek damages as a result of injuries they or their heirs have sustained as a result of defendants' conduct. In addition, the Derivative Claimants have suffered a loss of consortium, love, services and affection, and have incurred financial expenses and economic losses as a direct and proximate result of the personal injuries and damages suffered by their children, who were Research Participants. Thus, the pursuit of damages by the class representatives

for their injuries and losses will work to benefit the entire proposed class they seek to represent.

79. Common questions of fact and law applicable as to all members of the Plaintiffs' Class, predominate over any questions affecting only individual members of the Classes. These common legal and factual questions, which do not vary from Class member to Class member, include, but are not limited to, the following:

(a) whether defendants knew of prior adverse reactions, dangers, and need for continued medical monitoring of those patients who received the NuMED CP Stent and failed to inform the Research Subjects of these adverse reactions;

(b) whether the defendants failed to adequately and properly test the stent and implantation procedure after the design, manufacture and use;

(c) whether the defendants failed to investigate and analyze prior adverse reactions information in order to warn and/or notify Research Subjects of the dangers of participating in the program;

(d) whether defendants committed common law fraud in intentionally misrepresenting the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reason for terminating the Trial;

(e) whether defendants' misrepresentations set forth above were done with the knowledge that they were exaggerated and/or false when made;

(f) whether, by their actions, defendants increased the risk of harm, thereby causing the injuries and/or death of the plaintiff and other members of the class;

(g) whether defendants conducted adequate study, testing and analysis to determine whether the NuMED CP Stent was harmful to Research Subjects;

(h) whether defendants engaged in unconscionable, deceptive and/or unreasonable business practices and conduct;

(i) whether defendants knowingly or intentionally concealed, suppressed or omitted material information intended to be relief upon by others in connection with the implantation of the NuMED CP Stent;

(j) whether the class has been injured by virtue of defendants' intentional, reckless, careless, unconscionable and/or deceptive business practices and conduct;

(k) whether defendants failed to follow and abide by local state and federal law, including the Nuremberg Code, the Belmont Report, the Declaration of Helsinki, §21 CFR 56, and §45 CFR 46;

(l) whether defendants falsely and fraudulently misrepresented in their advertisements, promotional materials and other materials the safety and adverse results of participating in the NuMED CP Sent;

(m) whether the defendants willfully and fraudulently forged the parents' and/or guardians' signatures on certain NuMED consent forms;

(n) whether defendants knew or should have known that implementing the NuMED CP Stent posed a substantial increased risk of serious adverse health effects, including, but not limited to, death;

(o) whether defendants continued to recruit individuals to participate in NuMED, notwithstanding their knowledge of the dangerous, unknown nature of the stent;

(p) whether defendants earned substantial profits as a result of their conduct herein;

(q) whether defendants knowingly omitted, suppressed or concealed material facts about the unsafe and dangerous nature of the NuMED CP Stent from government regulators, the Institutional Review Board, the medical community and/or the consuming public, and/or failed to obtain Human Subjects approval from the IRB at A.I. duPont;

(r) whether defendants' wrongful advertising, marketing and/or other business conduct constitute false, deceptive and/or unfair business practices in violation of local, state and federal law; and,

(s) whether defendants violated local, state and federal law statutes and regulations designed to protect against injuries caused by the NuMED Stent.

80. Plaintiffs' claims are typical of the claims of the members of the Plaintiff Class; all of whom have been subjected to the Implantation Procedure and implantation of the NuMED CP

Stent, which was designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and used by defendants. Plaintiffs are a member of the Plaintiff Class and have sustained, and/or will continue to sustain, damages and injuries, and are facing irreparable harm arising out of defendants' tortious conduct.

81. Plaintiffs are fair and adequate representatives of the Plaintiff Class because they are members of the Plaintiff Class, and their interests do not conflict with the interests of the members of the Plaintiff Class they seek to represent. Further, plaintiffs are represented by experienced and able counsel, who have litigated numerous other products liability class actions, and they intend to prosecute this action vigorously for the benefit of the entire Plaintiff Class. Plaintiffs and their counsel will fairly and adequately protect the interests of the members of the Plaintiff Class. The interests of the plaintiffs, and the separate Class members they seek to represent, are aligned because of their implantation with the NuMED CP Stent, and their consequential injuries caused by the NuMED CP Stent and Implantation Procedure.

82. Plaintiffs, and each Plaintiff Class member, have a similarly strong interest in obtaining the damages for personal injury and/or wrongful death.

83. Plaintiffs have, or will obtain, adequate financial resources to assure that the interests of the classes will not be harmed.

84. Maintenance of this action as a class action for the classes alleged is a fair and efficient method for adjudication of this controversy. It would be impracticable and undesirable for each member of Plaintiffs' Class who has suffered harm to bring a separate action. In addition, the maintenance of separate actions would place a substantially and unnecessary burden on the courts,

and would result in inconsistent adjudications, while a single class action can determine, with judicial economy, the rights of all class members.

85. Alternatively, certification of the Class is appropriate pursuant to Rule 23 of the Federal Rules of Civil Procedure because the questions of law and fact common to members of the class predominate over any question affecting only individual members. This class action is superior to other available remedies for the fair and efficient adjudication of this controversy.

86. Notice may be provided to class members by a combination of published notices and first class mail, using techniques and forms of notice similar to those customarily used in drug-related products liability causes and complex class actions.

87. Plaintiffs know of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action certified for each of the described separate classes.

FIRST CAUSE OF ACTION
NEGLIGENCE

88. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows on behalf of themselves and all others similarly situated.

89. Defendant, NuMED, is the designer, manufacturer, seller and/or supplier of the NuMED CP Stent.

90. All defendants are the creators, researchers and/or users of the Implantation Procedure.

91. The NuMED CP Stent was not accompanied by appropriate warnings of the risks

caused by implantation of the stent. The warnings given by defendants did not accurately reflect the risks, incidences, symptoms, scope or severity of the risks involved with implantation.

92. Defendants failed to perform adequate testing concerning the safety of the NuMED CP Stent because adequate testing would have shown that the stent procedure posed a serious risk and would have permitted the defendant to provide adequate and appropriate warnings to plaintiffs, Plaintiff Class members and the public.

93. Defendants had a duty to exercise reasonable care in the manufacturing, selling and/or distribution of the stent, including the duty to assure that the product does not cause users to suffer from unreasonable, dangerous injuries.

94. Defendants had a duty to exercise reasonable care in the development, promotion and use of a procedure to implant the NuMED CP Stent.

95. Defendants are negligent in the design, testing, manufacturing, advertising, marketing, promoting, labeling, warnings given, and safety measures of the stent in that they:

(a) Failed to accompany the product with proper warnings regarding all possible adverse risks associated with its use;

(b) Failed to conduct adequate testing and surveillance to determine the safety of the stent;

(c) Failed to provide adequate training and instructions to medical care providers for appropriate use of the stent;

(d) Failed to warn the plaintiffs and the Class members, prior to actually encouraging the use of the stent, either directly or indirectly through third parties or related entities, about the following:

(i) The possibility of becoming disabled or dying as a result of the receipt of the stent and/or having to undergo medical/surgical treatment in order to correct or control the injuries caused by implantation of the stent; and,

(ii) Injuries may become protracted, debilitating, difficult and painful, and necessitate frequent visits to the doctor, clinic or hospital.

(e) Failed to warn that the risks associated with the stent could exceed the risks of the comparable forms of treatment available;

(f) Negligently marketed and over-marketed the stent despite the fact that the risks associated with its use were so high that no reasonable medical device company, exercising due care, would have done so;

(g) Remained silent, despite their knowledge of the growing public acceptance of the information and misrepresentations regarding the safety of the stent, and did so because the prospect for huge profits outweighed health and safety issues, all to the significant detriment of plaintiffs and Plaintiff Class;

(h) Failed to comply with their duty to warn, which arose when they knew, or with reasonable care should have known, that their devices were being used without warning of the true risks involved;

(i) Were otherwise careless, negligent, grossly negligent, reckless and acted with willful and wanton disregard for the rights of plaintiffs and Plaintiff Class;

(j) Breached plaintiffs' and Plaintiff Class members' right to be treated with dignity as follows:

(i) The Nuremberg Code and the Declaration of Helsinki are the minimum United States and international standards of conduct governing biomedical research on human subjects; they are in essence world statutes to which the citizens of all nations are subject.

(ii) The Nuremberg Code, drafted in response to the horrors of Nazi experimentation on human subjects, set forth basic principals to satisfy moral ethical and legal concepts.

(iii) The Nuremberg Code provides, in pertinent part:

> The voluntary consent of the human subject is absolutely essential . . . . . before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards

reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

. . .

The experiment should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem understudy that the anticipated results will justify the performance of the experiment.

. . .

The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

. . .

Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

. . .

The experiment should be conducted only by scientifically qualified persons.

(iv) The World Health Organization established the Declaration of Helsinki to further the goals of the Nuremberg Code and to set the minimum acceptable standards in all nations in which human clinical trials are conducted. These include:

Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

. . .

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

. . .

Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person.

. . .

Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objectives is in proportion to the inherent risk to the subject.

. . .
Concern for the interests of the subject must always prevail over the interest of science and society.
. . .
The right of the research subject to safeguard his or her integrity must always be respected.
. . .
Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable.
. . .
In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.

(v) The common law has recognized such standards as a source of the right of every human subject to be treated with dignity in the conduct of a clinical trial; such a right is a right of all citizens of the United States under the Constitution of the United States and the . . .

(vi) Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki, and were a breach of the right of plaintiffs and the members of the Class to be treated with dignity.

(vii) As a result of the defendants' actions, plaintiffs and the members of the Class have suffered damages.

(k) Failed to comply with Federal and State laws, including:

(i) 21 CFR §56 and 45 CFR §46.107, part of the code of Federal Regulations, establish the law of the United States with respect to the conduct of Institutional Review Boards.

(ii) 45 CFR §46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as the Nemours/A.I. duPont Hospital for Children.

(iii) The defendants failed to comply with the mandates of the federal regulations, and therefore the defendants' actions constitute negligence *per se*.

(iv) These regulations also require institutions such as the Center

to appoint an IRB to oversee the Trial, and to adhere to the opinions and directives of the IRB.

(v) The individual defendants failed to inform the IRB of the mandatory facts, complications and progress of the stent research; similarly, the IRB failed to have proper policies and procedures in place to ensure that any experimentation on humans was conducted as required by all legal and ethical mandates.

(vi) As set forth above, defendants have violated these regulations, to the great damage and detriment of plaintiffs and members of the Class.

(l) Failed to comply with the Belmont Report:

(i) The Belmont Report was prepared by the government in the late 1970's on behalf of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report is a longstanding government document defining the Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The purpose of this document is to outline, in specific detail, the ethical requirements of research on human subjects and describes:

1. the boundaries between biomedical and behavioral research, and the accepted and routine practice of medicine;

2. the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects;

3. appropriate guidelines for the selection of human subjects for participation in such research; and,

4. the nature and definition of informed consent in various research setting.

(ii) The defendants are obliged to comply with the mandates of the Belmont Report, but failed to do so.

(iii) As set forth above, defendants breached their responsibilities to the plaintiffs by failing to follow the ethical principals in the Belmont Report.

(iv) As a result of this breach, plaintiffs and other members of the Class have suffered damages as set forth above.

(m) Failed to comply with standards set forth by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

(n) whether defendants knew, or should have known, that implementing the NuMED CP Stent posed a substantial increased risk of serious adverse effects, including, but not limited to, death.

96. Defendants knew, or should have known, that patients such as plaintiffs and the Plaintiff Class would foreseeably suffer injuries as a result of defendants' failure to exercise ordinary care as described above.

97. Defendants' actions constitute knowing omission, suppression and/or concealment of material facts, made with the intent that others rely upon such omissions, suppression and/or concealment in connection with the use of the stent.

98. The conduct of defendants demonstrates that defendants acted unlawfully and negligently, used or employed unconscionable commercial and business practices, engaged in deception, fraud, false pretense, false promises or misrepresentation, and/or perpetrated knowing concealment, suppression or omission of material facts, with the intent that individuals such as plaintiffs and the Class rely upon such concealment, suppression and/or omission in connection with the promotion, marketing and use of the NuMED CP Stent.

99. As a direct and proximate cause of defendants' failure to supply appropriate warning for the stents, plaintiffs and the members of the Class have used the stent and have suffered injuries as a result.

100. As a direct and proximate result of the negligence, carelessness and other wrongdoing of defendants as described above, plaintiffs and members of the Class have used the stents and have suffered injuries.

WHEREFORE, Plaintiffs demand judgment from Defendants in excess of one hundred and fifty thousand dollars ($150,000.00), plus punitive damages, together with interest, costs, and any other relief that the Court deems appropriate on each of the counts herein.

SECOND CAUSE OF ACTION
FRAUD AND INTENTIONAL MISREPRESENTATION

101. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows on behalf of themselves and all others similarly situated.

102. Defendants committed common law fraud in intentionally misrepresenting the risks of undergoing the stent implantation and the complete truth behind the history of the NuMED Stent.

103. The misrepresentations set forth more fully herein were done with the knowledge that they were false when made.

104. Plaintiffs and the members of the Class justifiably relied upon the above-stated misrepresentations in making the decisions to participate and continue in the Trial.

105. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiffs' children and other members of the Class were induced to receive the stent.

WHEREFORE, Plaintiffs demand judgment from Defendants in excess of one hundred and fifty thousand dollars ($150,000.00), plus punitive damages, together with interest, costs, and any other relief that the Court deems appropriate on each of the above counts.

THIRD CAUSE OF ACTION
ASSAULT AND BATTERY

106. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and allege as follows on behalf of themselves and all others similarly situated.

107. Defendants failed to inform the plaintiffs, plaintiffs' decedents and other members of the Class of the risks and alternatives to of all treatment, care, therapy and procedures performed so as to afford the plaintiffs, plaintiffs' decedent and the members of the Class the opportunity to make an informed decision as to the performance of said procedures in violation of the minimal standard and the federal requirements as outlined herein; thus, the therapy plaintiffs and other members of the Class received constituted a battery.

WHEREFORE, Plaintiffs demand judgment from Defendants in excess of one hundred and fifty thousand dollars ($150,000.00), plus punitive damages, together with interest, costs, and any other relief that the Court deems appropriate on each of the above counts.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY

108. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and allege as follows on behalf of themselves and all others similarly situated.

109. Defendants designed, manufactured and supplied the stents and stent components which caused great physical and emotional damage to the plaintiffs' decedents and the members of the Class.

110. Defendants breached their duties and obligations to the plaintiffs, plaintiffs' decedents and the members of the Classes by various sections of the Restatement of Torts, 2d, including Section 402(a), and are liable for causing injuries to the plaintiffs by:

(a) designing, manufacturing, selling and/or distributing a product in a defective condition;

(b) designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

(c) designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

(d) failing to have adequate warnings on the product;

(e) failing to warn users of the dangers inherent in using this product;

(f) designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

(g) designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

(h) designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

(i) designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

(j) designing, manufacturing, selling and/or distributing a product which was defective, and which could cause injury to the user;

(k) failing to ensure that ultimate users were advised of the dangers of said product;

(l) failing to adequately warn of the risks and dangers of said product;

(m) failing to exercise reasonable care in the design of this product;

(n) failing to exercise reasonable care in the distribution of this product;

(o) failing to adequately and properly test this product;

(p) failing to use reasonable care under the circumstances;

(q) delivering a product which was defective and could cause injury to the user;

(r) product a product which was defective and could cause injury to the user;

(s) supplying a product which was defective and could cause injury to the user;

(t) knowing of prior adverse reaction to the stent and failing to inform the user of these adverse reactions;

(u) failing to adequately and properly test the product after its design and manufacture;

(v) failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

(w) violating applicable sections of the Restatement of Torts, 2d; and,

(x) engaging in other acts regarding the manufacturing, designing, testing, preparing, producing and distributing this product as will be learned in discovery.

111. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the damages outlined herein to the plaintiffs' children, and the injuries and/or death of other members of the Classes.

WHEREFORE, Plaintiffs demand judgment from Defendants in excess of one hundred and fifty thousand dollars ($150,000.00), plus punitive damages, together with interest, costs, and any other relief that the Court deems appropriate on each of the above counts.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS AND IMPLIED WARRANTIES

112. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and allege as follows on behalf of themselves and all others similarly situated.

113. In manufacturing, producing, promoting and distributing the NuMED CP Stent, defendants expressly and impliedly warranted that the aforementioned product was merchantable, fit and safe for the ordinary and particular purposes for which it was sold, and that it was free from all defects and dangers.

114. Upon information and belief, it is asserted that defendants advertised the stent as being safe and effective when it was not.

115. Defendants breached the express and implied warranties by producing, promoting and distributing the NuMED CP Stent in an unsafe, defective and unfit condition.

WHEREFORE, Plaintiffs demand judgment from Defendants in excess of one hundred and fifty thousand dollars ($150,000.00), plus punitive damages, together with interest, costs, and any other relief that the Court deems appropriate on each of the above counts.

SIXTH CAUSE OF ACTION
MEDICAL MONITORING

116. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and allege as follows on behalf of themselves and all others similarly situated.

117. As a direct result of defendants' acts, omissions and conduct, plaintiffs and members of the proposed Classes who have received NuMED CP Stent have been exposed to a hazardous procedure and product, and suffered a significantly increased risk of the side effects caused by this device. This increased risk makes periodic diagnostic and medical examinations reasonable and necessary.

118. Medical monitoring is necessary because:

(a) The NuMED CP Stent is a proven and admittedly hazardous product;

(b) Plaintiffs' exposure to the hazardous product and procedure was proximately caused by defendants' tortious conduct;

(c) Medical monitoring will detect injuries from the NuMED CP Stent and its implantation;

(d) This monitoring will be different from what normally is recommended to individuals who did not receive a NuMED CP Stent; and,

(e) Medical monitoring will assist in preventing further injuries from or as a consequence of implantation of the NuMED CP Stent.

119. Early detection and diagnosis of these injuries is clinically valuable because it can prevent, reduce and/or significantly delay additional injuries, resulting discomfort, suffering and/or death, and because these conditions can often appear to be asymptomatic absent proper testing.

120. Effective monitoring and testing procedures exist which make early detection and treatment of these injuries possible and beneficial. Early diagnosis of these diseases and conditions will allow prompt and effective treatments, which will reduce the risk of morbidity and mortality from which these patients would suffer if treatments were delayed until their conditions became overly symptomatic.

121. Plaintiffs and Class I members who received NuMED CP Stent are at a significantly increased risk for the existence of side effects caused by this device.

122. By virtue of their exposure to the NuMED CP Stent, plaintiffs and Class I members who received NuMED CP Stent are at a significantly increased risk for side effects and further injury. Accordingly, medical and scientific research is reasonably necessary for the diagnosis and treatment of such injuries.

123. Increased susceptibility to injuries and irreparable threat to the health of plaintiffs and the Classes from their receiving the NuMED CP Stent can be mitigated or addressed by the creation of a comprehensive medical monitoring program that:

(a) Notifies individuals who have received the NuMED CP Stent of the potential harm from the stent;

(b) Aids individuals who received the NuMED CP Stent in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring;

(c) Provides individuals who received NuMED CP Stent in Class I with state of the art medical testing;

(d) Provides for the accumulation and analysis of relevant medical and demographic information from Class members;

(e) Provides for the creation, maintenance and operation of a "Registry" in which relevant demographic and medical information concerning all Class members can be gathered, maintained and analyzed;

(f) Provides for medical research concerning the incident, prevalence, natural course and history, diagnosis and treatment of NuMED CP Stent-induced injuries; and,

(g) Allows for publication and dissemination of all such information to members of Class I and their physicians.

124. Members of Class I who have received a NuMED CP Stent have no adequate remedy at law because monetary damages alone will not compensate them for the continuing nature of the harm to them. A monitoring program that notifies them of possible injury and aid in their treatment can prevent the greater harm that may occur immediately, and which may be preventable if the health risks are diagnosed and treated before they occur or become worse.

125. Without a court-approved medical monitoring program, NuMED CP Stent recipients may not receive prompt medical care that could protect and prolong their productive lives, increase their prospects for improvement, and minimize disability.

126. By reason of the foregoing, plaintiffs demand medical monitoring together with any other relief that the Court deems appropriate based on each of the above counts.

PRAYER FOR RELIEF

WHEREFORE, the plaintiffs, for themselves and all others similarly situated, request that this Court enter judgment against the defendants and in favor of plaintiffs, on behalf of themselves and members of the Plaintiff Class, and to award the following relief:

A. Certifying this action as a class action pursuant to Federal Rules of Civil Procedure Rule 23;

B. Declaring the defendants financially responsible for notifying all Plaintiff Class members that the stent is dangerous, and for taking on other actions requested herein;

C. Creation of a Court-supervised trust fund, paid for by the defendants, to finance a medical monitoring program to deliver services, including, but not limited to, testing, preventative screening and surveillance for conditions resulting from, or potentially resulting from, insertion of the stent, as well as establishment of a medical research and education fund and a medical/legal registry;

D. Ordering that defendants refund and make restitution of all monies acquired from the sale of the stent to plaintiffs and Plaintiff Classes;

E. Award the plaintiffs and the Classes compensatory and punitive damages for the acts complained of herein;

F. Entering an appropriate award of attorneys' fees, expenses and costs of suit, pursuant to the rules governing class action procedure and other applicable law; and,

G. Such additional and further relief as this Court may deem just and appropriate.

JURY TRIAL DEMAND

Plaintiffs demand, on behalf of themselves and all other similarly situated, a trial by jury on all issues so triable.

Respectfully submitted,

BY:_____

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