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

Joseph L. Castle, II, et al.,	:	CIVIL ACTION
Plaintiffs and Counterclaim Defendants,	:	NO. 03-5252
v.	:	
Linda J. Crouse, M.D.,	:	
Defendant and Counterclaim Plaintiff.	:	JURY TRIAL DEMANDED

DEFENDANT AND COUNTERCLAIM PLAINTIFF LINDA J. CROUSE, M.D.'S ANSWER, ADDITIONAL DEFENSES AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendant and counterclaim plaintiff, Linda J. Crouse, M.D. ("Dr. Crouse"), by her attorneys, answers the complaint of plaintiffs, the Trustees of the AHP Settlement Trust (the "Trust") and asserts the following additional defenses and counterclaims:

ANSWER

1. Denied.

PARTIES

2. Admitted.

3. Admitted in part and denied in part. Dr. Crouse admits only that the Trust has its principal place of business in Philadelphia, Pennsylvania. The remaining allegations in paragraph 3 of the complaint are denied.

4. Admitted.

5. Admitted.

6. Admitted.

7. Admitted.

8. Admitted.

9. Admitted.

10. Admitted.

11. Admitted.

12. Admitted in part and denied in part. Dr. Crouse admits only that the Trustees are the plaintiffs in this action. The remaining allegations in paragraph 12 of the complaint are denied.

13. Admitted in part and denied in part. Dr. Crouse admits only that she is a Level III trained cardiologist and that she is board certified in internal medicine and cardiovascular diseases. The remaining allegations in paragraph 13 of the complaint are denied.

JURISDICTION AND VENUE

14. Denied.

15. Denied.

16. Denied.

17. No response is required. The Trustees allege in paragraph 17 of their complaint that, "for the convenience of the parties and the Court, the allegations of the complaint are divided by headings to which no response is required and which are merely intended to summarize the allegations that follow." Inasmuch as many of the Trustees' headings are pejorative and/or seek to portray Dr. Crouse negatively, she will not repeat them in her answer and denies them.

18. Admitted.

19. Admitted.

20. Admitted.

21. Admitted in part and denied in part. Dr. Crouse admits only that on or about November 17, 1999, Wyeth and Class Counsel executed the Settlement Agreement. The remaining allegations in paragraph 21 of the complaint are denied.

22. Denied. The allegations in paragraph 22 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

23. Admitted in part and denied in part. Dr. Crouse admits only that echocardiograms are ultrasonic examinations of the heart using high frequency sound waves to create moving (or still frame) images of the heart and its valves. The remaining allegations in paragraph 23 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

24. Denied.

25. Admitted in part and denied in part. Dr. Crouse admits only that an echocardiogram is the primary tool that cardiologists use to assess the levels of valvular regurgitation. The remaining allegations in paragraph 25 of the complaint are denied.

26. Denied.

27. Denied. The allegations in paragraph 27 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

28. Denied. The allegations in paragraph 28 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

29. Denied. The allegations in paragraph 29 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

30. Denied. The allegations in paragraph 30 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

31. Denied. The allegations in paragraph 31 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

32. Denied.

33. Denied.

34. Admitted in part and denied in part. Dr. Crouse admits only that the Settlement Court approved the Green Form. The remaining allegations in paragraph 34 of the complaint purport to characterize the Settlement Agreement and the Green Form, writings which should be referred to for their content, and are therefore denied.

35. Denied. The allegations in paragraph 35 of the complaint purport to characterize the Green Form, a writing which should be referred to for its content, and are therefore denied.

36. Denied. The allegations in paragraph 36 of the complaint purport to characterize the Green Form, and certain medical texts quoted or cited to therein, writings which should be referred to for their content, and are therefore denied.

37. Denied. The allegations in paragraph 37 of the complaint purport to characterize the Green Form, a writing which should be referred to for its content, and are therefore denied.

38. Denied. The allegations in paragraph 38 of the complaint purport to characterize the Green Form, a writing which should be referred to for its content, and are therefore denied.

39. Denied. The allegations in paragraph 39 of the complaint purport to characterize the Green Form, a writing which should be referred to for its content, and are therefore denied.

40. Denied. The allegations in paragraph 40 of the complaint purport to characterize the Green Form and the Settlement Agreement, writings which should be referred to for their content, and are therefore denied.

41. Denied.

42. Denied. The allegations in paragraph 42 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

43. Denied. To the extent the allegations in paragraph 43 of the complaint purport to characterize orders of the Court, they are denied, as the orders are writings which should be referred to for their content. The remaining allegations in paragraph 43 of the complaint are denied.

44. Admitted in part and denied in part. Dr. Crouse admits only that she is a Fellow of the American College of Cardiology and the American Heart Association, that she is Board Certified in Internal Medicine and in Cardiovascular Diseases, and that she serves as the Director of the Echocardiographic Laboratory at the Shawnee Mission Medical Center and the Women's Cardiovascular Center. The remaining allegations in paragraph 44 of the complaint purport to characterize the Settlement Agreement, a writing which should be referred to for its content, and are therefore denied.

45. Denied.

46. Admitted in part and denied in part. Dr. Crouse admits only that she signed Green Forms. The remaining allegations in paragraph 46 of the complaint are denied.

47. Denied.

48. Denied.

49. Denied.

50. Admitted in part and denied in part. Dr. Crouse admits only that she signed Green Forms and that in many cases, she did not meet the person whose medical condition she was certifying. The remaining allegations in paragraph 50 of the complaint are denied. By way of further response, Dr. Crouse denies the implication in paragraph 50 of the complaint that she was required to personally meet the person whose medical condition she was certifying, or that it is somehow improper for a cardiologist to interpret an echocardiogram without personally meeting the patient. To the contrary, nothing in the Settlement Agreement or the Green Form required a certifying cardiologist to personally meet the claimant. Moreover, as expert cardiologists for the Trust and Wyeth have repeatedly acknowledged, the standard of care does not require a cardiologist to meet a patient before interpreting an echocardiogram – just like a radiologist does not have to meet a patient to interpret an x-ray and determine that the patient has a broken arm.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied. By way of further response, the term "backflow," as currently used by the Trust, is not a recognized term in the fields of cardiology and echocardiography, but has been used improperly by the Trust and its co-conspirators, and has been incorporated by the Trust and taught to its numerous auditing cardiologists in its sham audit protocol and so-called "claims integrity program," as a way to deny payment of claims that should qualify for benefits under the parameters set forth in the Settlement Agreement and the Green Form.

64. Denied. By way of further response, see response set forth in paragraph 63, which is incorporated herein by reference.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

78. Denied.

COUNT I

79. Dr. Crouse incorporates herein by reference her responses to paragraphs 1 though 78 above as if fully set forth herein.

80. Denied.

81. Admitted in part and denied in part. Dr. Crouse admits only that she is a shareholder and owner of Kramer & Crouse Cardiology, P.C. (incorrectly identified in the complaint as Crouse & Kramer), that it is an ongoing medical practice, and that it operated and continues to operate a legitimate business – a cardiology practice. The remaining allegations in paragraph 81 of the complaint are denied.

82. Admitted in part and denied in part. Dr. Crouse admits only that she is one of the lead cardiologists in the Kramer & Crouse Cardiology, P.C. cardiology practice. The remaining allegations in paragraph 82 of the complaint are denied.

83. Denied.

84. Admitted in part and denied in part. Dr. Crouse admits only that, in addition to being a shareholder and owner of Kramer & Crouse Cardiology, P.C., she is also an employee of Kramer & Crouse Cardiology, P.C. The remaining allegations in paragraph 84 of the complaint are denied.

85. Denied.

86. Denied.

87. Denied.

88. Denied.

89. Denied.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

COUNT II

94. – 106. No response is required pursuant to the memorandum and order of the Court entered February 11, 2004 granting Dr. Crouse's motion to dismiss count II of plaintiffs' complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

COUNT III

107. Dr. Crouse incorporates herein by reference her responses to paragraphs 1 though 106 above as if fully set forth herein.

108. Denied.

109. Denied.

110. Denied.

111. Denied.

112. Denied.

113. Denied.

114. Denied.

COUNT IV

115. – 120. No response is required pursuant to the memorandum and order of the Court entered February 11, 2004 granting Dr. Crouse's motion to dismiss count IV of plaintiffs' complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

COUNT V

121. – 128. No response is required pursuant to the memorandum and order of the Court entered February 11, 2004 granting Dr. Crouse's motion to dismiss count V of plaintiffs' complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

COUNT VI

129. Dr. Crouse incorporates herein by reference her responses to paragraphs 1 though 128 above as if fully set forth herein.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Denied.

136. Denied.

COUNT VII

137. Dr. Crouse incorporates herein by reference her responses to paragraphs 1 though 136 above as if fully set forth herein.

138. Denied.

139. Denied.

140. Denied.

ADDITIONAL DEFENSES

By way of further answer and affirmative defense to plaintiffs' complaint, Dr. Crouse asserts the following additional affirmative defenses:

FIRST DEFENSE

Plaintiffs' complaint fails to state claims against Dr. Crouse upon which relief can be granted.

SECOND DEFENSE

Plaintiff's claims are barred, in whole or in part, by the applicable statute of limitations.

THIRD DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver and estoppel.

FOURTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of laches.

FIFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by acquiescence.

SIXTH DEFENSE

Any alleged misrepresentations or omissions by Dr. Crouse were not material.

SEVENTH DEFENSE

Any reliance by the Trust was unreasonable.

EIGHTH DEFENSE

Any damages allegedly suffered by the Trust were not caused by its reliance on any statements or omissions made by Dr. Crouse.

NINTH DEFENSE

Plaintiffs' damages, if any, were caused by parties other than Dr. Crouse.

TENTH DEFENSE

Plaintiffs' damages, if any, were caused by their own actions or inaction.

ELEVENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by their own comparative and/or contributory negligence.

TWELFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by their failure to mitigate their alleged damages.

THIRTEENTH DEFENSE

Plaintiffs lack standing to assert their claims against Dr. Crouse.

FOURTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of unclean hands and for reasons of public policy.

FIFTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Dr. Crouse's actions were and are privileged. She was retained as an expert for a limited purpose pursuant to a court proceeding and thus cannot be sued for her conduct in connection with giving her expert opinion. Plaintiffs' claims against Dr. Crouse violate public policy with respect to the privileges and immunities granted to expert witnesses in connection with expert testimony and/or opinions.

SIXTEENTH DEFENSE

The Trustees have filed their complaint against Dr. Crouse in a grossly negligent manner and/or without probable cause, in violation of 42 Pa.Cons.Stat. § 8351.

SEVENTEENTH DEFENSE

The attorneys for the Trustees have unreasonably and vexatiously multiplied the proceedings in this case. Accordingly, they should be required by the Court to satisfy personally

the excess costs, expenses, and attorneys' fees reasonably incurred by Dr. Crouse as a result of their conduct, pursuant to 28 U.S.C. § 1927.

COUNTERCLAIMS

Defendant and counterclaim plaintiff, Linda J. Crouse, M.D. ("Dr. Crouse"), by her attorneys, asserts the following counterclaims against plaintiffs and counterclaim defendants Joseph L. Castle, II, George A. Beller, M.D., Richard S. Cohen, Chris Harris, Allison Overseth, Rose-Marie Robertson, M.D., FACC, and Dean M. Trafelet (collectively, the "Trustees"). In support thereof, Dr. Crouse alleges the following:

INTRODUCTION

1. At the time the massive Diet Drugs class action lawsuits were settled in 1999, the settlement was hailed by class counsel and Wyeth alike as perhaps the greatest mass tort settlement ever. By 2004, these accolades ring hollow. Indeed, the multi-billion dollar AHP Settlement Trust has become an administrative nightmare, with no hope of satisfying the very claims for which it was established. In addition, this tragedy has taken on human proportions, as the Trustees, through their intentional pattern of conduct, have forever harmed the reputation of Dr. Crouse, one of the nation's preeminent echocardiologists. Based largely on a seriously flawed protocol, incorrect statistical and epidemiological assumptions and their fraudulent concept of "backflow," the Trustees have falsely accused Dr. Crouse of racketeering, fraud and other wrongdoing, and have widely disseminated these baseless assertions. As set forth herein, the Trustees, in concert with their co-conspirators, have violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968, and have committed numerous torts against Dr. Crouse.

THE PARTIES

2. Counterclaim plaintiff Linda J. Crouse, M.D. ("Dr. Crouse") is a citizen and resident of Leawood, Kansas. Dr. Crouse is an internationally known cardiologist and level III echocardiographer who is board certified in internal medicine and cardiovascular diseases. Dr. Crouse operates a medical practice at 7301 E. Frontage Road, Shawnee Mission, Kansas 66204.

3. The AHP Settlement Trust (the "Trust") is a judicially approved Trust that receives settlement funds from Wyeth Corporation ("Wyeth") (formerly known as American Home Products or AHP Corporation) pursuant to the nationwide class action settlement agreement (the "Settlement Agreement") resolving *In Re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation* (E.D. Pa., MDL Docket No. 1203) (the "Diet Drugs Litigation"). The Settlement Agreement, with amendments, is attached as Exhibit "A" to plaintiffs' complaint and is incorporated herein by reference. The Trust is created under the laws of the Commonwealth of Pennsylvania and has its principal place of business in Philadelphia, Pennsylvania.

4. On February 25, 2000, the United States District Court for the Eastern District of Pennsylvania appointed seven Trustees to operate the Trust, all of whom continue to serve as Trustees.

5. Counterclaim defendant George A. Beller, M.D. ("Dr. Beller") is a citizen and resident of Virginia and is a Trustee of the Trust. As set forth below, Dr. Beller is the superior at the University of Virginia of John M. Dent, M.D. ("Dr. Dent"). Dr. Dent is a hired expert for the Trust who has been complicit in the improper scheme to discredit Dr. Crouse and in the Trustees' fraudulent scheme to deny payments to tens of thousands of claimants who qualify for

benefits under the Settlement Agreement and is the champion of the distorted audit program, as set forth in detail below.

6. Counterclaim defendant Joseph L. Castle, II is a citizen and resident of Pennsylvania and is a Trustee of the Trust.

7. Counterclaim defendant Richard S. Cohen is a citizen and resident of New Jersey and is a Trustee of the Trust.

8. Counterclaim defendant Chris Harris is a citizen and resident of Texas and is a Trustee of the Trust.

9. Counterclaim defendant Allison Overseth is a citizen and resident of New York and is a Trustee of the Trust.

10. Counterclaim defendant Rose-Marie Robertson, M.D., FACC, is a citizen and resident of Tennessee and is a Trustee of the Trust.

11. Counterclaim defendant Dean M. Trafelet is a citizen and resident of Illinois and is a Trustee of the Trust.

JURISDICTION AND VENUE

12. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1332 (diversity), 28 U.S.C. § 1367 (supplemental jurisdiction) and 18 U.S.C. § 1964 (RICO).

13. Venue is proper pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to this action occurred in this judicial district.

BACKGROUND

Dr. Crouse

14. Dr. Crouse is an internationally known cardiologist at the pinnacle of her field.

15. Dr. Crouse received her medical degree from New York University School of Medicine in 1976. She completed her internship and residency in Internal Medicine at Bellevue Hospital – New York University from 1976 to 1980, the last year of which she served as Chief Medical Resident. Dr. Crouse completed fellowships in Cardiology at the University of Minnesota and at the University of California, San Francisco. She served as an NIH Research Fellow at the Pacemaker Institute at Beth Israel Hospital in Newark, New Jersey. She is a Fellow of the American College of Cardiology, and a Fellow of the American Heart Association.

16. Dr. Crouse has earned two board certifications from the American Board of Internal Medicine: the first in Internal Medicine in 1979, the second in Cardiovascular Diseases in 1983. She has achieved a level of training in echocardiology recognized by the American Society of Echocardiography as Level III, the highest level possible.

17. Between 1990 and 1998, Dr. Crouse was the Director of the Echocardiographic Laboratory at the Mid-America Heart Institute in St. Luke's Hospital, Kansas City, Missouri. Between 1994 and 1999, she was also the Medical Director of the Women's Cardiac Center at the Mid-America Heart Institute. Since 1997, she has been a Clinical Professor of Medicine at the University of Missouri-Kansas City, in Kansas City, Missouri. She is currently the Director of the Echocardiographic Laboratory at the Shawnee Mission Medical Center, as well as the Director of the Women's Cardiovascular Center.

18. Dr. Crouse is a member of the American Society of Echocardiography (the "ASE"), an association of physicians and sonographers who practice echocardiography and

further their education in that field. She was a member of the ASE's Board between 1994 and 1998.

19. Dr. Crouse was a founding member, and is the former President, of the Intersocietal Commission for the Accreditation of Echocardiographic Laboratories (the "ICAEL"), an organization formed to accredit echocardiographic laboratories. She has written standards for how echocardiology should be performed in laboratories, to ensure that laboratories across the United States provide high quality medical care. Until falling victim to the improper actions of the Trustees, as discussed herein, Dr. Crouse served on the Board of the ICAEL.

20. Since 2001, Dr. Crouse has served on the Board of Directors of the American Heart Association in Kansas City, Missouri. Until falling victim to the improper actions of the Trustees, as discussed herein, Dr. Crouse was scheduled to serve as President of the Kansas City chapter of the American Heart Association.

21. Dr. Crouse has published over 40 articles relating to echocardiography. One of Dr. Crouse's articles is cited in the portions of the textbook by Dr. Harvey Feigenbaum, entitled *Echocardiography*, which is relied upon in the Settlement Agreement.

22. From March through July 1998, Wyeth retained Dr. Crouse to participate in two studies to determine the health effects of Wyeth's diet drugs. Upon completing the initial two trials for Wyeth, Dr. Crouse was selected as a potential investigator for Wyeth in further research on Fen-Phen.

23. The Trust also selected Dr. Crouse to be a member of its screening panel in November 2001, to perform echocardiograms on people who had taken Fen-Phen in order to determine their entitlement to Matrix level benefits.

24. In addition to her academic endeavors, Dr. Crouse has her own private practice. In 1997, Dr. Crouse and her husband, Dr. Paul Kramer, also a cardiologist, formed Kramer & Crouse Cardiology, P.C., a three-person practice with a staff of 18 people.

25. Kramer & Crouse Cardiology, P.C's lead sonographer, Audrey Loeb, has been a sonographer for 20 years, the last eight of which have been spent working under Dr. Crouse's direct supervision in her office following procedures Dr. Crouse has mandated. Ms. Loeb has a Masters Degree in science, has taught ultrasound physics at the university level, and co-taught courses to physicians on how to perform and interpret echocardiograms. She is a registered Vascular Technologist, a registered Diagnostic Medical Sonographer, and a registered Diagnostic Cardiac Sonographer.

26. Dr. Crouse's office uses special "echo beds" on which the patients lie during their examinations. These beds have removable panels that allow the transducer to be positioned in the optimal location for imaging apical views of the heart. Although it is possible to perform an echocardiogram without an echo bed, echo beds improve the overall quality and accuracy of the images.

27. Over a period of a number of months in 2002, Dr. Crouse was retained by a number of lawyers and/or law firms to perform and interpret echocardiograms in connection with the Settlement Agreement. The echocardiograms performed under Dr. Crouse's supervision were done primarily by Audrey Loeb, Dr. Crouse's highly skilled sonographer, and were always appropriately supervised by Dr. Crouse.

28. In addition, during this same period, Dr. Crouse was retained by a number of lawyers and/or law firms to interpret echocardiograms in connection with the Settlement Agreement, where the echocardiograms were performed by others.

29. At all times, Dr. Crouse performed and interpreted the echocardiograms appropriately and in conformity with the Settlement Agreement and the Green Form.

30. Where appropriate and consistent with the Settlement Agreement and the Green Form, Dr. Crouse also attested to a number of Green Forms on behalf of claimants under the Settlement Agreement for whom she had interpreted an echocardiogram.

31. Further, Dr. Crouse also performed and interpreted echocardiograms and, where appropriate, attested to Green Forms, for a number of her own clinical patients who had ingested the Diet Drugs.

32. As set forth below, Dr. Crouse's reputation has been indelibly stained, and she has suffered substantial and irreparable professional, personal and financial harm, as a result of the improper and unlawful conduct of the counterclaim defendants.

The Diet Drugs And Resulting Mass Tort Litigation

33. From 1989 through September 1997, when its diet drugs were taken off the market, Wyeth, through its predecessor in interest, AHP, manufactured and sold the diet drugs Pondimin and Redux (commonly known together as "Fen-Phen," and referred to herein as the "Diet Drugs") to millions of Americans.

34. From January 1995 to mid 1997 alone, approximately 4 million people in the United States took Pondimin. From June 1996 through September 15, 1997 alone, approximately 2 million people in the United States took Redux.

35. In March 1997, researchers at the Mayo Clinic in Rochester, Minnesota began observing an association between the use of the Diet Drugs and a particular type of valvular heart disease. Eventually, the Mayo Clinic researchers observed this unusual form of valvular heart disease in 24 women who had used the Diet Drugs. The findings of the Mayo researchers were

first brought to the attention of the public in a July 8, 1997 press release and were eventually published on August 28, 1997 in the *New England Journal of Medicine.*

36. On July 8, 1997, the FDA issued a public health advisory, followed by letters to 700,000 physicians requesting information about similar patients. Based on information that the FDA received in response, the FDA requested the withdrawal of the Diet Drugs from the United States market. On September 15, 1997, AHP and the FDA announced that there would be no further sales of the Diet Drugs in the United States.

37. A wave of litigation followed. At the time class notice was issued in the Diet Drugs Litigation, approximately 18,000 individuals who used the Diet Drugs had filed lawsuits against AHP. In addition, over 100 plaintiffs had instituted class action lawsuits. For the actions filed in the federal judicial system, the Judicial Panel for Multidistrict Litigation entered an order transferring all actions to the United States District Court for the Eastern District of Pennsylvania for coordinated and/or consolidated pre-trial proceedings under MDL Docket No. 1203.

The Diet Drugs Class Settlement

38. In connection with the consolidated class actions, the Court appointed a plaintiffs' management committee (the "PMC"). The PMC was appointed by the Court to represent the interests of the class members as a whole. See Pre-Trial Order No. 6.

39. Wyeth made a corporate policy decision and concluded that it would not fight liability in the consolidated class actions, would abandon its arguments that the Diet Drugs did not cause valvular heart disease, and would instead attempt to achieve a global settlement of the Diet Drugs class action lawsuits.

40. On November 18, 1999, the parties executed the Settlement Agreement. The Court granted preliminary approval of the Settlement Agreement on November 23, 1999, and held a fairness hearing regarding the Settlement Agreement in May 2000.

41. Among other things, pursuant to the Settlement Agreement, Wyeth gave up the right to challenge plaintiffs' claims that the Diet Drugs caused valvular heart disease. In return, claimants who elected not to opt out of the Settlement Agreement entirely gave up the right to seek punitive damages and other rights. Moreover, for those claimants who do not elect to pursue intermediate or back-end opt-out rights contemplated by the Settlement Agreement, the Settlement Agreement provides for a pre-determined schedule of compensation based on a number of factors, including but not limited to, the severity of the claimant's valvular heart disease as defined in the Settlement Agreement, the age of the claimant, how long the claimant took the Diet Drugs, the presence or absence of certain other medical conditions, and other factors.

The Assumptions Underpinning The Settlement Agreement

42. During the fairness hearing, the PMC and Wyeth offered witnesses in support of the Settlement, including attorneys, legal experts, medical doctors and medical experts, epidemiologists and economists. In seeking approval of the Settlement Agreement, the PMC and Wyeth, through their expert witnesses, presented the Court with certain medical, statistical and epidemiological assumptions underlying the Settlement.

43. In particular, there are two broad categories of assumptions that appear now to have been incorrect.

44. The first category concerns the number of persons who might ultimately submit claims under the Settlement Agreement and, related thereto, the amount of settlement funds needed to be contributed by Wyeth to the Trust to properly fund the Settlement.

45. The second category concerns the medical assumptions incorporated in the Settlement Agreement, and reiterated in the Green Form, relating to which users of the Diet Drugs qualify for benefits under the Settlement Agreement and, similarly, the medical assumptions for determining the level of benefits for which a particular claimant qualifies under the Settlement Agreement.

46. As set forth below, whether intentionally or simply as a result of significant errors, the assumptions presented to the Court by Wyeth and the PMC as to both of the broad categories identified above were seriously flawed in numerous material ways. As a result of the erroneous medical, statistical and epidemiological assumptions utilized by the experts for Wyeth and the PMC, they seriously underestimated the number of qualified claimants and the amount of funds sufficient to properly fund the Settlement.

47. Nevertheless, on August 28, 2000, the Court approved the Settlement Agreement. See Pre-Trial Order No. 1415. The Settlement Agreement received final judicial approval on January 3, 2002.

The Relevant Terms Of The Settlement Agreement

48. To qualify for Matrix Level II benefits under the Settlement Agreement, a claimant must have, among other possibilities, a level of moderate or severe mitral regurgitation or mild or greater aortic regurgitation as defined in the Settlement Agreement and Green Form, which is documented by an echocardiogram performed in the manner specified in the Settlement Agreement.

49. The Settlement Agreement imposes requirements as to the manner in which an echocardiogram must be conducted if the echocardiogram is to be used to qualify a claimant for benefits under the Settlement Agreement.

50. Specifically, the Settlement Agreement requires that an echocardiogram be "conducted in accordance with the standards and criteria as outlined in Feigenbaum (1994) or Weyman (1994)." This refers to Dr. Harvey Feigenbaum's textbook *Echocardiography* 68-133 (5th ed. 1994), and to Dr. Arthur E. Weyman's ("Dr. Weyman") textbook *Principles and Practice of Echocardiography* 75-97 (2d ed. 1994).

51. In addition to directing that an echocardiogram be conducted in accordance with the standards and criteria as outlined in either of the Feigenbaum or Weyman texts, the Settlement Agreement also directs that the echocardiogram be "evaluated following the grading system of valvular regurgitation defined in Singh (1999)." This refers to J.P. Singh, et al., *Prevalence of Clinical Determinants of Mitral, Tricuspid and Aortic Regurgitation (The Framingham Heart Study)*, 83 Am. J. Cardiology 897, 898 (1999). Singh, in turn, relied upon the methodology set forth in Helmcke, et al., *Color Doppler Assessment of Mitral Regurgitation With Orthogonal Planes,* Circulation, 75(1): 175-83 (1987).

52. The Settlement Agreement further requires that the echocardiogram be "conducted by a Diagnostic Cardiac Sonographer who is able to produce and evaluate ultrasound images and related data used by physicians to render a medical diagnosis," and that the echocardiogram be "conducted under the supervision of, and read and interpreted by, a Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon with level 2 training in echocardiography as specified in the *Recommendations of the American Society of Echocardiography Committee on Physician Training in Echocardiography*."

53. Significantly, Dr. Dent, the Trust's expert, has acknowledged that Dr. Crouse performed her echocardiograms in accordance with the Settlement Agreement and the Green Form.

The Green Form

54. The Settlement Agreement contemplated that in connection with submitting a claim for Matrix Level Benefits, a claimant was required to submit a detailed form – the Green Form – a portion of which (Part II) was to be completed by a board-certified cardiologist with level 2 or higher training in echocardiography.

55. The Green Form requires that the board-certified cardiologist certify that the claimant had "an Echocardiogram which was conducted in accordance with the standards and criteria as outlined in Feigenbaum (1994) or Weyman (1994)." The Green Form incorporates the same protocol for performing and interpreting echocardiograms as set forth in the Settlement Agreement.

56. Among other things, the Green Form does not require a certifying cardiologist to take a claimant's medical history, does not require a physician-patient relationship between the certifying cardiologist and the claimant, does not require a cardiologist interpreting an echocardiogram to meet in person with the claimant, and does not require that an echocardiogram interpreted by a certifying cardiologist have been performed in that cardiologist's office.

The Many Significant Variables Affecting The Performance And Interpretation Of Echocardiograms

57. At the heart of the Trustees' false claims against Dr. Crouse, as well as their scheme to deny payments to tens of thousands of claimants who qualify for benefits under the terms of the Settlement Agreement, is the acquisition and interpretation of the echocardiograms

mandated by the Settlement Agreement. The acquisition and interpretation of echocardiograms is dependent on a number of factors – the echocardiogram machine is highly complex, the process by which echocardiographic images are acquired is highly technical, and the interpretation of the echocardiograms requires considerable skill and judgment.

58. Significantly, numerous variables affect the acquisition and interpretation of echocardiograms, most of which the Trustees have ignored in falsely accusing Dr. Crouse of fraud. For example, there is significant inter-reader variability, significant inter-machine variability, and inherent subjectivity among readers. There are many differences among echocardiogram machines. There are also many differences among patients. Echocardiograms are much more difficult to acquire on very heavy patients, such as many who ingested the Diet Drugs. In addition, images from echocardiograms degrade significantly with each generation of copy; yet, the Trust has often challenged Dr. Crouse's interpretations based on third or fourth generation copies of echocardiograms, which contain far less detail than the originals.

59. Notwithstanding these numerous variables, the Trustees and their co-conspirators have intentionally mischaracterized what is, at most, a difference of medical opinion among expert cardiologists, and recast it as "fraud," with the real goal of denying payment to tens of thousands of claimants who qualify for benefits under the Settlement Agreement and to whom the Trustees owe a fiduciary duty.

The Trust Fails To Implement A Viable Program To Permit Class Members To Obtain Echocardiograms In Accordance With The Terms Of The Settlement Agreement

60. The Settlement Agreement provided a 12-month period after final judicial approval of the Settlement Agreement within which the millions of users of the Diet Drugs had to obtain a screening echocardiogram to qualify for benefits under the Settlement Agreement.

61. While the Settlement Agreement provided that users of the Diet Drugs could obtain a high-quality echocardiogram through the Trust, the Trustees unreasonably delayed in implementing a viable program to provide echocardiograms on a timely basis. Indeed, despite their duty to do so, the Trustees were unable to establish a screening program that would permit all of the users of the Diet Drugs who sought echocardiograms to obtain one within the time originally permitted by the Settlement Agreement and the Court.

62. Accordingly, many attorneys representing potential claimants, as well as individual claimants, began to seek out and obtain echocardiograms privately – outside the Trust's screening echocardiogram program – as permitted by the Settlement Agreement. Many did so because they were concerned that they would be unable to obtain an echocardiogram through the Trust before the deadline.

The Trust Received Multiple Times The Number Of Claims That Were Predicted When The Settlement Was Approved, And Is Effectively Bankrupt

63. The Trust has received exponentially more claims than were predicted by the experts who testified on behalf of Wyeth and the PMC at the fairness hearing. Indeed, to date, the Trust has received at least 111,584 Green Forms and has received at least 1,023,984 of all primary forms from claimants.

64. The Trust at this point is effectively bankrupt.

65. The Trustees have paid out more than one-third of the Trust's total assets, and yet only a small fraction of the total claims submitted have been paid. Indeed, as of the monthly report of the Trust for the month ending December 31, 2003, filed with the Court on January 27, 2004, the Trust has paid out a total of $1,486,545,209. With respect to Matrix Level Claims, the Trust has paid out $1,105,218,721 for only 2,786 claims, which represents an average of $396,704 per claim. The Trust has received at least 111,584 Green Forms to date, not to mention

hundreds of thousands of other claims. Thus, simple arithmetic reveals that the Trust has used more than one-third of its assets to pay no more than three percent (3%) of the Matrix Level Claims submitted to it to date. If even a relatively small percentage of the claims are paid at the current average amount, the Trust will run out of funds. Indeed, even if only ten percent (10%) of the remaining claimants who submitted Green Forms are paid, these payments will far exceed the balance of funds remaining in the Trust.

The Medical Protocol And The Epidemiological And Statistical Assumptions Underlying The Settlement Agreement Were Flawed

66. The medical assumptions underlying the Settlement Agreement were based on outdated or poorly regarded medical literature and studies that utilized outdated echocardiography equipment. One result, for example, is that many members of the general public would qualify as having moderate mitral regurgitation as defined under the protocol set forth in the Settlement Agreement and Green Form, even though an echocardiologist would not consider them to have moderate mitral regurgitation in a clinical setting. Indeed, the Settlement Agreement's entire approach of relying solely on jet area to measure severity of mitral regurgitation is inherently flawed. The results of such errors in setting the parameters to qualify for benefits under the Settlement Agreement are profound – these errors alone have resulted in an exponential increase in the number of claimants seeking benefits over the amounts predicted at the time of the fairness hearing.

67. The protocol set forth in the Green Form is also flawed, including, among other things, the way in which it directs cardiologists to measure mitral regurgitation. Moreover, the Settlement Agreement and Green Form protocol provides no guidelines on what to measure (*e.g.*, the borders of mitral regurgitation).

68. Further, the Singh and Helmcke articles, upon which the protocol in the Settlement Agreement and Green Form rests in part, are based on studies that utilized outdated technology from 1987, are very vague, have been widely criticized and are not used in contemporary cardiology practice.

69. The Settlement Agreement and Green Form protocol is also vague or silent on numerous other critical factors such as standardization of machines, which settings to use, what boundaries to use to measure and quantify RJA/LAA, and numerous other deficiencies, all of which have a tremendous impact on the acquisition and interpretation of echocardiograms.

70. The Trustees were asleep at the switch for at least two years. Although they now contend that the cardiologists were to act as "gatekeepers," the Trust provided no direct training or communications to cardiologists as to what the Trust expected of cardiologists. The Trustees provided no training courses, no certification, and no training materials to cardiologists in connection with acquiring and interpreting echocardiograms under the Settlement Agreement and Green Form protocol and/or completing the Green Form.

71. Indeed, when Dr. Crouse was first retained by claimants' attorneys to perform and interpret echocardiograms pursuant to the Settlement Agreement and the Green Form, she and her staff repeatedly contacted the Trust to seek guidance on how the Trust wanted the studies to be done. For example, she sought clarification of the Settlement Agreement and Green Form protocol and measurements. She also inquired as to how the measurements were to be taken and whether she should average several beats. Despite numerous such requests for information from the Trust, the Trust never provided any meaningful information to Dr. Crouse or her staff which would have directed them to perform their services as now advanced by the Trustees. Moreover, she asked the Trust to identify the physicians acquiring and interpreting echocardiograms for the

Trust, so that she could contact the Trust's cardiologists directly to inquire about the protocol and the Trust's requirements. The Trust failed to provide this information to Dr. Crouse.

72. The results of the poorly defined and incorrectly constructed protocol are twofold. First, cardiologists were not given proper guidance on how to perform and interpret echocardiograms in accordance with the Settlement Agreement and Green Form. This has caused tremendous inconsistency, and has allowed the Trust, Wyeth and others to improperly second-guess the interpretations done by cardiologists, including Dr. Crouse, who attempted to comply in good faith with the protocol, notwithstanding that it was poorly conceived, vague, and not consistent with how skilled cardiologists would interpret echocardiograms and diagnose valvular heart disease in their clinical practices. Second, as a direct result of the poorly conceived protocol, thousands of claimants qualify for Matrix Benefits under the Settlement Agreement, notwithstanding that they would not be considered to have valvular heart disease in a clinical setting. In other words, the protocol, as specifically set forth in the Settlement Agreement and Green Form, is significantly over-inclusive in its definitions of moderate and severe mitral regurgitation and mild or greater aortic regurgitation as compared to the definitions utilized in a clinical setting.

73. Moreover, significant aspects of the epidemiological and statistical assumptions presented to the Court at the fairness hearing by the PMC and Wyeth, and upon which the Settlement Agreement was based, were fundamentally wrong and seriously underestimated the number of qualified claimants submitting claims to the Trust.

The Trustees Have Failed In Their Duties To Oversee The Trust

74. As set forth above, the Trust has had significant problems from its inception.

75. The Trustees could not even set up the initial screening echocardiogram program in such a manner that would permit users of the Diet Drugs to obtain a screening echocardiogram by the deadline imposed by the Court and the Settlement Agreement.

76. The Trust has missed one deadline after another. It has not even been able to perform such basic functions as opening and responding to mail in a timely manner.

77. The Trustees selected a young and inexperienced chief executive officer to oversee the $4.5 billion Trust, with the hope that he would "grow into the job." At the time he took the job, he was a practicing lawyer associated with counsel for the Trust.

78. The Trustees failed to timely implement a functioning claims processing procedure and have processed and paid claims at a glacial pace, with the result that tens of thousands of claims have been unreasonably delayed. Indeed, based on the number of claims received to date and the pace at which those claims have been processed so far, the Trust will take many decades just to process and pay the claims that it has already received.

79. Moreover, the Trust has failed to implement the 100% audit – for which it sought and obtained Court approval – in a viable manner, with the result that the processing and payment of claims has come to a virtual standstill. For example, in the monthly report of the Trust for the month ending December 31, 2003, filed with the Court on January 27, 2004, the Trust indicates that 37,193 Matrix Claims have been approved for audit, but only 2,980 have been sent to audit. This does not include the numerous other claims the Trust has received but not yet processed to send to audit. Indeed at its current audit rate, it will take the Trust 40 years to audit the Matrix Claims currently pending.

80. The Trustees have also failed to discharge their fiduciary duties in that they have neglected to inform the public that the Trust is insolvent and will not have sufficient funds to pay all claimants who are entitled to benefits under the Settlement Agreement.

81. In short, the Trustees have utterly failed to perform their duties as Trustees and, under their stewardship, the Trust has been rendered completely incapable of performing its raison d'etre – to timely process and pay claims of those persons injured as a result of ingesting the Diet Drugs.

The September 2002 Hearing At Which The Trustees And Wyeth Invent "Backflow"

82. Before she was sued in the above-captioned matter (the "RICO Action"), Dr. Crouse appeared before the Court as a non-party witness in a proceeding in the Diet Drugs Litigation (the "September 2002 Hearing"). That proceeding involved a challenge brought by the Trust, and joined by Wyeth and the PMC, to 88 claims for benefits under the Settlement Agreement. The Trust moved to prevent having to pay those claims, which were all submitted to the Trust by two New York law firms on behalf of their clients. Of the 88 claims at issue, 55 had certifications signed by Dr. Crouse, and the remainder were certified by another cardiologist, Richard L. Mueller, M.D. ("Dr. Mueller").

83. The Trust called Dr. Dent, a cardiologist and echocardiogram reader, as an expert witness at the September 2002 Hearing. Dr. Dent "eyeballed" (rather than measure as the protocol *required*) the challenged echocardiograms that had been interpreted by Dr. Crouse and Dr. Mueller. Dr. Dent's conclusions and opinions differed substantially not only from the conclusions and opinions reached by Dr. Crouse and Dr. Mueller, but also from the conclusions and opinions reached by the other expert cardiologists who testified at the September 2002 Hearing, including experts retained by Wyeth and the Trust. Dr. Dent testified that he

determined that each of the readings by Dr. Crouse and Dr. Mueller (also sued by the Trustees) was outside the bounds of medical reasonableness. In large part, Dr. Dent based his opinions on his claim that the phenomena that Drs. Crouse and Mueller interpreted as mitral regurgitation were actually "backflow."

84. Interestingly, Dr. Dent is a subordinate of counterclaim defendant and Trustee Dr. Beller at the University of Virginia. At a minimum, this fact casts serious doubt on Dr. Dent's objectivity and credibility in the September 2002 Hearing, considering the likelihood that he would testify in a manner that would please Dr. Beller, his boss.

85. Notwithstanding that (1) the September 2002 Hearing was conducted on an expedited basis; (2) it involved a limited record; (3) little or no discovery was taken; (4) Dr. Crouse was not a party; and (5) at most, the testimony showed a "difference of medical opinion" or "battle of the experts" among the various cardiologists – indeed, even the numerous experts for Wyeth and the Trust frequently reached contradictory conclusions – the Court nevertheless, based on misleading and/or insufficient evidence presented to it, made certain adverse determinations relating to Dr. Crouse and her acquisition and interpretation of echocardiograms.

86. The Trustees and Wyeth, who together presented three experts at the September 2002 Hearing, sprung the concept of "backflow" at the hearing itself – they did not refer to "backflow" in their pre-hearing submissions, the term was not disclosed in their expert reports, and Dr. Dent did not refer to "backflow" in his hand-written notes of his review of each of the challenged echocardiograms. Indeed, Dr. Dent has conceded that he did not use the term "backflow" until after he met with the Trust's lawyers just before the September 2002 Hearing. As a result, the New York law firms, and their expert, Dr. Roth, did not have a fair opportunity to

present expert testimony and other evidence to effectively rebut the false diagnosis of "backflow" presented by the Trustees and Wyeth.

87. Among other things, the Court was not presented with the following information at the September 2002 Hearing:

- "backflow" is not a term or concept used in the echocardiography field and is not widely taught to cardiology fellows;
- the use of wall filters, the appropriate setting of Nyquist limits – which the Trustees and Dr. Dent concede as to Dr. Crouse's echocardiograms – and other aspects of the physics of the echocardiographic equipment used by Dr. Crouse, preclude "backflow" from being detected because, under the Trustees' definition, "backflow" is a low velocity event;
- the physics of echocardiography and the operation of echocardiogram machines;
- the effect of using the flawed protocol of the Settlement Agreement and the Green Form, as set forth herein, which resulted in substantial numbers of claimants qualifying as having moderate or severe mitral or aortic regurgitation under the Settlement Agreement, when they would not receive such a diagnosis in a clinical setting; and
- the numerous problems with the mistaken assumptions and flawed epidemiology and statistical analysis underlying the Settlement Agreement, which underestimated the pool of claimants and resulted in severe under-funding of the Trust.

88. The Trustees subsequently relied largely upon the findings of the Court arising out of the September 2002 Hearing to create their current baseless RICO Action against Dr. Crouse. They did so even though those findings were based largely on the improper testimony of Dr. Dent, and the creation by Dr. Dent and the Trustees of the fictitious concept of "backflow" to mislead the Court into concluding that what Dr. Crouse interpreted as moderate mitral regurgitation as defined by the Settlement Agreement and the Green Form, was really "backflow," not regurgitation.

Rather Than Acknowledge The Multiple Problems With The Settlement Agreement And The Administration Of The Trust, The Trustees, In Concert With Wyeth And The PMC, Attempt To Blame Others For Their Failures By Falsely Charging "Massive Fraud" And Unilaterally Changing The Ground Rules

89. The September 2002 Hearing, and the events leading up to it, were but a small piece of a larger scheme by the Trustees and Wyeth, with the approval and complicity of the PMC, to cover up the now obvious facts that (1) the Trust is under-funded and is effectively bankrupt; (2) Wyeth, the PMC and the Trustees seriously underestimated the number of claimants likely to qualify for Matrix Benefits; (3) there were serious errors in the criteria to qualify for Matrix Benefits, and in the protocols for submitting claims, such that many members of the general population who took the Diet Drugs but may not be considered to be FDA Positive in a clinical setting nevertheless qualify for substantial Matrix Benefits under the Settlement Agreement; and (4) the Trust has been seriously mismanaged.

90. Rather than acknowledge the glaring errors which go to the very heart of the Settlement Agreement and the existence of the Trust itself, the Trustees, in concert with Wyeth and others, have engaged in a calculated and intentional scheme to shift the blame to others, including Dr. Crouse, while unilaterally and improperly disallowing or delaying the claims of whole classes of injured claimants entitled to benefits under the Settlement Agreement.

91. There are two primary components to this improper scheme.

92. First, Wyeth, the Trustees and the PMC have sought to materially change the requirements for claimants to receive payments from the Trust. This "changing the rules of the game" is designed to substantially reduce or limit the number of claimants who will ultimately receive payments under the Settlement Agreement. Even more outrageous is the fact that the Trustees, Wyeth and the PMC seek to apply the changed rules of the game retroactively to the

beginning of the Trust, and challenge those such as Dr. Crouse who adhered to the rules as they existed at the time.

93. Second, the Trustees, Wyeth and the PMC seek to deflect any blame for the obvious failures of the Settlement Agreement and the Trust by blaming others rather than admitting that they made mistakes.

94. The Trustees, Wyeth and the PMC have implemented this second prong of the scheme primarily by accusing whole categories of persons involved in various aspects of the Diet Drugs litigation and settlement process – many of the nation's leading cardiologists, prominent trial attorneys, reputable sonographers and even whole categories of injured claimants such as those represented by counsel or those who went to a cardiologist who attested to more than 20 Green Forms – of engaging in "massive fraud."

95. This cry of "massive fraud" started before the September 2002 Hearing through a claim of a purported eyewitness, C. V. Compton Shaw. When it turned out that this eyewitness himself was a total fraud, the Trustees withdrew his affidavit and created a new tactic – attacking the echocardiograms. They have now reached a fever pitch. The Trustees, along with Wyeth and the PMC, have now created an atmosphere akin to the Salem Witch Trials, in which everyone involved is deemed guilty and can only save themselves by admitting their guilt.

96. According to the bogus "massive fraud" theory disingenuously promulgated by the Trustees, Wyeth and the PMC, the only possible explanation for the exponentially larger than predicted number of claimants seeking benefits from the Trust is that virtually everyone involved – from the physicians to the sonographers to the claimants' lawyers to the claimants themselves – must be participants in the "massive fraud." The Trustees, Wyeth and the PMC stubbornly fail to acknowledge that the larger than expected number of claimants, and the under-funding of the

Trust, are the result of incorrect medical assumptions underlying the Settlement Agreement, and incorrect epidemiological and statistical assumptions as to the number of potential claimants.

97. Moreover, the Trustees have expended enormous sums in retaining large teams of attorneys to engage in a witch hunt to uncover some of the purported "massive fraud." Unfortunately for Dr. Crouse, the Trustees' army of pseudo-prosecutors has largely taken a "shoot first and ask questions later" approach, with absolutely no regard for the catastrophic harm caused to professionals or the very injured claimants for whom the Trust was expressly created and to whom the Trustees owe a fiduciary duty.

98. It is not surprising that the Trustees, Wyeth and the PMC have all invested significant resources in promulgating the "massive fraud" story. All have tremendous financial incentive to hide the fact that the basic assumptions underpinning the Settlement Agreement are false.

99. Wyeth is seeking to save literally billions of dollars that it will likely have to pay to properly fund the bankrupt Trust. It has demonstrated repeatedly that it cares little for the plight of the victims of its dangerous and defective Diet Drugs, and is seeking only to limit its further financial exposure.

100. The PMC has received in excess of $150 million to date, and anticipates receiving substantial additional fees – potentially in the hundreds of millions of dollars. The PMC is concerned that, if the basic assumptions underpinning the Settlement Agreement are exposed as false (or, at a minimum, erroneous), the whole settlement may collapse, thus killing their "goose that laid the golden egg."

101. The Trustees are concerned that their ineptitude in overseeing the Trust will be exposed. The administration of the Trust has been a disaster – it has repeatedly failed to meet

significant deadlines imposed by the Settlement Agreement and the Court, has paid exorbitant and unprecedented administrative fees and expenses, and has been a failure at its primary mission of administering and paying claims submitted pursuant to the Settlement Agreement. In addition, the Trust has become a virtual cottage industry for the numerous lawyers, physicians, accountants and other professionals who have earned literally hundreds of millions of dollars in its employ and hope to perpetuate the "feeding frenzy." The Trustees have turned the Trust into nothing more than a complying puppet to Wyeth and the PMC.

The Fraudulent "Backflow" Scheme

102. One of the primary vehicles that the Trustees and their co-conspirators have employed to further their scheme is the bogus concept of "backflow," first introduced at the September 2002 Hearing and used by the Trust and its hired gun, Dr. Dent, to preclude recovery for numerous claimants who otherwise qualify for benefits under the Settlement Agreement and the Green Form, and to falsely accuse Dr. Crouse of fraud.

103. Specifically, the Trustees, Dr. Dent, Wyeth, the PMC and others have devised an improper and fraudulent scheme to create a new medical term (or take an obscure, unknown and seldom used term) – "backflow" – and misapply it in such a way that they mischaracterize mitral regurgitation as "backflow" and thus *not regurgitation at all* (the "fraudulent backflow scheme"). The Trustees and their co-conspirators have used the fraudulent backflow scheme to improperly deny or delay the claims of tens of thousands of claimants who qualify for benefits under the terms of the Settlement Agreement. The Trustees and their co-conspirators have also used the fraudulent backflow scheme as the primary underpinning of their trumped-up RICO Action against Dr. Crouse. Moreover, they are teaching the false concept of backflow to scores

of auditing cardiologists under the Trust's 100% audit, as a fraudulent means of rejecting claims that should qualify for benefits under the Settlement Agreement.

104. Simply stated, the term "backflow" is not a commonly recognized medical term. The Trustees invented the term during the September 2002 Hearing in order to attack the validity of a select group of echocardiogram interpretations by Drs. Crouse and Mueller.

105. According to Dr. Dent, one of the architects of the fraudulent backflow scheme, the term backflow can be characterized as "a very transient appearing flow" which appears in the left atrium "and then just in a flash of a second it is gone."

106. Dr. Dent has asserted that cardiologists are trained to recognize the difference between backflow and mitral regurgitation.

107. Backflow, as articulated by the Trustees' own experts, has several identifiable characteristics: it is "a low velocity blood flow that lasts one-tenth of a second or less [*i.e.*, evanescently or in a flash] and is a normal phenomenon that exists in virtually everyone" which occurs "during the early part of systole."

108. Mitral regurgitation, on the other hand, is characterized by the Trust as being a high velocity blood flow, which lasts throughout at least several frames of systole and originates from the mitral valve. According to the Trust, it must be measured on the T-wave of the electrocardiogram.

109. Continuous Wave Doppler ("CW Doppler") is an older form of Doppler used to detect mitral regurgitation. According to Dr. Weyman, mitral regurgitation characteristically produces a high-velocity, turbulent, systolic flow disturbance (jet) in the left atrium, which can be detected by pulsed, continuous wave or color flow Doppler. CW Doppler will establish the

existence or absence of mitral regurgitation and is quite effective at detecting the beginning and the end of mitral regurgitation as well as the velocity of the jet.

110. Significantly, Dr. Crouse's findings of mitral regurgitation are confirmed by CW Doppler, which conclusively refutes the Trustees' intentionally false claim that Dr. Crouse mischaracterized "backflow" as mitral regurgitation.

111. Although CW Doppler is not considered an effective tool to measure the severity of the mitral regurgitation, it is considered an effective tool to measure the velocity and duration of regurgitant jets – two factors that are critical to a finding of backflow per the Trustees' definition.

112. Moreover, as a low velocity event, "backflow," as defined by the Trustees, could not have been recorded on the echocardiograms performed by Dr. Crouse because the Nyquist limits were set appropriately and at a high level – as the Trustees and Dr. Dent have acknowledged – and the use of high wall filters on Dr. Crouse's echocardiography machines precludes the capture of low velocity events.

The Auditing Process, And The Auditing Cardiologist Training Course, Are A Sham

113. The Trustees and their co-conspirators have implemented an audit program and have received Court approval to audit 100% of claims, based largely on the fraudulent backflow scheme.

114. In furtherance thereof, the Trustees and their co-conspirators – primarily Dr. Dent – have designed the "Auditing Cardiologist Training Course". All cardiologists who wish to serve as auditors for the Trust – and receive lucrative compensation for their services – must take the Auditing Cardiologist Training Course and pass a test demonstrating that they agree with its concepts. In many instances, the Trust pays its auditing cardiologists to simply review

echocardiograms approximately as much as Dr. Crouse charged for performing and interpreting echocardiograms, an amount which the Trustees have sought to characterize as exorbitant when paid to Dr. Crouse.

115. In connection with the Auditing Cardiologist Training Course prepared by Dr. Dent for the Trust, Dr. Dent – without authorization or any legitimate claim of ownership – used copies of echocardiograms performed by Dr. Crouse's office as illustrations throughout the training materials. Significantly, Dr. Dent and the Trustees improperly purport to copyright Dr. Crouse's echocardiograms by placing a logo: "©2003 The AHP Settlement Trust" on the images of Dr. Crouse's echocardiograms. Dr. Dent also repeatedly purports to copyright and/or attributes to himself images of echocardiograms performed by Dr. Crouse's office.

116. The Auditing Cardiologist Training Course, which is given to experienced cardiologists, bears little resemblance to the protocol set forth in the Settlement Agreement and the Green Form. Rather, it is plainly intended to teach the auditors to reject claims that would be entitled to benefits under the Settlement Agreement. For example, the Auditing Cardiologist Training Course teaches auditing cardiologists to use their subjective opinions and beliefs to reject claims that they do not believe constitute, for example, moderate mitral regurgitation in a clinical setting, even if the echocardiogram objectively demonstrates an RJA/LAA of greater than 20% and would qualify for Matrix Benefits under the objective standard clearly mandated by the Settlement Agreement. The Auditing Cardiologist Training Course also permits the auditing cardiologist to "eyeball" an echocardiogram and reject it based on this imprecise method, even though the Settlement Agreement requires cardiologists to precisely measure the regurgitant jet and left atrium by planimetering with the echocardiogram machine.

117. Whereas Dr. Crouse was constrained to interpret the echocardiograms according to the guidelines articulated in the Settlement Agreement and Green Form – guidelines which she had no part in establishing and which she, like most experienced cardiologists, does not use in clinical practice – the auditors were deliberately instructed to interpret studies according to completely different rules, some of which are pure fabrications and entirely unfounded in the medical literature. To qualify as an auditor and receive the large payments being offered to auditors, these cardiologists had to demonstrate their willingness to apply these alternative and fallacious guidelines. Moreover, the specific use of echocardiograms from Dr. Crouse's echocardiography laboratory as examples in the auditor training program can reasonably be expected to prejudice all auditors in their review of all studies from her facility.

118. Even more significantly, the Auditing Cardiologist Training Course teaches the "backflow" myth created by Dr. Dent and the Trustees as part of the fraudulent backflow scheme. The Trustees and Dr. Dent go so far as to use images of echocardiograms performed by Dr Crouse's office in the Auditing Cardiologist Training Course, and falsely use an echocardiogram that unquestionably demonstrates mitral regurgitation as "Examples of 'Backflow'" in furtherance of the fraudulent backflow scheme.

119. Further, the auditor training course purports to teach that mitral regurgitation occurs on the T-wave of the electrocardiogram and that the blue areas planimetered during or just after the QRS complex, therefore, cannot be indicative of such regurgitation. This "teaching point" flies in the face of nearly the entire published literature regarding mitral regurgitation. Dr. Dent, the so-called claims integrity program, and the Trustees either knowingly or recklessly included false, fabricated, and completely unfounded "teaching points" to induce the auditors to

mischaracterize classic mitral regurgitation features as indicative of "backflow" – a phenomenon that does not exist and cannot be recorded.

120. Many of the experienced cardiologists taking the Auditing Cardiologist Training Course had never heard of the term "backflow" or had heard of it only as a seldom-used term used in the context of valve replacement, before being taught the concept by the Auditing Cardiologist Training Course. However, to pass the qualifying test to be an auditor, these cardiologists had to characterize echocardiographic findings as "backflow," a phenomenon which does not exist and which, even if it did exist, could not possibly have been recorded using the wall filters, Nyquist limits and echocardiographic machines used to generate the images. Hence, the aspiring auditing cardiologists were required to misrepresent mitral regurgitation as something that could not possibly have been depicted on the echocardiogram images to qualify as auditors and receive substantial compensation for each audited echocardiogram. This is part of an intentional scheme by the Trustees and their co-conspirators to induce experienced cardiologists to provide medically unreasonable interpretations of phenomena which, according to the original guidelines in the Settlement Agreement and Green Form, should have qualified claimants for benefits.

121. Through the Auditing Cardiologist Training Course, the Trustees, Dr. Dent, and their co-conspirators have sought to involve the auditing cardiologists as – perhaps unwitting – co-conspirators in the fraudulent backflow scheme.

122. Further, as set forth below, the Trustees have repeatedly sought to improperly manipulate the audit process by submitting claims for repeated audit when the Trust's auditor has found the claim to be medically reasonable, in the hopes of receiving an opposite finding so that

the Trustees can deny the claim. Similarly, the Trustees have improperly used the audit process to reject even those claims found medically reasonable by the Trust's hired expert, Dr. Dent.

The "Claims Integrity Program" And The "Medical Practices Questionnaires"

123. The Trustees also have sought to change the rules of the game by embarking on what they euphemistically call the "Claims Integrity Program." While purporting to establish the Claims Integrity Program to assist in detecting fraudulent claims, the Trustees have actually used the Claims Integrity Program as a tool to delay unnecessarily or deny claims that qualify for benefits under the Settlement Agreement, and to obtain free litigation discovery for use in their bogus RICO Action against Dr. Crouse and pending or contemplated lawsuits against other cardiologists and/or claimants' attorneys.

124. The centerpiece of the Claims Integrity Program is the Medical Practices Questionnaire (the "MPQ"), an 18-page document containing 39 detailed questions (most with sub-parts) addressed to certifying cardiologists such as Dr. Crouse.

125. The Trustees have mailed thousands of MPQs to claimants around the country. The Trustees refuse to audit – or pay – the claims of these claimants unless the certifying cardiologist who signed part II of the Green Form answers these boilerplate, openly hostile forms that closely resemble litigation requests for admission. Moreover, many of the questions in the MPQ have nothing whatsoever to do with whether a particular claimant has valvular heart disease as set forth in the Settlement Agreement, but rather plainly appear to be aimed solely at building a litigation case against cardiologists.

126. The Claims Integrity Program and the MPQs are a sham concocted by the Trustees and their co-conspirators to further their improper scheme to deny payments to tens of

thousands of claimants who qualify for benefits under the Settlement Agreement, while simultaneously falsely accusing Dr. Crouse and others of fraud.

Other Significant Changes In The Rules Of The Game

127. The Trustees, along with their co-conspirators, are also changing the rules of the game with regard to numerous other significant issues relating to the performance and interpretation of echocardiograms, and the completion and submission of Green Forms, including the following:

- Whether a cardiologist needed to personally take a claimant's medical history in connection with attesting to a Green Form under the Settlement Agreement.
- Whether a cardiologist needed to personally review a claimant's medical records in connection with attesting to a Green Form under the Settlement Agreement.
- Whether a cardiologist needed to meet with the patient in connection with attesting to a Green Form under the Settlement Agreement.
- The level of supervision required in connection with an echocardiogram and the meaning of that term in the context of the Settlement Agreement.
- Whether the regurgitant jet area and the left atrium area (the "RJA/LAA") should or should not be measured in the same frame.
- The definition of "mitral regurgitation."
- The definition of "spreading" of a mitral regurgitation jet.
- The protocol under the Settlement Agreement and Green Form as compared to the Trust's audit procedures – which are very different from and inconsistent with the Green Form protocol.
- The credentials for auditors.
- Where to perform an echocardiogram.
- Requirements relating to the retention and maintenance of medical records.

128. With respect to all of the foregoing, the Trustees are attempting to change position and/or to contradict or deviate from the terms of the Settlement Agreement and the Green Form, for the express purpose of improperly denying or delaying claims that qualify for benefits under the Settlement Agreement and to falsely accuse Dr. Crouse and others of committing fraud.

The Trustees And Their Co-Conspirators Have Engaged In A Pattern Of Improperly Denying Even Those Claims That Have Been Approved For Payment By The Trust's Own Auditors And/Or Were Found Medically Reasonable By The Trust's Own Experts

129. The Trustees and their co-conspirators have engaged in a pattern of improperly denying even those claims that have been approved for payment by the Trust's own auditors and/or were found medically reasonable by the Trust's own experts.

130. For example, during the September 2002 Hearing, Dr. Dent testified that certain of the challenged claims were medically reasonable.[1] Despite his testimony, and the Court's finding in Pretrial Order No. 2640 that these claimants were, in fact, deserving of benefits, the Trustees submitted them to audit anyway. The Trust's auditors, pursuant to the Trust's audit protocol, found the claims to be medically unreasonable and, as a result, the Trustees withheld payment.

131. As another example, the Trustees submitted to audit claims that were determined by Dr. Dent to be "medically unreasonable" in his testimony at the September 2002 Hearing, and which the Court permitted the Trust to not pay (pending submission of new echocardiograms and Green Forms) in Pretrial Order No. 2640. Significantly, the Trust's auditor found these claims to be medically reasonable. Nevertheless, after the favorable review of these claims, the Trustees decided to not pay the benefits. After counsel for the claimants filed a motion to compel the payment of benefits, the Trustees resubmitted the claims to audit, to the same auditor who

[1] The names and identifying information relating to the claimants discussed herein are being intentionally omitted to protect their confidentiality.

previously found the claims to be medically reasonable. The auditor inexplicably changed his mind and decided that the claims were now medically unreasonable. The auditor submitted an affidavit stating that his initial approval of the claims came before he participated in the auditor training course.

132. There have been numerous other occasions where the Trustees have submitted claims to multiple audits, when the Trustees or their attorneys have been dissatisfied by the auditor's finding that the claim is medically reasonable. The Trustees have engaged in an improper pattern of shopping for an auditor's opinion until they find one that supports a denial of the claim.

133. Even more shocking, the Trustees have included in "Exhibit 'C'" to their complaint against Dr. Crouse, as purported "examples" of her alleged fraud in interpreting echocardiograms, a number of claims which Dr. Dent – the Trust's paid expert – and/or the Trust's own auditors have found to be medically reasonable.

The Trustees And Their Co-Conspirators Engaged In Mail And Wire Fraud

134. The Trustees, their co-conspirators, and others acting in concert with them, have used and caused the use of the mails and commercial interstate carriers throughout the duration of the false backflow scheme, which is ongoing. Among other things, the Trustees, their co-conspirators, and others acting at their direction, have sent through the mail thousands of denial letters, medical practices questionnaires, letters to attorneys pursuant to the so-called Claims Integrity Program, auditors' training materials and other documents containing numerous false statements concerning the false backflow scheme. By way of example only, Exhibit "A" to Dr. Crouse's answer, additional defenses and counterclaims to plaintiffs' complaint, which is incorporated herein by reference, is a partial listing, including 1,972 mailings made by the

Trustees, their co-conspirators, or others acting on their behalf. To protect the confidentiality and privacy of the claimants identified therein, Exhibit "A" is being filed under seal.

135. The Trustees and their co-conspirators have severely harmed and continue to harm Dr. Crouse and others through the false backflow scheme, as set forth herein.

136. The Trustees, their co-conspirators, and others acting in concert with them, have used and caused the use of the telephone, telefax and internet in interstate commerce throughout the duration of the false backflow scheme, which is ongoing. Among other things, the Trustees, their co-conspirators, and others acting at their direction, used the telephone and telefax to contact one another, other co-conspirators, Wyeth and the PMC, and others, to devise the conspiracy and to set up appointments, convey information, and otherwise further their purposes and the purposes of the false backflow scheme. In addition, the Trustees and their co-conspirators have used the internet extensively to promulgate and further the false backflow scheme including, but not limited to, placing the false auditors' training materials and other false "backflow" material on the Trust's web site.

137. The repeated use of the mail to devise or execute any scheme or artifice to defraud or for obtaining or avoiding the payment of money by means of false or fraudulent pretenses, by means of the mail, constitutes mail fraud, in violation of 18 U.S.C. § 1341.

138. The repeated use of the telephone and telefax and internet in interstate commerce to devise or execute any scheme or artifice to defraud or for obtaining or avoiding the payment of money by means of false or fraudulent pretenses, by means of telephone or telefax, constitutes wire fraud, in violation of 18 U.S.C. § 1343.

The Trustees' Concerted Campaign To Discredit And Ruin Dr. Crouse

139. The Trustees have engaged in an improper concerted effort to discredit and ruin Dr. Crouse – professionally and personally.

140. The Trustees, in concert with one or more co-conspirators, have contacted the members of at least two prestigious professional associations on which Dr. Crouse either served on the board or on significant committees, and caused her to be removed. This conduct was improper, not privileged and was done for the express purpose of causing harm to Dr. Crouse.

141. In particular, through their improper communications, either directly or indirectly through one or more co-conspirators acting at their direction, the Trustees caused the American College of Cardiology (the "ACC") to demand Dr. Crouse's resignation from the ACC Echocardiography Committee. Serving on the ACC Echocardiography Committee is a prestigious position in the echocardiographic community and a recognition of Dr. Crouse's preeminence in the field.

142. Moreover, through their improper communications, either directly or indirectly through one or more co-conspirators acting at their direction, the Trustees caused the ICAEL to vote to remove Dr. Crouse from its Board of Directors. The ICAEL is an organization formed to accredit echocardiographic laboratories. This conduct was extremely harmful to Dr. Crouse, because she was a founding member, and is the former President, of the ICAEL.

143. Further, Dr. Crouse serves on the board of the Kansas City chapter of the American Heart Association, and was asked to serve as its president. Through their improper communications, either directly or indirectly through one or more co-conspirators acting at their direction, the Trustees caused the Kansas City chapter of the American Heart Association to rescind its invitation to Dr. Crouse to serve as president.

Dr. Crouse Has Suffered Significant Harm As A Result Of
The Improper Actions Of The Trustees And Their Co-Conspirators

144. As a result of the improper conduct of the Trustees and their co-conspirators, as set forth above, Dr. Crouse has suffered significant harm to her reputation, as well as to her business and property.

145. Dr. Crouse's professional and personal reputation has been indelibly stained. She has been removed from or asked to resign prestigious professional boards. She has not been asked to speak at the same level of professional meetings at which, in the past, she was routinely asked to speak. Negative articles have been written about her and published throughout the nation, both in medical periodicals and in news media of general circulation. Other physicians are reluctant to refer patients to her, which is significant, because, as a specialist, Dr. Crouse relies in large part on referrals as the source of her patients.

146. In addition to the significant harm to her professional and personal reputation, Dr. Crouse has also suffered substantial financial harm. She has experienced a substantial decline in patients and in referrals from other physicians, which translates directly to a loss in revenues for her medical practice, and in income to Dr. Crouse, as a direct result of the improper actions of the Trustees and their co-conspirators. This loss in income amounts to hundreds of thousands, if not millions of dollars, and is ongoing.

147. Dr. Crouse has also lost significant amounts of fees due and owing from claimants' attorneys for whom she interpreted echocardiograms and performed other services, including preparing and signing Green Forms, because the attorneys have now refused to pay her for her services as a result of the improper actions of the Trustees and their co-conspirators.

148. Further, as a result of the improper conduct of the Trustees and their co-conspirators, Dr. Crouse has been effectively precluded from performing any work whatsoever in connection with the Diet Drugs Litigation or the Settlement Agreement.

149. Finally, Dr. Crouse has been forced to expend significant sums, and will be required to continue to do so, to defend the bogus RICO Action improperly concocted by the Trustees and their co-conspirators and based on the fraudulent backflow scheme.

COUNT I

VIOLATION OF § 1962(c) OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT

150. Dr. Crouse incorporates herein by reference paragraphs 1 through 149 above as if fully set forth herein.

151. The Trustees violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968.

152. The Trustees, their co-conspirators, and others, have conducted or participated, and continue to conduct or participate, in the conduct of the affairs of the Trust. The Trust is an enterprise engaged in, or the activities of which affect, interstate commerce.

153. In the alternative, the enterprise is an association in fact consisting of the Trust, Dr. Dent, Wyeth and the PMC. This enterprise is an ongoing organization that functions as a unit and engages in activity separate and apart from the fraudulent activity alleged herein. It has continuity in structure and personnel, a common and shared purpose, and an ascertainable structure distinct from that inherent in the pattern of activity described herein. This association-in-fact enterprise, *inter alia*, manages a multi-billion dollar settlement trust, administers the claims of tens of thousands of claimants injured by the Diet Drugs, pays settlement benefits and reports to the Settlement Court. The enterprise operated, and continues to operate, a legitimate

business – a settlement trust. This association-in-fact enterprise is engaged in, or its activities affect, interstate commerce.

154. The Trustees are each key persons controlling the actions of the enterprise. They act as fiduciaries to the Trust beneficiaries and as operators and managers of the enterprise. Each of the Trustees is a "person" employed by and associated in fact with the enterprise as set forth herein. Each of the Trustees conduct and participate in the conduct of the enterprise's affairs through a pattern of racketeering activity, as set forth in detail herein, within the meaning of 18 U.S.C. §§ 1962(c) and (d).

155. The Trustees and the co-conspirators worked together on a repeated, continuous and on-going basis to create, promulgate and enforce the false backflow scheme, as described above, and to conceal their scheme from the Settlement Court and the Trust beneficiaries, for the purpose of covering up the gross mismanagement of the Trust, the severe under-funding of the Trust, and the incorrect and/or false material assumptions on which the Settlement Agreement was based, and for the purpose of falsely accusing Dr. Crouse of committing crimes and fraud. In furtherance of the false backflow scheme, the Trustees and their co-conspirators repeatedly used the mail, interstate carriers and the wires on or about August 18, 2003, September 17, 2003, December 8, 2003, January 12, 2004 and in connection with the 1,972 mailings identified with specificity in Exhibit "A," as well as on other dates.

156. As set forth above and in Exhibit "A," each of the Trustees did and continues to cooperate, jointly and severally, in the commission of two (2) or more RICO predicate acts that are itemized in the RICO statute at 18 U.S.C. § 1961(1)(B), and did so in violation of 18 U.S.C. §§ 1962(c) and (d).

157. Specifically, the Trustees, their co-conspirators and others committed multiple acts of mail and wire fraud on or about August 18, 2003, September 17, 2003, December 8, 2003, January 12, 2004 and in connection with the 1,972 mailings identified with specificity in Exhibit "A" and on numerous other dates. They used the mail and wires, and caused others to use the mail and wires, to carry out their false representations for the purpose of executing the fraudulent backflow scheme to defraud claimants of the Trust, and to falsely accuse Dr. Crouse of crimes and fraud, in violation of 18 U.S.C. §§ 1341 and 1343. The Trustees, their co-conspirators and others continue to commit mail fraud and wire fraud as part of their ongoing and open-ended pattern of conduct.

158. The Trustees, their co-conspirators and others committed multiple acts of wire fraud as set forth herein and on numerous other dates. They used the telephone, telefax and internet in interstate commerce, and caused others to use telephone, telefax and internet in interstate commerce, to further execute the fraudulent backflow scheme to defraud claimants of the Trust, and to falsely accuse Dr. Crouse of crimes and fraud, in violation of 18 U.S.C. § 1343.

159. The Trustees directed that the co-conspirators employed by or associated with the enterprise engage in a pattern of racketeering activity as that term is defined in 18 U.S.C. § 1961(5) and described above in paragraphs 81 through 142 and Exhibit "A."

160. As a direct and proximate result of the Trustees' and the co-conspirators' violations of RICO, as set forth herein, Dr. Crouse has been injured in her business or property. Moreover, the impact caused by the Trustees' pattern of unlawful conduct, if not remedied by the Court, will continue to harm Dr. Crouse and others.

COUNT II

VIOLATION OF § 1962(d) OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT

161. Dr. Crouse incorporates herein by reference paragraphs 1 through 160 above as if fully set forth herein.

162. The Trustees and the co-conspirators have conspired together, and continue to conspire, on a repeated and continuous basis to create, promulgate and enforce the false backflow scheme, as described above, and to conceal their scheme from the Settlement Court and the Trust beneficiaries, for the purpose of covering up the gross mismanagement of the Trust, the severe under-funding of the Trust, and the incorrect and/or false material assumptions on which the Settlement Agreement was based, and for the purpose of falsely accusing Dr. Crouse of committing crimes and fraud. In furtherance of the false backflow scheme, the Trustees and their co-conspirators repeatedly used the mail, interstate carriers and the wires on or about August 18, 2003, September 17, 2003, December 8, 2003, January 12, 2004 and in connection with the 1,972 mailings identified with specificity in Exhibit "A," as well as on other dates.

163. The Trustees and their co-conspirators employed by the enterprise have conspired together, and continue to conspire, to conduct, and to participate in the conduct of the affairs of an enterprise through a pattern of racketeering activity as that term is defined in 18 U.S.C. § 1961(5) and described above in paragraphs 81 through 142 and Exhibit "A".

164. As set forth above and in Exhibit "A", each of the Trustees did cooperate, jointly and severally, in the commission of two (2) or more RICO predicate acts that are itemized in the RICO statute at 18 U.S.C. § 1961(1)(B), and did so in violation of 18 U.S.C. §§ 1962(c) and (d).

165. Specifically, the Trustees, their co-conspirators and others conspired together and continue to conspire to commit multiple acts of mail and wire fraud on or about August 18, 2003, September 17, 2003, December 8, 2003, January 12, 2004 and in connection with the 1,972 mailings identified with specificity in Exhibit "A" and on numerous other dates. They conspired and continue to conspire to use the mail and wires, and to cause others to use the mail and wires, to deliver materially false representations for the purpose of executing the fraudulent backflow scheme to defraud claimants of the Trust, and to falsely accuse Dr. Crouse of crimes and fraud, in violation of 18 U.S.C. § 1341 and § 1343. The Trustees, their co-conspirators and others continue to commit mail fraud and wire fraud as part of their ongoing and open-ended pattern of conduct.

166. The Trustees, their co-conspirators and others conspired together and continue to conspire to commit multiple acts of wire fraud as set forth herein and on numerous other dates. They conspired together and continue to conspire to use the telephone, telefax and internet in interstate commerce, and to have others to use telephone, telefax and internet in interstate commerce, to further execute the fraudulent backflow scheme to defraud claimants of the Trust, and to falsely accuse Dr. Crouse of crimes and fraud, in violation of 18 U.S.C. § 1343.

167. As a direct and proximate result of the Trustees' and the co-conspirators' conspiracy to violate RICO, as set forth herein, Dr. Crouse has been injured in her business or property. Moreover, the impact caused by the Trustees' pattern of unlawful conduct, if not remedied by the Court, will continue to harm Dr. Crouse and others.

COUNT III

INTENTIONAL MISREPRESENTATION AND FRAUD

168. Dr. Crouse incorporates herein by reference paragraphs 1 through 167 above as if fully set forth herein.

169. The Trustees and their co-conspirators repeatedly and intentionally made false representations and statements relating to the fraudulent backflow scheme and the false concept of backflow, as set forth with particularity herein.

170. Among other things, the Trustees and their co-conspirators repeatedly made false statements to Dr. Crouse, claimants and others, that mitral regurgitation diagnosed by Dr. Crouse in connection with interpreting echocardiograms in accordance with the Settlement Agreement and the Green Form is "backflow" and thus is not mitral regurgitation.

171. These statements were false when made.

172. The Trustees and their co-conspirators either knew that they were making false representations or, in the alternative, they acted with wanton and reckless disregard for the truth of their representations regarding "backflow."

173. The Trustees and their co-conspirators knew that their false representations would be relied upon and were material to Dr. Crouse, claimants' attorneys for whom Dr. Crouse interpreted echocardiograms, claimants whose echocardiograms Dr. Crouse interpreted, the Trust's auditors and the Court.

174. The Trust's auditors relied on the Trustees' and their co-conspirators' false representations regarding "backflow" when they completed the auditors' training program and when they denied claims as "medically unreasonable" as a result of finding "backflow." The Court relied on the Trustees' and their co-conspirators' false representations regarding

"backflow" when it issued Pretrial Memorandum and Order 2640 – based in large part on Dr. Dent's testimony on "backflow" – and permitted the Trust to deny payment to numerous claimants. Claimants and claimants' attorneys for whom Dr. Crouse performed and/or interpreted echocardiograms relied on the Trustees' and their co-conspirators' false representations regarding "backflow" when they refused to retain Dr. Crouse to perform any additional professional services and when they refused to pay Dr. Crouse substantial sums due and owing to Dr. Crouse for professional services that she already performed.

175. Dr. Crouse, at the outset of the program, justifiably relied on the representations made by the Trustees relating to the protocol under the Settlement Agreement and the Green Form. Dr. Crouse also justifiably relied on the Trustees to disclose any significant requirements or standards in connection with acquiring and/or interpreting echocardiograms under the Settlement Agreement and the Green Form that the Trustees would impose, including their newly created concept of "backflow." However, despite their duty to do so, the Trustees omitted to disclose that they would create a new concept called "backflow" and would apply it to echocardiograms interpreted by Dr. Crouse in such a way as to characterize mitral regurgitation as "backflow." This omission by the Trustees was material.

176. The Trustees and their co-conspirators intended to mislead Dr. Crouse, claimants' attorneys for whom Dr. Crouse interpreted echocardiograms, claimants whose echocardiograms Dr. Crouse interpreted, the Trust's auditors and the Court into relying on their false representations. Indeed, the entire fraudulent backflow scheme as described herein was intentionally devised by the Trustees and their co-conspirators to hide the fact that the Trustees have failed in their duties to oversee the Trust, that the Settlement Agreement was based on incorrect and false assumptions and that the Trust was severely under-funded. The Trustees and

their co-conspirators have used the fraudulent backflow scheme to improperly deny benefits to tens of thousands of claimants who qualify for benefits under the terms of the Settlement Agreement and to falsely accuse Dr. Crouse of crimes and fraud.

177. The Trustees' and their co-conspirators' conduct was outrageous and evidenced either an evil motive or reckless indifference to the rights of others.

178. As a direct and proximate result of the Trustees' and their co-conspirators' intentional misconduct, Dr. Crouse has been harmed.

COUNT IV

NEGLIGENT MISREPRESENTATION

179. Dr. Crouse incorporates herein by reference paragraphs 1 through 178 above as if fully set forth herein.

180. The Trustees and their co-conspirators repeatedly and negligently made false representations and statements, as set forth herein, relating to the fraudulent backflow scheme and the false concept of backflow.

181. Among other things, the Trustees and their co-conspirators repeatedly made false statements to Dr. Crouse, claimants, and others that mitral regurgitation diagnosed by Dr. Crouse in connection with interpreting echocardiograms in accordance with the Settlement Agreement and the Green Form is "backflow" and thus is not mitral regurgitation.

182. The Trustees and their co-conspirators acted negligently by failing to ascertain the truth or falsity of these representations and statements before they were made.

183. These representations and statements were false when made. The Trustees and their co-conspirators knew or should have known that the representations and statements were false under the circumstances in which they were made.

184. The Trustees and their co-conspirators knew or should have known that their false representations would be relied upon and were material to Dr. Crouse, claimants' attorneys for whom Dr. Crouse interpreted echocardiograms, claimants whose echocardiograms Dr. Crouse interpreted, the Trust's auditors and the Court.

185. The Trustees and their co-conspirators knew or had reason to know that they would harm Dr. Crouse if they negligently failed to make accurate statements concerning "backflow" and concerning the echocardiograms performed and/or interpreted by Dr. Crouse in connection with the Settlement Agreement.

186. The Trustees and their co-conspirators failed to make any reasonable investigation as to the truth of their statements and representations.

187. The Trust's auditors relied on the Trustees' and their co-conspirators' negligent representations regarding "backflow" when they completed the auditors' training program and when they denied claims as "medically unreasonable" as a result of finding "backflow." The Court relied on the Trustees' and their co-conspirators' negligent representations regarding "backflow" when it issued Pretrial Memorandum and Order 2640 – based in large part on Dr. Dent's testimony on "backflow" – and permitted the Trust to deny payment to numerous claimants. Claimants and claimants' attorneys for whom Dr. Crouse performed and/or interpreted echocardiograms relied on the Trustees' and their co-conspirators' negligent representations regarding "backflow" when they refused to retain Dr. Crouse to perform any additional professional services and when they refused to pay Dr. Crouse substantial sums due and owing to Dr. Crouse for professional services that she already performed.

188. Dr. Crouse, at the outset of the program, justifiably relied on the representations made by the Trustees relating to the protocol under the Settlement Agreement and the Green

Form. Dr. Crouse also justifiably relied on the Trustees to disclose any significant requirements or standards in connection with acquiring and/or interpreting echocardiograms under the Settlement Agreement and the Green Form that the Trustees would impose, including their newly created concept of "backflow." However, despite their duty to do so, the Trustees omitted to disclose that they would create a new concept called "backflow" and would apply it to echocardiograms interpreted by Dr. Crouse in such a way as to characterize mitral regurgitation as "backflow." This omission by the Trustees was material.

189. The Trustees and their co-conspirators knew and intended that their representations would induce Dr. Crouse, claimants' attorneys for whom Dr. Crouse interpreted echocardiograms, claimants whose echocardiograms Dr. Crouse interpreted, the Trust's auditors and the Court, to act on them.

190. The Trustees' and their co-conspirators' conduct, as alleged herein, was intentional, outrageous, willful and wanton.

191. As a direct and proximate result of the Trustees' negligent misrepresentations, Dr. Crouse has been harmed.

COUNT V

TORTIOUS INTERFERENCE WITH EXISTING AND PROSPECTIVE CONTRACTUAL RELATIONS

192. Dr. Crouse incorporates herein by reference paragraphs 1 through 191 above as if fully set forth herein.

193. Dr. Crouse has legally valid and binding contractual relationships with numerous attorneys and/or law firms representing claimants (collectively, the "Claimants' Attorneys"), to perform and/or interpret echocardiograms, and to provide related professional services, in connection with the Diet Drugs Settlement. Dr. Crouse was entitled to receive substantial

compensation for providing these services pursuant to the contracts with the Claimants' Attorneys.

194. At all material times, the Trustees knew of Dr. Crouse's contractual relationships with the Claimants' Attorneys to provide professional services in connection with the Diet Drugs Settlement.

195. By creating and implementing the false backflow scheme and by falsely accusing Dr. Crouse of committing crimes and fraud, the Trustees sought to unlawfully and wrongfully induce the Claimants' Attorneys to terminate their contracts and end their relationships with Dr. Crouse. As a result, the Trustees unlawfully and wrongfully interfered with those relationships and Dr. Crouse's contractual rights.

196. The Trustees have acted intentionally, maliciously and willfully in interfering with Dr. Crouse's contractual rights under her agreements with the Claimants' Attorneys.

197. As a direct and proximate result of the Trustees' unlawful and wrongful interference with Dr. Crouse's contracts with the Claimants' Attorneys and Dr. Crouse's rights under those agreements, Dr. Crouse has been damaged. Among other things, the Claimants' Attorneys have terminated their contracts with Dr. Crouse, have refused to use her professional services, and have refused to pay her for substantial professional services that she already performed.

198. In addition, as a result of her expertise and preeminence in the field of echocardiology, as well as her experience with performing and interpreting echocardiograms pursuant to the protocols of the Settlement Agreement and the Green Form, Dr. Crouse had numerous prospective contractual or economic relationships. Dr. Crouse also has existing and

prospective contractual and economic relationships with her patients and with numerous physicians and medical practices that refer patients to Dr. Crouse.

199. The Trustees were aware of these existing and prospective contractual and/or economic relationships.

200. By creating and implementing the false backflow scheme and by falsely accusing Dr. Crouse of committing crimes and fraud, the Trustees sought to unlawfully and wrongfully interfere with Dr. Crouse's existing and prospective relationships with patients, referring physicians and others, and with professional associations, including causing Dr. Crouse to be removed from prominent committees of the ACC and from the board of the ICAEL. The Trustees also sought to unlawfully and wrongfully induce others to not contract with, hire or retain Dr. Crouse to perform professional services.

201. As a result of the conduct of the Trustees, as set forth herein, Dr. Crouse has been harmed. Among other things, referrals to Dr. Crouse from other physicians have declined significantly as a result of the Trustees' improper actions. Further, she has sustained and will continue to sustain irreparable harm.

202. The Trustees' conduct, as alleged herein, was intentional, outrageous, willful and wanton.

COUNT VI

DEFAMATION

203. Dr. Crouse incorporates herein by reference paragraphs 1 through 202 above as if fully set forth herein.

204. The Trustees and their co-conspirators have made numerous false and pejorative statements and comments about Dr. Crouse, including that she committed fraud and/or crimes,

that she misdiagnosed "backflow" as mitral regurgitation and that she over-traced regurgitated jets.

205. For example, on or about September 18, 2003, the Trustees published on the Trust's internet web site the following:

> September 18, 2003 -- The AHP Settlement Trust, today sued Kansas City, Missouri cardiologist Linda Crouse, MD for directing the filing of fraudulent claims. The complaint, filed in federal court in Philadelphia, alleges that Dr. Crouse intentionally defrauded the Trust by falsely certifying that thousands of claimants had serious valvular heart disease (VHD) thereby causing the Trust to pay millions of dollars in false claims and delaying compensation to legitimate claimants. To access a copy of the complaint click here.
>
> The complaint is one of several proactive efforts undertaken by the Trust in its effort to fulfill its commitment to legitimate claimants. The Trust has developed a Claims Integrity Program aimed at rooting out dishonest and unethical behavior within the claims process. Click here for more information about the Claims Integrity Program.
>
> The lawsuit accuses Dr. Crouse of mail and wire fraud, violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), conspiracy to violate RICO, intentional misrepresentation and fraud, conspiracy to commit fraud, gross negligence, unjust enrichment and other violations. The suit seeks unspecified compensatory and punitive damages, to be determined at trial.

206. The statement quoted above continues to appear on the Trust's web site as of the date Dr. Crouse filed her counterclaims.

207. The Trustees and their co-conspirators have also made numerous other false and pejorative statements and comments about Dr. Crouse.

208. These statements were defamatory in nature in that they falsely accused Dr. Crouse of dishonesty, unprofessional conduct, and incompetence.

209. These defamatory statements were published by the Trustees and their co-conspirators.

210. These defamatory statements applied to Dr. Crouse.

211. The recipients of these defamatory statements understood their defamatory meaning.

212. The recipients of these defamatory statements understood that they were intended to be applied to Dr. Crouse.

213. Special harm has resulted to Dr. Crouse from the publication of these defamatory statements. Among other things, Dr. Crouse's professional reputation has been impaired, her standing in the medical and professional community has been diminished, and she has suffered personal humiliation, mental anguish and suffering. As a result of the Trustees' defamatory statements, Dr. Crouse was removed from prominent committees of the ACC and from the Board of the ICAEL. In addition, Dr. Crouse has suffered pecuniary harm as a result of the Trustees' publication of these defamatory statements. She has lost numerous referrals of patients from other physicians. She also has been effectively barred from performing any professional services relating to the Diet Drugs Settlement Agreement.

214. The defamatory statements made by the Trustees were not privileged. In the alternative, the Trustees abused a conditionally privileged occasion when they made the defamatory statements about Dr. Crouse.

215. The defamatory statements made by the Trustees were made maliciously or negligently. Indeed, the Trustees acted with actual malice towards Dr. Crouse.

216. The Trustees' conduct, as alleged herein, was intentional, outrageous, willful and wanton.

217. As a direct and approximate result of the Trustees' defamatory statements, Dr. Crouse has been harmed.

COUNT VII

CIVIL CONSPIRACY

218. Dr. Crouse incorporates herein by reference paragraphs 1 through 217 above as if fully set forth herein.

219. The Trustees and their co-conspirators did, unlawfully, knowingly and willfully combine, conspire, confederate and agree together to make false representations concerning "backflow," including but not limited to repeated statements that mitral regurgitation diagnosed by Dr. Crouse from interpreting echocardiograms in accordance with the Settlement Agreement and the Green Form is "backflow" and thus is not mitral regurgitation, and to concoct and promulgate the fraudulent backflow scheme as described herein.

220. It was the overall scheme of the conspiracy for the Trustees and their co-conspirators to commit the various acts described herein to hide the fact that the Trustees have failed in their duties to oversee the Trust, that the Settlement Agreement was based on incorrect and false assumptions and that the Trust was severely under-funded. The Trustees and their co-conspirators have used the fraudulent backflow scheme to improperly deny benefits to tens of thousands of claimants who qualify for benefits under the terms of the Settlement Agreement and to falsely accuse Dr. Crouse of crimes and fraud.

221. The conspiracy was carried out by the methods and means, among others, described in this counterclaim.

222. In furtherance of the conspiracy and to achieve its objectives, the Trustees and their co-conspirators committed the overt acts, among others, described in this counterclaim.

223. The Trustees' conduct, as alleged herein, was intentional, outrageous, willful and wanton.

224. As a direct and proximate result of the conspiracy and the Trustees' essential participation therein, Dr. Crouse has been harmed.

JURY DEMAND

Dr. Crouse demands a trial by jury, both with respect to plaintiffs' claims set forth in their complaint, and with respect to her counterclaims, as to all such claims so triable.

PRAYER FOR RELIEF

WHEREFORE, defendant and counterclaim plaintiff Linda J. Crouse, M.D. respectfully requests judgment in her favor and against plaintiffs and counterclaim defendants:

(1) Dismissing plaintiffs' complaint against her in its entirety with prejudice;

(2) Awarding Dr. Crouse her costs incurred in defending against plaintiffs' complaint, together with reasonable attorneys' fees;

(3) Awarding Dr. Crouse compensatory damages with respect to her counterclaims in an amount in excess of $75,000, exclusive of interest and costs;

(4) Awarding Dr. Crouse punitive damages with respect to her counterclaims, in an amount sufficient to punish counterclaim defendants for their egregious and intentional misconduct and to deter them and others from engaging in similar misconduct;

(5) Awarding Dr. Crouse treble damages pursuant to 18 U.S.C. § 1964(c) and such other damages as permitted by RICO;

(6) Awarding Dr. Crouse her attorneys' fees and costs with respect to her counterclaims;

(7) Permanently enjoining the Trustees from purporting to copyright and from using images from echocardiograms performed by Dr. Crouse's office in the Trust's Auditing Cardiologist Training Course and/or in any other manner; and

(8) Such other relief as the Court deems just and proper.

Abraham C. Reich (Pa. I.D. No. 20060)
Gerald E. Arth (Pa. I.D. No. 48137)
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Attorneys for Defendant and
Counterclaim Plaintiff
Linda J. Crouse, M.D.

Dated: February 24, 2004

EXHIBIT "A"

Exhibit "A" to defendant and counterclaim plaintiff Linda J. Crouse, M.D.'s answer, additional defenses and counterclaims to plaintiffs' complaint is filed under seal to protect the privacy and confidentiality of the claimants identified therein.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing defendant and counterclaim plaintiff Linda J. Crouse, M.D.'s answer, additional defenses and counterclaims to plaintiffs' complaint was served this day via hand delivery on the following:

Richard L. Scheff
Susan L. Burke
Scott A. Coffina
MONTGOMERY, MCCRACKEN, WALKER & RHOADS, LLP
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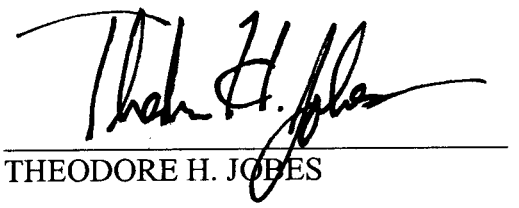
Attorneys for Plaintiffs



THEODORE H. JOBES

Dated: February 24, 2004