

IN THE COURT OF COMMON PLEAS OF PENNSYLVANIA
PHILADELPHIA COUNTY

IN RE TRASYLOL PRODUCTS : JUNE TERM, 2008
LIABILITY LITIGATION : NO. 5229
:
This Document Relates to All Cases :

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NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this Complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may be entered against you by the court without further notice for any money claims in this complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

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Le han demandado a usted en la corte. Si usted quiere defenderse de estas de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrtia sus defenses o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademias, la corte puede decidir a favor del demandante y requiere que usted compla con todas las provisions de esta demanda. Usted puede perder dinero o sus propiedades u ostros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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In Re: TrasyloL Litigation-CMAMD



08060522900008

**IN THE COURT OF COMMON PLEAS OF PENNSYLVANIA
PHILADELPHIA COUNTY**

IN RE TRASYLOL PRODUCTS
LIABILITY LITIGATION

JUNE TERM 2008

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PLAINTIFFS' AMENDED MASTER COMPLAINT

1. Plaintiffs, by the undersigned counsel, hereby submit this Master Complaint against Defendants BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS INC., and BAYER HEALTHCARE A.G. (hereinafter collectively "Defendants" or "Bayer") for equitable relief, monetary restitution, and/or compensatory and punitive damages. Plaintiffs make the following allegations based upon their personal knowledge, and upon information and belief, as well as upon their attorneys' investigative efforts, regarding the drug product Trasylol®.

2. This Master Complaint is submitted pursuant to Case Management Order No. 1 which is applicable to all coordinated Trasylol personal injury actions brought in the Court of Common Pleas of Pennsylvania, Philadelphia County. This Master Complaint is submitted to serve only the administrative functions of efficiency and economy of presenting certain common claims and common questions of fact and law for consideration by this Court in the context of this coordinated proceeding. This Master Complaint does not necessarily include all claims asserted in all of the actions that have been transferred to this Court, nor is it intended to consolidate for any purposes the separate claims of the plaintiffs herein. Those matters are set forth in the individual

actions filed by each of the respective Plaintiffs. This Master Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor by it do any Plaintiffs relinquish the right to add or assert or seek leave to add or assert any additional claims or predicates for claims depending upon further information that they may uncover.

The Parties

3. Plaintiffs are individuals, or the duly authorized representatives of individuals and/or the estates of deceased individuals who, at all times relevant to the allegations in the complaint, resided in the United States of America. Primary Plaintiffs bring these civil actions for equitable relief, monetary restitution, and/or compensatory and punitive damages for injuries and/or wrongful deaths suffered as a direct result of their exposure to Trasylol during major surgery. In addition, Secondary Plaintiffs assert derivative claims including, but not limited to, loss of consortium and survivorship. Not all claims asserted in this Master Complaint will necessarily be held by, nor asserted by, all Plaintiffs, and not all claims in this Master Complaint are asserted by each Plaintiff against every Defendant.

4. Defendant BAYER CORPORATION is a corporation formed in the State of Indiana with its principal place of business located in Pittsburgh, Pennsylvania. Bayer Corporation is a wholly owned subsidiary of Defendant BAYER HEALTHCARE A.G. At all times material to this lawsuit, Bayer was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce, either directly or indirectly, the drug product Trasylol.

5. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., as successor in interest of BAYER PHARMACEUTICALS CORPORATION, is a wholly owned subsidiary of Defendant Bayer Corporation, incorporated in the state of Delaware, with its principal place of business located in Wayne, New Jersey. Prior to January 1, 2008, Bayer Pharmaceuticals Corporation was a wholly owned subsidiary of Defendant Bayer Corporation. Bayer Pharmaceuticals Corporation's principal place of business was located in West Haven, Connecticut. The development of Trasylol for sale in the United States, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labeling and promotional activities regarding Trasylol, the decision to suspend marketing of Trasylol, and other actions central to the allegations of this lawsuit, were undertaken by Defendant Bayer Pharmaceuticals Corporation in the State of Connecticut and elsewhere.

6. Pursuant to Case Management Order No. 1 in this coordinated litigation, service of process of any abbreviated complaints ("Short Form Complaints") upon Defendants BAYER CORPORATION and BAYER HEALTHCARE PHARMACEUTICALS INC. shall be effective when sent by registered U.S. mail, return receipt requested, to Douglas A. Pearson, Esq., 100 Bayer Road, Building 14, Pittsburgh, PA 15205-9741, or, upon amended order of the Court, his successor. In addition, a copy of each notice transmitted to the Defendants in the foregoing manner shall be provided to Lead and Liaison Counsel for Defendants. Service will be effective ten (10) days after mailing.

7. Defendant BAYER HEALTHCARE A.G., a healthcare and medical products company, is a German corporation with its principal place of business in

Leverkusen, Germany. Bayer HealthCare A.G. is a wholly owned subsidiary of the managing holding company Defendant BAYER A.G. Bayer A.G. is also a German corporation with its principal place of business in Leverkusen, Germany. At all times relevant herein, Bayer HealthCare A.G., and its predecessor Bayer A.G., was in the business of designing, testing, manufacturing, distributing and promoting certain pharmaceutical products, including Trasylol.

8. Pursuant to Case Management Order No. 1 in this coordinated litigation, service of process of any abbreviated complaints ("Short Form Complaints") upon Defendant BAYER HEALTHCARE A.G. shall be effective when sent by registered U.S. mail, return receipt requested, to Alexander Bey, Esq., General Counsel, Bayer HealthCare AG, Law and Patents Department, 51368 Leverkusen, GERMANY, or, upon amended order of the Court, his successor. In addition, a copy of each notice transmitted to the Defendant in the foregoing manner shall be provided to Lead and Liaison Counsel for Defendants. Service will be effective ten (10) days after mailing.

Allegations of Fact

9. Trasylol® is the brand name of a drug product known generically as "aprotinin for injection" or aprotinin bovine which is available for medical use only by prescription. It is a member of a class of prescription drug products known as antifibrinolytics, which are used as a means of controlling or reducing bleeding and limiting or avoiding blood transfusions in current medical practice. Since at least the early 1990's, antifibrinolytic therapies have been widely accepted by the medical community for use during cardiac and other types of surgery to reduce the number of patients requiring blood transfusion and to reduce total blood loss.

10. The aprotinin protein, which is the active pharmaceutical ingredient in Trasylol, is a naturally occurring proteolytic enzyme inhibitor derived from bovine lung tissue. Aprotinin consists of 58 amino acid residues in a single-chain polypeptide, consisting of 6512 daltons and is cross-linked by three disulfide bridges. The reactive bond site for Aprotinin is lysine – 15 – alanine – 16, and it forms reversible stoichiometric complexes.

11. Aprotinin was first discovered in or about 1930 in Germany. Since the 1950's, Aprotinin was sold outside the United States as a treatment for acute pancreatitis and for several other indications. Trasylol is manufactured in Germany by Bayer Healthcare A.G.

12. From 1994 to 2007, Bayer sold Trasylol in the United States in 100 and 200 milliliter vials. When used during surgery, Trasylol was generally delivered to the patient intravenously in the operating room by a health care professional and without the specific knowledge of the patient.

13. Amicar® (epsilon-aminocaproic acid or "EACA") and Cyklokapron® (tranexamic acid or "TEA") are additional drug products in the antifibrinolytic class. EACA was first sold in the United States in or about 1964, and TEA was first sold in the United States in or about 1986.

14. In 1987, a study was published by Dr. David Royston *et al.* in *The Lancet* suggesting that the use of aprotinin in repeat coronary artery bypass graft (also known as "CABG") surgery would reduce blood loss and the need for transfusions in patients undergoing CABG surgery.

15. In December 1993, the U.S. Food and Drug Administration (the “FDA”) approved Trasylol for sale in interstate commerce in the United States as a prescription drug product and approved Trasylol’s principal label, known as the “Package Insert,” based on the criteria employed by the federal agency pursuant to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.* In that Package Insert, Trasylol was indicated “for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of repeat coronary artery bypass graft surgery [and] in selected cases of primary coronary artery bypass graft surgery where the risk of bleeding is especially high . . . or where transfusion is unavailable or unacceptable.”

16. According to the FDA, the risk of renal toxicity associated with exposure to Trasylol was known to Bayer in 1993.

17. In October 1994, the FDA approved amendments to the Trasylol Package Insert to provide an optional, lower dosage regimen of aprotinin.

18. In August 1997, the FDA approved amendments to the Trasylol Package Insert to highlight information about the risk of anaphylactic shock and certain other adverse effects associated with exposure to aprotinin.

19. In August 1998, the FDA approved amendments to the Trasylol Package Insert. In that Package Insert, Trasylol was indicated for use during both primary and repeat CABG surgeries.

20. Between August 1998 and December 2006, no material safety information was reviewed and approved or deemed not approvable by the FDA for inclusion in the Trasylol Package Insert.

21. The FDA required Bayer to conduct certain post-approval clinical studies and/or evaluations and analyses as conditions of its approval of the revised Package Insert in 1998. Bayer did not fulfill those obligations and/or did not conduct those clinical studies and/or evaluations and analyses so as to generate clinically meaningful information about the safety of Trasylol.

22. Further, Bayer failed to conduct any clinical or cohort studies comparing the safety and efficacy of Trasylol with EACA and/or TEA and failed to conduct any epidemiological studies to assess extent and nature of the risk of renal failure and/or death.

23. Despite pre-existing clinical and animal evidence, only a minority of 45 clinical studies conducted on aprotinin exposure during surgery prior to FDA's approval in 1993 commented on renal function and, of those, none had an adequate number of patients to determine, with statistical significance, whether Trasylol exposure increased the risk of renal failure.

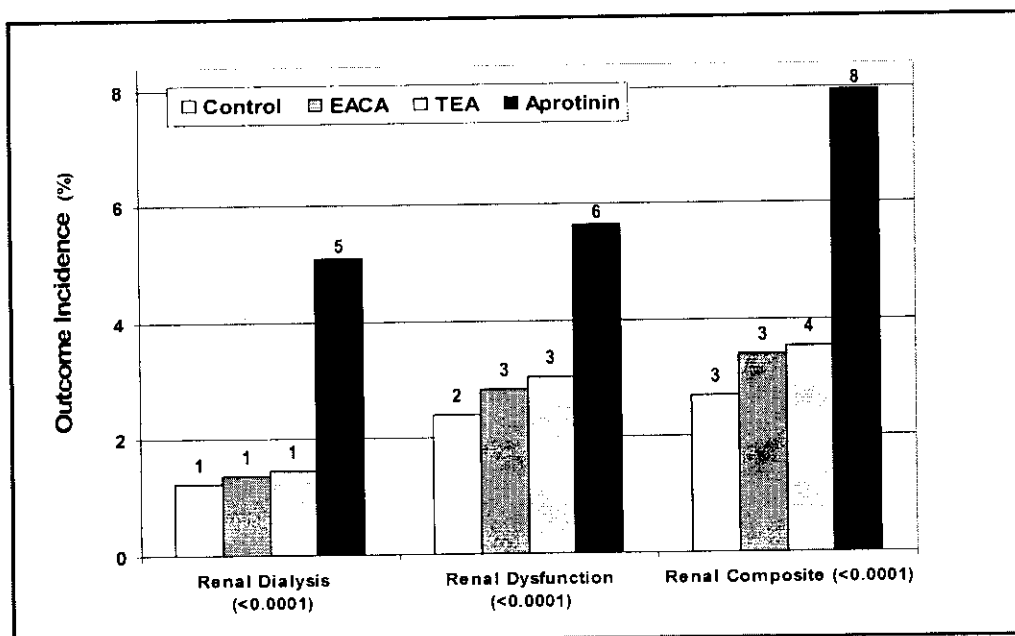
24. Bayer aggressively promoted Trasylol to physicians through medical journal advertisements, mass mailings, and direct communications from the Bayer sales force, among other methods. Bayer sponsored continuing medical education ("CME") seminars and paid physicians to advocate the use of Trasylol, orally and in writing, over the use of other antifibrinolytics and in various types of surgery, and to downplay the significance of the adverse effects of Trasylol and in particular the risk of renal injury.

25. Bayer regularly represented in its advertising and promotional messages that the risk of renal and certain other injuries including death, associated with exposure

to Trasylol were “comparable to placebo,” “had no adverse effect on renal function” and other similar false and misleading messages. These messages represented to physicians that Trasylol did not cause renal injuries and/or did not cause more injuries than the number of injuries resulting from surgery without the use of Trasylol. In other advertising and promotional messages, Bayer overstated the benefits of Trasylol.

26. According to Bayer, an estimated 4.3 million patients were given Trasylol. Bayer estimated that Trasylol sales generated about \$293 million in 2005 alone, making it the company’s 11th largest-selling drug. In late 2005, Bayer forecast that Trasylol would someday generate upwards of \$600 million annually.

27. On January 26, 2006, *The New England Journal of Medicine* (“NEJM”) published an article by Mangano *et al.* reporting an association of Trasylol (aprotinin injection) with renal toxicity and renal failure and ischemic events (myocardial infarction and stroke) in patients undergoing coronary artery bypass grafting surgery. This study was an observational study of patients who received either Trasylol, EACA or TEA, or no specific drug treatment. A graph presented by Dr. Mangano illustrates the increased risk of renal injuries associated with exposure to aprotinin versus EACA, TEA, or no Antifibrinolytic drug:



27. Overall, Dr. Mangano found more than a doubling in the risk of renal injury in patients exposed to aprotinin compared to those patients not exposed (odds ratio of 2.52 (1.66-3.82)) as well as an increased risk of cardiovascular and cerebrovascular adverse events and death.

28. On January 20, 2006, in the medical journal *Transfusion*, Karkouti *et al.* also showed an association between the use of aprotinin and renal toxicity among patients undergoing cardiac surgery with cardiopulmonary bypass.

29. In February 2006, the FDA issued a public health advisory regarding the results of the Mangano and Karkouti studies and expressing a desire to hold an advisory committee meeting to discuss the safety of Trasylol.

30. Upon receiving the Mangano study, Bayer established a “Trasylol Steering Committee” (“TSC”) that included numerous highly ranked Bayer employees, both from Bayer’s United States offices, but also from the Bayer home offices in Germany, to oversee Bayer’s total response to the studies and any regulatory responses. Bayer’s TSC began a coordinated response to the Mangano and Karkouti studies intended to call their science and findings into question and hopefully lay the groundwork for a favorable result from the FDA’s proposed advisory committee meeting. As part of this assault on the studies, Bayer wrote to the FDA to allege “serious methodological and statistical flaws” in the studies.

31. On February 1, 2006, Bayer contacted Dr. Alex Walker, a pharmacoepidemiologist and the Senior Vice President for Epidemiology at a company named “i3,” regarding the possibility of conducting its own retrospective study to

compare Trasylol with EACA and TEA, in order to rebut the conclusions of Drs. Mangano and Karkouti.

32. After independent reviewers approved of the i3's protocol and design, Bayer endorsed the study's commencement. On June 19, 2006, Bayer official Dr. Ernst Weidmann signed an agreement with i3 to begin the study. The appendix to that agreement required i3 to deliver the preliminary results of the study within 3 months, just in time for the FDA's September 21, 2006 advisory committee meeting.

33. In May 2006, the FDA announced that it would convene a meeting of its Cardiovascular and Renal Drugs Advisory Committee on September 21, 2006, to evaluate the data regarding Trasylol. The FDA asked Bayer to submit information relative to Trasylol and, specifically, the issues raised by the Mangano and Karkouti studies. Bayer submitted voluminous information to the FDA and had numerous contacts with the agency about Trasylol and the meeting, but did not ever inform the FDA about the work being conducted by Dr. Walker and i3.

34. The i3 study confirmed the findings of Drs. Karkouti and Mangano. The i3 study examined the medical records of approximately 67,000 patients, of whom 30,000 had received Trasylol. The study showed that patients who received Trasylol were at an increased risk for death, kidney failure, congestive heart failure, and stroke. By September 14, 2006, Bayer's Trasylol response team were in possession and aware of the preliminary results of the i3 study and were aware that it confirmed the findings of the earlier published studies of Trasylol. Bayer did not inform the FDA about the work being conducted by Dr. Walker or existence of the preliminary report until after the September 21, 2006 advisory committee meeting.

35. Bayer continued to prepare for the September 21, 2006 advisory committee meeting. Despite learning of the study's results a week earlier, Bayer failed to inform the advisory committee that the results of the i3 study confirmed the results of the Trasylol studies being discussed at the hearing. In fact, at no point did Bayer even mention that it had commissioned such a study to create "independent data" by which to compare the Mangano and Karkouti studies.

36. At the September 21, 2006 meeting, the FDA's advisory committee invested a great deal of time in questioning the science of Mangano and Karkouti's studies and questioned whether it made sense to act without additional studies confirming the risks of Trasylol.

37. The FDA advisory committee ultimately voted 18-0 to recommend that there should be no change to the safety labeling of Trasylol.

38. Days later, after communication from Dr. Walker that the results of the study represented a public health issue, Defendants forwarded information concerning the i3 study to the FDA. Thus, the FDA first learned of the work conducted by Dr. Alexander Walker, including a 67,000 patient-study performed at Defendants' request, only after the advisory committee had adjourned.

39. Bayer continued to publicly question the science and results of its own study. Bayer continued to sell Trasylol despite these studies proving the danger of the drug.

40. On September 29, 2006, the FDA issued a second Public Health Advisory related to Trasylol which noted the i3 study results and that the FDA did not have access to this study at the September 21, 2006 advisory committee meeting. Essentially, the

FDA reiterated its February 2, 2006 Public Health Advisory, noting that studies questioning the safety of Trasylol existed.

41. As a result of the recommendations of the FDA's advisory committee, the articles authored by Mangano *et al.* and Karkouti *et al.*, along with other reports and data known to and/or in the possession of the Defendants, the FDA required that the Package Insert for Trasylol include additional Warnings and Precautions, beginning in December 2006. The Warnings and Precautions included the risks of renal injury and renal failure associated with the use of aprotinin, and recommended that aprotinin be reserved for patients who are at an increased risk of blood loss and blood transfusion.

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

The new labeling for Trasylol (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. Trasylol 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. Trasylol should be administered only in the operative setting where cardiopulmonary bypass can be started quickly. Trasylol 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).

43. On January 25, 2007, Bayer announced it was discontinuing three clinical studies of Trasylol. The studies were to investigate the safety and efficacy of Trasylol with regard to transfusion requirements and blood loss in adults undergoing spinal fusion surgery, pneumonectomy or esophagectomy for cancer, and total cystectomy in bladder cancer.

44. On September 12, 2007, a joint meeting of the FDA's Cardiovascular and Renal Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee was held. The purpose of the meeting was to follow up on the September 2006 meeting, as well as to discuss the findings of additional studies showing an increased mortality rate in Trasylol-treated patients. Bayer appeared at the hearing and strongly supported the safety and efficacy of Trasylol. At that meeting, the advisory committee voted 16-1 to recommend that Bayer be allowed to continue selling Trasylol with the label revisions instituted in December 2006.

45. In October 2007, Bayer was notified that the Executive Committee of a Canadian-based clinical study of Trasylol in high-risk cardiac surgery patients had halted the study. A planned periodic data analysis in this clinical trial, the *Blood conservation using antifibrinolytics: A randomized trial in a cardiac surgery population* ("BART") study conducted by the Ottawa Health Research Institute, indicated an increase in all-cause mortality (that almost reached conventional statistical significance for 30-day mortality) for patients in the Trasylol treatment arm compared to patients who received the alternative drug products EACA or TEA.

46. On or about November 5, 2007, Defendants discontinued the sale of Trasylol. The FDA stated at that time: "[I]t is not possible to determine and identify a

population of patients undergoing cardiac surgery for which the benefits of Trasylol outweigh the risks.”

47. In May 2008, the New England Journal of Medicine published an article by Hebert, et al. finding an association of Trasylol with increased mortality when compared with other antifibrinolytic agents. Sadly, the lead author, Paul Hebert, concluded, “This study could have been done by the company [Bayer] five to ten years ago.”

48. Following publication of the BART study, on May 14, 2008 Bayer notified the FDA of its intent to remove all remaining supplies of Trasylol from hospital pharmacies and warehouses. The following day, Trasylol production and marketing was terminated worldwide.

49. Primary Plaintiffs are individuals (or the representatives of individuals) who were exposed to Trasylol during surgery and who experienced renal insufficiency, renal failure, cardiac injuries, vessel reclosure and/or other related adverse experiences, including death, as a direct and proximate result of their exposure to Trasylol. Said injuries further caused extensive anxiety, distress, fear, pain, suffering, and depression, while they substantially reduced the ability to enjoy life.

50. Secondary Plaintiffs are spouses and survivors who experienced injuries as a direct and proximate result of Primary Plaintiffs’ exposure to and injury from Trasylol.

51. As a result of the negligence, failure to warn and negligent misrepresentations of the defendants, Plaintiffs have suffered severe injuries including but not limited to cardiogenic shock, myocardial infarction, renal failure, kidney damage,

cardiac injury, stroke and other related conditions and sequelae, and as a result have had to undergo and will continue to undergo pain, suffering, mental anguish, inconvenience, humiliation, inability to work, inability to perform normal tasks for themselves and their families, and loss of companionship and society. This complaint is meant to state all potential injuries recognized by applicable law and plaintiffs will not be limited in the claims by the failure to designate individual injuries in this master complaint.

COUNT I
NEGLIGENCE

52. Plaintiffs repeat and reiterate the allegations previously set forth herein.

53. Defendants are liable to Plaintiffs due to their negligent development, study, manufacture, distribution and sale of Trasylol.

54. At all times relevant to this lawsuit, Defendants owed a duty to consumers, like Plaintiffs and their health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of Trasylol and to suspend distribution and sale of Trasylol when Defendants discovered it to be unreasonably dangerous.

55. Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying, manufacturing, promoting, selling, and/or distributing Trasylol into the stream of commerce, and providing adequate information regarding the appropriate use of this drug product.

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

- (1) Defendants failed to use ordinary care in designing, testing, and manufacturing Trasylol so as to reveal and communicate the high risk to users of unreasonable, dangerous side-effects, some of which are fatal, such as renal failure and cardiac death, when compared to the use of alternative drug products in its class or compared to the use of no drug products;
- (2) Defendants failed to accompany Trasylol with adequate information 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 either compared to the use of alternative drug products in its class or compared to the use of no drug products;
- (3) Defendants failed to conduct adequate post-marketing studies, non-clinical and clinical testing and post-marketing surveillance and analyses to determine and communicate the safety profile, adverse events and side effects of Trasylol either compared to the use of alternative drug products in its class or compared to the use of no drug products;
- (4) Defendants failed to warn Plaintiffs or their physicians prior to actively encouraging the sale of Trasylol, either directly or indirectly, orally or in writing, about the possibility of cardiac death, renal failure, and other adverse events resulting in injury and death as a result of the use of this drug, either compared to the use of alternative drug products in its class or compared to the use of no drug products;

- (5) Defendants continued to promote the safety and effectiveness of Trasylol, while downplaying its risks, even after Defendants knew or should have known of the risks of Trasylol, either compared to the use of alternative drug products in its class or compared to the use of no drug products;
- (6) Defendants knew or should have known that the use of Trasylol involved a risk of cardiac death, kidney failure, renal injury, and other adverse events causing injury and death and/or that Trasylol was unreasonably dangerous either compared to the use of alternative drug products in its class or compared to the use of no drug products, and failed to communicate that information to Plaintiffs and their physicians;
- (7) At the time of Plaintiffs' surgeries, Defendants had or should have had scientific data which indicated the true association between the use of Trasylol and the risk of kidney failure, renal injury, death, or other injuries either compared to the use of alternative drug products in its class or compared to the use of no drug products, and could have distributed that information to Plaintiffs and their physicians even if that information was not included in the FDA-approved product labeling;
- (8) Defendants failed to provide consumers, like Plaintiffs and their health care providers, with scientific data which indicated that Trasylol was unreasonably dangerous either compared to the use of alternative drug products in its class or compared to the use of no drug products, that there were no patients in whom the benefits of Trasylol outweighed the risks, and failed to promptly withdraw Trasylol from the market;

(9) Defendants affirmatively represented to physicians and the public that “Trasylol had no adverse effect on renal function” when pre-approval clinical data confirmed the risk of renal impairment and Defendants had never performed any post-approval epidemiological studies to assess the risk of Trasylol on renal function; and

(10) Defendants were otherwise careless or negligent.

57. Although Defendants knew or should have known that Trasylol caused unreasonably dangerous side effects, either compared to the use of alternative drug products in its class or compared to the use of no drug products, which many users would be unable to remedy by any means, Defendants continued to market this drug for use in surgeries, when there were safer and less expensive alternatives available.

58. Defendants knew or should have known that consumers, like Plaintiffs, would suffer injury as a result of Defendants’ failure to exercise ordinary care, as described above. Defendants, as manufacturers of drug products, are held to the level of knowledge of an expert in the field.

59. As a direct and proximate cause of Defendants’ negligent acts and/or omissions, Plaintiffs suffered injuries and damages, as set forth in their individual Complaints.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and treble damages, together with interest, costs of suit, attorneys’ fees, and all such other relief as the Court deems proper.

COUNT II **NEGLIGENT MISREPRESENTATIONS**

60. Plaintiffs repeat and reiterate the allegations previously set forth herein.

61. Defendants represented and marketed Trasylol as being safe and effective.

62. After Defendants became aware of the risks of using Trasylol, however, Defendants failed to communicate to the Plaintiffs and other members of the general public, that the ingestion of this drug could have the increased risk of serious life threatening issues including renal failure and cardiovascular events.

63. Therefore, Plaintiff brings this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

- a) Plaintiff incorporates all facts and allegations previously stated in this Complaint;
- b) Defendants failed to warn the Plaintiffs, and other consumers, of the defective condition of Trasylol, as manufactured and/or supplied by Defendants;
- c) Defendants, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Trasylol in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;
- d) the above misrepresentations were made to the Plaintiffs, Plaintiffs' physicians, as well as the general public;
- e) the Plaintiffs and their healthcare providers justifiably relied on Defendants' misrepresentations; and
- f) Consequently, the Plaintiffs' ingestion of Trasylol was to his detriment and to the detriment of each of the Plaintiffs. Defendants' negligent misrepresentations proximately caused the Plaintiffs' injuries and monetary losses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and treble damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
WRONGFUL DEATH

64. Plaintiffs repeat and reiterate the allegations previously set forth herein.

65. Plaintiffs bring their claims for wrongful death under the appropriate statutes of liability and damages law governing their action including but not limited to 42 Pa.C.S. §8301 (the Pennsylvania Wrongful Death Statute) and Pa.R.C.P. 2202(a) ,if applicable, as the personal representatives of the estate of deceased plaintiffs, on their own behalf and on behalf of all those persons entitled by law to recover damages.

66. As a direct and proximate result of the aforesaid, some of the Plaintiffs who ingested the Defendants' product Trasyolol were caused to contract the diseases and injuries described herein, causing extreme pain, suffering and mental anguish, and died as direct and proximate result of defendant's negligence as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants, in the amount in excess of \$75,000.00, together with exemplary damages in an amount to be determined upon the trial of this Action.

COUNT IV
SURVIVAL ACTION

67. Plaintiffs repeat and reiterate the allegations previously set forth herein.

68. Plaintiffs bring this action on behalf of the Estates of their decedents under the appropriate statutes of liability and damages law governing their action including but not limited to 42 Pa. C.S.A. § 8302, if applicable, and the applicable decisional law.

69. Plaintiffs claim on behalf of said Estates damages suffered by the reason of the death of the decedents, including but not limited to and pain and suffering of Decedents prior to their deaths.

WHEREFORE, Plaintiffs demand judgment against Defendants, in an amount in excess of \$75,000.00, together with exemplary damages in an amount to be determined upon the trial of this Action.

COUNT V
LOSS OF CONSORTIUM

70. Plaintiffs repeat and reiterate the allegations previously set forth herein.

71. Plaintiff's spouse was at all times relevant herein, the husband/wife of Plaintiff and as such, lives and cohabits with her/him.

72. By reason of the foregoing, Plaintiffs' spouse has been caused, presently and in the future the loss of his companionship, services, society has been lost, and as such Plaintiffs' spouse, has been caused great mental anguish and suffering.

73. By reason of the foregoing, Plaintiffs' spouse has necessarily paid and has become liable to pay for medical aid, treatment, and for medications, and will necessarily incur further expenses of a similar nature in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and treble damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
PUNITIVE DAMAGES

74. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

75. Plaintiffs are entitled to punitive damages because Defendants' actions were reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiffs and their physicians, by making false representations about and concealing pertinent information regarding Trasylol. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Trasylol, including renal failure and death, despite information demonstrating the product was unreasonably dangerous.

76. The conduct of the Defendants in designing, testing, manufacturing, promoting, advertising, selling, marketing, and distributing Trasylol, and in failing to warn Plaintiff's Decedent and other members of the public of the dangers inherent in the use of Trasylol, which were 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, including Plaintiff's Decedent.

77. 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.

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

(1) 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 Plaintiffs and Plaintiffs' decedents, and in conscious disregard of the foreseeable harm caused by Trasylol;

(2) Defendants spent millions of dollars a year researching and developing medicines and aggressively marketing Trasylol, but devoted far less attention to conducting sufficient pre-clinical testing, clinical testing, comparison testing, and adequate post-marketing surveillance of this drug;

(3) Defendants violated state and/or federal laws by selling and distributing a drug product that was misbranded and/or adulterated under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.* and parallel state Food, Drug and Cosmetic Acts and state common law; and

(4) Defendants continued to promote the safety of Trasylol, while providing no warnings at all about the unreasonable risk to consumers of death, kidney failure, congestive heart failure, and stroke associated with it, even after Defendants knew of that risk from multiple studies.

79. Defendants knew that Trasylol had unreasonably dangerous risks and caused serious side effects of which Plaintiffs and their physicians would not be aware. Defendants nevertheless advertised, marketed, distributed, and sold the medicine knowing that there were safer methods and products available.

80. Defendants' above-described actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

81. One or more of the aforementioned violations of law by the Defendants were committed with reckless disregard for the safety of the public and of Plaintiffs as a product user.

82. One or more of the aforementioned violations of law by Defendants were committed willfully and deliberately, and caused substantial financial injury to the consuming public and Plaintiffs.

83. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendants as set forth above, Plaintiffs are entitled to punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and treble damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants as follows:

- (1) Compensatory damages in an amount in excess of the jurisdictional amount as provided by law and to be supported by the evidence at trial;
- (2) An award of attorneys' fees, pre-judgment and post-judgment interest, and cost of suit, as provided by law;
- (3) Such other legal and equitable relief as this Court deems just and proper. Awarding pre-judgment and post-judgment interest to the Plaintiffs;

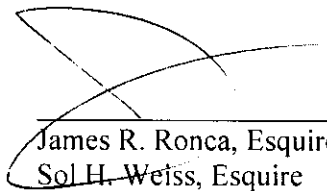
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Respectfully submitted,

ANAPOL, SCHWARTZ, WEISS, COHAN,
FELDMAN AND SMALLEY, P.C.

By:



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~~Sol H. Weiss, Esquire~~

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