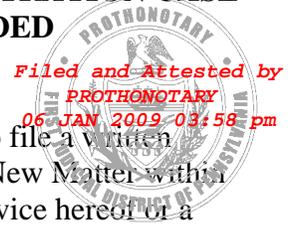


**THIS IS NOT AN ARBITRATION CASE
JURY TRIAL DEMANDED**



To Plaintiff:

You are hereby notified to file a written response to the enclosed New Matter within twenty (20) days from service hereof or a judgment may be entered against you.

/s/ Rachel Castillo Rosser
Rachel Castillo Rosser

ECKERT SEAMANS CHERIN & MELLOTT, LLC
By: Albert G. Bixler, Esquire
Identification No. 45639
By: Rachel Castillo Rosser, Esquire
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Attorneys for Defendant
Bayer Corporation

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

IN RE TRASYLOL PRODUCTS LIABILITY : JUNE TERM 2008
LITIGATION :
: No. 5229
This Document Relates to All Actions :
:

**DEFENDANT BAYER CORPORATION'S MASTER ANSWER AND
NEW MATTER IN RESPONSE TO PLAINTIFFS' AMENDED MASTER COMPLAINT**

Defendant Bayer Corporation, for its Answer to Plaintiffs' Amended Master Complaint (hereinafter, the "Complaint"), states as follows:

1. Although the Complaint contains allegations referring to Bayer Corporation and other entities collectively as "Defendants," "Defendant," and/or "Bayer," Bayer Corporation is not answering the Complaint on behalf of any entity other than Bayer Corporation and is not

answering allegations that are directed to any entity other than Bayer Corporation. Bayer Corporation denies liability for any injuries or damages alleged in the Complaint and denies the remaining allegations in paragraph 1 of the Complaint.

2. Bayer Corporation admits that this Court entered Case Management Order No. 1 for Trasylol Personal Injury Cases on July 15, 2008. That Order speaks for itself and Bayer Corporation denies the allegations in paragraph 2 of the Complaint to the extent they are inconsistent with the contents of that Order. Bayer Corporation denies liability for any injuries or damages alleged in the Complaint and denies the remaining allegations in paragraph 2 of the Complaint.

3. After reasonable investigation, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first and fourth sentences in paragraph 3 of the Complaint and therefore denies those allegations. Bayer Corporation denies liability for any injuries or damages alleged in the Complaint and denies the remaining allegations in paragraph 3 of the Complaint.

4. Bayer Corporation admits that it is an Indiana corporation with its principal place of business in Pittsburgh, Pennsylvania. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time period to which the allegations in the third sentence of paragraph 4 of the Complaint refer but admits that at certain times prior to January 2003 it was promoting, marketing, distributing, testing, and/or selling Trasylol® in interstate commerce in the United States. Bayer Corporation denies that it has developed, manufactured, or licensed Trasylol®. Because of the vagueness of the allegation in paragraph 4 that Bayer Corporation was “warranting” Trasylol®, Bayer Corporation is without knowledge or information sufficient

to form a belief as to the truth of that allegation. Bayer Corporation denies the remaining allegations in paragraph 4 of the Complaint.

5. Bayer Corporation admits that Bayer HealthCare Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in Wayne, New Jersey; that Bayer HealthCare Pharmaceuticals Inc. is indirectly wholly owned by Bayer Corporation; and that Bayer HealthCare Pharmaceuticals Inc. is successor in interest to Bayer Pharmaceuticals Corporation. Bayer Corporation further admits that at certain times in and after November 2002 and prior to January 2008 Bayer Pharmaceuticals Corporation was a wholly owned subsidiary of Bayer Corporation and had its principal place of business in West Haven, Connecticut. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time frame to which the allegations in the third sentence of paragraph 5 of the Complaint refer, but admits that at certain times in and after January 2003, and prior to January 2008, Bayer Pharmaceuticals Corporation maintained certain records relating to Trasylol®, sponsored clinical studies of Trasylol®, was promoting and labeling Trasylol®, and from time to time submitted to the United States Food and Drug Administration (“FDA”) New Drug Application supplements for Trasylol®. Bayer Corporation further admits that Bayer Pharmaceuticals Corporation issued a press release on November 5, 2007, announcing that it had elected temporarily to suspend marketing of Trasylol®. Bayer Corporation denies that Bayer Pharmaceuticals Corporation developed Trasylol®. After reasonable investigation, because of the vagueness of the phrase “other actions central to the allegations of this lawsuit,” Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies them. Bayer Corporation denies the remaining allegations in paragraph 5 of the Complaint.

6. Paragraph 6 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation admits that this Court entered Case Management Order No. 1 for Trasylol Personal Injury Cases on July 15, 2008. That order speaks for itself, and Bayer Corporation denies the allegations in paragraph 6 of the Complaint to the extent they are inconsistent with the contents of that order or subsequent orders of this Court relating to case management. Bayer Corporation denies the remaining allegations in paragraph 6 of the Complaint.

7. Bayer Corporation admits that Bayer HealthCare AG is a German corporation with its principal place of business in Leverkusen, Germany; that Bayer HealthCare AG is a wholly owned subsidiary of Bayer AG; and that Bayer AG is a German corporation with its principal place of business in Leverkusen, Germany. Bayer Corporation is without knowledge or information sufficient to form a belief as to the time frame to which the allegations in the fourth sentence of paragraph 7 of the Complaint refer but admits that at certain times in and after October 2003 Bayer HealthCare AG was testing and/or manufacturing Trasylol® and that at certain times prior to October 2003 Bayer AG was designing, testing, and/or manufacturing Trasylol®. Bayer Corporation denies that Bayer HealthCare AG has designed, distributed, or promoted Trasylol® and denies that Bayer AG has distributed or promoted Trasylol®. Bayer Corporation denies the remaining allegations in paragraph 7 of the Complaint.

8. Paragraph 8 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation admits that this Court entered Case Management Order No. 1 for Trasylol Personal Injury Cases on July 15, 2008. That order speaks for itself and Bayer Corporation denies the allegations in paragraph 8 of the Complaint to the extent they are inconsistent with the contents of that order or subsequent orders

of this Court relating to case management. Bayer Corporation denies the remaining allegations in paragraph 8 of the Complaint.

9. Bayer Corporation admits that Trasylol® is a prescription pharmaceutical, that Trasylol® is the proprietary name for aprotinin injection, and that Trasylol® has been indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in certain coronary artery bypass graft surgical settings specified in its FDA-approved labeling. Bayer Corporation admits that antifibrinolytics may be used to reduce or prevent bleeding when fibrinolysis contributes to bleeding. Bayer Corporation admits that Trasylol® is a proteinase inhibitor which, through inhibition of various hemostatic factors and processes, results in the attenuation of inflammatory responses, fibrinolysis, and thrombin generation, and that Trasylol®'s effects include inhibition of fibrinolysis. Bayer Corporation further admits that Trasylol® from time to time is referred to as an "antifibrinolytic," although its mechanism of action is different from those of other drugs referred to as "antifibrinolytics." Bayer Corporation denies the remaining or inconsistent allegations in paragraph 9 of the Complaint.

10. Bayer Corporation admits that aprotinin is the active ingredient in Trasylol®, that Trasylol® is a natural proteinase inhibitor obtained from bovine lung, that Trasylol® consists of 58 amino acid residues that are arranged in a single polypeptide chain, cross-linked by three disulfide bridges, that it has a molecular weight of 6512 daltons, that the active center of the aprotinin molecule is located on the lysine 15 and alanine 16 amino acid residues, and that aprotinin forms reversible stoichiometric enzyme-inhibitor complexes. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 10 of the Complaint.

11. Bayer Corporation admits that, in or around 1930 in Germany, Dr. Kraut and others isolated a kallikrein inhibitor from bovine lung; that aprotinin was first marketed as

“Trasylol” in Germany in 1959 for treatment of pancreatitis; and that aprotinin from time to time has been sold outside the United States. The allegation in paragraph 11 of the Complaint that Trasylol was sold “for several other indications” is vague and ambiguous, and therefore Bayer Corporation, after reasonable investigation, is without knowledge or information sufficient to form a belief as to the truth of that allegation, and therefore denies that allegation. Bayer Corporation admits that at certain times in and after October 2003 Bayer HealthCare AG manufactured Trasylol® in Germany. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 11 of the Complaint.

12. Bayer Corporation admits that the FDA-approved labeling for Trasylol® stated that Trasylol® was supplied in 100 and 200 milliliter vials and should be administered by a health care professional intravenously through a central line during surgery. After reasonable investigation, Bayer Corporation is without knowledge or information sufficient to form a belief as to the state of mind of individuals who may have been administered Trasylol®, and therefore denies that allegation. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 12 of the Complaint.

13. Bayer Corporation admits that aminocaproic acid and tranexamic acid are antifibrinolytic agents and admits upon information and belief that the FDA approved the sale and distribution in the United States of aminocaproic acid in 1964 and of tranexamic acid in 1986. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 13 of the Complaint.

14. Bayer Corporation admits that an article authored by Dr. David Royston et al. was published in *The Lancet* on or about December 5, 1987. That article speaks for itself, and Bayer Corporation denies the allegations in paragraph 14 of the Complaint to the extent they are

inconsistent with the contents of that article. Bayer Corporation denies the remaining allegations in paragraph 14 of the Complaint.

15. Bayer Corporation admits that the FDA approved the sale and distribution of Trasylol® in the United States in December 1993 and approved labeling, including a package insert, for Trasylol® at that time; admits that the FDA regulates prescription drugs pursuant to, *inter alia*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (“the FDCA”) and conducts its regulatory activities, including review and approval of labeling for prescription drugs, pursuant to the FDCA and regulations promulgated under the FDCA; and admits the remaining allegations in the first sentence of paragraph 15 of the Complaint. Bayer Corporation further admits that, at the time it was approved by the FDA for sale and distribution in the United States, Trasylol® was indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass graft surgery in the course of repeat coronary artery bypass graft surgery, and for selected cases of primary coronary artery bypass graft surgery where the risk of bleeding is especially high (impaired hemostasis, e.g., presence of aspirin or other coagulopathy) or where transfusion is unavailable or unacceptable. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 15 of the Complaint.

16. Bayer Corporation admits that potential renal effects of Trasylol® were discussed with the FDA in connection with the preclinical and clinical studies of Trasylol®. Bayer Corporation further admits that the “Indications and Usage” section of the FDA-approved labeling for Trasylol® in January 1994 stated that “selected use of Trasylol® in primary CABG patients is based on the risk of renal dysfunction and on the risk of anaphylaxis (should a second procedure be needed)” and discussed laboratory findings and data regarding renal dysfunction,

kidney failure, and serum creatinine elevations in the “Adverse Reactions” section. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations and therefore denies the remaining allegations in paragraph 18 of the Complaint.

17. Bayer Corporation admits that the Trasylol® package insert approved by the FDA in October 1994 states under the heading “DOSAGE AND ADMINISTRATION” that Trasylol is given “in both dose Regimen A and Regimen B (half dose Regimen A).” Bayer Corporation denies the remaining or inconsistent allegations in paragraph 17 of the Complaint.

18. Bayer Corporation admits that on August 8, 1997, the FDA approved a supplemental New Drug Application for Trasylol® that provided for new and revised statements in the Trasylol® package insert regarding the risk of anaphylactic reactions to Trasylol® as well as new data regarding other potential adverse reactions. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 18 of the Complaint.

19. Bayer Corporation admits that the Trasylol® package insert approved by the FDA in August 1998 states under the heading “INDICATIONS AND USAGE” that “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 coronary artery bypass graft surgery.” Bayer Corporation denies the remaining or inconsistent allegations in paragraph 19 of the Complaint.

20. Bayer Corporation denies the allegations in paragraph 20 of the Complaint.

21. Bayer Corporation admits that it agreed to provide the FDA with post-marketing evaluations and analysis of reported adverse drug events in connection with the Supplemental

New Drug Application approved by the FDA on August 28, 1998. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 21 of the Complaint.

22. Because of the vagueness of the allegations, Bayer Corporation, after reasonable investigation, is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Complaint and therefore denies them.

23. Because of the vagueness of the allegations, Bayer Corporation, after reasonable investigation, is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint and therefore denies them.

24. Bayer Corporation denies the allegations in paragraph 24 of the Complaint.

25. Bayer Corporation denies the allegations in paragraph 25 of the Complaint.

26. Bayer Corporation admits that from January 1, 1985, through March 31, 2006, there had been an estimated cumulative 4.38 million patient exposures worldwide to Trasylol®; that it was reported in the 2005 Annual Report of Bayer AG that in 2005 Trasylol® generated sales of €230 million and was listed as eleventh among “Best-Selling Bayer HealthCare Products”; and that in late 2005 it was estimated that the sales potential of Trasylol® could exceed €500 million. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 26 of the Complaint.

27. Bayer Corporation admits that an article authored by Mangano et al. was published in *The New England Journal of Medicine* on or about January 26, 2006. That article speaks for itself, and Bayer Corporation denies the allegations in the first paragraph 27 of the Complaint to the extent they are inconsistent with the contents of that article. Bayer Corporation denies the remaining allegations in the first paragraph 27 of the Complaint.

27. The article authored by Mangano et al. speaks for itself, and Bayer Corporation denies the allegations in the second paragraph 27 of the Complaint to the extent they are inconsistent with the contents of that article. Bayer Corporation denies the remaining allegations in the second paragraph 27 of the Complaint.

28. Bayer Corporation admits that an article authored by Karkouti et al. titled “A propensity score case-control comparison of aprotinin and tranexamic acid in high-transfusion-risk cardiac surgery” was published in the online edition of *Transfusion* on or about January 20, 2006. That article speaks for itself, and Bayer Corporation denies the allegations in paragraph 28 of the Complaint to the extent they are inconsistent with the contents of that article. Bayer Corporation denies the remaining allegations in paragraph 28 of the Complaint.

29. Bayer Corporation admits that on or about February 8, 2006, the FDA issued a Public Health Advisory discussing, inter alia, an article relating to Trasylol® authored by Mangano et al. that had been published in *The New England Journal of Medicine* in January 2006 and an article relating to Trasylol® authored by Karkouti et al. that had been published in the online edition of *Transfusion* in January 2006, and stating that the FDA “anticipates the public presentation of the recently reported information and other data at an advisory committee in the near future.” The FDA Advisory speaks for itself, and Bayer Corporation denies the allegations in paragraph 29 of the Complaint to the extent they are inconsistent with the contents of that Advisory. Bayer Corporation denies the remaining allegations in paragraph 29 of the Complaint.

30. Bayer Corporation admits, upon information and belief, that in or about April 2006 a steering committee was formed to discuss issues related to Trasylol® and that the members of that committee included employees of Bayer Pharmaceuticals Corporation and

Bayer HealthCare AG. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 30 of the Complaint.

31. Bayer Corporation admits, upon information and belief, that on February 1, 2006, an employee of Bayer HealthCare AG contacted Dr. Alexander Walker of i3 Drug Safety to discuss the possibility of conducting an observational study involving Trasylol®, aminocaproic acid, and tranexamic acid. Upon information and belief, Bayer Corporation admits that Dr. Alexander Walker is a physician and pharmacoepidemiologist and was senior vice president for epidemiology at i3 Drug Safety. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 31 of the Complaint.

32. Because of the vagueness of the phrase “independent reviewers,” Bayer Corporation, after reasonable investigation, is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 32 of the Complaint and therefore denies them. Bayer Corporation admits, upon information and belief, that a Services Agreement between Bayer HealthCare AG and i3 Drug Safety, under which i3 Drug Safety was to conduct an observational study of data drawn from a commercial database involving patients who had undergone coronary artery bypass graft surgery, was signed by Dr. Ernst Weidmann on behalf of Bayer HealthCare AG on or about June 19, 2006. Bayer Corporation admits, upon information and belief, that, under the Services Agreement, i3 Drug Safety agreed, inter alia, to deliver to Bayer HealthCare AG, within three months after the date of receipt of the fully executed contract, a preliminary report based exclusively on electronic data from the commercial database. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 32 of the Complaint.

33. Bayer Corporation admits that the FDA announced in July 2006 that it would convene a public meeting of the Cardiovascular and Renal Drugs Advisory Committee on September 21, 2006, to discuss Trasylol®. Bayer Corporation further admits, upon information and belief, that, at the request of the FDA in advance of the meeting, Bayer Pharmaceuticals Corporation submitted materials including a briefing document addressing, inter alia, an article relating to Trasylol® authored by Mangano et al. that had been published in *The New England Journal of Medicine* in January 2006 and an article relating to Trasylol® authored by Karkouti et al. that had been published in the online edition of *Transfusion* in January 2006. Because of the vagueness of the allegations in paragraph 33 of the Complaint concerning “voluminous information” and “numerous contacts,” after reasonable investigation Bayer Corporation is without knowledge or information sufficient to form a belief as to those allegations and therefore denies them. Bayer Corporation denies the remaining allegations in paragraph 33 of the Complaint.

34. Bayer Corporation admits, upon information and belief, that two of employees of Bayer HealthCare AG received a preliminary report concerning the ongoing observational study by i3 Drug Safety on or about September 14, 2006. Bayer Corporation admits that the ongoing observational study by i3 Drug Safety and the preliminary report from that study were not discussed at the September 21, 2006, meeting of the Cardiovascular and Renal Drugs Advisory Committee convened by the FDA and admits, upon information and belief, that Bayer Pharmaceuticals Corporation submitted information regarding the i3 Drug Safety study, including the preliminary report, to the FDA on September 27, 2006. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 34 of the Complaint.

35. Because of the vagueness of the allegation, after reasonable investigation Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegation in the first sentence of paragraph 35 of the Complaint and therefore denies it. Bayer Corporation denies the remaining allegations in paragraph 35 of the Complaint.

36. Bayer Corporation admits that the FDA convened a public meeting of the Cardiovascular and Renal Drugs Advisory Committee on September 21, 2006, to discuss Trasyolol®. The transcript and minutes of that meeting speak for themselves, and Bayer Corporation denies the allegations in paragraph 36 of the Complaint to the extent they are inconsistent with the contents of that transcript and those minutes. Bayer Corporation denies the remaining allegations in paragraph 36 of the Complaint.

37. Bayer Corporation admits that the minutes of the September 21, 2006, Advisory Committee meeting reflect that the Committee voted yes, 18 to 0 with one abstention, in response to the question, “Based upon the presentations today, do you regard the totality of clinical data as supporting acceptable safety and efficacy for Trasyolol usage among certain CABG/CPB patients?” The transcript and minutes of the September 21, 2006, meeting speak for themselves, and Bayer Corporation denies the allegations in paragraph 37 of the Complaint to the extent they are inconsistent with the contents of that transcript and those minutes. Bayer Corporation denies the remaining allegations in paragraph 37 of the Complaint.

38. Bayer Corporation admits that at the request of Bayer HealthCare AG Dr. Alexander Walker of i3 Drug Safety was performing an observational study of data drawn from a commercial database involving patients who underwent coronary artery bypass graft surgery but denies that the study properly is characterized as a “67,000 patient-study.” Bayer Corporation further admits, upon information and belief, that Dr. Walker sent an email on

September 26, 2006 (received on September 27, 2006) to inform two employees of Bayer HealthCare AG of his belief that the preliminary report from the ongoing observational study by i3 Drug Safety had implications for public health. Upon information and belief, Bayer Corporation admits that on September 27, 2006, Bayer Pharmaceuticals Corporation submitted to the FDA information regarding the ongoing observational study of Trasyol® by i3 Drug Safety, including the preliminary report. Bayer Corporation further admits that an FDA statement issued on September 29, 2006, stated that FDA was not aware of the preliminary report when it held the September 21, 2006, Advisory Committee meeting. Bayer Corporation is without knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 38 of the Complaint, and therefore denies them.

39. Bayer Corporation admits that, at a September 12, 2007, joint meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, which was open to the public, representatives of Bayer Pharmaceuticals Corporation and other participants presented testimony and evidence regarding, *inter alia*, deficiencies in the i3 Drug Safety study. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 39 of the Complaint.

40. Bayer Corporation admits that on or about September 29, 2006, the FDA issued a Public Health Advisory discussing, *inter alia*, the ongoing observational study by i3 Drug Safety, and further admits that on February 8, 2006, the FDA had issued a Public Health Advisory discussing the article by Mangano et al. published in the *New England Journal of Medicine* in January 2006 and the article by Karkouti et al. published in the online edition of *Transfusion* in January 2006. Those FDA Advisories speak for themselves, and Bayer Corporation denies the allegations in paragraph 40 of the Complaint to the extent they are inconsistent with the contents

of the Advisories. Bayer Corporation denies the remaining allegations in paragraph 40 of the Complaint.

41. Bayer Corporation admits that the FDA receives and reviews various sources of information regarding approved pharmaceuticals and that a revised Trasylol® package insert was approved by the FDA on December 15, 2006. The package insert speaks for itself, and Bayer Corporation denies any characterization made by Plaintiffs and denies the allegations in paragraph 41 of the Complaint to the extent they are inconsistent with the contents of the FDA-approved labeling. Bayer Corporation denies the remaining allegations in paragraph 41 of the Complaint.

42. Bayer Corporation admits that on or about December 15, 2006, the FDA issued an “FDA Alert” portions of which are quoted in the indented portions of paragraph 42 of the Complaint. By way of further answer, the Alert issued by the FDA on December 15, 2006 is a writing which speaks for itself, and Bayer Corporation denies any characterization made by Plaintiffs and denies the allegations in paragraph 42 of the Complaint to the extent they are inconsistent with the contents of the Alert. Bayer Corporation denies the remaining allegations in paragraph 42 of the Complaint.

43. Bayer Corporation admits that three ongoing clinical studies for Trasylol®, which were investigating the safety and efficacy of Trasylol® on transfusion requirements and blood loss in adults undergoing elective spinal fusion surgery, pneumonectomy or esophagectomy for cancer, and radical or total cystectomy in bladder cancer, have been discontinued. Bayer Corporation admits that on January 25, 2007, a press release was issued regarding the discontinuation of those three studies. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 43 of the Complaint.

44. Bayer Corporation admits that the FDA's Cardiovascular and Renal Drugs Advisory Committee, in joint session with the Drug Safety and Risk Management Advisory Committee (collectively, the "Advisory Committee"), met on September 12, 2007, concerning Trasyolol®. Bayer Corporation further admits that representatives of Bayer Pharmaceuticals Corporation appeared at the meeting, and that the Advisory Committee voted 16 to 1, with one member abstaining, to recommend continued marketing authorization for Trasyolol. By way of further answer, the transcript and minutes of the September 12, 2007, Advisory Committee meeting are writings which speak for themselves, and Bayer Corporation denies any characterization made by Plaintiffs and denies the remaining allegations in paragraph 44 of the Complaint to the extent they are inconsistent with the contents of that transcript and those minutes. Bayer Corporation denies the remaining allegations in paragraph 44 of the Complaint.

45. Bayer Corporation admits that on or about October 19, 2007, Bayer Pharmaceuticals Corporation was informed that the executive committee of a study conducted in Canada by the Ottawa Health Research Institute, titled "Blood conservation using antifibrinolytics: A randomized trial in a cardiac surgery population" (the "BART" study), had halted patient enrollment in the aprotinin treatment group arm of the study. Bayer Corporation further admits that Bayer Pharmaceuticals Corporation was informed that a planned periodic data analysis indicated reduced bleeding but also an increase in all-cause mortality (that almost reached conventional statistical significance for 30-day mortality) for patients receiving Trasyolol® compared to patients who received either aminocaproic acid or tranexamic acid. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 45 of the Complaint.

46. Bayer Corporation admits that, on or about November 5, 2007, Bayer Pharmaceuticals Corporation elected to temporarily suspend marketing of Trasylol until final results from the BART study could be compiled, received and evaluated, and that the FDA announced the marketing suspension on November 5, 2007. By way of further answer, the November 5, 2007, FDA press release is a writing which speaks for itself, and Bayer Corporation denies any characterization made by Plaintiffs and denies the allegations in paragraph 46 of the Complaint to the extent they are inconsistent with the contents of that press release. Bayer Corporation denies the remaining allegations in paragraph 46 of the Complaint.

47. Bayer Corporation admits that an article authored by Dean A. Fergusson, Paul C. Hébert, and others was published in the May 29, 2008, edition of *The New England Journal of Medicine*. By way of further answer, that article is a writing which speaks for itself, and Bayer Corporation denies any characterization made by Plaintiffs and denies the allegations in paragraph 47 of the Complaint to the extent they are inconsistent with the contents of that article. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 47 of the Complaint.

48. Bayer Corporation admits that, on or about May 14, 2008, the FDA announced that Bayer HealthCare Pharmaceuticals Inc. had notified the FDA that it would begin removing the remaining Trasylol® stock from the United States market. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 48 of the Complaint.

49. Bayer Corporation is without knowledge or information sufficient to form a belief as to whether or when Trasylol® was administered to Plaintiffs or to individuals for whom Plaintiffs are representatives. Bayer Corporation denies liability for any injuries or damages alleged in the Complaint and denies the remaining allegations in paragraph 49 of the Complaint.

50. Bayer Corporation is without knowledge or information sufficient to form a belief as to the relationships between Plaintiffs and other persons alleged to have received Trasylol®. Bayer Corporation denies liability for any injuries or damages alleged in the Complaint and denies the remaining allegations in paragraph 50 of the Complaint.

51. Paragraph 51 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies the allegations in paragraph 51 of the Complaint.

52. Bayer Corporation incorporates by reference its responses to each and every paragraph of the Complaint.

53. Bayer Corporation denies the allegations in paragraph 53 of the Complaint.

54. Paragraph 54 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies liability for any injury alleged in the Complaint, denies that its duties are accurately stated, denies that it breached any applicable duty of care relating to Plaintiffs' claims, and denies the remaining allegations in paragraph 54 of the Complaint.

55. Paragraph 55 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies liability for any injury alleged in the Complaint, denies that its duties are accurately stated, denies that the warnings for Trasylol® were inadequate, denies that it breached any applicable duty of care relating to Plaintiffs' claims, and denies the remaining allegations in paragraph 55 of the Complaint.

56. Bayer Corporation denies the allegations in paragraph 56 of the Complaint, including all subparts thereof.

57. Bayer Corporation denies the allegations in paragraph 57 of the Complaint.

58. The second sentence of paragraph 58 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies that it manufactured Trasylol®. After reasonable investigation, Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the second sentence of paragraph 58 of the Complaint because of the vagueness of those allegations and therefore denies those allegations. Bayer Corporation denies the remaining allegations in paragraph 58 of the Complaint.

59. Bayer Corporation denies the allegations in paragraph 59 of the Complaint.

60. Bayer Corporation incorporates by reference its responses to each and every paragraph of the Complaint.

61. Bayer Corporation admits that at certain times prior to January 2003 it marketed Trasylol®, and further admits that Trasylol® is safe and effective when used in accordance with FDA-approved labeling. Bayer Corporation denies the remaining or inconsistent allegations in paragraph 61 of the Complaint.

62. Bayer Corporation denies the allegations in paragraph 62 of the Complaint.

63. Bayer Corporation denies the allegations in paragraph 63 of the Complaint, including all subparts thereof.

64. Bayer Corporation incorporates by reference its responses to each and every paragraph of the Complaint.

65. Paragraph 65 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies liability for any injury alleged in the Complaint and denies the allegations in paragraph 65 of the Complaint.

66. Bayer Corporation denies the allegations in paragraph 66 of the Complaint.

67. Bayer Corporation incorporates by reference its responses to each and every paragraph of the Complaint.

68. Paragraph 68 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies liability for any injury alleged in the Complaint and denies the remaining allegations in paragraph 68 of the Complaint.

69. Bayer Corporation denies liability for any injury alleged in the Complaint, denies that Plaintiffs are entitled to the relief requested in paragraph 69, and denies the remaining allegations in paragraph 69 of the Complaint.

70. Bayer Corporation incorporates by reference its responses to each and every paragraph of the Complaint.

71. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 71 of the Complaint.

72. Bayer Corporation denies the allegations in paragraph 72 of the Complaint.

73. Bayer Corporation denies the allegations in paragraph 73 of the Complaint.

74. Bayer Corporation incorporates by reference its responses to each and every paragraph of the Complaint.

75. Bayer Corporation denies the allegations in paragraph 75 of the Complaint.

76. Bayer Corporation denies the allegations in paragraph 76 of the Complaint.

77. Paragraph 77 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer Corporation denies liability for any injury alleged in the Complaint, denies that its duties are accurately stated, denies that it

breached any applicable duty of care relating to Plaintiffs' claims, and denies the remaining allegations in paragraph 77 of the Complaint.

78. Bayer Corporation denies the allegations in paragraph 78 of the Complaint, including all subparts thereof.

79. Bayer Corporation denies the allegations in paragraph 79 of the Complaint.

80. Bayer Corporation denies the allegations in paragraph 80 of the Complaint.

81. Bayer Corporation denies the allegations in paragraph 81 of the Complaint.

82. Bayer Corporation denies the allegations in paragraph 82 of the Complaint.

83. Bayer Corporation denies the allegations in paragraph 83 of the Complaint.

WHEREFORE, Bayer Corporation respectfully requests this Court to dismiss Plaintiffs' Complaint, with prejudice, along with other such relief as this Court deems appropriate.

NEW MATTER

The following New Matter is asserted with respect to claims asserted in the Master Complaint and in related Short-Form complaints as defined in section V of Pre-Trial Order No. 4 entered on May 22, 2008. For its New Matter, Bayer Corporation states as follows:

84. Plaintiffs' Complaint and each and every count contained therein fail to state a cause of action or claim upon which relief can be granted against Bayer Corporation.

85. Some or all of Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitation, prescription, or preemption, statutes of creation, and/or statutes of repose.

86. Plaintiffs' claims are barred, in whole or in part, by laches, waiver, and/or estoppel.

87. Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

88. The alleged damages and injuries, if any, were the result of unavoidable circumstances that could not have been prevented by any person or entity, including Bayer Corporation.

89. Neither Plaintiffs nor Plaintiffs' decedents suffered any actual injury, loss, or damages because of the alleged use of Trasyolol®.

90. The injuries, losses, and/or damages claimed by Plaintiffs and/or Plaintiffs' decedents, if any, resulted from an intervening or superseding cause and/or causes, and no act or omission on the part of Bayer Corporation was a proximate or competent producing cause of such alleged injuries, losses, and/or damages.

91. The injuries sustained by Plaintiffs or Plaintiffs' decedents, if any, were caused, in whole or in part, by pre-existing or subsequent physical, medical, and/or physiological conditions, for which Bayer Corporation has no legal responsibility.

92. The acts and omissions of Plaintiffs, Plaintiffs' decedents, and/or other persons or entities, over whom Bayer Corporation had no supervision or control and for whose actions and omissions Bayer Corporation has no legal responsibility, caused and/or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrine of contributory and/or comparative negligence. Plaintiffs' recovery, if any, therefore is barred or should be reduced and/or apportioned in accordance with any applicable law.

93. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part from collateral sources. To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under any applicable law.

94. To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Bayer Corporation, if any, should be reduced accordingly.

95. To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Plaintiffs' claims are barred by release.

96. Plaintiffs' claims are barred because Trasylol® was neither defective nor unreasonably dangerous in its design, manufacture, marketing, or sale and was reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying Trasylol® at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate warnings and instructions. At all times relevant, Bayer Corporation acted reasonably in connection with Trasylol®.

97. The claims in the Complaint are barred in whole or in part by the learned intermediary doctrine.

98. Neither Plaintiffs nor Plaintiffs' decedents detrimentally relied on any labeling, warnings, or information concerning Trasylol®.

99. The Complaint fails to state a claim upon which relief can be granted in that the methods, standards, and techniques utilized with respect to the design, manufacture, testing, distribution, marketing, and sale of Trasylol®, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art. Trasylol®, including its labeling approved by the United States Food and Drug Administration, complied with the state of

scientific and medical knowledge at the time of its design, testing, manufacture, distribution, marketing, and sale. Plaintiffs' recovery accordingly is barred.

100. Trasylol® complied with the applicable product safety regulations promulgated by the United States Food and Drug Administration. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, distribution, marketing, and sale of Trasylol®, and that it was neither defective nor unreasonably dangerous.

101. If Plaintiffs or Plaintiffs' decedents sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of Trasylol®. Plaintiffs' recovery accordingly is barred.

102. If Plaintiffs or Plaintiffs' decedents sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by an inherent characteristic of Trasylol® which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community. Plaintiffs' recovery accordingly is barred under any applicable law.

103. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal government's regulation of the manufacturing, testing, marketing, sale, and labeling of prescription drugs.

104. Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the United States Food and Drug Administration is charged under law with determining the content of warnings and labeling for prescription drugs.

105. Plaintiffs cannot state a claim with regard to the warnings and labeling for prescription drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the United States Food and Drug Administration.

106. This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the United States Food and Drug Administration.

107. Any claims by Plaintiffs relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

108. Plaintiffs' claims are barred in whole or in part because the commercial speech relating to Trasylol® was not false or misleading and is protected under the First Amendment of the United States Constitution and by applicable state constitutional provisions.

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

110. The Complaint fails to state a claim upon which relief can be granted as to costs, attorney fees, expenses, pre-judgment interest, post-judgment interest, or treble damages.

111. Any claim for pre-judgment interest is barred by Plaintiffs' failure to make a demand for payment or offer of settlement in writing.

112. Plaintiffs are not real parties in interest and lack capacity and/or standing to bring the claims asserted in the Complaint.

113. Plaintiffs' recovery of damages in this action is barred or limited by applicable wrongful death law and jurisprudence.

114. Plaintiffs' Complaint fails to state a claim upon which relief can be granted against Bayer Corporation under any applicable state product liability law.

115. Bayer Corporation asserts all available defenses under any applicable state product liability law.

116. Plaintiffs' claims are barred pursuant to Restatement (Second) of Torts § 402A, comment k.

117. Plaintiffs' claims are barred because Trasylol® provides net benefits for a class of patients.

118. Bayer Corporation did not sell or distribute Trasylol® directly to Plaintiffs or Plaintiffs' decedents, and neither Plaintiffs nor Plaintiffs' decedents received or relied upon any representations as alleged in the Complaint.

119. Plaintiffs' Complaint fails to allege fraud, misrepresentation, deceit, concealment, suppression and/or omission with the required particularity.

120. The conduct and activities of Bayer Corporation with respect to the product which is the subject matter of this action were fair and truthful and were based upon the state of knowledge existing at the relevant time alleged in the Complaint, and therefore Plaintiffs' claims are barred under applicable state consumer protection law.

121. The Complaint fails to state a claim against Bayer Corporation upon which relief can be granted for punitive or exemplary damages.

122. Bayer Corporation denies any conduct for which punitive or exemplary damages could or should be awarded and denies that Plaintiffs have produced evidence sufficient to support or sustain the imposition of punitive damages against Bayer Corporation pursuant to the applicable standards of proof.

123. Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad, would violate Bayer Corporation's constitutional rights as secured by the Fifth, Seventh, and Fourteenth Amendments to the United States Constitution, and would contravene the prohibition of excessive fines and other provisions of the United States Constitution and any applicable state constitution.

124. Plaintiffs cannot recover punitive or exemplary damages against Bayer Corporation because such an award, which is penal in nature, would violate Bayer Corporation's rights under the United States Constitution and any applicable state constitution, unless Bayer Corporation is afforded the same procedural safeguards as are criminal defendants.

125. Any imposition of punitive or exemplary damages in this case against Bayer Corporation would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute an undue and unreasonable burden on interstate commerce.

126. With respect to Plaintiffs' demand for punitive or exemplary damages, Bayer Corporation incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under any applicable state law.

127. The imposition of punitive or exemplary damages would violate the open court provision(s) of applicable state constitution(s) and other applicable law.

128. No act or omission of Bayer Corporation was intentional, reckless, willful misconduct, wanton, reckless, and/or with actual malice, oppression, and/or fraud, or with conscious disregard and indifference to the rights, safety and welfare of Plaintiffs or Plaintiffs' decedents, or evidencing that entire want of care which would raise the presumption of conscious indifference to the consequences, and therefore any award of punitive or exemplary damages is

barred. Bayer Corporation asserts all statutory or judicial protections from punitive or exemplary damages that are available under applicable law, and any award of punitive or exemplary damages is barred.

129. The claim for punitive or exemplary damages against Bayer Corporation cannot be sustained under any applicable state law because, in all respects pertinent to this action, Bayer Corporation complied with applicable industry standards and did not engage in a deliberate course of conduct which knowingly endangered those using Trasylol®.

130. Plaintiffs' claims of injury and claims for damages are speculative.

131. Plaintiffs' Complaint fails to state a claim upon which relief can be granted for joint and several liability.

132. Bayer Corporation preserves all objections and defenses relating to venue.

133. This Court is not an appropriate or convenient forum for the adjudication of this matter.

134. Bayer Corporation relies upon all rights, defenses and presumptions accorded to it under applicable law.

135. Bayer Corporation adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer Corporation's defenses pleaded in this Answer.

136. Bayer Corporation reserves its right to assert additional defenses as discovery is taken and this case proceeds.

WHEREFORE, Bayer Corporation denies any and all liability with regard to Plaintiffs' claims and respectfully requests that Plaintiffs' claims against it be dismissed with prejudice and that Bayer Corporation be awarded such general, further relief as justice may require.

JURY DEMAND

Bayer Corporation hereby demands trial by a jury of twelve on all issues so triable.

DATED: January 6, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I caused true and correct copies of the foregoing DEFENDANT BAYER CORPORATION'S MASTER ANSWER AND NEW MATTER IN RESPONSE TO PLAINTIFFS' AMENDED MASTER COMPLAINT was electronically filed with the Court and that a copy of same was served on all counsel of record listed below via first class mail, postage prepaid (unless otherwise indicated) on this 6th day of January, 2009.

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