

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----X  
SIGMOND TOMASZEWSKI, individually and  
On behalf of all others similarly situated,

Plaintiffs,

-against-

MERCK & CO., INC., and  
SCHERLING-PLOUGH CORP.,

Defendants.  
-----X

EV 08 258  
CLASS ACTION COMPLAINT  
AND JURY DEMAND

AMON, J.

REYES, M.J

Plaintiff, SIGMOND TOMASZEWSKI, by and through his undersigned attorneys,  
PARKER WAICHMAN ALONSO LLP, BECNEL LAW FIRM, LLC, DOUGLAS &  
LONDON, P.C., LEVIN SIMES KAISER and GORNICK LLP, BAILEY PERRIN  
BAILEY LLP and WEITZ & LUXENBERG, P.C. hereby commences this action  
individually, and on behalf of the Class identified below, and seeks Class status on behalf of  
himself and the Class as described below.

FILED  
IN CLERK'S OFFICE  
U.S. DISTRICT COURT E.D.N.Y.

★ JAN 17 2008 ★  
BROOKLYN OFFICE

NATURE OF THE CASE/OVERVIEW

1. Plaintiff brings this action on behalf of all persons residing in the United States who purchased Vytorin<sup>®</sup>. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure (hereinafter "F.R.C.P.") to recover compensatory, equitable, and actual and punitive damages, injunctive relief, and attorneys' fees.

2. Plaintiff seeks to represent the following class:

Vytorin<sup>®</sup> Class: All citizens, residents, or domiciliaries of the  
United States who have purchased Vytorin<sup>®</sup> and such citizens',

residents' and domiciliaries' estates, representatives, administrators, spouses, children, relatives and "significant others" as their heirs or survivors.

3. Defendants Merck & Co., Inc. and Schering-Plough Corporation (hereafter collectively referred to as "Defendants") designed, researched, manufactured, tested, sought approval by the United States Food and Drug Administration (hereinafter "FDA"), advertised, promoted, marketed, sold and/or distributed Vytorin<sup>®</sup> for the reduction of total cholesterol, low-density lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously raising high density lipoprotein cholesterol.

4. Vytorin<sup>®</sup> combines Zetia<sup>®</sup>, a cholesterol-lowering agent developed at Schering-Plough Corporation with Zocor<sup>®</sup>, Merck & Co., Inc.'s cholesterol-lowering medicine.

5. Vytorin<sup>®</sup> generates approximately five (5) billion dollars a year in sales for Merck & Co., Inc. and Schering-Plough Corporation.

6. As a result of the defective nature of Vytorin<sup>®</sup>, the drug is ineffective at reducing total cholesterol, low-density lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously raising high-density lipoprotein cholesterol levels.

7. As a result of the defective nature of Vytorin<sup>®</sup>, the drug increases the arterial intima-media thickness thereby greatly increasing the risk of myocardial infarction and/or cerebral vascular accidents.

8. As a result of the defective nature of Vytorin<sup>®</sup>, the drug increased the fatty plaques in the arteries including the carotid of the participants in the clinical trial known as ENHANCE.

9. As a result of the defective nature of Vytorin<sup>®</sup>, the drug increased the intima-

media thickness (IMT) of the clinical trial participants that used Vytorin® as compared to the clinical trial participants that used Zocor.

10. The ENHANCE clinical trials showed that Vytorin® was no better at reducing artery clogging than the older and much less expensive Zocor.

11. The ENHANCE clinical trial did not show that Vytorin® is any more effective than Zocor on its own in affecting the rate of atherosclerosis progression.

12. At all times relevant, Defendants misrepresented the safety of Vytorin® and negligently designed, manufactured, marketed, advertised, promoted, sold and distributed Vytorin® as a safe and effective medication to reduce total cholesterol, low-density lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously raising high-density lipoprotein cholesterol levels.

13. At all times relevant, Defendants failed to warn of the dangers of Vytorin® including but not limited to the fact that Vytorin® increased the intima-media thickness (IMT) of the clinical trial participants that used Vytorin® as compared to the clinical trial participants that used Zocor.

14. At all times relevant, Defendants knew, and had reason to know, or should have known, that Vytorin® was not efficacious in managing hyperlipidemia thereby defrauding Plaintiff, members of the Plaintiff Class, physicians, patients and the population-at-large while accelerating the advancement of cardiovascular disease (hereinafter "CVD") leading to, in some patients, myocardial infarction and/or cerebral vascular accidents.

15. At all times relevant to this action, Defendants knew, and had reason to know, or should have known, that its representations that Vytorin® was safe and effective were materially false and misleading.

16. As a result of the defective nature of Defendants' product, Vytorin<sup>®</sup> fails to control hyperlipidemia thereby placing patients at an increased risk of accelerating or worsening CVD, which could result in myocardial infarction or cerebral vascular accident. Defendants knew, had reason to know, and/or should have known of this tendency and the resulting risk of injuries and deaths, as well as the total lack of efficacy, but failed to warn Plaintiff and all other Plaintiff Class members, and/or their physicians, preventing Plaintiff and Plaintiff Class members, and/or their physicians, and or the medical community from making informed choices about the selection of cholesterol lowering medications.

17. As a result of the defective nature of Defendants' product, Vytorin<sup>®</sup> accelerates the thickening of arterial intima-media hereby placing patients at an increased risk of myocardial infarction or cerebral vascular accident. Defendants knew, had reason to know, and/or should have known of this tendency and the resulting risk of injuries and deaths, but failed to warn Plaintiff and all other Plaintiff Class members, and/or their physicians, preventing Plaintiff and Plaintiff Class members, and/or their physicians, and or the medical community from making informed choices about the selection of cholesterol lowering medications.

18. Defendants concealed their knowledge of the defects in their products from the Plaintiff, all Plaintiff Class members, and/or their physicians, hospitals, pharmacists and/or the FDA.

19. Consequently, Plaintiff and all Plaintiff class members seek compensatory damages as a result of their use of Vytorin<sup>®</sup>, which causes, may cause and/or continue to cause Plaintiff and all Plaintiff Class members to suffer economic loss, physical pain, mental anguish, medical and other expenses.

20. Further, Plaintiff and all Plaintiff Class members seek equitable and other relief

for themselves, and all others similarly situated, to compensate them in whole or in part for the following economic issue which confront them as a result of their relying upon the safety and efficacy of Vytorin®:

- a. the increased cost of medical expenses, including but not limited to, those un-reimbursed by insurance policies, those uninsured, and/or the payment of higher insurance rates due to their use of Vytorin®;
- b. additional medical monitoring above and beyond that which is needed prior to Plaintiff and Plaintiff Class members' use of Vytorin®; and
- c. for whatever further relief the Court deems just and proper under the circumstances.

#### **JURISDICTION & VENUE**

21. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 and the Class Action Fairness Act. Venue is proper in this Court because Plaintiff resides within the District.

22. At all times relevant hereto, Merck & Co., Inc. was engaged in the business of manufacturing, marketing, promoting, selling, and/or distributing Vytorin®.

23. At all times relevant hereto, Schering-Plough Corporation, was engaged in the business of manufacturing, marketing, promoting, selling, and/or distributing Vytorin®.

24. Merck & Co., Inc. placed defective Vytorin® into the stream of interstate and worldwide commerce.

25. Schering-Plough Corporation placed defective Vytorin® into the stream of interstate and worldwide commerce.

26. As a direct and proximate result of Merck & Co., Inc. placing Vytorin® into stream of commerce, Plaintiff and the class members have suffered and continue to suffer

monetary damages, and will continue to suffer such damages indefinitely.

27. As a direct and proximate result of Scherling-Plough Corporation placing Vytorin® into stream of commerce, Plaintiff and the class members have suffered and continue to suffer monetary damages, and will continue to suffer such damages indefinitely.

28. Plaintiff and class members have incurred and will incur significant financial damages.

29. Upon information and belief, at all relevant times, Merck & Co. Inc., was present and doing business in the State of New York and in the Eastern District of New York in particular.

30. At all relevant times, Merck & Co., Inc. transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

31. At all relevant times, Merck & Co., Inc. expected or should have expected that its acts would have consequences within the United States of America, and the Eastern District of New York in particular.

32. Upon information and belief, at all relevant times, Scherling-Plough Corporation was present and doing business in the State of New York and in the Eastern District of New York in particular.

33. At all relevant times, Scherling-Plough Corporation transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

34. At all relevant times, Scherling-Plough Corporation expected or should have expected that its acts would have consequences within the United States of America, and the Eastern District of New York in particular.

#### **PARTIES**

35. Plaintiff, Sigmond Tomaszewski, is and was at all times hereinafter mentioned, a

citizen of the United States of America, and resides in the State of New York.

36. In or about, January, 2007, Plaintiff, Sigmond Tomaszewski purchased and used Vytorin<sup>®</sup> and as such, Plaintiff, Sigmond Tomaszewski is a member of the proposed Class herein.

37. Defendant Merck & Co., Inc. is a publicly traded corporation, duly formed and existing under and by the virtue of the laws of the State of New Jersey, with its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey 08889.

38. Defendant Scherling-Plough Corporation is a corporation, duly formed and existing under and by the virtue of the laws of the State of New Jersey, with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

#### **FACTUAL ALLEGATIONS**

39. Vytorin<sup>®</sup> is a combination drug product comprised of two approved lipid-altering drugs, ezetimibe (Zeita<sup>®</sup>) and simvastatin (Zocor<sup>®</sup>) and was approved for market by the FDA on July 23, 2004.

40. Vytorin<sup>®</sup> is marketed as a cholesterol reducer frequently prescribed as additional therapy for patients whose cholesterol remains high even after taking statins.

41. Zeita<sup>®</sup> inhibits the intestinal absorption of cholesterol and was approved for market by the FDA in 2002 for the treatment of primary hyperlipidemia. Zocor<sup>®</sup> is an HMG-CoA reductase inhibitor which blocks the rate-limiting enzyme in cholesterol synthesis that has been on the market since 1991.

42. Vytorin<sup>®</sup>'s New Drug Application (hereinafter "NDA") was submitted to the FDA on September 24, 2003 with fourteen clinical studies, including two clinical studies from the Zeita<sup>®</sup> NDA.

43. Of the fourteen clinical studies submitted to the FDA only two were relied upon for Vytorin<sup>®</sup>'s indication for treatment of primary hypercholesterolemia. One of the two studies (P680) accounts for 43% of the study participants in the two studies. P680 was a clinical trial from the Zeita<sup>®</sup> NDA. This means that Vytorin<sup>®</sup>'s indication for the treatment of primary hypercholesterolemia is based on only one (1) clinical trial consisting of only eight hundred and eighty seven (887) study participants.

44. The FDA relied primarily on the proven efficacy of Zeita<sup>®</sup> and Zocor<sup>®</sup> for its approval of Vytorin<sup>®</sup>'s indication for the treatment of primary hyperlipidemia and not data from study participants taking Vytorin<sup>®</sup>.

45. Clinical Study P038 was the only clinical efficacy study out of fourteen clinical trials that used the to-be-marketed formulation of Vytorin<sup>®</sup> and it was not used to support Vytorin<sup>®</sup>'s indication for the treatment of primary hypercholesterolemia.

46. The trial known as ENHANCE (Ezetimibe and Simvastatin in Hyperlipidemia Enhances Atherosclerosis Regression) began in June 2002 and ended in April 2006.

47. The ENHANCE study compared Vytorin<sup>®</sup> 80 with Zocor<sup>®</sup> alone.

48. Zocor<sup>®</sup> alone is widely believed by the medical community to reduce arterial intima-media thickness.

49. The intima-media of an artery can become thick thereby restricting blood flow. This process is known as atherosclerosis. The thickening of the intima-media is caused by a buildup of plaque.

50. The ENHANCE study was unlike previous Vytorin<sup>®</sup> studies in that the primary endpoint was to measure the change in ultrasound-determined average carotid artery intima-media thickness (IMT) on a per subject basis between baseline and endpoint.



51. All the study participants in the ENHANCE study patients had been treated and their arteries measured by April 2006. Cardiologists expected to see results of ENHANCE at a medical conference in November, 2006 then at another in March, 2007. Defendants recently announced that they will present the data with a new primary endpoint at the American College of Cardiology Conference in March, 2008.

52. In response to Schering-Plough Corporations announcement that they will present the data at the American College of Cardiology Conference in March, 2008 with a new primary endpoint, on December 11, 2007, Congress launched an investigation into the delay in Defendants reporting the ENHANCE study data.

53. Defendants did not register ENHANCE in the government clinical trial database [www.clinicaltrials.gov](http://www.clinicaltrials.gov) until approximately one year after April, 2006.

54. Upon information and belief, Defendants were aware at least as early as April, 2006 that Vytorin<sup>®</sup> failed to slow the accumulation of fatty plaque in the arteries.

55. Upon information and belief, Merck & Co., Inc. was aware at least as early as April, 2006, that Vytorin<sup>®</sup> contributed to plaque formation over Zocor.

56. Upon information and belief, Merck & Co., Inc. was aware at least as early as April, 2006, that Vytorin<sup>®</sup> raised the risk of myocardial infarction and cerebral vascular accidents in patients taking Vytorin<sup>®</sup>.

57. Upon information and belief, Scherling-Plough Corporation was aware at least as early as April, 2006 that Vytorin<sup>®</sup> failed to slow the accumulation of fatty plaque in the arteries.

58. Upon information and belief, Scherling-Plough Corporation was aware at least as early as April, 2006, that Vytorin<sup>®</sup> contributed to plaque formation.

59. Upon information and belief, Scherling-Plough Corporation was aware at least as

early as April, 2006, that Vytorin<sup>®</sup> raised the risk of myocardial infarction and cerebral vascular accidents in patients taking Vytorin<sup>®</sup>

60. Merck & Co., Inc. recklessly failed to disclose that Vytorin<sup>®</sup> was ineffective for the treatment of high-cholesterol and continued to sell Vytorin<sup>®</sup> with this knowledge.

61. Merck & Co., Inc. intentionally failed to disclose that Vytorin<sup>®</sup> was ineffective for the treatment of high-cholesterol and continued to sell Vytorin<sup>®</sup> with this knowledge.

62. Scherling-Plough Corporation recklessly failed to disclose that Vytorin<sup>®</sup> was ineffective for the treatment of high-cholesterol and continued to sell Vytorin<sup>®</sup> with this knowledge.

63. Scherling-Plough Corporation intentionally failed to disclose that Vytorin<sup>®</sup> was ineffective for the treatment of high-cholesterol and continued to sell Vytorin<sup>®</sup> with this knowledge.

64. Defendants knew, or had reason to know, of the defect in Vytorin<sup>®</sup> at least as early as April, 2006. This knowledge was concealed from Plaintiff, Plaintiff Class members, the medical community, and the public at large.

65. Defendants' dangerous and careless conduct of concealment, equates to conduct purposely committed, without regard for the rights and safety of the Plaintiff and members of the Class.

#### **CLASS DEFINITION**

66. Plaintiff brings this action pursuant to Federal Rules of Civil Procedure Rule 23 on behalf of himself, and all others similarly situated, including the classes and subclasses defined as follows:

#### **Vytorin<sup>®</sup> Class:**

All citizens, residents or domiciliaries of the United States who are presently or have purchased Vytorin® and such citizens', residents' and domiciliaries' estates, representatives, administrators, spouses, children, relatives and "significant others" as their heirs or survivors.

67. Excluded from the Class are:

- a. Merck & Co., Inc.'s officers and directors;
- b. Scherling-Plough Corporation's officers and directors;
- c. any judge or judicial official assigned to this matter and his or her immediate family; and
- d. any legal representative, successor, or assign of any excluded persons or entities.

68. Plaintiff and Plaintiff Class contemplate sub-classes so as to ameliorate any choice of law concerns and/or be compliant with Fed.R.Civ.P. 23(a) and 23(b); more specifically such sub-classes are contemplated based upon the 50 states and the Commonwealth of Puerto Rico and the District of Columbia.

69. While Plaintiff and Plaintiff Class may seek sub-classes as set forth above, this will be the subject of the Class certification briefing which will be filed and prepared as soon as practical. To this end, Plaintiff and the Plaintiff Class therefore, and in the alternative to the proposed Class set forth above, define the proposed Class and/or initial subclass herein as:

All citizens of New York state or residents of the State of New York who are presently or have purchased Vytorin® and such citizens' and residents' estates, representatives, administrators, spouses, children, relatives and "significant others" as their heirs or survivors.

### CLASS ACTION ALLEGATIONS

70. Numerosity of the Class: The proposed Class is so numerous that joinder is impractical. The disposition of these claims through this class action will be more efficient and will benefit the parties and the Court. Some estimates place the number of patients taking Vytorin® in the "millions", but suffice to say there may be hundreds of thousands of members of the Class. The identities of the individual members of the class are ascertainable through, *inter alia*, medical and pharmaceutical records, as well as Class members may be informed of the pendency of this class action by direct mail, internet, or other means.

71. Predominance of Common Questions of Fact and Law: A well-defined community of interest in the questions of law and fact common to the Vytorin® Class predominate over questions affecting only individual class members including, but not limited to, the following:

- a. whether defendants' failure to give adequate and timely warning of the dangers of the Vytorin® constitutes negligence and/or negligence *per se*;
- b. whether Defendants concealed adverse information from Plaintiff and the Vytorin® Class regarding the testing and safety of the Vytorin®;
- c. whether Defendants violated applicable state consumer protection laws;
- d. whether Plaintiff and the Class members are entitled to recover compensatory, exemplary, punitive, and/or other damages as a result of Defendants' unlawful conduct;
- e. what is the proper mechanism for assessing and awarding damages and administering other relief to the Class members, including relief to reduce the threat of future harm to Class members;
- f. whether Defendants designed, manufactured, and/or marketed a defective product;
- g. whether Defendants failed the safety concerns of Vytorin® shown in reports and/or studies;
- h. whether Defendants' conduct in designing, manufacturing, failing to warn,

selling and/or marketing Vytorin<sup>®</sup> fell below the duty of care owed by Defendants to Plaintiff and members of the Plaintiff Class;

- i. whether Defendants recklessly delayed reporting of the results of the ENHANCE clinical trial to the FDA, the medical community, pharmaceutical community, other regulatory authorities, the public, the Defendants herein and the Plaintiff class actions members;
- j. whether Defendants intentionally delayed reporting of the results of the ENHANCE clinical trial to the FDA, the medical community, pharmaceutical community, other regulatory authorities, the public, the Defendants herein and the Plaintiff class actions members;
- k. whether Defendants violated Federal statutes in not timely reporting the data from the ENHANCE study;
- l. whether Defendants violated Federal regulations in not timely reporting the data from the ENHANCE study;
- m. whether Defendants violated State statutes in not timely reporting the data from the ENHANCE study;
- n. whether Defendants violated State regulations in not timely reporting the data from the ENHANCE study;
- o. whether Defendants negligently, recklessly, intentionally, or concealed information about the safety and efficacy of Vytorin<sup>®</sup> from the Plaintiff and the Plaintiff Class, as well as their physicians, hospitals, healthcare professionals, and the FDA;
- p. whether Defendants watered down and/or diluted the actual risk of and safety concerns of Vytorin<sup>®</sup>;
- q. whether Defendants under-reported the adverse events associated with Vytorin<sup>®</sup>;
- r. whether Defendants' inadequately, improperly, negligently, recklessly, and/or fraudulently compared test results of the safety and/or efficacy of Vytorin<sup>®</sup> versus other available hyperlipidemia treatments;
- s. whether Defendants are strictly liable in tort for selling a defective product;
- t. whether Defendants' conduct constitutes fraudulent concealment;
- u. whether Defendants conduct constitutes fraudulent misrepresentation;
- v. whether Defendants' conduct constitutes negligent misrepresentation;

- w. whether Defendants' conduct constitutes fraudulent concealment;
- x. whether Defendants' conduct constitutes negligence;
- y. whether Defendants are liable for intentional and/or negligent infliction of emotional distress;
- z. whether Defendants breached express warranties;
- aa. whether Defendants breached implied warranties of merchantability;
- bb. whether Defendants failed to adequately warn or notify consumers regarding the dangerous side effects, safety concerns, lack of efficacy of Vytorin<sup>®</sup>;
- cc. whether Defendants failed to test and/or failed to adequately test the Vytorin<sup>®</sup>, generally;
- dd. whether Plaintiff Class members have sustained irreparable harm and whether they are entitled to equitable relief including restitution and, if so, the nature and extent of such damages;
- ee. whether the Plaintiff Class is entitled to compensatory damages and, if so, the nature and extent of such damages;
- ff. whether Defendant is liable for punitive damages, and if so, how much is necessary and appropriate to punish them for their conduct, deter others and fulfill the policies and purposes of punitive and/or exemplary damages;
- gg. how any and all punitive and/or exemplary damages awarded to Plaintiff should be equitably allocated among the Plaintiff and the Plaintiff Class;
- hh. whether Defendants acted to defraud, misrepresent, and deceive the Plaintiff and/or the Plaintiff Class;
- ii. Whether Defendants failed to adequately test their products;
- jj. whether Defendants failed to adequately reveal the results, if any, that were yielded by the testing of their product to the Plaintiff, Plaintiff Class, their physicians, hospitals, the FDA, and other healthcare professionals;
- kk. whether Defendants failed to adequately warn of the side effects and safety concerns of Vytorin<sup>®</sup>, and/or supplement its warnings as it discovered new side effects and safety concerns revealed through the aforementioned tests, studies, and/or reports;
- ll. whether Defendants failed to adequately warn of the side effects and safety concerns of Vytorin<sup>®</sup>, and/or supplement its warnings as they discovered

new side effects and safety concerns that Vytorin<sup>®</sup> caused because of underreporting, underestimating, and/or downplaying the serious and dangerous side effects of Vytorin<sup>®</sup>;

mm. whether the safety defects in the Defendants' Vytorin<sup>®</sup> constitute a design defect for purposes of strict products liability;

72. Typicality: Having been a victim of Defendants' unlawful conduct, Plaintiff is a member of the Vytorin<sup>®</sup> Class. Plaintiff purchased and ingested Vytorin<sup>®</sup>. All members of the class have purchased and ingested Vytorin<sup>®</sup>. Plaintiff and members of the Vytorin<sup>®</sup> Class have similarly suffered harm arising from Defendants' violations of law, as alleged herein.

73. Adequacy of Representation: Plaintiff is an adequate representative of the Plaintiff Class because he is a member of the Plaintiff Class and his interests do not conflict with the interests of the members of the Plaintiff Class he seeks to represent. Further, Plaintiff is represented by experienced and able counsel who have litigated numerous other mass torts and products liability class actions, and they intend to prosecute this action vigorously for the benefit of the entire Plaintiff Class. Plaintiff and his counsel will fairly and adequately protect the interests of the members of the Plaintiff Class.

74. Superiority: A class action is superior to other available methods for the efficient adjudication of this litigation since individual litigation of each Class members' claims is impracticable. It would be unduly burdensome to the courts in which individual litigations would proceed. Further, individual litigations present a potential for inconsistent and/or contradictory judgments and further increases the delay and expense to all parties and the courts. By contrast, the class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court. Additionally, notice of the pendency and/or resolution of this class action can be provided to Class members by direct mail, as upon information and belief, Defendants herein have kept

detailed records as to their sale of Vytorin®.

75. This action is also properly certified under the provisions of Federal Rule of Civil Procedure Rule 23 because:

- a. the prosecution of separate actions by individual members of the Class would create a risk of inconsistency of varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Defendants' financing activities;
- b. due to the nature of the relief sought, the prosecution of separate actions by the individual members of the Class would create a risk of adjudications with respect to them that would as a practical matter, be dispositive of the interests of the other members of the Class not parties to such adjudications or would substantially impair or impede the ability of such members of the Class to protect their interests; and
- c. by failing to make the written disclosures required by applicable laws, Defendants have and acted or refused to act in respects generally applicable to the Class, thereby making appropriate final injunctive relief with regard to the members of the Class as a whole in terms of the nature of the relief sought.

#### **EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

76. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through suppressing reports, failing to follow through on FDA notification requirements, failing to disclose a known defect to physicians or Class members, and misrepresenting their product as safe for intended use, actively concealed from Plaintiff, the Class, Plaintiff's and the Class's prescribing physicians the true risks associated with Vytorin®.

77. As a result of Defendants' actions, Plaintiff, and the Class, and their prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff and Class members had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.



78. Furthermore, defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Vytorin®. Defendants were under a duty to disclose the true character, quality and nature of Vytorin® because this was non-public information over which the Defendants had and continues to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff and Class members, medical providers and/or to their facilities. In addition, the Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

79. Plaintiff and the Class had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Plaintiff and the Class could not have reasonably discovered the wrongdoing at any time prior to January 15, 2008. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the risks about which they were aware. Plaintiff and the Class and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations.

**FIRST CAUSE OF ACTION  
AS AGAINST THE DEFENDANT  
(NEGLIGENCE AND NEGLIGENCE PER SE)**

80. Plaintiff, SIGMOND TOMASZEWSK, individually, and on behalf of all others similarly situated, repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set

forth herein.

81. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Vytorin<sup>®</sup> into the stream of commerce, including a duty to assure that the product would work as intended, marketed, promoted, and/or advertised and/or did not cause users to suffer unreasonable, dangerous side effects.

82. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Vytorin<sup>®</sup> into interstate commerce in that Defendants knew or should have known that permitted the product not to work and/or function as intended and/or created a high risk of unreasonable, dangerous side effects, including but not limited to increase risk for myocardial infarction and/or cerebral vascular accident, as well as other severe and permanent health consequences.

83. The negligence of the Defendant, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- a. manufacturing, producing, promoting, formulating, creating, and/or designing Vytorin<sup>®</sup> without thoroughly testing it;
- b. manufacturing, producing, promoting, formulating, creating, and/or designing Vytorin<sup>®</sup> without adequately testing it;
- c. not conducting sufficient testing programs to determine whether or not the aforesaid product was safe for use; in that Defendants herein knew or should have known that Vytorin<sup>®</sup> was unsafe and unfit for use by reason of the dangers to its users and/or because there was no efficacy data and/or testing performed;
- d. selling Vytorin<sup>®</sup> without making proper and sufficient tests to determine the dangers and/or total lack of efficacy to its users;
- e. negligently failing to adequately and correctly warn the Plaintiff and

Plaintiff Class members, the public, the medical and healthcare profession, and/or the FDA of the dangers and/or lack of efficacy of Vytorin®;

- f. negligently failing to recall or otherwise notify users at an earliest date that it became known that said product was, in fact, dangerous and defective and/or lacked any efficacy;
- g. failing to provide adequate instructions regarding safety precautions and/or efficaciousness to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Vytorin®;
- h. failing to test Vytorin® and/or failing to adequately, sufficiently and properly test Vytorin®;
- i. negligently advertising and recommending the use of the aforesaid drug without sufficient knowledge as to its dangerous propensities and/or lack of efficacy;
- j. negligently representing that Vytorin® was safe and efficacious for use for its intended purpose, when, in fact, it lacked any efficacy and its safety is questionable;
- k. negligently representing that Vytorin® had equivalent safety and efficacy as other lie, comparable, and/or similarly intended medications;
- l. negligently designing Vytorin® in a manner which was dangerous and lacked efficacy to their users;
- m. negligently manufacturing Vytorin® in a manner which was dangerous and lacked efficacy to their users;
- n. negligently producing Vytorin® in a manner which was dangerous and lacked efficacy to their users;
- o. negligently assembling Vytorin® in a manner which was dangerous and lacked efficacy to their users;
- p. concealing information concerning tests, and/or reports, and/or studies from the Plaintiff and Plaintiff Class members in knowing that Vytorin® was unsafe, dangerous, and/or non-conforming with accepted industry standards, as well as lacked efficacy and /or efficacy data; and
- q. improperly concealing and/or misrepresenting information from the Plaintiff and Plaintiff Class members, healthcare professionals, and/or the public, concerning the severity of risks and dangers of Vytorin® and/or the

lack of efficacy of Vytorin®.

84. Defendants under-reported, underestimated and downplayed the serious dangers and/or the lack of efficacy of Vytorin®.

85. Defendants negligently compared the safety risk, efficacy, and/or dangers of Vytorin® with other, non-defective statins and/or other cholesterol lowering medication and/or treatments.

86. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Vytorin® in that they:

- a. failed to use due care in designing and manufacturing Vytorin® so as to avoid the aforementioned risks and/or lack of efficacy to individuals when Vytorin® was used for its intended purpose;
- b. failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Vytorin®, which includes the efficaciousness of same;
- c. failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Vytorin® as well as accurate efficacy data;
- d. failed to warn Plaintiff and Plaintiff Class members of the severity and duration of such adverse effects as well as the lack of long-term efficacy, as the warnings given did not accurately reflect the symptoms, severity of the side effects and true efficaciousness;
- e. failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety and/or efficacy of Vytorin®;
- f. failed to warn Plaintiff and Plaintiff Class members, prior to actively encouraging the sale of Vytorin®, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects and/or failed efficacy; and
- g. were otherwise negligent.

87. Despite the fact that Defendant knew or should have known that Vytorin<sup>®</sup> caused unreasonably dangerous side effects and/or lacked efficacy, Defendants continue to market, manufacture, distribute and/or sell Vytorin<sup>®</sup> to consumers, including the Plaintiff and Plaintiff Class members.

88. Defendants knew or should have known that consumers such as the Plaintiff and Plaintiff Class members would foreseeably suffer injury, both physical and economic, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

89. Defendants' actions and or inactions, as set forth herein, by virtue of violating statutes, ordinances and/or rules and/or regulations, constituted negligence per se.

90. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury, and/or be at increased risk of suffering injury, including personal injuries and financial harm, as a result of Defendants' failure to exercise ordinary care, as set forth above.

91. Defendants' negligence was the proximate cause of Plaintiff's injuries and those of the Plaintiff Class, harm and economic loss which they suffered and/or will continue to suffer.

92. By reason of the foregoing Plaintiff and Plaintiff Class experienced and/or are at risk of experiencing serious and dangerous side effects, as well as have incurred financial damage and injury.

93. As a result of the foregoing acts and omissions the Plaintiff and Plaintiff Class requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff and Plaintiff Class are informed and believe and

further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

94. By reason of the foregoing, Plaintiff and Plaintiff Class have been damaged as against the Defendants in the sum of ONE BILLION DOLLARS (\$1,000,000,000.00).

**SECOND CAUSE OF ACTION  
(STRICT LIABILITY)**

95. Plaintiff, SIGMOND TOMASZEWSK, individually, and on behalf of all others similarly situated, repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

96. At all times herein mentioned, the Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Vytorin<sup>®</sup> used by Plaintiff SIGMOND TOMASZEWSK, and the Plaintiff Class members.

97. That Vytorin<sup>®</sup> was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

98. At those times, the Vytorin<sup>®</sup> was in an unsafe, defective, and inherently dangerous condition, which was unreasonably dangerous to users, and in particular, Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class.

99. Vytorin<sup>®</sup> was so defective in design or formulation that when it left the hands of the manufacturer and/or suppliers the foreseeable risks exceeded the benefits associated with the design or formulation Vytorin<sup>®</sup>.

100. At all times herein mentioned, Vytorin<sup>®</sup> was in a defective condition and unsafe,

and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

101. Defendants knew, or should have known, that at all times herein mentioned Vytorin® was in a defective condition, and was/is inherently dangerous and unsafe.

102. At the time of use of Vytorin® by Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class for the purposes and in a manner normally intended, namely for treatment of hyperlipidemia.

103. Defendants, with this knowledge, voluntarily sought FDA approval and continue to market their Vytorin® product in a dangerous condition for use by the public, and in particular the Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class.

104. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

105. Defendants' Vytorin® product was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed in a defective condition by Defendants and were unreasonably dangerous to their intended users, including Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class.

106. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class. Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

107. Neither the Plaintiff, SIGMOND TOMASZEWSK, nor the members of the Plaintiff Class acting as a reasonably prudent person could discover that Vytorin® was defective as herein mentioned and perceived its danger.

108. Vytorin<sup>®</sup> designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, but not limited to, failure to reduce total cholesterol levels, LDL cholesterol levels and triglycerides while simultaneously increase HDL cholesterol levels, acceleration of the process of atherosclerosis, and the induction of myocardial infarction and/or cerebral vascular accidents, and/or other severe and permanent health consequences.

109. Vytorin<sup>®</sup> designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants is defective due to inadequate warnings and/or inadequate testing.

110. Vytorin<sup>®</sup> designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants is defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, but not limited to, acceleration of the process of atherosclerosis, failure to reduce total cholesterol levels, LDL cholesterol levels and triglycerides while simultaneously increase HDL cholesterol levels, and the induction of myocardial infarction and/or cerebral vascular accidents, and/or other severe and permanent health consequences.

111. By reason of the foregoing, the Defendants are strictly liable in tort to the Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Vytorin<sup>®</sup>.

112. Defendants' defective design, manufacturing defect, and inadequate warnings of Vytorin<sup>®</sup> were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

113. That said defects in Defendants' Vytorin<sup>®</sup> were a substantial factor in causing



Plaintiff's injuries and injuries to the members of the Plaintiff Class and/or placing the Plaintiff and members of the Plaintiff Class at increased risk of serious injury and/or harm.

114. As a direct and proximate result of the defective condition of Vytorin<sup>®</sup>, as manufactured and sold by said Defendants, Plaintiff and members of the Class, suffered and will continue to suffer damages.

115. By reason of the foregoing Plaintiff and Plaintiff Class experienced and/or are at risk of experiencing serious and dangerous side effects, as well as have incurred financial damage and injury.

116. As a result of the foregoing acts and omissions the Plaintiff and Plaintiff Class requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff and Plaintiff Class are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

117. By reason of the foregoing, Plaintiff and Plaintiff Class have been damaged as against the Defendants in the sum of ONE BILION DOLLARS (\$1,000,000,000.00).

**THIRD CAUSE OF ACTION**  
**(BREACH OF EXPRESS WARRANTY)**

118. Plaintiff, SIGMOND TOMASZEWSK, individually, and on behalf of all others similarly situated, repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

119. Defendants expressly warranted that Vytorin<sup>®</sup> was safe and well accepted by users.

120. Vytorin<sup>®</sup> does not conform to these express representations because the

prescription drug is not safe and it is associated with numerous serious side effects not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class suffered and/or will continue to suffer, and/or are at increased risk to suffer severe and permanent personal injuries, harm and/or economic loss.

121. Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class did rely on the express warranties of the Defendants herein.

122. Members of the medical community, including physicians and/or other healthcare professionals, relied upon the representations and warranties of the Defendants in recommending and/or prescribing Vytorin®.

123. The Defendants herein breached the aforesaid express warranties, as Vytorin® was defective.

124. Defendants expressly represented to Plaintiff, the Plaintiff Class and/or their physicians, healthcare providers, and/or the FDA that Vytorin® is safe, efficacious, and fit for use for the purposes intended, that the prescription drug is of merchantable quality, that Vytorin® did not produce any dangerous side effects in excess of those risks associated with other, non-defective antihyperlipidemia agents, that the side effects the prescription drug did produce were accurately reflected in the warnings and that Vytorin® was adequately tested and fit for its intended use.

125. Defendants impliedly warrant further that Vytorin® is safe and efficacious, and that the Vytorin® is more effective than Zetia® or Zocor® alone.

126. Defendants knew or should have known that, in fact, the aforesaid representations and warranties are false, misleading and untrue in that Vytorin® is not fit for the use

intended, and, in fact, produced serious injuries to the users that are not accurately identified and represented by Defendants.

127. By reason of the foregoing Plaintiff and Plaintiff Class experienced and/or are at risk of experiencing serious and dangerous side effects, as well as have incurred financial damage and injury.

128. As a result of the foregoing acts and omissions the Plaintiff and Plaintiff Class requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff and Plaintiff Class are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

129. By reason of the foregoing, Plaintiff and Plaintiff Class have been damaged as against the Defendants in the sum of ONE BILLION DOLLARS (\$1,000,000,000.00).

**FOURTH CAUSE OF ACTION  
(BREACH OF IMPLIED WARRANTY)**

130. Plaintiff, SIGMOND TOMASZEWSK, individually, and on behalf of all others similarly situated, repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

131. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold the Vytorin<sup>®</sup> for the treatment of hyperlipidemia.

132. At the time Defendants marketed, sold, and distributed Vytorin<sup>®</sup> for use by Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class, Defendants knew of the use for which Vytorin<sup>®</sup> was intended and impliedly warranted the product to be of

merchantable quality and safe and fit for such use.

133. The Defendants impliedly represented and warranted to the Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class and/or their physicians, healthcare providers, and/or the FDA that Vytorin<sup>®</sup> was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

134. That said representations and warranties aforementioned is false, misleading, and inaccurate in that Vytorin<sup>®</sup> is unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

135. Plaintiff, SIGMOND TOMASZEWSK, members of the Plaintiff Class and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

136. Plaintiff, SIGMOND TOMASZEWSK, members of the Plaintiff Class and/or their physicians and/or healthcare professionals reasonably relies upon the skill and judgment of Defendants as to whether Vytorin<sup>®</sup> is of merchantable quality and safe and fit for its intended use.

137. Vytorin<sup>®</sup> was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said product without substantial change in the condition in which they were sold.

138. The Defendants herein breached the aforesaid implied warranties, as Vytorin<sup>®</sup> was not fit for their intended purposes and uses.

139. By reason of the foregoing Plaintiff and Plaintiff Class experienced and/or are at risk of experiencing serious and dangerous side effects, as well as have incurred financial

damage and injury.

140. As a result of the foregoing acts and omissions the Plaintiff and Plaintiff Class requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff and Plaintiff Class are informed and believe and further allege that the Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

141. By reason of the foregoing, Plaintiff and Plaintiff Class have been damaged as against the Defendants in the sum of ONE BILLION DOLLARS (\$1,000,000,000.00).

**FIFTH CAUSE OF ACTION**  
**(FRAUDULENT MISREPRESENTATION)**

142. Plaintiff, SIGMOND TOMASZEWSK, individually, and on behalf of all others similarly situated, repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

143. The Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff and Plaintiff Class members, and/or the FDA, and/or the public in general, that said product, Vytorin<sup>®</sup>, had been tested and was found to be safe and/or effective for use.

144. That representations made by Defendant were, in fact, false.

145. The Defendants failed to timely disclose the results from the ENHANCE clinical trial as they fraudulently misrepresented that the results did not concern the safety and well being of the clinical trial participants, the Plaintiff herein and the Plaintiff class action members.

146. The Defendants failed to timely disclose the results from the ENHANCE clinical trial as they fraudulently misrepresented that they did not have any unexpected data relating to

safety and/or efficacy of the clinical trial participants, the Plaintiff herein and the Plaintiff class action members.

147. In fact Defendants during all times herein allegedly continued to issue press releases and other communications to the medical profession, pharmaceutical profession, the public, the Plaintiff herein, and the Plaintiff class action members that Vytorin<sup>®</sup> was superior to other cholesterol reducing medications while they knew that the data coming from the ENHANCE clinical trial showed otherwise.

148. In fact Defendants during all times herein allegedly continued to issue press releases and other communications to the medical profession, pharmaceutical profession, the public, the Plaintiff herein, and the Plaintiff class action members that Vytorin<sup>®</sup> is any more effective than the Zocor on the rate of atherosclerosis progression.

149. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

150. These representations were made by said Defendant with the intent of defrauding and deceiving the Plaintiff and Plaintiff Class members, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase said product, Vytorin<sup>®</sup>, for use for the reduction of total cholesterol, low-dense lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously raising high dense lipoprotein cholesterol, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and Plaintiff Class members herein.

151. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff and Plaintiff Class members used Vytorin<sup>®</sup>, the Plaintiff and Plaintiff Class members were unaware of the falsity of said representations and reasonably believed them to be true.

152. In reliance upon said representations, the Plaintiff and Plaintiff Class members were induced to and did purchase and use Vytorin<sup>®</sup>, thereby sustaining damage and injury and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

153. Said Defendants knew and were aware or should have been aware that Vytorin<sup>®</sup> had not been sufficiently tested, was defective in nature, and/or that they lacked adequate and/or sufficient warnings.

154. Defendants knew or should have known that Vytorin<sup>®</sup> had a potential to, could, and would cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings and that Vytorin<sup>®</sup> lacked any efficacy testing data that was accurate or which made is more efficacious than like medications.

155. Defendants brought Vytorin<sup>®</sup> to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff and Plaintiff Class members.

156. By reason of the foregoing Plaintiff and Plaintiff Class experienced and/or are at risk of experiencing serious and dangerous side effects, as well as have incurred financial damage and injury.

157. As a result of the foregoing acts and omissions the Plaintiff and Plaintiff Class requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff and Plaintiff Class are informed and believe and

further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

158. By reason of the foregoing, Plaintiff and Plaintiff Class have been damaged as against the Defendants in the sum of ONE BILLION DOLLARS (\$1,000,000,000.00).

**SIXTH CAUSE OF ACTION  
(FRAUDULENT CONCEALMENT)**

159. Plaintiff, SIGMOND TOMASZEWSK, individually, and on behalf of all others similarly situated, repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

160. At all times during the course of dealing between Defendants and Plaintiff, members of the Plaintiff Class and/or Plaintiffs' healthcare providers, and/or the FDA, Defendants misrepresented the safety of Vytorin®.

161. At all times during the course of dealing between Defendants and Plaintiff, SIGMOND TOMASZEWSK, members of the Plaintiff Class and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the efficacy of Vytorin® in that the product fails to reduce total cholesterol, low-density lipoprotein (LDL) cholesterol and triglyceride levels while simultaneously raising high-density lipoprotein cholesterol levels and accelerates atherosclerosis.

162. Defendants knew or were reckless in not knowing that its representations were false.

163. Defendant fraudulently concealed and/or intentionally omitted the following material information: that Vytorin® is not as safe as other available antihyperlipidemia medications and that Vytorin® lacks any established and/or known efficacy.



164. Defendant fraudulently concealed and/or intentionally omitted the following material information: that the risks of adverse events with Vytorin® are higher than those with other available antihypercholesterolemia medications.

165. Defendants fraudulently concealed and/or intentionally omitted the following material information: that the risks of adverse events with the Vytorin® were not adequately tested for and/or known by Defendants.

166. Defendants fraudulently concealed and/or intentionally omitted the following material information: that Defendants were aware of dangers of Vytorin®, in addition to and above and beyond those associated with other anticholesterolemia medications.

167. Defendants fraudulently concealed and/or intentionally omitted the following material information: that Vytorin® is defective, and it causes dangerous side effects, including but not limited to, acceleration of the process of atherosclerosis, failure to reduce total cholesterol levels, LDL cholesterol levels and triglycerides while simultaneously increase HDL cholesterol levels, and the induction of myocardial infarction and/or cerebral vascular accidents, and/or other severe and permanent health consequences, in a much more and significant rate than other available anticholesterolemia medications.

168. Defendants fraudulently concealed and/or intentionally omitted the following material information: that the results of the aforementioned ENHANCE study shows that Vytorin® accelerates the process of atherosclerosis and/or fails to reduce total cholesterol levels, LDL cholesterol levels and triglycerides while simultaneously increasing HDL cholesterol levels.

169. Defendants fraudulently concealed and/or intentionally omitted the following material information: that patients needed to be monitored more regularly than normal while

using Vytorin®.

170. Defendants were under a duty to disclose to Plaintiff, SIGMOND TOMASZEWSK, members of the Plaintiff Class and/or their physicians, hospitals, healthcare providers, and/or the FDA the aforementioned as it pertains to Vytorin®.

171. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause damage and injury to users of Vytorin®, including the Plaintiff, SIGMOND TOMASZEWSK, and members of the Plaintiff Class.

172. Defendants' concealment and omissions of material facts concerning, inter alia, the safety and/or efficacy of Vytorin® was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff- SIGMOND TOMASZEWSK, members of the Plaintiff Class and/or their physicians, hospitals and/or healthcare providers into reliance, continued use of Vytorin®, and actions thereon, and to cause them to purchase, recommend, dispense and/or use Vytorin®.

173. Defendants concealment and omissions of material facts concerning, inter alia, the safety and/or efficacy of Vytorin® was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, SIGMOND TOMASZEWSK, members of the Plaintiff Class and/or their physicians, hospitals and/or healthcare providers into reliance, continued use of Vytorin®, and actions thereon, and to cause them to purchase, recommend, dispense and/or use Vytorin®, solely for their financial gain and without regard for the safety of their customers, the Plaintiffs herein and the Plaintiff class action members.

174. Defendants knew that Plaintiff, SIGMOND TOMASZEWSK, members of the Plaintiff Class and/or their physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these

included material omissions of facts surrounding Vytorin<sup>®</sup>, as set forth herein.

175. Plaintiff, as well as his doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

176. By reason of the foregoing Plaintiff and Plaintiff Class experienced and/or are at risk of experiencing serious and dangerous side effects, as well as have incurred financial damage and injury.

177. As a result of the foregoing acts and omissions the Plaintiff and Plaintiff Class requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff and Plaintiff Class are informed and believe and further allege that the Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

178. By reason of the foregoing, Plaintiff and Plaintiff Class have been damaged as against the Defendants in the sum of ONE BILLION DOLLARS (\$1,000,000,000.00).

**SEVENTH CAUSE OF ACTION**  
**(VIOLATION OF CONSUMER PROTECTION STATUTES)**

179. Plaintiff, on behalf of himself and all others similarly situated, repeats, reiterates, realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

180. Defendants engaged in commercial conduct by selling Vytorin<sup>®</sup>.

181. Defendants misrepresented and omitted material information regarding Vytorin<sup>®</sup> by failing to disclose known risks.

182. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation,

and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement Vytorin® in violation of New York General Business Law ("GBL") § 349 & § 350 and other similar statutes.

183. New York and all other states and the District of Columbia have enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that Vytorin® was fit to be used for the purpose for which they were intended, when Defendants knew it was defective, dangerous, ineffective, unsafe and by other acts alleged herein.

184. Defendants engaged in the deceptive acts and practices alleged herein in order to sell Vytorin® to the public, including Plaintiff and the Class members.

185. As a direct and proximate result of the Defendants' violations of GBL § 349 & § 350 and other various consumer protection statutes enacted in other states and the District of Columbia, Plaintiff and the Class members have suffered damages. Plaintiff and the Class members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

186. By reason of the foregoing, Plaintiff and Plaintiff Class have been damaged as against the Defendants in the sum of ONE BILLION DOLLARS (\$1,000,000,000.00).

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff and members of Class demand judgment against Merck & Co., Inc. and Scherling-Plough Corporation as follows:

- i. An order certifying the Class, appointing Plaintiff as class representatives, and appointing PARKER WAICHMAN ALONSO LLP; BECNEL LAW FIRM, LLC; DOUGLAS & LONDON, P.C.; LEVIN SIMES KAISER and GORNICK LLP; BAILEY PERIN BAILEY, LLP and WEITZ & LUXENBERG, P.C. as counsel to the Class;
- ii. Equitable, injunctive and declaratory relief, including enjoining Defendants from distributing Vytorin<sup>®</sup>;
- iii. Damages in an amount to be determined at trial;
- iv. Pre judgment and post judgment interest at the maximum rate allowable at law;
- v. Treble, exemplary, and/or punitive damages in an amount to be determined at trial;
- vi. The costs and disbursements incurred by Plaintiff and Class members in connection with this action, including reasonable attorneys' fees;
- vii. All statutory damages;
- viii. Disgorgement of Defendants' profits from the sale Vytorin<sup>®</sup>;
- ix. Such other and further relief under all applicable state of federal law and any relief the Court deems just and appropriate.

Dated: New York, New York  
January 17, 2008

**PARKER WAICHMAN ALONSO LLP**

By: 

Jerrold S. Parker (JP-6865)

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Great Neck, New York 11021

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-and-

**DOUGLAS & LONDON, P.C.**

By: 

Michael A. London (ML-7510)

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-and-

**BECNEL LAW FIRM, LLC,**  
106 West 7<sup>th</sup> Street  
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-and-

**LEVIN SIMES KAISER and  
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-and-

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-and-

**WEITZ & LUXENBERG, P.C.**  
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New York, New York 10038  
Tel. (212) 558-5500  
Fax (212) 44-5461

**DEMAND FOR JURY TRIAL**

Plaintiff, individually and on behalf of the Class, hereby demands a trial by jury as  
to all issues so triable.



MICHAEL A. LONDON (ML-7510)