

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

PENNSYLVANIA EMPLOYEES BENEFIT
TRUST FUND

Plaintiffs,

Civil Action No.

vs.

MERCK & CO., INC., SCHERING-
PLOUGH CORPORATION and
MERCK/SCHERING-PLOUGH
PHARMACEUTICALS

**COMPLAINT and
DEMAND FOR JURY TRIAL**

Defendants.

INTRODUCTION

The Pennsylvania Employees Benefit Trust Fund (“PEBTF”) brings this action as an injured purchaser and/or reimbursing party of prescription drugs. The PEBTF seeks to obtain compensatory, punitive and other damages, restitution, civil penalties under applicable laws, injunctive and other equitable relief against Defendants Merck & Co., Inc., Schering-Plough Corporation and Merck/Schering-Plough Pharmaceuticals (“Defendants”), and, in support thereof, avers the following:

NATURE OF THE PROCEEDING

1. Plaintiff seeks damages and injunctive relief arising from Defendants’ sale and marketing of Zetia and Vytorin. Zetia is a brand-name prescription drug used to lower cholesterol levels. Zetia’s purported mechanism of action is to decrease cholesterol absorption in

the intestinal tract, which differs from others cholesterol lowering drugs, known as statins, which work in the liver. Vytorin consists of Zetia and Zocor. Zocor is a statin that is available in a generic form as simvastatin.

2. For more than a year, Defendants have known (but have failed to make public) that their own study shows that Zetia does not reduce the fatty arterial plaques that can cause heart attack and stroke. Despite this knowledge, Defendants have touted the Zetia “*difference*,” claiming that it would reduce arterial plaque. Defendants’ failure to reveal that Zetia does not in fact reduce arterial plaque constitutes a deceptive practice employed by Defendants to cause physicians to prescribe, and patients to take, Vytorin or Zetia instead of the much less expensive and equally effective generic drug simvastatin.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 because claims set forth in this Complaint arise under the laws of the United States, specifically 18 U.S.C. § 1961, *et seq.* This Court has personal jurisdiction over Defendants, which are licensed to conduct and/or systematically and continuously did conduct business in Pennsylvania, including marketing, advertising and selling drugs, including Zetia and Vytorin, to residents of Pennsylvania, and specifically, beneficiaries of the PEBTF.

4. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a), because Defendants engaged in substantial conduct relevant to Plaintiff’s claims within this District and caused harm to Plaintiff’s beneficiaries residing within this District. Defendants all do substantial business throughout the United States and within this Federal District, and at all times relevant hereto, Defendants developed, manufactured, promoted, marketed, distributed, tested,

warranted and sold in interstate commerce the aforementioned prescription drugs, Zetia and Vytorin.

PARTIES

5. Plaintiff, Pennsylvania Employees Benefit Trust Fund (“PEBTF”), is a health and welfare trust fund providing the full panoply of medical, prescription drug, dental, vision and mental health and substance abuse coverage to virtually all 188,000 active employees and their dependents, of the Commonwealth of Pennsylvania under the jurisdiction and control of the Governor. The PEBTF covers the employees of certain independent agencies as well. Altogether, the PEBTF provides coverage for approximately 175,000 individuals.

6. In addition, the PEBTF administers the Commonwealth of Pennsylvania’s Retired Employees Health Plan (“REHP”) covering approximately 95,000 retirees and their dependents.

7. The PEBTF is a trust fund operating under an Agreement and Declaration of Trust, supervised by a Board of Trustees, with nine (9) Trustees appointed by the Governor and nine (9) Trustees appointed by various unions have collective bargaining relationships with the Commonwealth. The PEBTF was established on October 1, 1988. The PEBTF is a citizen of the Commonwealth of Pennsylvania but is not a Commonwealth entity.

8. The PEBTF is a tax-exempt entity pursuant to Section 501(c)(9) of the Internal Revenue Code.

9. The PEBTF receives the majority of its funding pursuant to the provisions of various collective bargaining agreements between the Commonwealth of Pennsylvania and participating unions. The collective bargaining agreements set forth the contribution rate per

employee per month, which the Commonwealth is contractually committed to remit to the PEBTF, as well as that for which the employees themselves are responsible.

10. With the exception of the vision and dental, all other benefits provided by the PEBTF are completely self-insured. The PEBTF has administrative services only contracts (“ASO”) with medical plans throughout the Commonwealth, including four Blue Cross plans and a number of HMOs.

11. The PEBTF administers its program from its office at 150 South 43rd Street, Suite 1, Harrisburg, PA 17111-5700, where it employs approximately 165 employees.

12. The PEBTF has annual revenues of approximately six hundred million dollars (\$600,000,000).

13. The PEBTF is defined and qualified as a governmental plan under ERISA, and is therefore ERISA exempt.

14. The PEBTF has, over the past 18 years, had contractual relationships with various prescription benefit managers (“PBM”). Its present PBM is MEDCO.

15. The PEBTF expends approximately one hundred and fifteen million dollars (\$115,000,000) per year on prescription drugs for its members and their families, exclusive of prescription benefits which are provided under the REHP which is entirely underwritten by the Commonwealth itself.

16. From October, 2002 through the present, PEBTF has expended more than \$9,000,000 for Zetia and Vytorin.

17. Defendant, Merck & Co., Inc. (“Merck”), is a New Jersey corporation with its principal place of business in New Jersey and its headquarters is located at One Merck Drive, Whitehouse Station, NJ 08889. Merck is a global pharmaceutical company with sales of \$22.6 billion in 2006. Merck, through its joint venture partnership with Schering-Plough Corporation, develops and markets Zetia and Vytorin. Defendant Merck does business in Pennsylvania, maintains a manufacturing plant in West Point, Pennsylvania and has a registered agent for service in Philadelphia, Pennsylvania. At all times relevant hereto it developed, manufactured, and sold in interstate commerce and in Pennsylvania and this Federal District, Zetia and Vytorin.

18. Defendant, Schering-Plough Corporation (“Schering”), is a New Jersey corporation with its headquarters at 2000 Galloping Hill Road, Kenilworth, NJ 07033. Schering is a global health care company with leading prescription, consumer and animal health products with sales of \$10.5 billion in 2006. Schering, through its joint venture partnership with Merck, develops and markets Zetia and Vytorin. Schering-Plough Corporation, has sufficient business contacts with the Commonwealth of Pennsylvania to make it amenable to service of process, but does not maintain a regular place of business or a designated agent for service of process in Pennsylvania. Schering-Plough Corporation may be served pursuant to the Federal Rules of Procedure and the Pennsylvania Rules of Procedure at the following address: **Schering-Plough Corporation, 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.**

19. Defendant, Merck/Schering-Plough Pharmaceuticals (“MSP”), is a joint venture partnership between Merck and Schering. MSP maintains its headquarters at 351 N. Sumneytown Pike, North Wales, PA 19454. In May 2000, Merck and Schering entered into agreements to create an equally-owned partnership to develop and market new prescription

medicines in the cholesterol-management area. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company. In general, Merck and Schering agreed that the collaborative activities under these agreements would operate in a virtual joint-venture to the maximum degree possible by relying on the respective infrastructures of the two companies. The cholesterol agreements do not provide for any jointly owned facilities and, as such, products resulting from the collaboration are manufactured in facilities owned by either Schering or Merck. The cholesterol agreements provide for the sharing of the operating income generated by the Merck/Schering cholesterol partnership based upon percentages that vary by product, sales level and country. In the U.S. market, the Schering and Merck share profits on Zetia and Vytorin sales equally, with the exception of the first \$300 million of annual Zetia sales, on which Schering receives a greater share of profits. In 2006, Zetia had sales of \$1.92 billion and Vytorin has sales of \$1.95 billion.

FACTUAL ALLEGATIONS

A. The Nature of Zetia and Vytorin

20. Zetia is an anti-hyperlipidemic brand-name prescription drug used to lower cholesterol levels. It acts by decreasing cholesterol absorption in the intestinal tract, which differs from other cholesterol lowering drugs, known as statins, which work in the liver. The generic name for Zetia's active ingredient is ezetimibe.

21. Zetia was developed by Schering-Plough, and is jointly marketed by Defendants under the trade names Ezetrol, Zetia and Ezemibe. Defendants also jointly market Vytorin and Inegy (outside of the U.S.), which are a combination of Zetia and the statin Zocor. About 70% of patients who take Zetia do so in the form of Vytorin or Inegy. Zocor, which lost

its patent protection in June 2006, is available in generic form at about one-third the price of Zetia or Vytorin. The generic form of Zocor is simvastatin.

22. The FDA approved Zetia in October 2002. In approving Zetia, the FDA did not demand or obtain any proof that using Zetia has any effect on the buildup of plaque in arteries or that Zetia actually reduces the risk of heart attacks or stroke. Instead, the FDA approved Zetia based on the basis of a trial that showed it could lower LDL (low-density lipoprotein) cholesterol by 15 to 20 percent.

23. Vytorin is a prescription tablet containing two medicines, ezetimibe (Zetia) and simvastatin (Zocor). With the knowledge that Zocor would lose its patent protection in June 2006, Defendants developed Vytorin to help further the profitable life of Zocor. The FDA approved Vytorin in July 2004.

24. Zetia and Vytorin are key components of Merck and Schering-Plough's profitability. According to Merck's 2006 10-K, sales for Zetia and Vytorin were:

<i>(\$ in millions)</i>	2006	2005	2004
Zetia	\$1,928.8	\$1,396.7	\$1,053.0
Vytorin	1,955.3	1,028.3	132.4
	<hr/> \$3,884.1 <hr/>	<hr/> \$2,425.0 <hr/>	<hr/> \$1,185.4 <hr/>

25. In 2007 combined sales of Zetia and Vytorin rose to \$1.1 billion during the fourth-quarter, from \$755 million a year earlier. Bank of America estimates that Vytorin and

Zetia accounted for close to 60% of Defendant Schering-Plough's earnings in 2007 and accounted for about 15% of Defendant Merck's earnings in 2007.

B. The Marketing of Zetia and Vytorin

26. Defendants have consistently marketed Zetia to consumers, physicians, and third party payors as a drug that lowers LDL in a "different" manner, stressing that lowering LDL allegedly reduces or slows the buildup of plaque in arteries.¹ For example, the Zetia website stresses that LDL cholesterol is bad because it allegedly builds up in the walls of arteries and forms plaque:

Cholesterol is a type of fat found in your blood. Your total cholesterol is made up of LDL and HDL cholesterol. LDL cholesterol is called "Bad" Cholesterol because it can build up in the wall of your arteries and form plaque. Over time, plaque buildup can cause a narrowing of the arteries. This narrowing can slow or block blood flow to your heart, brain, and other organs. High LDL cholesterol is a major cause of heart disease and stroke.

Normal Artery



Artery With Buildup of Plaque



HDL cholesterol is called "Good" Cholesterol because it keeps the bad cholesterol from building up in the arteries.²

¹The Zetia website asserts that Zetia is a "different way to help fight cholesterol."
<http://www.zetia.com/ezetimibe/zetia/consumer/index.jsp> (last visited on November 24, 2008).

²http://www.zetia.com/ezetimibe/zetia/consumer/understanding_cholesterol/index.jsp?WT.svl=2&pg=default&vp=sh&src=leftnav (last visited on November 24, 2008).

27. The Zetia website also stresses that Zetia reduces “bad” cholesterol, i.e., LDL. For example, a video on the Zetia website states in part that “when added to a healthy diet, [Zetia] is proven to lower Bad Cholesterol. In a clinical study of people with high cholesterol, ZETIA lowered Bad Cholesterol by an average of 30 points-that’s 18%.* These are average results. Individual results may vary.”³

28. Similarly, the Vytorin website asserts that LDL is “bad” cholesterol because it allegedly builds up in artery walls to form plaque. The website states, “LDL (low-density lipoprotein) cholesterol is known as “bad cholesterol” because it can build up in the walls of your arteries and form a thick, hard plaque that clogs your arteries and blocks the flow of blood to your heart and brain.”⁴ The Vytorin website also states: “Having high LDL (bad) cholesterol can put you at risk for heart disease, heart attack, or stroke-especially if you have any of these additional risk factors...”⁵

29. The Vytorin website then asserts that Vytorin lowers “bad” cholesterol, creating the plain impression that taking Vytorin will decrease the buildup of plaque by lowering LDL. The website states, “VYTORIN is proven to lower bad cholesterol 45%-60% (average effect depending on the dose; 52% at the usual starting dose) when diet and exercise aren’t enough. It’s the only product to help block the absorption of cholesterol and reduce the

³http://www.zetia.com/ezetimibe/zetia/consumer/about_zetia/zetia_alone.jsp?WT.svl=2&pg=d

⁴http://www.vytorin.com/ezetimibe_simvastatin/vytorin/consumer/sources_of_cholesterol/questions.jsp (last visited on November 24, 2008).

⁵*Id.*

cholesterol your body makes naturally. You should still exercise and watch your diet while taking VYTORIN.”⁶

30. At all times relevant hereto, Defendants marketed Zetia as lowering “bad” cholesterol, while also claiming that the reduction of “bad” cholesterol decreases the buildup of plaque in arteries.

C. The ENHANCE trial

31. In 2002, Defendants began a trial known as the ENHANCE trial, which is an acronym for “Effect of Combination Exetimibe and High-Dose Simvastatin v. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia.” As the Wall Street Journal reported in an article on January 17, 2008, “At the time, cardiologists were asking Schering and Merck to show that Zetia - which works differently from highly popular statins - didn’t just lower cholesterol but also helped patients live longer and prevented heart attacks. Large studies looking at such outcomes take a long time and the ENHANCE study offered an interim look that focused on how much plaque formed in the arteries of Vytorin users.”

32. The ENHANCE trial was designed to prove that Vytorin could slow the growth of plaque in carotid arteries, which supply blood to the brain, more than simvastatin alone. The trial studied 720 people with heterozygous familial hypercholesterolemia, an inherited form of high cholesterol that affects about 0.2% of the population. The study pitted Vytorin against simvastatin, which is the generic name for Zocor (Vytorin consists of Zocor, a statin, and Zetia).

⁶*Id.*

D. Defendants Delayed Reporting the Results of the ENHANCE trial

33. The ENHANCE trial was completed in April 2006 but Defendants did not release any result in either 2006 or 2007.

34. After several news reports about the delay of the results, Merck/Schering announced in December 2007 that it would be releasing the results shortly. Instead, in November 2007, Defendants announced that they had changed the ENHANCE trial's "primary endpoint," i.e., the main medical result being measured. Specifically, Defendants stated that they would focus on the common carotid artery. Previously, Defendants had stated that the primary objective of the ENHANCE trial was to measure changes at three points of the carotid artery-the internal carotid, the carotid bulb and the common carotid - at the beginning of the study and after two years. Changing a trial's primary measure is a violation of sound scientific protocol. After an outpouring of criticism, Defendants announced that they would not change the primary endpoints. But Defendants still did not release any results of the trial.

35. Finally, on January 14, 2008, Defendants issued a press release to announce results of the ENHANCE trial.

E. Results of the ENHANCE trial

36. According to Defendants' press release, the ENHANCE researchers found that while Vytorin lowered LDL more than simvastatin alone, **it did not slow the growth of carotid artery plaques more than simvastatin, a statin now available as a much less expensive generic.** (As explained above, Vytorin consists of simvastatin, which is sold as Zocor, and Zetia.) In fact, the patients who took Vytorin had slightly more plaque growth than the patients who took simvastatin alone.

37. Thus the ENHANCE study contradicts Defendants' claim that by lowering LDL, Zetia also reduces the buildup of arterial plaque. As MedPage Today reports, Dr. Steven Nissen (chairman of cardiovascular medicine at the Cleveland Clinic and a past president of the American College of Cardiology) "said the ENHANCE results, issued today as a press release, were stunning, adding that on the basis on this evidence there was no good reason to prescribe ezetimibe [i.e., Zetia], because 'if it doesn't work in [heterozygous familial hypercholesterolemia], why use it?'"⁷

38. Moreover, there is *no evidence of any kind* to support a claim that Zetia reduces (or slows the buildup of) arterial plaque. In an article dated November 21, 2007, the New York Times quoted Dr. Eric J. Topol, a cardiologist and director of the Scripps Translational Science Institute in La Jolla, California, as saying, "Statins have diverse effects beyond simple LDL cholesterol lowering, such as potent anti-inflammatory actions. *There has yet to be a clinical trial to show that ezetimibe improves clinical outcomes.*"⁸

F. Effect of the ENHANCE trial on Defendants' marketing

39. As explained above, Defendants have touted that Zetia is different, claiming that it lowers "bad" cholesterol, which Defendants claim would in turn reduce arterial plaque. But the "different" way that Zetia lowers LDL provides no benefit at all to patients, according to the ENHANCE trial.

⁷<http://www.medpagetoday.com/Cardiology/CoronaryArteryDisease/tb/7954>.

⁸<http://query.nytimes.com/gst/fullpage.html?res=950CE6DC1330F932A15752C1A9619C8B63&sec=&spon=&pagewanted=all> (emphasis added).

40. Defendants attribute part of the reason for the delay in releasing the results from the ENHANCE trial on their efforts to reanalyze the data. However, the decisions to reanalyze the data were made by an internal group called the “Cholesterol Development Committee,” and were a significant departure from the original analysis plan as published in an article in the American Heart Journal in 2005.

41. A steering committee to oversee the scientific aspects of a study that is independent of the pharmaceutical corporate sponsor is usually named before a study begins. However, in ENHANCE, no steering committee was named and Defendants controlled the data and the analyses. As a result, “There is no way to determine that the decision [to re-analyze data] is being driven by science or the best interests of the company,” stated Yale University cardiologist, Harlan Krumholz, who further stated “It’s in [Defendants] great interest to delay this study if there is any possibility that it doesn’t come out positive.”

42. This interest in delay is easily quantified: generic Zocor alone costs 3 cents a pill as compared to the approximately \$3 per pill cost of Vytorin. Total combined sales of Zetia and Vytorin in 2007 were approximately \$5 billion.

43. Despite the results of the ENHANCE trial, Defendants have not changed this marketing approach. In particular, Defendants’ websites for Vytorin and Zetia continue to market those drugs as reducing “bad” cholesterol, which in turn they assert reduces the buildup of arterial plaque, a claim that is directly refuted by the ENHANCE study.

44. Merck and Schering-Plough entered into, and through various overt acts implemented, an agreement between themselves to illegally promote Vytorin and Zetia through the MSP Enterprise, including, but not limited to, suppressing the results of the ENHANCE

study for a period of almost two years, and to use false and deceptive marketing techniques claiming Vytorin was more efficacious than, and just as safe as, the much cheaper generic simvastatin in reducing arterial plaque buildup, and implemented that agreement as alleged in this Complaint, in furtherance of this agreement and conspiracy, in concert of action, and each aiding and abetting the other, such that Defendants are jointly and severally liable for the resulting damages to plaintiffs.

CAUSES OF ACTION

COUNT I

VIOLATION OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW

45. Plaintiff hereby incorporates each of the preceding paragraphs as if fully set forth herein at length.

46. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacture, promotion and sale of Vytorin and Zetia. By failing to timely release the results of the ENHANCE trial, which demonstrates that Zetia does not reduce or slow the buildup of arterial plaque, Defendants reaped billions of dollars in profits that they otherwise would not have obtained and caused Plaintiff to expend money on the expensive drugs Zetia and Vytorin when they would have obtained the same results by paying for the generic form of Zocor, known as simvastatin.

47. Pennsylvania's Unfair Trade Practices and Consumer Protection Law (73 P.S. § 201-1, *et seq.*) prohibits the act, use, or employment of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice in connection with the

sale of any merchandise. This law also prohibits conduct which creates likelihood of confusion or of misunderstanding.

48. Defendants have engaged in acts and practices, as described in this Complaint, which were and are likely to mislead the general public in violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law. Defendants have advertised, marketed and sold their drugs through the use of misleading, incomplete and deceptive advertising, promotion and product information, in violation of the consumer protection statutes.

49. At all times herein, the Defendants violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law by disseminating untrue and misleading statements and engaging in conduct likely to deceive consumers, by engaging in acts and practices with intent to induce members of the public to purchase and use the drugs Zetia and Vytorin.

50. The foregoing practices constitute false and misleading advertising, unlawful trade practices, and deceptive trade practices within the meaning of the Pennsylvania Unfair Trade Practices and Consumer Protection Law.

51. The unlawful, unfair and fraudulent business practices of the Defendants described above present a continuing threat to members of the public in that the Defendants continue to engage in the conduct described above.

52. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased Vytorin or Zetia.

53. Either directly or indirectly (through its beneficiaries' physicians), Plaintiff relied upon Defendants' misrepresentations and/or omissions (as described herein) in purchasing Vytorin and Zetia.

54. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has been damaged by purchasing Vytorin and Zetia between October 2002 and the present.

55. Pursuant to 73 P.S. § 201-9.2(a), Plaintiffs, and the Class, are entitled to recover their actual damages and treble damages.

56. Pursuant to 73 P.S. § 201-9.2(b), any permanent injunction entered by this Court is prima facie evidence the Defendants engaged in conduct in violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law.

COUNT II

UNJUST ENRICHMENT

57. Plaintiff hereby incorporates each of the preceding paragraphs as if fully set forth herein at length.

58. Defendants have received benefits from Plaintiff in the form of the prices Plaintiff paid for Vytorin and Zetia from October, 2002 through the present. By failing to timely release the results of the ENHANCE trial, which demonstrates that Zetia does not reduce or slow the buildup of arterial plaque, Defendants reaped billions of dollars in profits that they otherwise would not have obtained and caused Plaintiff to expend money on the expensive drugs Zetia and

Vytorin when they would have obtained the same results by paying for the generic form of Zocor, known as simvastatin.

59. Defendants are aware of their receipt of those benefits.

60. Defendants voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiff paid for Zetia and Vytorin when they otherwise would not have done so and paid for the drugs at a higher price than they would have paid but for the Defendants' wrongful conduct.

61. Defendants continue to retain those benefits to the detriment of Plaintiff.

62. As a result of Defendants' unjust enrichment, Plaintiff has sustained damages in an amount to be determined at trial and seek full disgorgement and restitution of Defendants' ill-gotten gains acquired as a result of the unlawful or wrongful conduct alleged above.

63. Plaintiff is entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits to the extent and in the amount, deemed appropriate by the Court and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

COUNT III

VIOLATION OF 18 U.S.C. § 1962(c)

64. Plaintiff hereby incorporates each of the preceding paragraphs as if fully set forth herein at length.

65. Defendants are “persons” within the meaning of the Racketeer Influenced and Corrupt Organizations (“RICO”) law, specifically 18 U.S.C. § 1961(3), who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

66. MSP is an “enterprise” within the meaning of RICO, 18 U.S.C. § 1961(4). MSP is a joint partnership created, controlled, and conducted by Defendants Merck and Schering-Plough. MSP was created and used by Merck and Schering-Plough to develop, market and sell Vytorin and Zetia, and to effectuate their pattern of racketeering activity.

67. In the alternative, there is an “association in fact” of all three Defendants for the purpose of developing, marketing, and selling Vytorin and Zetia as an “enterprise” within the meaning of RICO, 18 U.S.C. § 1961(4). This “Association In Fact Enterprise” was created, controlled and conducted by all three Defendants to develop, market and sell Vytorin and Zetia and to effectuate their pattern of racketeering activity. All three Defendants are defendants for purposes of this alternative RICO enterprise.

68. Each of the alternative enterprises described in paragraphs 66 and 67 above is an ongoing organization that functions as a continuing unit, and they are referred to hereinafter collectively as “Enterprises.”

69. The Enterprises engaged in and affected interstate commerce when they marketed, sold and provided Vytorin and Zetia to thousands of individuals throughout and among the United States.

70. Defendants Merck and Schering-Plough have exerted ongoing and continuous control over MSP in the following manner:

- i. Defendants Merck and Schering-Plough have participated in the operation and management of the daily affairs of MSP;
- ii. Defendants Merck and Schering-Plough have asserted direct control over the information and content disseminated to Plaintiff, Plaintiff's individual members, and physicians regarding the efficacy of Vytorin and Zetia;
- iii. Defendants Merck and Schering-Plough have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Plaintiff, Plaintiff's individual members, and physicians throughout the United States; and
- iv. Defendants Merck and Schering-Plough have placed their own employees and agents in positions of authority and control in MSP.

71. In the alternative, all Defendants have exerted ongoing and continuous control over the Association In Fact Enterprise described above in the following manner:

- i. Defendants Merck, Schering-Plough and MSP have participated in the operation and management of the daily affairs of the Association In Fact Enterprise;
- ii. Defendants Merck, Schering-Plough and MSP have asserted direct control over the information and content disseminated to Plaintiff, Plaintiff's individual members, and physicians regarding the efficacy of Vytorin and Zetia;

- iii. Defendants Merck, Schering-Plough and MSP have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Plaintiff, Plaintiff's individual members, and physicians throughout the United States; and
- iv. Defendants Merck, Schering-Plough and MSP have placed their own employees and agents in positions of authority and control in the Association In Fact Enterprise.

72. Defendants Merck and Schering-Plough have conducted and participated in the affairs of MSP, and all Defendants have conducted the affairs of the Association In Fact Enterprise, through a pattern of racketeering activity that includes predicate acts indictable under 18 U.S.C. 1341 (mail fraud) and 1343 (wire fraud), through the following actions, among others, as is set forth in detail above:

- i. At all times relevant hereto, Defendants fraudulently promoted Zetia and Vytorin in violation of 18 U.S.C. 1341 and 1343. Defendants consistently described Vytorin's and Zetia's ability to reduce bad cholesterol, falsely linking the drugs' reduction of bad cholesterol with a reduction (or slowing of the growth) of arterial plaque, which Defendants consistently asserted causes heart disease, heart attack, and stroke. Defendants specifically cited many authorities, including the American Heart Association, to lend misleading credibility to their claims regarding the drug's capabilities.

- ii. Notwithstanding their knowledge of the ENHANCE study's results in April 2006, Defendants delayed the release of this study until January 14, 2008, while continuing to falsely tout Vytorin's and Zetia's safety and effectiveness in a comprehensive marketing scheme that concealed the results of the ENHANCE study, misrepresented their drugs' abilities and perpetrated a fraud via the mails and wires as defined by 18 U.S.C. 1341 and 1343. Defendants' marketing scheme took the form of thousands of misleading mailings, radio and television advertisements, print media advertising, and misrepresentations to physicians and insurers.
- iii. Defendants' website for Vytorin continues to exhibit several examples of Defendants' misleading message that lowering bad cholesterol is equivalent to reducing the risks of heart disease, heart attack and stroke, a message that was negated by Defendants' ENHANCE study results. Defendants' website for Zetia is titled "A different way to fight cholesterol" (emphasis in original). It states, "ZETIA works differently," going on to contrast Zetia with statins. Neither the Zetia nor the Vytorin websites explained that the "different" or distinct ways these drugs work produce no cardiovascular benefits for the patients taking them. Defendants uniformly omitted all mentions of the ENHANCE study, which would have negated Defendants' claims about the purported benefits of Zetia and Vytorin. Such fraudulent misrepresentations of Zetia and Vytorin's capabilities violate 18 U.S.C. 1343.

- iv. The Zetia website claims the drug reduces bad cholesterol by an average of 30 points, or 18%. The Vytorin website has similar claims, stating that Vytorin reduces bad cholesterol by 45%-60%. Both the Vytorin and Zetia websites deliberately and misleadingly convey-through the suppression and omission of the ENHANCE results – the message that Vytorin and Zetia will decrease the buildup of harmful plaque through lowering LDL.
- v. The full results of the ENHANCE study were, after two years' delay (and a continuous record of concealment by Defendants) finally presented at the American College of Cardiology conference on March 30, 2008. Having demonstrated “zero” benefit for the patients who took it, the American College of Cardiology and American Heart Association released statements recommending that Vytorin be a medicine of the last resort, to be used only when other medications cannot be tolerated. Statements from the American College of Cardiology, the American Heart Association, and prominent cardiologists across the country establish the medical consensus regarding Vytorin's ineffectiveness. Notwithstanding this medical consensus, Defendants have continued to market Zetia and Vytorin. Neither the Vytorin nor the Zetia website initially contained any reference to the results of the ENHANCE study, even after its results were released. A link entitled “Information about the ENHANCE Trial” was eventually added, but later removed. That link connected to a series of press releases from Defendants and provided no statement about ENHANCE or any direct link to the study itself or independent parties'

statements on the study. The Vytorin and Zetia websites now contain no information on the ENHANCE trial, and earlier contained links to no statement later than January 17, 2008, with no link to the American Cardiology Conference's April 1, 2008 statements on Vytorin, stating that the ENHANCE trial "reinforces the need to adhere to current American College of Cardiology/American Heart Association Guidelines, which recommend statins to the maximally tolerated dose or to goal as first line treatment for patients with coronary artery disease."

- vi. In a two-page advertisement taken out in the January 20, 2008 *New York Times* and re-run in January 23, 2008, Merck and Schering-Plough, mentioned, but did not reveal the ENHANCE study's results. They continued to imply that the purported benefits of Zetia and Vytorin were equivalent to cholesterol medications that slow the growth of fatty plaque in the arteries. The advertisement stated, "In fact, Zetia and Vytorin have been proven to lower LDL (bad) cholesterol along with diet [sic], in multiple clinical studies involving thousands of patients. Both the American College of Cardiology and the American Heart Association agree that lowering bad cholesterol is important. Elsewhere, the advertisement stated, "LDL is called 'bad cholesterol' because it can cause build up in the wall of your arteries and form plaque." However, the advertisement did not state that the ENHANCE study had shown that Vytorin did not slow-and may have contributed to-the growth of fatty plaque in the arteries.

73. In implementing their fraudulent scheme, Defendants were aware that Plaintiff and Plaintiff's individual members depended on the Defendants' honesty in representing the safety and medical efficacy of Zetia and Vytorin.

74. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting the efficacy of Zetia and Vytorin in treating patients with high cholesterol; (b) concealing from Plaintiff, Plaintiff's individual members and physicians, and the public the results of the ENHANCE study, which showed that Zetia and Vytorin were ineffective in slowing the growth of fatty plaque in the arteries; and (c) publishing or causing to have published materials containing false information, in that the material facts for the ENHANCE study were concealed, suppressed, or omitted from such materials.

75. The unlawful predicate acts of racketeering activity committed by Defendants number in the thousands, had a common purpose, were related, had continuity throughout, and continue to the present. Defendants used thousands of mail and interstate wire communications to create, execute, and manage their fraud scheme, in violation of 18 U.S.C. 1341 and 1343. Defendants' scheme involved national marketing and sales plans and programs, encompassing physicians and victims throughout the country. Defendants' use of the mails and wires to perpetrate their fraud involved thousands of communications, including marketing and advertising materials touting the effectiveness of Zetia and Vytorin, such materials being sent to physicians and media outlets throughout the country. From the time the Enhance study was completed in April 2006, Defendants intensively marketed Zetia and Vytorin on television, radio, the internet and in print media, spending more than \$200 million on direct-to-consumer advertising through the first three quarters of 2006, thereby promoting fraudulent representations of the drugs' abilities in violation of 18 U.S.C. 1343. In addition to their radio, television, and

print media advertising, Defendants repeatedly disseminated their fraudulent representations to the medical community and the public. By repeatedly misrepresenting the abilities of their product via the mails and wires, Defendants perpetrated thousands of unlawful predicate acts.

76. Defendants further used mail and interstate wire communications to suppress the results of the ENHANCE study. Upon information and belief, Defendants further used mail and interstate wire communications to communicate with various physicians, including John J. Kastelein, M.D., Ph.D., regarding delays in the release of the ENHANCE study and communicated with the expert panel with respect to the alleged minutes of the expert panel meeting. Upon information and belief, Defendants further used mail and interstate wire communications to communicate among themselves regarding the results and suppression of the ENHANCE study, and to transfer money among themselves as part of the revenues generated from the sales of Vytorin and Zetia. In addition, upon information and belief, Defendants used mail and interstate wire communications to communicate with Michael L. Bots, M.D., Ph.D., Associate Professor of Epidemiology at Julius Center for Health Services and Primary Care at the University Medical Center of Utrecht in the Netherlands, regarding his study of the ENHANCE results, to communicate with the expert panelists to set up the expert panel meeting and regarding the results of the expert panel meeting, and to pay Dr. Bots and the expert panelists.

77. The predicate acts committed by Defendants were related, were committed by Defendants for a common purpose, occurred over a period of several years, continue to the present, involved millions of similarly deceptive mail and wire communications, and injured the business and property of millions of consumers and thousands of TPPs throughout the United States. These predicate acts, examples of which are specified herein, involved not only the

concealment and suppression of material information from the misleading advertisements, promotional, and “educational” materials disseminated, via mail and wire to the medical community and the public on a continuous basis, but email correspondence and communications disseminated by Defendants to the medical experts it enlisted in its attempts to conceal, manipulate, and misrepresent the results of the ENHANCE study, many of which are quoted in this Complaint. Defendants’ pattern and practice of racketeering activity is continuing.

78. The predicate acts committed by Defendants were and are similar, continuous, and related. From at least 2004 to the present, Defendants were aware that they had no scientific basis to claim that Zetia and Vytorin, compared to Zocor alone, reduced or slowed the growth of arterial plaque. However, notwithstanding this knowledge, Defendants heavily promoted, and continue to promote, Zetia and Vytorin’s purported distinct mechanism of action as an advantage in treating high cholesterol, claiming overall health benefits as a result, including cardiovascular benefits. Defendants’ marketing of Vytorin consistently focused on reducing the health risk associated with high cholesterol, including plaque formation leading to heart disease, heart attack and stroke. Defendants’ advertisements explained the nature of cholesterol, the difference between good and bad cholesterol, the fact that excessive LDL cholesterol levels cause arterial plaque formation, and the adverse health risks associated with excessive plaque, including heart disease, heart attack and stroke. Defendants have consistently marketed Zetia to partners, consumers, and physicians as a drug that lowers LDL cholesterol in a “different” manner, stressing that lowering LDL is important because LDL causes plaque to build up in arteries. Defendants’ website for Zetia is titled “A different way to fight cholesterol” (emphasis in original). It states, “ZETIA works differently,” going on to contrast Zetia with statins. Neither the Zetia nor the Vytorin website explained that the “different” or distinct ways these

drugs work produces no cardiovascular benefits for the patients taking them. Defendants uniformly omitted all mentions of the ENHANCE study, which would have negated Defendants' claims about the purported benefits of Zetia and Vytorin. This consistent message of a "different" approach to lowering cholesterol and the uniform omission of all mentions of the ENHANCE study illustrate how Defendants' predicate acts of mail and wire fraud were similar, continuous, and related.

79. The victims of Defendants' predicate acts of mail and wire fraud number at least in the hundreds of thousands, and may number in the millions based on the number of Zetia and Vytorin prescription and their volume of sales. The cholesterol-reduction market is the single largest pharmaceutical category in the world. Unlike Zocor, which is now subject to competition from generic drugs, Zetia and Vytorin command name-brand prices. Generic versions of Zocor sell for 75 cents to \$1 per day at most retail pharmacies, and as little as 10 cents per day at discount pharmacies. Prescriptions for Vytorin and Zetia, on the other hand, each cost roughly \$3 per day. Notwithstanding their high costs relative to available generic statins, Zetia and Vytorin represent nearly 20 percent of the American market for cholesterol-lowering drugs. In 2007, 800,000 prescriptions for Zetia and Vytorin were written weekly in the United States. Given this high volume of prescriptions, the number of victims of Defendants' predicate acts of fraud number in the tens to hundreds of thousands.

80. Defendants' fraudulent scheme involved the repetition of similar misrepresentations, which were made to hundreds of thousands of consumers, physicians, and health insurers.

81. Defendants' scheme was calculated to ensure that Plaintiff would pay for Zetia and Vytorin despite the ready availability of less expensive, safer and effective alternatives.

82. Each of Defendants' fraudulent mailing and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. 1961 (1). Collectively, these violations are a "pattern of racketeering activity" within the meaning of 18 U.S.C. 1961(5).

83. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiff.

84. The above described racketeering activities amounted to a common course of conduct intended to deceive Plaintiff. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiff.

85. The pattern of racketeering activity alleged herein and each of the Enterprises are separate and distinct from each other. Defendants Merck and Schering-Plough engaged in the pattern of racketeering activity alleged herein for the purpose of conducting the affairs of MSP, and alternatively, all Defendants engaged in the pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Association-In-Fact Enterprise.

86. Plaintiff has been injured in its business and property by reason of these violations in that they have made millions of dollars in payments for Zetia and Vytorin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

87. Plaintiff's injuries to its business and property were directly and proximately caused by Defendants' racketeering activity as described above.

88. By virtue of these violations of 18 U.S.C. 1962, Defendants are jointly and severally liable to Plaintiff for three times the damages Plaintiff has sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT IV

VIOLATION OF 18 U.S.C. 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. 1962(c)

89. Plaintiff hereby incorporates each of the preceding paragraphs as if fully set forth herein at length.

90. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

91. Defendants Merck and Schering-Plough, or alternatively all Defendants, have violated 1962 (d) by conspiring to violate 18 U.S.C. 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of MSP, or, alternatively, the Association-In-Fact Enterprise, described above, through a pattern of racketeering activity. Defendants Merck and Schering-Plough, or, alternatively, all Defendants, agreed to join the conspiracy, agreed to commit, and did commit the predicate acts described in this Complaint, and know that these acts were part of a pattern of racketeering activity.

92. As demonstrated in detail above, Defendants Merck & Schering-Plough, or, alternatively, all Defendants, and their co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff of money.

93. The nature of the above-described acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. 1962(d) violation of RICO by conspiring to violate 18 U.S.C. 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

94. As a direct and proximate result of Merck's and Schering-Plough's, or, alternatively, all Defendants', overt acts and predicate acts in furtherance of violating 18 U.S.C. 1962(d) by conspiring to violate 18 U.S.C. 1962(c), Plaintiff has been and is continuing to be injured in its business or property as set forth more fully above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants in each claim for relief, jointly and severally, as follows:

- a) On Plaintiff's claim for Violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, in the amount of Plaintiff's actual expenditure for Zetia and Vytorin from October, 2002 through the present along with treble damages as set forth in 73 P.S. § 201-9.2(a);
- b) On Plaintiff's claim for unjust enrichment, for recovery in the amount of Plaintiff's actual expenditure for Zetia and Vytorin from October, 2002 through the present, such amount to be determined at trial, plus Plaintiff's costs in this suit, including all reasonable attorneys' fees.

c) On Plaintiff's claim for violation of 18 U.S.C. § 1962(c) and 1962(d), three times Plaintiff's actual damages plus attorneys fees and costs as provided for in the RICO statute.

d) For an Order otherwise requiring Defendants to refund and make restitution of all monies acquired from the sale of Zetia and Vytorin to Plaintiff;

e) For injunctive relief, enjoining the Defendants from the acts of unfair competition and untrue and misleading advertising alleged above, and ordering the Defendants to return all funds acquired by means of any act or practice declared by this Court to be unlawful or fraudulent, or to constitute unfair competition or untrue or misleading advertising;

f) Awarding Plaintiff prejudgment interest on all damages;

g) Awarding Plaintiff other appropriate equitable relief;

h) Awarding Plaintiff costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

i) Awarding Plaintiff such other and further relief as may be just and proper under the circumstances.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands trial by jury on all issues so triable.

s/ Stephen A. Corr
Stephen A. Corr, Esquire
Pa. Bar No.: 65266
MELLON, WEBSTER & SHELLY
87 N. Broad Street
Doylestown, PA 18901
(215) 348-7700
scorr@mellonwebster.com

Co-Counsel for Plaintiff

Patrick R. Casey, Esquire
Pa. Bar No.: 67065
THE CASEY LAW FIRM
Bank Towers Building, Suite 308
321 Spruce Street
Scranton, PA 18503
(570) 343-9003
pcasey@thecaseylawfirm.com

J. Paul Sizemore, Esquire
Calif. Bar No.: 254981
SIZEMORE TAYLOR, LLP
1601 N Sepulveda Blvd, # 644
Manhattan Beach, CA 90266
(310) 944 2454
psul@sizemoretaylor.net

Thomas P. Cartmell, Esquire
Missouri Bar No.: 45366
WAGSTAFF & CARTMELL, LLP
4740 Grand Avenue
Kansas City, MO 64112
(816) 701-1100
tcartmell@wcllp.com

Richard Kirschner
KIRSCHNER & GARTRELL, P.C.
Pa. Bar No.: 04029
4910 Massachusetts Avenue, N.W.
Suite 215
Washington, D.C. 20016-4368
(202) 775-0087
LeagleRK@aol.com