



3. Defendant BAYER CORPORATION, (hereinafter “Bayer”), maintains its principal place of business in Pittsburgh, Pennsylvania. Bayer is a corporation formed in the State of Indiana with its principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205. It is a wholly owned subsidiary of Defendant Bayer A.G. Bayer does business in and has substantial contacts with the State of Tennessee. At all times material to this lawsuit, Bayer was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, and/or selling in interstate commerce and the State of Tennessee, either directly or indirectly, the pharmaceutical Trasylol®, also known as Aprotinin.

4. Defendant BAYER HEALTHCARE, is a division of Bayer Pharmaceutical Corporation, a wholly owned subsidiary of Defendant Bayer Corporation with its principal place of business located at 400 Morgan Lane, West Haven, Connecticut, 06516. At all times material to this lawsuit, Bayer Healthcare was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, and/or selling in interstate commerce and the State of Tennessee, either directly or indirectly, the pharmaceutical Trasylol®, also known as Aprotinin.

5. Defendant BAYER A.G., a global diversified chemical company, is a German corporation, with its principal place of business in Leverkusen, Germany. At all times relevant herein, Bayer A.G. was in the business of designing, testing, manufacturing, distributing and promoting certain pharmaceutical products, including Trasylol®. Additionally, at all times relevant hereto, Bayer Corporation and Bayer A.G. shared many of the same officers and directors. Service on Bayer A.G. is being performed pursuant to the Hague Convention on service abroad. Hereinafter Bayer Corporation, Bayer Healthcare and Bayer A.G. may be collectively referred to as the “Defendants”.

## **Facts**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

### **History of Trasylol®**

6. Trasylol® (also known as Aprotinin injection) is a naturally occurring proteolytic enzyme inhibitor obtained from bovine lung. Aprotinin consists of 58 amino acid residues. It is a single-chain polypeptide, consisting of 6512 daltons and is cross-linked by three disulfide bridges.

7. The reactive bond site for Aprotinin is lysine – 15 – alanine – 16, and it forms reversible stoichiometric complexes.

8. Aprotinin reacts with the serine site of the enzyme.

9. Aprotinin was discovered in the 1930s when Kraut et al isolated a kallikrein inhibitor from bovine lung.

10. Aprotinin was launched as Trasylol® in Germany in 1959.

11. Trasylol® was approved by the FDA in 1993 and is used to control bleeding in open heart surgeries. It is supplied as a clear, colorless, sterile isotonic solution for intravenous administration.

12. Trasylol® is indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of open heart surgical procedures.

13. Trasylol® is a broad spectrum protease inhibitor, which modulates the systemic inflammatory response associated with cardiopulmonary bypass surgery. The effects of

Trasylol® use in cardiopulmonary bypass surgery involve a reduction in inflammatory response, which translates into a decreased need for blood transfusions.

14. The following is the warning carried by Trasylol® prior to the FDA Advisory Board Committee Meeting: “Anaphylactic or anaphylactoid reactions are possible when Trasylol® is administered. Hypersensitivity reactions are rare in patients with no prior exposure to aprotinin. The risk of anaphylaxis is increased in patients who are re-exposed to aprotinin-containing products. The benefit of Trasylol® to patients undergoing primary CABG surgery should be weighed against the risk of anaphylaxis should a second exposure be required.”

15. Trasylol® inhibits pro-inflammatory cytokine release and maintains glycoprotein homeostasis

16. According to Bayer, since its approval, an estimated 4.3 million patients have been given Trasylol®.

17. Bayer estimated that Trasylol® generated about \$293 million in sales in 2005 alone, making it the company’s 11<sup>th</sup> largest-selling drug.

18. In late 2005, Bayer forecast that Trasylol® would someday generate upwards of \$600 million annually.

#### **Trasylol®’s Association With the Increased Risk of Renal Failure**

19. On January 26, 2006, *The New England Journal of Medicine* (NEJM) published an article by Mangano et al reporting an association of Trasylol® with, among other things, serious renal toxicity in patients undergoing coronary artery bypass grafting surgery. This study was an observational study of patients who received either Trasylol®, one of two alternative drugs intended to decrease perioperative bleeding (aminocaproic acid or tranexamic acid), or no specific drug treatment.

20. The FDA evaluated this study, along with other studies in the literature, and reports submitted to the FDA through the MedWatch program, to determine if labeling changes or other actions were warranted.

21. While the FDA was continuing its evaluation it provided the following recommendations to healthcare providers and patients:

Physicians who use Trasylol should carefully monitor patients for the occurrence of toxicity, particularly to the kidneys, heart, or central nervous system and promptly report adverse event information to Bayer, the drug manufacturer, or to the FDA MedWatch program, as described at the end of this advisory.

Physicians should consider limiting Trasylol use to those situations where the clinical benefit of reduced blood loss is essential to medical management of the patient and outweighs the potential risks.

#### **FDA September 21, 2006 Advisory Board Committee Meeting and the Walker Study**

22. The FDA Advisory Board Committee convened on September 21, 2006 to discuss its findings regarding the safety of Trasylol® and determine whether the warning on Trasylol® needed to be changed.

23. After reviewing what it considered to be all of the available data on the safety of Trasylol®, the 19-member advisory panel recommended to the FDA that Defendant Bayer didn't need to strengthen a warning to doctors about the drug.

24. Just days later, the FDA was contacted by Alexander Walker, a professor at Harvard's School of Public Health, about a 67,000 patient-study he assisted in conducting at Bayer's request.

25. Bayer knew of this study and data and failed to disclose this data to the FDA at the September 21 Advisory Board Committee meeting. This data confirmed that Trasylol® increased the risk of renal failure, among other things.

26. This study, conducted at the request of Bayer, examined 67,000 hospital records of patients undergoing bypass surgery. The study suggests that the patients who received Trasyolol® were at an increased risk for death, kidney failure, congestive heart failure, and stroke.

27. On December 15, 2006, the FDA sent an Alert to healthcare professionals advising of a change in the product label for Trasyolol®:

The new labeling for Trasyolol (December 2006) has a more focused indication for use, a new Warning about renal dysfunction, a revised Warning about anaphylactic reactions, and a new Contraindication. Trasyolol is now indicated only for prophylactic use to reduce peri-operative blood loss and the need for blood transfusion in patients who are at *an increased risk for blood loss and blood transfusion* undergoing cardiopulmonary bypass in the course of coronary artery bypass grafting (CABG) surgery. Trasyolol should be administered only in the operative setting where cardiopulmonary bypass can be started quickly. Trasyolol should not be administered to any patient with a known or suspected exposure to aprotinin within the past 12 months.

FDA is evaluating additional recently submitted epidemiological safety study data (discussed below), in the context of all other safety and efficacy information available on aprotinin. This review may result in other actions, including additional changes to the full prescribing information (product labeling).

Moreover, as of December 2006, the Defendants revised the label for Trasyolol to include a specific statement in the WARNING section of the label that use of Trasyolol creates an increase risk of renal dysfunction and renal failure.

#### **General Allegations Concerning Plaintiff and Her Damages**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

28. On or about February 12, 2004, Plaintiff underwent open heart surgery at Maury Regional Hospital, Columbia, Tennessee.

29. With no contributory negligence on her part, Plaintiff was administered Trasylol®, a pharmaceutical product designed, manufactured, promoted, distributed and sold by Defendants.

30. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Plaintiff began experiencing renal insufficiency and renal failure soon after her open heart surgery. At no time did Plaintiff have any knowledge that her renal insufficiency and renal failure might be related from or caused by Trasylol®, nor did she have any reason to suspect that those problems might in any way be related to or caused by Trasylol®.

31. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Plaintiff was forced to be placed on long term hemodialysis, and continues with these treatments to the present time.

32. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Plaintiff has sustained permanent and devastating injuries, including but not limited to, end-stage renal disease requiring continuing dialysis treatments. All of said injuries have caused and will continue in the future to cause Plaintiff extensive anxiety, distress, fear, pain, suffering, and depression, while they have substantially reduced Plaintiff's ability to enjoy life.

33. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Plaintiff has sustained and will sustain a loss of earnings and diminution of earning capacity in the future.

34. As a direct, proximate and legal result of the negligence, carelessness, and other

wrongdoing of the Defendants, as described herein, Plaintiff has required reasonable and necessary health care, attention and services, and has incurred medical, incidental, and service expenses thereupon. Plaintiff alleges, on information and belief, that she will in the future be required to obtain medical and/or hospital care, attention, and services, as a direct, proximate and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein.

### **Count I - Negligence**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

35. At all times material to this lawsuit, Defendants owed Plaintiff a duty of reasonable care and safety.

36. Defendants' duties included, but were not limited to, carefully and properly designing, testing, manufacturing, licensing, packaging, promoting, advertising, selling, and/or distributing Trasylol® into the stream of commerce, and providing warnings with regard to this drug.

37. Defendants negligently and carelessly breached the above-described duties to Plaintiff by committing negligent acts and/or omissions including but not limited to:

- (A) Defendants failed to use ordinary care in designing, testing, and manufacturing Trasylol® so as to avoid the high risk to users of unreasonable, dangerous side-effects, some of which are fatal, such as renal failure;

- (B) Defendants failed to accompany Trasylol® with adequate warnings that would alert doctors, consumers, and other users to the potential adverse side effects associated with the use of these drugs and the nature, severity and duration of such adverse effects;
- (C) Defendants failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety and side effects of Trasylol®;
- (D) Defendants failed to warn Plaintiff prior to actively encouraging the sale of Trasylol®, either directly or indirectly, orally or in writing, about the possibility of becoming disabled as a result of the use of these drugs;
- (E) Defendants continued to promote the safety of Trasylol®, while downplaying any risks, even after Defendants knew of the risk of renal failure; and
- (F) Defendants were otherwise careless or negligent.

38. Although Defendants knew or should have known that Trasylol® caused unreasonably dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market this drug to doctors for use in cardiac surgeries, when there were safer and less expensive alternatives available.

39. Defendants knew or should have known that consumers, like Plaintiff, would suffer injury as a result of Defendants' failure to exercise ordinary care, as described above.

40. As a direct and proximate cause of Defendants' negligent acts and/or omissions,

Plaintiff suffered, and continues to suffer from, each of the injuries and damages set forth in this Complaint.

**Count II - Strict Liability**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

41. At all times material to this lawsuit, Defendants manufactured Trasylol®.
42. At all times material to this lawsuit, Defendants was engaged in the business of distributing and selling Trasylol®.
43. Defendants sold the Trasylol®, which was administered to Plaintiff during her cardiac surgery, as alleged in this Complaint.
44. The Trasylol® administered to Plaintiff, was defective and, because of its defects, was unreasonably dangerous to persons who might reasonably be expected to require its use. In addition, this drug was dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff, and any benefit of this drug was far outweighed by the serious and undisclosed risks of its use. Among other things, it is defective in design and failure to warn.
45. The Trasylol® administered to Plaintiff was defective at the time it was distributed by the Defendants or left its control.
46. The Trasylol® administered to Plaintiff was expected to reach the user without substantial change in the condition in which it was sold.
47. The Trasylol® administered to Plaintiff reached her without substantial change in the condition in which it was sold.
48. Plaintiff was a person who would reasonably be expected to use Trasylol®.

49. The defects in the Trasylol® administered to Plaintiff were a direct and proximate cause of the injuries and damages sustained by Plaintiff as set forth in this Complaint.

**Count III – Failure to Warn**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

50. Trasylol® is unreasonably dangerous, even when used for its intended purpose.

51. Defendants, as a manufacturer of pharmaceutical drugs are held to the level of knowledge of an expert in the field, and further, Defendants had knowledge of the dangerous risks of Trasylol®.

52. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to Plaintiff or Plaintiff's surgeon.

53. Defendants had a continuing duty to warn consumers and physicians, including Plaintiff, of its product, and the risks and dangers associated with it, and negligently and/or wantonly breached its duty as follows:

- (A) Failed to include adequate warnings with the medications that would alert Plaintiff and Plaintiff's surgeons to the dangerous risks of Trasylol®;
- (B) Failed to provided adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, kidney failure;
- (C) Continued to aggressively promote Trasylol®, even after it knew or should have known of the risks of injury from this drug.

54. By failing to warn Plaintiff and Plaintiff's surgeons of the adverse health risks associated with the administration of Trasyolol®, Defendants breached its duty to Plaintiff of reasonable care and safety.

55. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff suffered and continues to suffer the injuries and damages set forth in this Complaint.

#### **Count IV – Fraud, Misrepresentation & Suppression**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

56. At all relevant times herein, Defendants was in the business of manufacturing, promoting, advertising, selling and distributing Trasyolol®.

57. Through its actions and omissions in advertising, promoting, reporting to the FDA, labeling, and otherwise, Defendants fraudulently, intentionally and/or negligently made public misrepresentations of material facts to, and/or concealed material facts from physicians, the FDA, and consumers like Plaintiff, concerning the character and safety of Trasyolol®.

58. Those public misrepresentations and omissions include, but are not limited to those set forth in the general allegations section of this Complaint. Those misrepresentations and omissions include but are not limited to the following:

- (A) Defendants failed to disclose that sufficient pre-clinical and clinical testing and adequate post-marketing surveillance to determine the safety and side effects of Trasyolol®;
- (B) Defendants failed to timely disclose, and/or intentionally concealed, the interim and final results of the Walker Study

showing that Trasylol® use dramatically increased the risk for renal failure; and

- (C) Defendants failed to include adequate warnings with Trasylol® about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including without limitation, the risk of renal failure; and
- (D) Defendants concealed and continue to conceal past and present facts from the consuming public, including Plaintiff, when it had a duty to disclose.

59. Defendants knew or should have known that these representations were false and that Plaintiff and Plaintiff's surgeons would rely on them. Defendants were obligated to disclose the foregoing risks, but failed to adequately and timely do so even after it was in possession of information concerning those risks. Defendants' representations that Trasylol® was safe for its intended use were false, since this drug was, in fact, dangerous to the health of Plaintiff when used to reduce perioperative bleeding in patients undergoing cardiac surgery, and there were alternative products available that were less expensive, effective and posed less risk.

60. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Trasylol® and communicating that information to Plaintiff.

61. At the time of Defendants' fraudulent misrepresentations and active concealment, Plaintiff was not aware of the falsity of the foregoing representations, nor was she aware that material facts concerning Trasylol® had been concealed or omitted. In reliance upon Defendants' misrepresentations, Plaintiff's surgeon was induced to and did order Trasylol® to be

administered to Plaintiff during her cardiac surgery. If Plaintiff had known the true facts concerning the risks of the use of Trasyolol®, in particular, the risk of renal failure, she would have requested Trasyolol® not be used in her surgery, and requested the use of one of the safer alternatives.

62. Plaintiff's and Plaintiff's doctor's reliance upon Defendants' misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Trasyolol®, while Plaintiff was not in a position to know the true facts, and because Defendants aggressively marketed the use of this drug and concomitantly downplayed the risks in its use, thereby inducing Plaintiff's surgeon to use these drugs, in lieu of other, safe alternatives. At all times relevant hereto, Defendants' corporate officers, directors and/or managing agents knew of and ratified the acts of Defendants, as alleged herein.

63 The misrepresentations and active concealment by the Defendants constitutes a continuing tort against Plaintiff.

64. As a direct and proximate result of Plaintiff and Plaintiff's surgeon's reliance on Defendants' misrepresentations and concealment concerning the risks and benefits of Trasyolol®, Plaintiff suffered and continues to suffer from the injuries and damages as set forth in this Complaint.

#### **Count V - Express Warranties**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

65. Trasylol® was designed, tested, manufactured, distributed, promoted and sold by the Defendants; and was expected to, and did, reach Plaintiff without a substantial change in its condition.

66. Defendants, through their advertising and promotional materials, expressly warranted that Trasylol® was safe for the use for which it were intended, namely as a means to reduce perioperative bleeding in patients undergoing cardiac surgery.

67. Defendants breached said express warranties in that Trasylol® was unsafe in light of the risk of life-threatening side effects associated with its use, including, but not limited to, renal failure.

68. Plaintiff relied to his detriment on Defendants' express warranties.

69. As a direct and proximate result of Defendants' breach of express warranties, Plaintiff suffered and continues to suffer from the injuries and damages set forth in this Complaint.

#### **Count VI - Implied Warranties**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

70. Trasylol® was designed, tested, manufactured, distributed, promoted and sold by the Defendants; and was expected to, and did, reach Plaintiff without a substantial change in its condition.

71. Defendants, through its advertising and promotional materials, impliedly warranted that Trasylol® was safe for the use for which it were intended, namely as a means to reduce perioperative bleeding in patients undergoing cardiac surgery.

72. Defendants breached said implied warranties in that Trasylol® was unsafe in light of the risk of life-threatening side effects associated with its use, including, but not limited to, renal failure.

73. Plaintiff relied to her detriment on Defendants' implied warranties.

74. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff suffered and continues to suffer from the injuries and damages set forth in this Complaint.

### **Count VII - Deceptive Trade Practices**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

75. Defendants, by misrepresenting the safety of Trasylol® and concealing its risks with intent that consumers like Plaintiff rely upon such concealment, violated Tennessee's Consumer Protection Act of 1977 § 47-18-101.

76. In violation of Tennessee's Consumer Protection Law, Defendants withheld the risk of renal failure associated with Trasylol®, which was known to the Defendants.

77. As a direct and proximate result of Defendants' violations of Tennessee's Consumer Protection Law, Plaintiff suffered and continues to suffer the injuries and damages set forth in this Complaint.

### **Count VIII - Wantonness**

Plaintiff hereby adopts and incorporates by reference all the above allegations and further states as follows:

78. The conduct of the Defendants in designing, testing, manufacturing, promoting, advertising, selling, marketing, and distributing Trasylol®, and in failing to warn Plaintiff and

other members of the public of the dangers inherent in the use of Trasylol®, which were well known to the Defendants, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, particularly Plaintiff.

79. At all times material hereto, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Trasylol®.

80. Defendants breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward Plaintiff in the following ways:

- (A) Upon information and belief, Defendants actually knew of Trasylol®'s defective nature, as set forth herein, but continued to design, manufacture, market, and sell Trasylol® so as to maximize sales and profits at the expense of the health and safety of the consuming public, including Plaintiff, and in conscious disregard of the foreseeable harm caused by Trasylol®;
- (B) Defendants, which spent millions of dollars a year researching and developing medicines, and aggressively marketing Trasylol®, devoted far less attention to conducting sufficient pre-clinical testing, clinical testing and adequate post-marketing surveillance of this drug;
- (C) Defendants continued to promote the safety of Trasylol®, while providing no warnings at all to consumers about the risk of death, kidney failure, congestive heart failure, and stroke associated with

it, even after Defendants knew of that risk from multiple studies including the Walker Study.

81. Defendants knew that Trasylol® had unreasonable dangerous risks and caused serious side effects of which Plaintiff would not be aware. Defendants nevertheless advertised, marketed, distributed, and sold the medicine knowing that there were safer methods and products available.

82. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendants as set forth above, Plaintiff has sustained injuries and damages as set forth below.

WHEREFORE, Plaintiff prays for judgment against Defendants, Bayer Corporation, Bayer Healthcare and Bayer A.G., on grounds set forth above in an amount determined by the jury to be necessary and just, including compensatory and punitive damages.

**Claim for Damages**

Plaintiff, Ada Williams, has sustained injuries and damages, and does make claim for these:

- (A) Reasonable and necessary health care expenses incurred in the past;
- (B) Reasonable and necessary health care expenses which will be incurred in the future;
- (C) Physical pain and suffering in the past;
- (D) Physical pain and suffering which will be endured in the future;
- (E) Mental anguish suffered in the past;
- (F) Mental anguish which will be endured in the future;
- (G) Punitive Damages

(H) All other incidental and consequential damages, fees and expenses.

**PLAINTIFF DEMANDS A TRIAL OF ALL ISSUES BY STRUCK JURY**

By: \_\_\_\_\_  
LEE COLEMAN  
Attorney for Plaintiff  
Hughes and Coleman  
444 James Robertson Parkway  
Suite 201  
Nashville, Tennessee 37219  
(856) 523-9192

OF COUNSEL FOR PLAINTIFF:

Craig P. Niedenthal  
Elizabeth A. Ellis  
CORY, WATSON, CROWDER & DEGARIS  
2131 Magnolia Avenue  
Birmingham, Alabama 35205  
(205) 328-2200  
Fax: (205) 324-7896  
[cniedenthal@cwcd.com](mailto:cniedenthal@cwcd.com)  
[bellis@cwcd.com](mailto:bellis@cwcd.com)

DEFENDANTS' ADDRESSES:

**BAYER CORPORATION**  
Corporation Service Company  
2908 Poston Avenue  
Nashville, Tennessee 37203

**BAYER HEALTHCARE, a  
Division of Bayer Pharmaceuticals Corporation**  
Corporation Service Company  
2908 Poston Avenue

**BAYER A.G., a Foreign Corporation**  
51368 Leverkusen  
Germany