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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VYTORIN/ZETIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	Master Docket No. 08-285 (DMC) MDL 1938
IBEW LOCAL 164 WELFARE FUND, FIRE & POLICE RETIREE HEALTH CARE FUND OF SAN ANTONIO, GOVERNMENT EMPLOYEES HEALTH ASSOCIATION, INC., PIPEFITTERS LOCAL 537 TRUST FUND, TEAMSTERS HEALTHCARE, MIDWESTERN TEAMSTERS HEALTH & WELFARE FUND, UFCW & EMPLOYERS ARIZONA HEALTH & WELFARE TRUST, COUNTY OF SUFFOLK, LOUISIANA HEALTH INSURANCE INDEMNITY COMPANY d/b/a BLUECROSS BLUESHIELD OF LOUISIANA, HELEN ARONIS, KENNETH BEVER, GLENDA MORGAN, ROY COSGROVE, CHARLES MILLER, ANNA IANNUZZI, ROBERT MASTONDREA, ROBERT LOVE, DONALD VARINO, FRANCES WEILAND, and DANIEL TOLLEFSON, on behalf of themselves and all others similarly situated, Plaintiffs, v. MERCK & CO., INC.; SCHERING-PLOUGH CORPORATION; MERCK/SCHERING-PLOUGH PHARMACEUTICALS, Defendants.	**FIRST AMENDED AND MASTER CLASS ACTION COMPLAINT and DEMAND FOR JURY TRIAL**
THIS DOCUMENT RELATES TO: ALL CASES	

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Plaintiffs IBEW Local 164 Welfare Fund, Fire & Police Retiree Health Care Fund of San Antonio, Government Employees Health Association, Inc., Pipefitters Local 537 Trust Fund, Teamsters Healthcare, Midwestern Teamsters Health & Welfare Fund, UFCW & Employers Arizona Health & Welfare Trust, County of Nassau, Louisiana Health Insurance Indemnity Company d/b/a BlueCross BlueShield of Louisiana, Helen Aronis, Kenneth Bever, Glenda Morgan, Roy Cosgrove, Charles Miller, Anna Iannuzzi, Robert Mastondrea, Robert Love, Donald Varino, Frances Weiland, and Daniel Tollefson, on behalf of themselves and all others similarly situated, by way of this First Amended and Master Class Action Complaint[1] against

[1] This proposed class action, originally filed in the District of New Jersey as *IBEW LOCAL NO. 164 Welfare Fund, v. Merck & Co., Inc.*, et. al., Civil Action No. 08-1674 (DMC), is hereby amended to serve as the Plaintiffs' Master Class Action Complaint for purposes of discovery, pre-trial motions and rulings, class certification, and trial of certified claims or issues in these multi-district litigation ("MDL") proceedings. As more fully described in the Plaintiffs' contemporaneously filed Letter Brief and Status Report to the Court, this pleading, consistent with Fed. R. Civ. P. 1's directive to secure the "just, speedy and inexpensive determination of every action and proceeding" is intended and designed to set forth central facts and issues capable of determination in this MDL proceeding, consistent with 28 U.S.C. § 1407 and the limitations imposed by *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*¸ 523 U.S. 26 (1998). However, this pleading is not designed for the adjudication of all claims of all parties. Additional or different claims of other litigants may, depending upon the scope of this Court's class certification ruling and trial plan, be matters for determination on remand by transferor

Defendants Merck & Co., Inc., Schering-Plough Corporation and Merck/Schering-Plough Pharmaceuticals, say:

NATURE OF THE ACTION

1. This is a class action for fraud and unjust enrichment that arises from the scheme of Merck & Co., Inc. ("Merck"), Schering-Plough Corporation ("Schering-Plough"), and Merck/Schering-Plough Pharmaceuticals ("MSP") (collectively, "Defendants") to suppress critical information about the efficacy and safety of the drugs Vytorin and Zetia, and thereby earn billions of dollars of profits from the sales of those drugs. This Complaint asserts claims for the economic losses incurred by consumers and Third Party Payors ("TPPs") as a direct result of Defendants' scheme. This Complaint does not assert, and is not intended to assert, Class standing for wrongful death or personal injury claims, or any damages therefrom.

2. In the 1990s, Merck was selling a blockbuster drug, Zocor, which lowers cholesterol and which was a key to Merck's financial success. Zocor is a statin, which is a class of cholesterol-lowering drugs that has been scientifically proven to reduce the risk of heart attacks in some people.

3. In 1999, Zocor sales were $2.6 billion in the United States, and Merck reported that "worldwide sales of Zocor reached almost $5.3 billion in 2000." However, Merck knew that

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courts. Accordingly, as the accompanying Letter Brief fully sets forth, this pleading neither waives nor dismisses, nor shall have either claim preclusion or issue preclusion effects on, any claims or causes of action not included in this pleading that are asserted by any other plaintiffs in actions that have been or will be made a part of these MDL proceedings, except by operation of Fed. R. Civ. P. 23 (and its class notice and opt-out provisions) on claims or issues asserted in this Complaint and certified by this Court. All other claims are reserved for such further actions or proceedings that on remand or otherwise, may remain necessary or appropriate pursuant to the determination(s) of this Court. *See Taylor v. Sturgell*, 128 S. Ct. 2161, 2166-67 (2008) ("'It is a principle of general application in Anglo-American jurisprudence that one is not bound by a judgment *in personam* in a litigation in which he is not designated as a party or to which he has not been made a party by service of process.'" (quoting *Hansberry v. Lee*, 311 U.S. 32, 40 (1940)).

the United States patent for Zocor was set to expire in January 2006, and that other patents for Zocor around the world would expire before 2006. Merck also knew that once those patents expired, Zocor would be subject to fierce price competition from far cheaper, generic versions of Zocor, which would cause Merck to lose billions of dollars of sales annually in the United States alone and billions more around the world.

4. Merck also knew that it did not have a new cholesterol-lowering drug in its pipeline, which meant that it had no prospects of replacing Zocor in the foreseeable future. As a result, Merck undertook to effectively extend the patent life of Zocor by combining it with another cholesterol-lowering drug being developed by Schering-Plough. Thus, in 2000, Merck and Schering-Plough formed the joint venture Merck/Schering-Plough Pharmaceuticals ("MSP"), an enterprise controlled by Merck and Schering-Plough. MSP was conceived and established, and its affairs conducted, to develop, market and sell a drug that would effectively extend the patent life of Zocor.

5. In December 2001, Defendants submitted a New Drug Application to the Food and Drug Administration ("FDA") for the drug Zetia, which is patented by Schering-Plough. Zetia is the brand name for ezetimibe. Zetia is not a statin, and works differently from statins. Specifically, Zetia decreases cholesterol absorption in the intestinal tract, while statins increase the ability of the liver to remove LDL-cholesterol from the blood. The United States patent for Zetia is not scheduled to expire until at least 2015.

6. On October 25, 2002, the FDA approved Zetia for the reduction of "bad" and total cholesterol. As part of the approval process, Defendants provided evidence to the FDA only as to Zetia's ability to lower "bad" cholesterol, but provided no evidence as to whether Zetia had

any effect on the buildup of plaque in arteries or whether Zetia reduced the risk of heart attacks or stroke.

7. In November 2002, Defendants began marketing Zetia as an effective means of lowering "bad" cholesterol in a manner intended to and having the effect of convincing people that Zetia reduces or retards the growth of arterial plaque and/or heart disease.

8. Even before Defendants obtained FDA approval for Zetia and starting selling it, they initiated another key component of their plan to effectively extend the patent life of Zocor. Defendants developed Vytorin, the brand name for a drug that combines Zetia, a non-statin, with Zocor, a statin. Defendants knew that the Zocor-Zetia combination would have United States patent protection eight years longer than Zocor alone, because the United States patent for Zetia is not scheduled to expire until at least 2015. As a result, generic versions of Vytorin could not reach the market until at least 2015.

9. Defendants' plan was simple. Defendants knew that they could not effectively extend the patent life of Zocor by urging physicians to prescribe, and patients to take, both Zetia and Zocor, because generic simvastatin could be substituted once it became available in 2005, when Zetia's patents expired. As a result, they decided to market Vytorin as a combination of Zetia and Zocor, which would prevent substituting generic simvastatin for the Zocor component of the combined drug. They would then market Vytorin as a new and improved version of Zocor, claiming Vytorin would lower cholesterol more than Zocor alone. Moreover, they would claim that lowering "bad" cholesterol, *by any means*, would reduce or retard the growth of arterial plaque, which is a cause of heart attacks and other adverse cardiac events. Their goal was to influence physicians who were prescribing Zocor, and consumers who were taking Zocor, to shift to the combined Vytorin pill instead of Zocor alone, effectively extending the effective

patent life for Zocor. Defendants also planned to use the same marketing plan to convince physicians and patients who prescribed and used other statins to start prescribing and taking Vytorin.

10. On September 24, 2003, Defendants submitted a New Drug Application for Vytorin to the FDA. In support of that application Defendants did not submit any evidence that Vytorin has a beneficial effect on arterial plaque or that it reduces the risk of adverse cardiac events in any respect. Instead, Defendants submitted a 12-week study, which showed that individuals taking Vytorin experienced a larger reduction of "bad" cholesterol than individuals who took only the generic version of Zocor, known as simvastatin. Based on that study alone, the FDA approved Vytorin in July 2004 as effective for lowering bad cholesterol, but not for the reduction of the risk of heart disease.

11. Defendants began aggressively marketing Vytorin on August 1, 2004 by claiming in a flood of nationwide print, internet, and broadcast marketing that it reduces arterial plaque (or slows its growth) more than Zocor alone.

12. In 2002, even before they submitted to the FDA the New Drug Applications for Zetia or Vytorin, Defendants had begun a clinical trial, known as "ENHANCE," an acronym for "Effect of Combination Exetimibe and High-Dose Simvastatin v. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia." The ENHANCE study, which Defendants funded and helped design, was intended to prove that Vytorin's combination of Zetia and Zocor stops or reduces the growth of fatty arterial plaque better than Zocor alone. This study, Defendants assumed, would give them the necessary basis for their claim that Vytorin is superior to statins in reducing "bad" cholesterol and that taking

Vytorin would reduce the risk of heart attacks more than taking statins alone. Thus, ENHANCE pitted Vytorin against simvastatin, the generic name for the Zocor component of Vytorin.

13. ENHANCE turned out, however, to be an unqualified disaster for Defendants. By early 2006 at the latest, Defendants learned that the study showed not only that Vytorin was *less* effective in reducing arterial plaque build-up than Zocor, but also that Vytorin posed serious safety concerns. Thus, the ENHANCE clinical trial proved that Defendants' marketing and promotion claims as to the efficacy of Vytorin and Zetia were false.

14. Defendants did not release the results of the ENHANCE study when they became known to Defendants no later than late 2005 or early 2006. Instead, Defendants undertook an aggressive strategy to conceal and suppress the negative ENHANCE results, and Defendants succeeded in this scheme until January 14, 2008, when the pressure to release the results could no longer be withstood. Simultaneously with their ongoing concealment of the ENHANCE results, Defendants continued their aggressive print and broadcast media promotion to the health community and directly to consumers of Vytorin's supposed superior efficacy and safety compared to Zocor even though they knew the ENHANCE study proved that Defendants' marketing claims were false. Defendants continued to tout the Vytorin and Zetia "difference," claiming that these products would reduce arterial plaque. Defendants' actions to suppress the ENHANCE study results showing that Vytorin does *not*, in fact, reduce arterial plaque, and that Vytorin is *not* superior to Zocor alone, constitutes a pattern and practice of knowing and deceptive conduct employed by Defendants to protect and increase Zetia and Vytorin sales, revenues, and market share by causing physicians to prescribe, consumers and TPPs to purchase, and patients to take, Vytorin or Zetia. During the period of their silence about, and active

suppression of, the ENHANCE results, Defendants sold billions of dollars worth of Vytorin and Zetia that they would not have sold if proper disclosures had been made.

15. The motivation for this cover-up is not only plausible but demonstrable. Merck's Forms 10-K for 2006 and 2007 reveal that global Vytorin sales for 2004, 2005, 2006, and 2007 were, respectively, $132.4 million, $1.028 billion, $1.995 billion, and $2.779 billion. Thus, global sales of Vytorin grew 42% in 2007 and 90% in 2006. In addition, Merck's Forms 10-K for 2006 and 2007 reveal that global Zetia sales for 2004, 2005, 2006, and 2007 were, respectively, $1.053 billion, 1,397 billion, $1.929 billion, and $2.407 billion. The public financial record demonstrates that that these drugs were hugely important to Defendants' financial viability. Vytorin and Zetia accounted for 60% to 70% of Schering-Plough's earnings per share. Moreover, while maintaining silence about the negative ENHANCE results, Schering-Plough acknowledged its continuing dependence on the drugs' success. In its 2006 and 2007 Forms 10-K, Schering-Plough stated that its "ability to generate profits and operating cash flow depends largely upon the continued profitability of …VYTORIN and ZETIA." Schering-Plough's April 20, 2006 Form 8-K stated: "Our cholesterol franchise [Vytorin and Zetia] is pivotal…."

16. By covering up the negative ENHANCE results for at least two years, and by not disclosing those results while affirmatively and deceptively touting in public the efficacy and benefits of Vytorin and Zetia, Defendants caused consumers and TPPs to pay billions of dollars for Vytorin and Zetia. Had Defendants not suppressed the results of the ENHANCE trial for nearly two years, Plaintiffs would not have paid billions of dollars for Vytorin and Zetia during this period (since other statins were available throughout this period), and surely not the premium prices Defendants obtained for these two drugs.

PARTIES

A. Plaintiffs

17. The following Vytorin consumers seek to represent the proposed Class and its proposed Vytorin Consumer Subclass:

a. Plaintiff Helen Aronis is a citizen of California. During the Class Period, Ms. Aronis was prescribed, paid for, and used Vytorin and Zetia.

b. Plaintiff Kenneth Bever is a citizen of California. During the Class Period, Mr. Bever was prescribed, paid for, and took Vytorin.

c. Plaintiff Glenda Morgan is a citizen of California. During the Class Period, Ms. Morgan was prescribed, paid for, and took Vytorin and Zetia.

d. Plaintiff Roy Cosgrove is a citizen of Florida. During the Class Period, Mr. Cosgrove was prescribed, paid for, and took Vytorin.

e. Plaintiff Charles Miller is a citizen of Florida. During the Class Period, Mr. Miller was prescribed, paid for, and took Vytorin.

f. Plaintiff Anna Iannuzzi is a citizen of New Jersey. During the Class Period, Ms. Iannuzzi was prescribed, paid for, and took Vytorin.

g. Plaintiff Robert Mastondrea is a citizen of New Jersey. During the Class Period, Mr. Mastondrea was prescribed, paid for, and took Vytorin.

h. Plaintiff Robert Love is a citizen of Texas. During the Class Period, Mr. Love was prescribed, paid for, and took Vytorin.

i. Plaintiff Donald Varino is a citizen of Texas. During the Class Period, Mr. Varino was prescribed, paid for, and took Vytorin and Zetia.

j. Plaintiff Frances Weiland is a citizen of Minnesota. During the Class Period, Ms. Weiland was prescribed, paid for, and took Vytorin and Zetia.

k. Daniel Tollefson is a citizen of Minnesota. During the Class Period, Mr. Tollefson was prescribed, paid for, and took Vytorin.

18. The following TPPs seek to represent the proposed Class and its proposed Third Party Payor Subclass:

a. Plaintiff IBEW Local 164 Welfare Fund ("Local 164") is a multi-employer welfare plan, organized and operating in the State of New Jersey, with its principal place of business at 205 Robin Road, Suite 315, Paramus, New Jersey 07652. Local 164 provides reimbursement for health, vision, dental and prescription drug claims incurred by approximately 10,000 electricians, apprentices, wiremen, and trainees in Hudson, Bergen and Essex counties, New Jersey. Throughout the Class Period, Local 164 paid or reimbursed eligible participants' prescription drug benefits for Zetia and Vytorin in the State of New Jersey, and elsewhere, other than for resale, and was injured by the illegal and improper conduct alleged herein, incurring substantial losses as a result of these payments.

b. Plaintiff Fire & Police Retiree Health Care Fund of San Antonio ("FPSA") is a retiree health care fund established by the State Legislature of Texas to provide health care benefits for persons who retired from the San Antonio police or fire departments. FPSA is domiciled in San Antonio. At various times during the Class Period, FPSA paid or reimbursed eligible Trust participants' prescription drug benefits for Zetia and Vytorin in Texas and elsewhere other than for resale, and incurred substantial losses as a result.

c. Plaintiff Government Employees Health Association, Inc. ("GEHA") is incorporated in the State of Missouri, with its principal place of business at 310 N.E. Mulberry, Lee's Summit, Missouri 64086. GEHA is the third-largest national health insurance plan serving federal employees and retirees, as well as their families. GEHA has over 232,000 health plan

members and provides health insurance to over 425,000 people across the United States (including New Jersey, California, Florida, Texas, and Massachusetts) and around the world. GEHA is a self-insured and not-for-profit association. At various times throughout the Class Period, GEHA paid for or reimbursed its members' Vytorin and Zetia prescriptions and incurred substantial losses as a result.

d. Plaintiff Pipefitters Local 537 Trust Fund ("Local 537") is a Taft-Hartley Fund governed by a Board of Trustees consisting of three trustees appointed by management and three labor trustees, and is located at 35 Travis Street, Unit 1, Allston, Massachusetts, 02134. In addition to providing a number of other benefits, the Fund provides major medical benefits, including prescription drug benefits, to all union members and their eligible dependants. Currently there are 5,223 individuals, both union members and their dependants, who receive major medical benefits, including prescription drug benefits through the Fund. Beginning on December 7, 2007, Plaintiff paid or reimbursed eligible Trust participants' prescription drug benefits for Zetia and Vytorin in Massachusetts and elsewhere, other than for resale, and incurred substantial losses as a result.

e. Plaintiff Teamsters HealthCare ("Teamsters") is a Taft-Hartley Fund managed by a Board of Trustees consisting of an Executive Director, three Union Trustees and four Employer Trustees, and is located at 14 Sever Street, Charlestown, Massachusetts 02129. Plaintiff provides, among other things, prescription drug benefits and pharmacy services through Teamster Rx. Currently there are over 18,000 individuals, both union members, their dependants, retirees and their spouses, who receive major medical benefits, including prescription drug benefits through the Fund. Beginning on April 1, 2006, Plaintiff paid or reimbursed eligible Trust

participants' prescription drug benefits for Zetia and Vytorin in Massachusetts and elsewhere other than for resale, and incurred substantial losses as a result.

f. Plaintiff Midwestern Teamsters Health & Welfare Fund ("Midwestern Teamsters") is an employee benefits fund administered pursuant to the terms and provisions of the Agreement and Declaration of Trust creating Midwestern Teamsters Health & Welfare Fund, and is required to be maintained and administered in accordance with the provisions of the Labor Management Relations Act of 1947 and the Employee Retirement Income Security Act of 1974 (as amended), 29 U.S.C. §§ 1001 *et seq.* Midwestern Teamsters' place of business is Tedro & Associates, Inc., 2160 Foster Avenue, Wheeling, Illinois 60090. Midwestern Teamsters covers the cost of health care and medically necessary drugs for its eligible participants. During the Class Period, Midwestern Teamsters wrongly paid claims administration fees and reimbursed prescription costs for Zetia and Vytorin, when the much cheaper and also safer generic simvastatin was equally as effective.

g. Plaintiff UFCW & Employers Arizona Health & Welfare Trust ("UFCW") is an employee benefits fund administered pursuant to the terms and provisions of Agreement and Declaration of Trust in accordance with the provisions of the Labor Management Relations Act of 1947 and the Employee Retirement Income Security Act of 1974 (as amended), 29 U.S.C. §§ 1001 *et seq.* UFCW's address and place of business is c/o Southwest Service Administrators, Inc., 2400 West Dunlap, Ste. 250, Phoenix, Arizona 85021. UFCW covers the cost of health care and medically necessary drugs for its eligible participants. During the Class Period, UFCW wrongly paid claims administration fees and reimbursed prescription costs for Vytorin, when the much cheaper and also safer generic simvastatin was equally as effective.

h. Plaintiff County of Suffolk is a governmental entity existing under the laws of the State of New York, with principal offices at 100 Veterans Memorial Highway, Hauppauge, New York. During the Class Period, the County of Suffolk wrongly paid claims administration fees and reimbursed prescription costs for Vytorin and Zetia, when the much cheaper and also safer generic simvastatin was equally as effective.

i. Plaintiff Louisiana Health Insurance Indemnity Company d/b/a BlueCross Blue Shield of Louisiana ("BCBSLA") is a Louisiana corporation with its principal place of business at 5525 Reitz Avenue, Baton Rouge, Louisiana 70809. During the Class Period, BCBSLA wrongly paid claims administration fees, and reimbursed prescription costs, for Vytorin and Zetia, when the much cheaper and also safer generic simvastatin was equally as effective.

B. Defendants

19. Defendant Merck is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Merck reported global sales of $22.6 billion in 2006 and $24.2 billion in 2007. Through a joint venture with Schering-Plough, Merck developed and markets Zetia and Vytorin.

20. Defendant Schering-Plough is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Schering-Plough develops, promotes, and sells consumer and animal pharmaceuticals throughout the world. Schering-Plough reported net sales of $10.6 billion in 2006 through its joint venture with Merck, and $12.7 billion in 2007.

21. Defendant MSP is a joint venture partnership created in May 2000 between Merck and Schering-Plough, with its principal place of business at 351 N. Sumneytown Pike, North Wales, Pennsylvania 19454. MSP uses the resources of Merck and Schering-Plough and Merck and Schering-Plough committed their manufacturing facilities to MSP. In May 2000,

Merck and Schering-Plough entered into agreements to create separate equally-owned partnerships to develop and market new prescription medicines in the cholesterol-management and respiratory therapeutic areas. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company, and provide for the sharing of operating income generated by the Merck/Schering-Plough cholesterol partnership based upon percentages that vary by product, sales level and country. In the U.S. market, Merck and Schering-Plough share profits on Zetia and Vytorin sales equally, with the exception of the first $300 million of annual Zetia sales, on which Schering-Plough receives a greater share of profits. In 2006, Zetia sales were $1.92 billion and Vytorin's sales were $1.95 billion.

JURISDICTION AND VENUE

22. This action was originally filed in this district as a proposed Class action on April 4, 2008. This Court has subject matter jurisdiction under 28 U.S.C. § 1331, because this action arises under the laws of the United States, and under 28 U.S.C. § 1964(c), because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962, *et seq.*

23. This Court also has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332(d), because members of the proposed nationwide Class are citizens of states different from Defendants' citizenship, and the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs.

24. This Court has jurisdiction over the TPPs' individual claims pursuant to 28 U.S.C. § 1332(a), because the TPPs' citizenship is different from Defendants' and the amount in controversy as to each TPP exceeds $75,000, exclusive of interest and costs.

25. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965, and by order of the Judicial Panel on Multidistrict Litigation. Merck and

Schering-Plough reside in this District. Further, a substantial part of the events and omissions giving rise to the claims alleged in this Complaint occurred in this District.

FACTUAL ALLEGATIONS

A. Background: Cholesterol and the Treatment of Cholesterol

26. Cholesterol is a fatty substance or "lipid" that is produced naturally by the liver. Cholesterol travels through the bloodstream packaged inside a protein called a lipoprotein.

27. One type of cholesterol is low-density lipoprotein cholesterol ("LDL-C"), which is called "bad" cholesterol because it purportedly is primarily responsible for cholesterol-related health problems, including heart disease, heart attack, and stroke. Too much LDL-C in the blood purportedly can lead to the accumulation of plaque in arteries, reducing blood flow to the limbs, brain, and heart, leading to blood clots, and eventually causing atherosclerosis and arteriosclerosis.

28. Another type of lipoprotein is the so-called "good" or high-density lipoprotein ("HDL"), which carries cholesterol through the bloodstream as HDL-C. HDL-C is considered "good" because it helps return "bad" cholesterol to the liver where it can be eliminated from the body.

29. A high "bad" cholesterol level purportedly is a risk factor for heart disease. Heart disease is an umbrella term for a number of disorders, including atherosclerosis, that adversely affect the functioning of the human heart. Atherosclerosis occurs when cholesterol and other substances build up in the walls of arteries and form hard substances called plaque.

30. Coronary arteries bring blood to the heart. Atherosclerosis due to plaque can slow the flow of blood to the heart through the cardiac arteries, causing chest pain (stable angina), shortness of breath and other symptoms. If the blood supply to the heart is completely stopped

by a blockage, a heart attack results. Further, a general decrease in the amount of oxygen-rich blood caused by narrowing of the arteries may lead to coronary artery disease ("CAD").

31. Often considered strictly a cardiac problem, atherosclerosis can damage arteries anywhere in the body. For example, persons with atherosclerosis in arteries leading to the limbs may develop circulation problems in the arms and legs called peripheral arterial disease. Persons with atherosclerosis in arteries supplying blood to the head are at risk for transient ischemic attack (TIA), or stroke. Atherosclerosis can also lead to a bulge in the wall of one's artery (aneurysm).

32. Apart from atherosclerosis, plaque caused by high levels of LDL cholesterol is highly dangerous for other reasons. Pieces of accumulated arterial plaque can break apart and move through the bloodstream, a common cause of heart attack and stroke. Blood clots can form around the plaque deposits and block blood flow. A clot that moves into the heart, lungs, or brain can cause a stroke, heart attack, or pulmonary embolism.

33. Marketed since 1987, statin drugs have for years dominated drug therapy for reducing LDL-C. Statins, which work through the liver, are defined as "any drugs in a class of lipid-lowering drugs that reduce serum cholesterol levels by inhibiting a key enzyme involved in the synthesis of cholesterol." Statins inhibit HMG-CoA reductase, the enzyme that controls cholesterol production. By inhibiting this enzyme, statins slow down cholesterol production and increase the ability of the liver to remove LDL-cholesterol from the blood.

B. Merck Knew That Zocor Would Face Generic Competition By 2006

34. Notwithstanding its past success with the cholesterol-lowering drug Mevacor and huge sales of Zocor, Merck was under pressure to develop another blockbuster drug. Merck's patents on two drugs – its hypertension drug Vasotec (which accounted for over $2.3 billion in sales in 1999), and its ulcer drug Pepcid (which generated $850 million in revenues in 2000) –

expired in 2000, at which point generic versions of those drugs could and did severely reduce Merck's sales.

35. Merck knew that Zocor sales would likewise plunge once that drug lost patent protection in the United States in 2006 (and in various other countries before 2006). Merck also knew that it had no new cholesterol-lowering drug in its pipeline to replace lost Zocor sales.

C. Defendants Merck and Schering Form a Joint Venture to Develop and Implement a Scheme To Effectively Extend the Life of Merck's Zocor Patents by Combining Zocor with Schering's Zetia To Create Vytorin

36. In 2000, Merck and Schering-Plough implemented a scheme to effectively extend the life of Zocor's United States and worldwide patents. In that year, Merck and Schering-Plough formed the joint venture MSP, knowing that Schering-Plough already had the patent for the drug Zetia, which lowers cholesterol but is not a statin. Unlike statins, Zetia does not work in the liver, but instead works in the intestines to prevent the absorption of cholesterol.

37. Moreover, Defendants knew that while some scientific evidence showed that statins reduce the risk of adverse cardiac events for at least some people, no scientific evidence existed that Zetia lowers the risk of adverse cardiac events for anyone or even that it reduced (or slowed the growth) of arterial plaque. Therefore, Defendants planned to combine Zetia with Zocor, and to market the combined drug as more effective than Zocor alone at lowering cholesterol, and to further deceptively market the combined drug as more effective at reducing (or slowing the growth of) arterial plaque and, thus, reducing the risk of adverse cardiac events.

38. Such a combined drug would effectively extend the patent life of Zocor because the combined drug would be protected by the Zetia patent, which was not scheduled to expire until 2015.

39. On October 25, 2002, the FDA approved Zetia for reducing bad cholesterol. As part of the approval process, Defendants submitted a 12-week study trial that showed it could

lower LDL (low-density lipoprotein) cholesterol by 15 to 20 percent more than simvastatin alone. Defendants submitted no evidence that Zetia had any effect on the buildup of plaque in arteries or that Zetia actually reduced the risk of heart attacks or stroke.

40. MSP first sold Zetia in the United States in November 2002. When Zetia came to market, Defendants promoted Zetia as "a different way to help fight cholesterol." They also marketed Zetia to physicians, consumers and others by falsely claiming that the reduction of "bad" cholesterol had been proven to reduce or retard the growth of arterial plaque, which in turn is a risk factor for adverse cardiac heart events. In fact, there was no evidence that the method by which Zetia reduces "bad" cholesterol has *any* such beneficial effect.

41. In furtherance of the scheme, Defendants submitted a New Drug Application for Vytorin to the FDA on September 24, 2003. Vytorin, the brand name for a single pill combining Zetia and Zocor, is also jointly marketed by Merck and Schering-Plough through MSP. Defendants submitted a 12-week study, which showed that individuals taking Vytorin experienced significantly greater reduction of "bad" cholesterol than individuals who took only the generic version of Zocor, known as simvastatin. Again, Defendants did not submit evidence to the FDA regarding the drug's effect on plaque buildup or heart attack/stroke risk reduction. Based on the 12-week study alone, the FDA approved Vytorin in July 2004. Defendants began selling Vytorin on or about August 1, 2004.

D. Defendants' Marketing, Advertising and Promotional Program for Zetia and Vytorin

42. Shortly after the FDA approved Vytorin, the Associated Press issued a story after speaking with Adam Schechter, Vice President and General Manager of MSP. The story reported that MSP "is planning extensive marketing, through ads aimed at consumers, sales representatives visiting and giving free samples to doctors and efforts to get Vytorin listed on

managed care companies' formularies of preferred drugs." Such marketing was implemented with dispatch.

43. By the time Defendants began marketing Vytorin, there was an established medical consensus that high cholesterol, and in particular "bad" cholesterol, was something to be aware of and monitored as one aged. Furthermore, both the medical community and the public were aware that for certain populations serious potential health consequences linked to high cholesterol, and especially "bad" cholesterol – including heart disease, heart attack, and stroke.

44. Defendants were aware that the medical community and public at large had been highly sensitized to the potential health risks of high cholesterol. Defendants' marketing messages for Vytorin were designed to be read, understood, and have their intended effect within the context of these longstanding public assumptions and beliefs, including that lowering "bad" cholesterol would reduce the risks of heart disease, heart attack and stroke.

45. Defendants' marketing of Vytorin consistently focused on reducing the health risks reportedly 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.

46. Defendants' promotion of Zetia and Vytorin included educational materials explaining cholesterol, the two sources of cholesterol (family genetics and food), and methods to combat high cholesterol, including diet, exercise and medications. Many of Defendants' advertisements purported to be tools for the reader to use in deciding whether treatment for high cholesterol was necessary, and whether Vytorin was appropriate for that purpose. Defendants

specifically cited many authorities, such as the American Heart Association, among others, in their advertisements to support their message. In doing so, Defendants implied that their claims regarding Vytorin were consistent with the views of mainstream health professionals and educational bodies.

47. A central focus of Defendants' marketing, advertising, and promotional campaign for Vytorin and Zetia was the message that the specific combination of drugs (the statin Zocor and the non-statin Zetia) in Vytorin would more effectively reduce "bad" cholesterol than Zocor alone. For example, Defendants' marketing materials stated that: "Everyone's cholesterol comes from 2 sources. And targeting both is an effective way to lower it. The good news is that you can target both sources with a product that helps block absorption of cholesterol from food *and* reduces the cholesterol that your body makes." Defendants also flooded the media with the claim that Vytorin is the only product that "helps block the absorption of cholesterol that comes from food, and reduces the cholesterol your body makes naturally . . . . The result is that less bad cholesterol ends up in your bloodstream."

48. Defendants consistently marketed Zetia and Vytorin to TPPs, 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. Thus, Defendants claimed that Zetia and Vytorin work "differently." Moreover, in their public statements and advertising, Defendants consistently and repeatedly emphasized that "lower is better" and that their products were in step with the latest science.

49. Defendants maintained that LDL cholesterol is bad because it builds up in the walls of arteries and forms plaque. Defendants further claimed that over time, plaque buildup can cause a narrowing of the arteries, which can slow or block blood flow to the heart, brain, and

other organs. Defendants also claimed that when added to a healthy diet, Zetia is proven to lower "bad" cholesterol. Defendants claimed that in a clinical study of people with high cholesterol, Zetia lowered "bad" cholesterol by an average of 30 points or 18%.

50. Defendants also claimed that having high "bad" cholesterol can put a person at risk for heart disease, heart attack, or stroke, even though there was no evidence *at all* that Zetia had any effect on a person's risks for heart disease, heart attack, or stroke.

51. Before and throughout the Class Period, Defendants' express, implied, repeated, consistent, and unmistakable message in promoting Vytorin and Zetia was that high cholesterol was seriously unhealthy, because it caused increased plaque formation, which in turn has been associated with an increased risk for heart disease, heart attack, and stroke. Defendants asserted that by combining Zetia and Zocor, they had created a superior medication to statins in the treatment of high cholesterol, increased plaque formation, and the associated risk for heart disease, heart attack, and stroke. In one widely-disseminated advertisement, for example, Defendants asserted that "VYTORIN was clinically proven to lower LDL (bad) cholesterol more than *Lipitor* or *Crestor* alone."

E. Defendants Designed and Funded The ENHANCE Study in 2002 To Substantiate Their Health Claims for Vytorin

52. Scientific research has established that in certain patient populations statins slow atherosclerotic progression, reduce cardiovascular events, and decrease mortality.[2] Based on that research, the manufacturers of statin drugs such as Lipitor and Crestor claim not only that their drugs reduce LDL-C, but also that their drugs benefit at least some patients in terms of reduced heart attacks and deaths from cardiac illnesses.

[2] Thavendiranathan, P., Bagai, A., Brookhart, M.A., Choudhry, N.K., "Primary Prevention of Cardiovascular Diseases With Statin Therapy: A Meta-analysis of Randomized Controlled Trials," Arch. Intern. Med. 2006;166:2307-2313.

53. To compete with Lipitor, Crestor and other statins, Defendants needed to be able to make the same type of impact-on-health claims for Vytorin and Zetia. Defendants had to position Vytorin and Zetia as products that could do what statins did, only better. But neither Vytorin nor Zetia had or has ever been proven in a clinical trial to reduce heart attacks.

54. As a result, Defendants' researchers designed a study in 2002 (even before they submitted the New Drug Applications to the FDA for Zetia and Vytorin) that they hoped would establish that Vytorin's combination of Zetia and Zocor stops or reduces the growth of fatty arterial plaque better than Zocor alone. This, they assumed, would give them the necessary basis to claim that Vytorin is not just superior to statins in reducing LDL-C but, more importantly, was at least as effective, if not more effective, than statins in its "impact on cardiac health."

55. The ENHANCE study, which Merck and Schering-Plough funded, was an international, randomized, controlled clinical trial conducted on 720 European patients with genes that cause abnormally high cholesterol levels (familial hypercholesterolemia). The study pitted Vytorin against simvastatin.

56. ENHANCE's predetermined primary outcome, or "primary end point," was the change from the baseline in the mean carotid artery intima-media thickness ("CA IMT"), which was defined as the average of the means of the CA IMT at six pre-determined carotid sites: the right and left common carotid arteries, carotid bulbs, and right and left internal carotid arteries. The CA IMT measurements of these sites were taken at the beginning of the test period (i.e., at "baseline") and at 6, 12, 18 and 24 month intervals. Preliminary data for the early interval measurements were available for the early entrants by early 2004. The last measurements on early entrants had been made by the fall of 2004.

57. According to a February 2005 *American Heart Journal* article co-authored by the principal investigator of ENHANCE, one of his colleagues, and two employees of the Schering-Plough's research and development arm (known as the Schering-Plough Research Institute or "SPRI") (the "*American Heart Journal* Article"), ENHANCE's secondary end points included:

> (1) the incidence of carotid plaque regression, (2) change in maximal CA IMT, (3) the proportion of participants showing decreased CA IMT, (4) the incidence of new carotid plaque formation, (5) change in composite end point of carotid artery and femoral artery IMT, (6) change in distal common carotid arterial lumen and distensibility using M-mode ultrasound, and (7) the percent change from baseline in the lipid parameters and hsCRP at end point.

58. The *American Heart Journal* Article described the clinical logic for prescribing ezetimibe (Zetia) alone or in combination with statins:

> Lowering serum low-density lipoprotein cholesterol (LDL-C) has been shown to slow the progression of atherosclerosis and to decrease cardiovascular events and mortality; thus, lowering LDL-C is a primary objective in the prevention of coronary heart disease. Greater reductions in LDL-C produce greater reduction in events, and recent data suggest that the lower the absolute level of LDL-C, the greater the benefit, even if LDL-C levels before treatment were within the reference range. At present, aggressive lipid lowering with 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins), which inhibit hepatic cholesterol synthesis, has shown the greatest ability to lower LDL-C. This approach has become the cornerstone of treatment guidelines currently in use around the world.
>
> In some patients, however, adequate LDL-C lowering is not achieved with statins, even at maximal recommended or tolerated doses. In other patients, use of statins is limited by side effects. The addition of a second agent with a complementary mechanism of action may facilitate the attainment of such therapeutic objectives.[3]

59. The authors of the *American Heart Journal* article emphasized that the measurements and analysis of the ultrasound images would be very precise: specific instruments

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[3] John J. P. Kastelein, M.D., Ph.D., Philip T. Sager, M.D., Eric de Groot, M.D., Ph.D., and Enrico Veltri, M.D., *Comparison of Ezetimibe plus Simvastatin versus Simvastatin Monotherapy on Atherosclerosis Progression in Familial Hypercholesterolemia: Design and Rationale of the Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression (ENHANCE) Trial*, AM. HEART J. (Feb. 2005) ("2005 ENHANCE Article").

(an "Acusan 128XP instrument . . . equipped with a 705-10-mHz L7 broadband transducer") and "extended frequency" software that was specifically developed for the trial were used to make and record the measurements using "digital, single-frame, ultrasound imaging technology"; the "sonographers [were] rigorously trained and certified . . . [and] blinded to treatment assignment"; "ultrasound images [were] analyzed by readers who have all been certified according to the prescribed protocol and who met prespecified variability tolerances"; and "[o]ngoing QA [quality assurance] and QC of scans [were] conducted at the Core Echo Laboratory of the Department of Vascular Medicine" in the Netherlands. The authors confidently wrote that:

> The rigorous training and certification process for study ultrasonographers and the single-frame digital imaging of IMT are new features of the IMT methodology, which in combination with intensive QA and QC procedures for the ultrasound images will minimize variability and optimize the precision of the IMT measurements.

60. ENHANCE's subjects were "recruited at 18 highly experienced lipid centers in eight countries (Netherlands, Norway, Sweden, South Africa, Spain, Denmark, Canada, United States)" where the study was conducted. As Dr. Kastelein (and others) explained in an April 3, 2008 article in the *New England Journal of Medicine* entitled "Simvastatin With or without Ezetimibe in Familial Hypercholesterolemia":

> From August 2002 to April 2004, a total of 1180 patients with familial hypercholesterolemia underwent screening. Of these patients, 720 then underwent randomization, with 363 assigned to the simvastatin-only group and 357 assigned to the simvastatin-plus-ezetimibe (combined-therapy) group.

61. ENHANCE used the "gold standard" for study designs. The test subjects were selected randomly in the screening phase by computer-generated random codes from the eligible group with familial hypercholesterolemia. Further, the study was "double-blinded" – neither the patients nor the researchers were supposed to know which drug the patients were taking during the trial.

62. As explained in an April 2007 FDA website article entitled "The Advancement of Controlled Clinical Trials" ("FDA Article"), randomization and double-blinding "are two ways used to minimize bias in clinical trials." The FDA Article also stated that "[b]linding is done to make sure that factors such as investigators' preferences or expectations, or participants' desire to please investigators or hopes of improvement, cannot influence and distort results."

63. The FDA Article also explained the importance of establishing clinical study endpoints or goals in advance, in order to prevent "data-fishing" for desired results. Robert Temple, M.D., director of the FDA's Office of Medical Policy, stated (as quoted in the FDA Article) that without these protocols, researchers would "go sifting through the data, breaking patients into lots of groups and picking the one that showed the drug worked! . . . If you go fishing through data like that, you'll always find something positive." Robert T. O'Neill, Ph.D., director of the FDA's Office of Biostatistics, explained that a fundamental, but crucial, concept called pre-specification arose from this type of distortion. He said that a "clear statement of the study's objectives is required and study investigators must specify in advance how they will judge a trial's success or failure." The FDA Article explained that "[s]tudy objectives must be included in a study plan, called a protocol, which describes what study procedures will be done, when, and by whom."

64. Merck and Schering-Plough described in advance the ENHANCE protocols, as well as its primary and secondary endpoints. Merck and Schering-Plough also clearly described ENHANCE's goal of determining whether Vytorin reduced CA IMT more than simvastatin alone.

65. In the *American Heart Journal* article, Dr. Kastelein and his co-authors further explained that Merck and Schering-Plough funded ENHANCE because they believed that

ENHANCE would show that Vytorin is more effective than simvastatin alone in reducing arterial plaque:

> The primary hypothesis is that CA IMT will differ between treatment groups, such that ezetimibe 10 mg/d and simvastatin 80 mg/d will be significantly more effective than placebo and simvastatin 80 mg/d in slowing or reversing the progression of CA IMT.

66. Specifically, Defendants designed ENHANCE to demonstrate that, in patients with hereditarily high cholesterol levels ("familial hypercholesterolemia"), the addition of Zetia to a statin would reduce the buildup of arterial plaque in their carotid arteries, resulting in a statistically significant reduction in the thickness of those arterial walls compared to patients taking only the statin generic Zocor.

67. As the 2005 ENHANCE Article stated: "The question of whether further modification of the lipid profile by the addition of a complementary non-statin agent can incrementally exert beneficial effects on atherosclerosis is of clinical importance." Atherosclerosis, the growth of fatty plaque on the arteries, is, according to ENHANCE's authors, "the disease process underlying most cardiovascular events," and can be caused by hyperlipidemia, or high cholesterol.

68. Accordingly, ENHANCE's primary endpoint or goal was the mean change in the intima-media thickness ("IMT") of the carotid artery at the six carotid artery measurement locations specified above. This well-validated measure of atherosclerosis correlates well with cardiovascular and cerebrovascular events. Defendants assumed that ENHANCE would show Vytorin reduced or retarded atherosclerosis, which would permit Defendants to claim Vytorin, like statins, actually contributed to cardiac health for certain patients.

F. The ENHANCE Study Results Confirm the Relative Inefficacy of Vytorin and Expose Its Health Risks

69. ENHANCE's data was sent to Merck and Schering-Plough (through MSP), and they forwarded the data to Dr. Kastelein and other researchers. ENHANCE's schedule called for evaluating the last patients in April 2006, "unblinding" the data in the summer of 2006 and sending the results to Dr. Kastelein for analysis. Dr. Kastelein was to present the findings at a national meeting of the American College of Cardiology in the fall of 2006.

70. In 2005, however, Defendants, who maintained the study's "clinical database", began to receive early data from the ENHANCE trial showing that the combination of Zetia (the non-statin) and Zocor (the statin) produced no better arterial plaque reduction than the statin simvastatin alone. By April 2006, the ENHANCE results showed that while the patients in the ENHANCE trial who took Vytorin did, on average, record significantly lower levels of LDL-C than the patients who took Zocor, no significant difference emerged between the two groups on the study's primary endpoint or outcome measure – the mean change in atherosclerosis, *i.e.*, the thickness of the walls of patients' carotid arteries. Put simply, adding Defendants' still-patented non-statin Zetia to the now generically available statin simvastatin added no benefit to the treatment of atherosclerosis. As cardiologist Dr. Harlan Krumholz of Yale University put it after the ENHANCE results later became public, ENHANCE raised the possibility that ezetimibe is an "expensive placebo."

71. Equally striking, the ENHANCE study results also showed that patients who took Vytorin actually suffered an *increase* in arterial-wall thickness, which can impede blood flow and represent plaque aggregation on the interior walls of blood vessels. The Vytorin-takers in the study showed a greater change in carotid artery intima-media thickness (CA IMT) than the group taking Zocor alone. ENHANCE also demonstrated that Vytorin was ineffective in

reducing fatty plaque in the arteries. That is exactly the kind of cardiac risk that the Vytorin was supposed to be removing, not creating.

G. Defendants Initiate a Scheme To Suppress the ENHANCE Study Results

72. In response to these results, Defendants immediately delayed public release of the information. In June 2006, a Schering-Plough executive told investors that the ENHANCE data would be ready by the end of 2006, meaning that the results of the study would not be announced, as originally planned, at the American College of Cardiology meeting that fall. At the time, this postponement received little notice in the medical community, since drug studies frequently are not released on schedule.

73. However, Defendants did not withhold announcement of the ENHANCE results because of ordinary delays in producing a drug study. They delayed because upper management at Schering-Plough already knew that "they were not going to get any good news" from ENHANCE. A former Senior Medical Director in Schering-Plough's Cardiovascular group, who worked with Schering-Plough's "Brand Team" during the time that the ENHANCE data was being gathered and finalized, has advised that Schering-Plough performed quality control assessments of the ENHANCE data in late 2005 and 2006. Updates on the progress of the ENHANCE study were shared at the quarterly Brand Review Meetings led by Carrie Cox, Schering-Plough's Executive Vice President and President of Global Pharmaceuticals.

74. Dr. Kastelein, ENHANCE's primary investigator, was prepared to publish ENHANCE's results in early 2007 and present them at the meeting of the American College of Cardiologists in the Spring. However, Defendants sought to further delay publishing the results, in order to find a way to either negate or mitigate the findings of the ENHANCE study.

75. As part of their scheme, in January 2007, Merck and Schering-Plough, through MSP, hired Dr. Michiel L. Bots, M.D., Ph.D., Associate Professor of Epidemiology at the Julius

Center for Health Services and Primary Care of the University Medical Center of Utrecht in the Netherlands, as an "independent consultant." Defendants asked Dr. Bots to advise them about, and to write a report detailing, purported problems with ENHANCE's CA IMT measurements.

76. Dr. Bots provided Merck and Schering-Plough his report on or about January 26, 2007. The plan to use Dr. Bots to undermine the ENHANCE study results had backfired. He found no problems with ENHANCE data that justified any delay in releasing the study's results.

77. According to the Bots Report[4], Merck and Schering-Plough set up three meetings in Amsterdam at the Core Echo Laboratory, where the image database was housed, to address the companies' purported concerns – one meeting on January 16, 2007 and two on January 18, 2007. The Bots Report defined Dr. Bots's objectives as: (i) determining if the reading of the ultrasound images had been done according to the pre-established protocols for the study; and (ii) determining how to address "outliers," which were large differences in CA IMT measurements between visits one week apart, which "were beyond what was to be expected from normal progression."

78. Dr. Bots wrote in his report that at the January 16, 2007 meeting, "the core lab showed how the measurements were done." Based upon this presentation and his discussions with the ENHANCE study team, Dr. Bots concluded that the CA IMT measurements "were indeed done in a manner that was described in the protocol." Twice more, Dr. Bots's report stated that the "CIMT measurements seem to be done according to the procedures outlined in the protocol." On this issue, Dr. Bots concluded that the "CIMT measurements in ENHANCE have been done in a consistent manner, leading to reproducibility findings that compare well with that of published studies from other multi-centre randomized trials."

[4] Dr. Bots's report only became public when it was obtained as part of the Congressional investigation, after the ENHANCE results were announced in January 2008.

79. On the purported "outliers" issue, Dr. Bots again found no problems with the ENHANCE data. Dr. Bots stated that the "core lab has re-evaluated all the images of the visits 3-4 [the first two measurement visits] that had a CIMT value that was 50% or more different" and re-evaluated similar images from visits 13-14 (the last two measurement visits). However, with respect to the "mean absolute CIMT difference and the standard deviations," Dr. Bots concluded that "data are well in line with the studies that have been published in the literature. Based on those findings there seems to be little concern regarding the validity and precision of the data."

80. Analyzing "how the reproducibility based on the original data changed when the 'corrected' outlier data were used," Dr. Bots found that "[t]his improved . . . the standard deviation of the mean differences" but "the improvement was very modest." Dr. Bots concluded that the "variability due to imaging and reading" was "excellent" and that the statistician's concerns about results were "beyond biological variation." In short, Dr. Bots found no reason to question the ENHANCE trial's data.

81. The Bots Report addressed the issue of missing data: "Of the common carotid segment CIMT was missing for 4% of the participants, for the bifurcation segment 12% and for the internal segment 12%." While "[m]issingness may affect the CIMT value," Dr. Bots concluded that these figures were "in line with observational studies" and that "the current statistical models that were used in the analysis of CIMT trial data do appear to take care of that in an adequate manner." Dr. Bots further rejected any concerns, saying:

> Since the study was blinded, and the sonographer can not identify which participants were "progressors" and which participants are "regressers," the effect of missing imaging information is likely to be a random phenomenon.

82. Dr. Bots concluded that all of the supposed issues with ENHANCE's data that Defendants raised after the fact amounted to nothing.

83. The "Conclusions" section of Dr. Bots's Report summarizes that "the evidence to me is sufficient to indicate that the data are fine." In the Report's "Summary" Dr. Bots likewise stated that "the evidence shown to me is sufficient to indicate that the CIMT data in ENHANCE are fine: i.e., no better, no worse than what has been reported in the literature."

84. With Dr. Bots's categorical confirmation of the validity and reliability of the ENHANCE data, Defendants then sought another way to negate the unfavorable study results and to further delay disclosure of the study results.

85. Defendants now suggested changing the way CA IMT was measured through selection of images, or changing the parameters used to define outliers. Dr. Bots refuted these suggestions also, saying they would change nothing:

> [It is] [i]mportant . . . to realize that the above mentioned activities might reduce measurement variability to some extent. Since this is expected to involve only a small number of the measurements, the expected effects on variability are likely to be modest. Again, randomization protects against bias in the estimate of the difference between treatment arms.

86. Dr. Bots did not serve Defendants' purpose, because his Report found no material issues or problems in following the protocols for the ENHANCE trial, taking and recording the CA IMT measurements, dealing with outliers, or addressing missing data. Dr. Bots's Report supported immediate release of the ENHANCE results, not the delay for which Defendants had hoped Dr. Bots would provide a scientifically plausible pretext.

87. Defendants were aware of the concern surrounding the delay in the release of the ENHANCE study and were already attempting to downplay the importance of the study. For example, at Schering-Plough's earnings report conference call on April 19, 2007, Tim Anderson, a Prudential Equity analyst, asked Schering-Plough's new CEO, Fred Hassan, if he was "worried about the outcome of the [ENHANCE] trial," Mr. Hassan responded by saying, among other things, that "the data analysis is ongoing for the ENHANCE trial," and that the

study "is a surrogate market trial in a very special population with very special doses. There is a much larger trial called the IMPROVE-IT trial which is more of an outcomes trial . . . . [W]e are pretty confident about the overall pattern of data for VYTORIN."

88. Mr. Hassan did not mention that ENHANCE had demonstrated that Zetia plus simvastatin was no better than simvastatin alone. Mr. Hassan's qualification that ENHANCE studied only "a very special population with very special doses" and his quick, subject-changing jump to discussing other studies and "the overall mix of the data" strongly imply his knowledge of ENHANCE's bad results and Defendants' continued scheme to obfuscate and conceal the negative results.

H. Defendants Further Delay The Release Of The ENHANCE Results

89. After the ENHANCE study was not presented at the American College of Cardiologists meeting in the fall of 2006, the ENHANCE study was rescheduled to be presented at the meeting of the American Heart Association in the fall of 2007. But Defendants also caused that presentation to be cancelled, apparently to Dr. Kastelein's frustration. On July 6, 2007, in an e-mail[5] to Dr. Enrico Veltri, Group Vice President of Global Clinical Development at SPRI, Dr. Kastelein wrote:

> Is it correct that SP has decided not to present at AHA, but to await the two other, completely unvalidated endpoints, which analysis is going to take us straight into 2008??!?? If this is true, SP must have taken this decision without even the semblance of decency to consult me as PI of the study. I can tell you if this is the case, our collaboration is over . . . this starts smelling like extending the study for no other then (sic) political reasons and I cannot live with that.

[5] The emails between Dr. Kastelein and the Defendants were not publicly revealed until they were produced during a 2008 Congressional inquiry.

90. Dr. Kastelein communicated with other senior SPRI researchers, asserting no good reason existed to delay disclosing ENHANCE's results. On July 6, 2007, Dr. Kastelein sent the following email to Schering-Plough's Dr. John Strony:

> Dear John
>
> [I]s it correct that SP has decided not to present at AHA [the American Heart Association conference from November 4-7, 2007], but to await the two other, completely unvalidated, endpoints, which analysis is going to take us straight into 2008 ??!!?? If this is true, SP must have taken this decision without even the semblance of decency to consult me as PI [principal investigator] of the study. I can tell you that if this is the case, our collaboration is over and I will take the appropriate steps to get in touch with the editors of major Journals as well as with the FDA. This starts smelling like extending the publication for no other then [sic] political reasons and I cannot live with that. This is the second day of a long overdue holiday after a terrible year, thank you very much for yet another terrible chapter of this trial.

91. Dr. Strony responded and explained away the delay as follows:

> The timeline for the reading of the femorals alone has been a movingtarget [sic]. First it was 8 weeks, then 12, and then 16. This is under the assumption of having 4 readers. However, one of the four has failed qualification and now we are down to three. If all runs smoothly (whichhas [sic] never happened in ENHANCE) we are told it will take 17 weeks for the primary readings. Don't forget the querying process and clean-up which is still not factored…

92. Dr. Kastelein replied to Dr. Strony on July 7, 2007, copying the message to Dr. Enrico Veltri, SPRI's Group Vice President of Global Clinical Development, Cardiovascular & Metabolic Diseases:

> I have been travelling half the globe in the last 6 months to a number of large and important meetings at the strong wish of Merck to chair them or to present ezetimibe data. At every single one of them I was cleared to say that ENHANCE would be presented by me at AHA. There is no reason whatsoever to include femorals; you will be seen as a company that tries to hide something and I will be perceived as being in bed with you

93. Dr. Veltri responded to the July 7, 2007 email. Dr. Veltri tendered still another excuse for delaying disclosure of ENHANCE's results.

94. Still not satisfied, Dr. Kastelein sent the following e-mail on July 13, 2007:

> Dear Rick,
>
> I am glad you took the trouble of providing me with such a long answer. The raging part of my former emails comes from an enormous amount of frustration and a feeling that I have no control whatsoever on anything that relates to ENHANCE. As you know, in my normal state of mind, I am a controlled individual and I am not hard to work with. However, in all my previous experiences as a member of a Steering Committee or as a PI [primary investigator], I felt I was in control. With ENHANCE, that is totally the opposite.
>
> The database is at SP, consultants like Gene Bond are in my opinion impossible to work with and never agree with me, Bo Yang has made several crucial mistakes on the way that cost us 9 months, Eric is a nightmare to work with in terms of organization and I can go on and on. The last example of this "never working with me" is the fact that you have decided to withdraw the abstract. This is not necessary. You could have sent in an empty abstract that as my friends at AHA tell me can be filled with data one week before AHA itself and if you were too late, you simply withdraw it. One phone call to me would have cleared all of this. This is exactly what I have done with Pfizer for the Torcetrapib latebreakers at ACC this year. The data were ready 3 days before ACC.
>
> Also, I am constantly under pressure from Merck to plan all sorts of activities, before, at and after AHA. Because I !! will be the one who have [sic] to stand up and present and defend the data, and I would deeply appreciate being involved again and not just simply at the end of a long decision line.

95. On August 20, 2007, seven months after issuance of Dr. Bots's Report, and after Dr. Kastelein's requests to publish the data had been rejected, Dr. Kastelein met with Merck and Schering-Plough executives to discuss releasing the ENHANCE results. Merck and Schering-Plough demanded that the test data be reviewed yet again. Under pressure, Dr. Kastelein agreed to their request to convene an expert panel to further analyze the issues Defendants had invented regarding the data's reliability.

96. The panel's members included John Robert Crouse, M.D. of Wake Forest University; James Stein, M.D., of the University of Wisconsin; David Orloff, M.D., of Med Pace, Inc., Cincinnati; Greg Evans, M.S., of Wake Forest University; and Dr. Bots, author of the aforementioned Bots Report.

97. Having extracted Dr. Kastelein's agreement to the formation of the expert panel, Merck and Schering-Plough continued to stall. They did not convene the independent expert panel until mid-November 2007.

I. Defendants Finally Convene The Expert Panel But Try to Use it To Change The ENHANCE Results

98. On November 16, 2007, Defendants finally convened the independent expert panel to discuss what the companies posited were problems with ENHANCE's data.

99. In addition to the experts listed above, twelve Merck and Schering-Plough employees also attended the November 16 meeting. These included: John Irvin, M.D., Merck's Senior Vice President of Global Research and Product Development; Tom Musliner, M.D., the Executive Director of Cardiovascular Disease, Clinical Research of Merck Research Laboratories; Michael Stepanavage, Ph.D, also of Merck Research Laboratories; Scott Korn, M.D., Merck's Executive Director, Worldwide Regulatory Affairs; and Andrew Tershakovec, M.D., Merck's Director of Clinical Development, U.S. Human Health.

100. Defendants wanted the panel to agree that the data was problematic, and, in connection with such problems, to agree that the ENHANCE's primary endpoint warranted changing.

101. ENHANCE's original primary endpoint, *i.e.*, the data being accumulated and studied, was plaque accumulation in the carotid arteries (the mean change in "CA IMT") at three pre-specified locations – the carotid bulb, the common carotid artery, and the internal carotid artery – for both the left and right carotid arteries, for a total of six measuring points.

102. By changing ENHANCE's endpoints, Defendants would be selecting data known to support their hypothesis that Vytorin helped treat atherosclerosis and discarding data that did not support that hypothesis. This is improper "data fishing."

103. Dr. Kastelein, ENHANCE's lead investigator, did not attend the November 16, 2007, panel meeting. The panelists were told that he did not attend so the experts would not feel limited by professional courtesy or otherwise inhibited in voicing questions, comments, or criticisms.

104. In fact, as was later revealed, Merck and Schering-Plough had kept Dr. Kastelein away from the meeting because Defendants did not want to risk having Dr. Kastelein, who had exhibited scientific integrity, to attend the meeting convened to address the ENHANCE study about which Dr. Kastelein had intimate knowledge. Defendants believed Dr. Kastelein would vehemently contest their attempt to change ENHANCE's primary endpoint. They also knew he had the experience, training, knowledge, and the facts of the study with which to make his argument convincing.

105. Dr. Kastelein's exclusion from a crucial meeting to review the ENHANCE study, in which he was the lead investigator, was highly irregular, and, in later months, was the subject of criticism from industry experts.[6]

106. The experts were also told that no minutes would be taken of the November 16, 2007 meeting. As discussed below at ¶¶ 143-156, Merck and Schering-Plough later reversed course and created minutes of the meeting, when Defendants concluded that the minutes were needed to support the story they were trying to fabricate.

107. The purported basis for changing the endpoints of the ENHANCE study from the six sites to only the common carotid artery site was that the images of plaque buildup from the

[6] For example, a January 11, 2008 *Forbes* article entitled "Inside Schering-Plough and Merck's Secret Panel," noted that the exclusion of Dr. Kastelein was "an unusual circumstance in such situation." The article continued, "It's 'shocking' that Kastelein would not be party to discussion of the ENHANCE trial, says Harlan Krumholz, a cardiologist at Yale University. 'There should be a scientific committee that's independent running a study. He should be taking a leadership role.'"

other sites were supposedly unreadable and, thus, unreliable. In truth, Schering-Plough and Merck selected some of the worst images the study had produced, and attempted to manipulate the panel to conclude that all of the study's images and data were flawed based upon these atypical images.

108. Thus, although Merck and Schering-Plough touted the panel as a scientifically independent group assembled to provide independent expert feedback about the ENHANCE data, the truth was that Merck and Schering-Plough carefully selected a very small number (50-75 out of 40,000) of ultrasound images from the ENHANCE study to show the expert panel, but later claimed in the falsified minutes of the meeting (discussed below) that the panel was granted "unrestricted access" to the data. In fact, the panel was granted restricted access to the worst images available.

109. The materials prepared for the November 16, 2007, expert panel also painted a seriously false picture of ENHANCE's data. One slide included the statements: "Existing data is not statistically analyzable" and "Existence of unacceptable number of biologically implausible IMT values," and under the heading "Statistical Issues," another slide stated, "There is tremendous risk analyzing this data." However, Merck was able to release preliminary results of the ENHANCE study based on this data (with all of the original endpoint measurements) just over a month after deciding not to change the primary endpoint.

110. Merck's and Schering-Plough's effort to manipulate the panel by showing them only the worst slides, and by using highly pejorative descriptions of those slides, creates a substantial inference that Defendants knew the content and ramifications of the ENHANCE results, and the negative impact such facts would have on Defendants' marketing strategy and market share, long before they disclosed them.

111. On November 19, 2007, only three days after the expert panel meeting, Merck and Schering-Plough, through MSP, issued a press release announcing that the companies had convened an independent expert panel to advise on the "prospective analysis" of ENHANCE. In the press release, the companies falsely asserted that the panel itself had recommended changing the primary endpoint – the fundamental metric, established before the trial began, for measuring and evaluating the drugs' performance. The November 19 press release stated that the primary endpoint would be changed to *only* the common carotid artery.

112. Merck and Schering-Plough knew that changing the primary endpoint was highly unusual and scientifically suspect but falsely asserted that the change nonetheless was required "to expedite the reporting of the study findings." The November 19 press release also falsely claimed that ENHANCE remained blinded.

113. Despite his exclusion from the panel, the November 19, 2007 press release represented that Dr. Kastelein agreed to the proposed endpoint change: "We view the experts panel's recommendation to narrow the primary endpoint to the common carotid artery as helpful." This was profoundly misleading. Dr. Kastelein had earlier expressed outrage when he learned of the proposal to manipulate the ENHANCE study.

114. In summary, the November 19 press release suggested that ENHANCE's data had not yet been analyzed, and that the results remained unknown to Defendants as well as everyone else. Merck and Schering-Plough also tried to avoid responsibility for the highly unorthodox maneuver of changing ENHANCE's endpoint, by suggesting that it was an independent panel of experts, not Merck and Schering-Plough themselves, that strongly supported the change.

115. Subsequently, the expert panelists denied that they ever made such a recommendation (although they did discuss it), and confirmed that the decision to change the primary endpoint originated with Merck and Schering-Plough.

J. Defendants' Conduct Regarding ENHANCE Comes Under Increasing Criticism

116. Underscoring the rank scientific invalidity of Merck's and Schering-Plough's attempt to create new and improved results while delaying disclosure of the true and unfavorable answers, outside scientists, doctors and commentators were strongly critical of the "change-the-endpoint" decision even before they had seen ENHANCE's results or learned that Defendants' proposed new primary endpoint would create better results for the companies.

117. Merck's and Schering-Plough expert panel was roundly criticized. *First*, industry professionals and others immediately saw the panel as a pretext for yet another review of, and challenge to, data that Dr. Bots had already extensively reviewed and found "fine." *Second*, the data under scrutiny had been collected under strict protocols established in advance and rigorously followed. *Third*, the panel was seen as providing "cover" for Defendants to violate accepted scientific testing principles and, after the fact, alter the ENHANCE's primary endpoints so that Defendants could selectively choose certain data and use it to support some claim or another while hiding the truth that ENHANCE disproved the study's key goal of showing that Zetia plus a statin reduced arterial plaque buildup. *Fourth*, Merck and Schering-Plough tried improperly to nudge the supposedly independent, scientifically rigorous expert panel into concluding that the data gathered during ENHANCE was flawed. *Fifth*, and perhaps most telling, Merck and Schering-Plough later tried to create supposed panel recommendations by creating versions of minutes of the November 16, 2007 meeting that fundamentally distorted what the experts had actually concluded.

118. At the same time that Defendants were setting up and conducting the "expert panel" meetings, *Forbes* was developing an article about Defendants' delayed release of the ENHANCE results. The article's author communicated with executives at both companies and with Dr. Kastelein. The *Forbes* article was published on November 19, 2007.

119. As quoted in the *Forbes* article, Dr. Allen J. Taylor, head of cardiology at Walter Reed Army Medical Center, stated that Merck and Schering-Plough may have been delaying as long as they could while hoping some better data might come from some other study: "It starts to raise suspicion. . . . The more time it takes, the more you start to wonder what is wrong." Dr. Robert Califf of Duke University, co-chairman of the IMPROVE-IT trial (comparing Vytorin and simvastatin), agreed, saying: "We'd all agree that having this long a delay after a study is over is a bad thing."

120. The *Forbes* article noted that cardiologists had expected the ENHANCE results to be presented at a medical meeting in November 2006, then at another meeting in March 2007, then at another in November 2007, "[b]ut none materialized." According to the *Forbes* article, the "two-year delay . . . has cardiologists expressing skepticism and spinning conspiracy theories. If the news were good, the companies would rush it out, the thinking goes. Delay doesn't bode well."

121. The *Forbes* article described "[a]nother source of suspicion" about ENHANCE. Top clinical experts recommend that outside researchers conducting studies – not the company whose drug and consequent billions of dollars are at stake – have control over the raw study data and computerized database created to analyze study results. In ENHANCE, however, Merck and Schering-Plough controlled and held the information and database. Dr Kastelein lamented that fact in his July 13, 2007 email to Dr. Veltri described above.

122. In the *Forbes* article, Dr. Kastelein tried to explain the delay, "narrat[ing] a long tale of woe, including switching roomfuls of VHS tapes to new digital imaging technology, training technicians and insuring the security of Internet connections." However, Dr. Kastelein also told *Forbes* that "everything went smoothly . . . in terms of recruiting patients and taking artery measurements." "I certainly want it finished," he said, adding "[t]here are all sorts of conspiracy theories that are not good for my reputation."

123. In the *Forbes* article, Dr. Paul Thompson, director of cardiology at Hartford Hospital in Connecticut, predicted that bad ENHANCE results would cause Pfizer and Astra-Zeneca sales representatives to turn up at every hospital in the country "within milliseconds," hawking Lipitor and Crestor, the largest competitors of Vytorin and Zetia.

124. The *Forbes* article also reported Merck and Schering-Plough's failure to register either ENHANCE or its results on the government website clinicaltrials.gov. All clinical trials are supposed to be listed on that site even before they begin, and are supposed to include clear definitions of the study's designs.[7]

125. On November 21, 2007, the *New York Times* published an article entitled "After A Trial, Silence." The article discussed the "growing chorus of complaints from cardiologists" over the delay, as the results were expected to be, but were not, presented at the ACC conference in March 2007. The article stated:

> [S]cientists generally assume that for a clinical trial to be valid, its goals must be defined before it begins and never changed afterward. Otherwise, the people conducting the trial could change their goals to conform the data the trial has actually produced.

[7] On October 23, 2007, *Forbes* emailed an MSP spokesperson to ask why the ENHANCE study was missing from clinicaltrials.gov. As reported in an April 3, 2008 *Forbes* article, MSP subsequently listed the study on October 31, 2007 according to the website's track-changes function.

> "This sounds highly unusual to me," said Dr. Bruce Psaty, a professor of medicine and epidemiology at the University of Washington [of the proposed ENHANCE primary endpoint change]. "You need to live with your primary endpoint."[8]

126. Dr. Kastelein was equally frustrated with the continuing delay. He told *The New York Times* that the delay was the result of Merck and Schering-Plough controlling the raw data and raising questions about its accuracy. "There was friction and tension," he said.

127. Apart from the criticism over their announced change in the primary endpoint, Merck and Schering-Plough were criticized for stonewalling the release of ENHANCE. A November 22, 2007 article on the WebMD website page *TheHeart.org* entitled "Concerns Raised on Delay of Ezetimibe Data" stated that "[t]here have been concerns raised in multiple press reports this week about delays in reporting to results of the first key study with the cholesterol drug ezetimibe. The results of the carotid ultrasound trial, ENHANCE, are indeed late, which has led to much speculation that the results are negative and the companies are therefore delaying their release…."

128. The WebMD article explained why cardiologists, the press and investors were anxiously awaiting release of the ENHANCE results: "[T]he ENHANCE trial is the first major study to be conducted with ezetimibe, which is why the results are so eagerly anticipated. Although it is not a clinical-outcome study, carotid ultrasound studies monitoring the effects of drug therapy on a atherosclerotic plaque are seen as a reliable surrogate and normally predict whether a drug will be effective in lowering cardiac events."

129. A November 26, 2007 article on the blog *Junkfood Science* explained that the "delays are concerning cardiologists because millions of people have been prescribed Zocor (simvastatin) with Zetia (ezetimibe), believing they prevent heart attacks and strokes."

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[8] Similarly, in a January 11, 2008 *Forbes* article, Dr. Psaty was quoted: "You just don't change a primary endpoint in a major importance trial part way through."

130. Nevertheless, Merck and Schering-Plough continued to delay and search for ways to challenge data that they knew showed that adding Zetia to simvastatin produced no additional cardiovascular benefit.

131. Merck and Schering-Plough did so because they knew that once ENHANCE's results were disclosed, Vytorin sales would plummet.

K. After The FDA And Congress Begin Investigations, Defendants Abandon Efforts To Change The Endpoint

132. On November 20, 2007, amid a blitz of criticism over the delayed release of ENHANCE's results and over the announced endpoint change, the FDA launched an investigation into ENHANCE.

133. On December 11, 2007, Representative John D. Dingell, Chairman of the Committee on Energy and Commerce, and Representative Bart Stupak, Chairman of the Oversight and Investigations Subcommittee, wrote Merck and Schering-Plough about the delays in disclosing the ENHANCE study results.

134. In addition to the delay issue, Congressmen Dingell and Stupak expressed concern that the study's endpoint now "appeare[d] to differ from the endpoint described in the initial study" and that Merck and Schering-Plough had engaged in "apparent manipulation of trial data."

135. The Congressmen requested that Merck and Schering-Plough preserve and provide information about ENHANCE, including all data and the names of any outside panel members that recommended changing the study's endpoint. A December 11, 2007, letter from Reps. Dingell and Stupak demanded information on the delay. The Congressmen's letter also noted that Defendants had not registered the ENHANCE study on clinicaltrials.gov (a registry of

federally and privately supported clinical trials maintained by the federal government) until October 2007, eighteen months after the study's end.[9]

136. The same day, December 11, 2007, facing mounting public criticism and investigations by the FDA and Congress, Merck and Schering-Plough abandoned their notion of rescuing ENHANCE by changing its primary endpoint for the ENHANCE study

137. Merck's and Schering-Plough's change was reported on a Frequently Asked Questions posting on Schering-Plough's website. In a response to the question "Why didn't you change the primary endpoint?" Schering-Plough wrote:

> We view the expert panel's advice to focus the primary endpoint on the common carotid artery as helpful as the common carotid artery is viewed by many clinicians and experts of the IMT procedure as the most reliable, reproducible and clinically meaningful segment of the carotid artery and least subject to artifact and variability. In consideration of this independent expert advice and the evolving medical science, Merck/Schering and the lead investigator have had further discussions about the trial, including input from other respected clinical trialists and scientists. The companies respect and appreciate the advice of the expert panel as well as the others whose advice and input we sought. As a result, we are planning to examine closely the data from the common carotid artery, and to present that data from the prespecified endpoints, in accordance with the study protocol and study analysis plan.

138. Here, again, Schering-Plough falsely stated, with Merck's cooperation and agreement, that the expert panel – not the companies – had initiated the concept of changing the primary endpoint. Neither Merck nor Schering-Plough ever disclosed that the endpoint alteration was designed to produce more favorable test results.

139. The *Wall Street Journal* reported on December 17, 2007, that Dr. Kastelein regretted "not standing up" to Merck and Schering-Plough when they told him in November

[9] Defendants contended in media reports that their failure to register the ENHANCE study on clinicaltrials.gov was an "oversight." In light of the facts described herein, including intense online industry insider scrutiny of and commentary on the ENHANCE study, this contention lacks credibility.

2007 that they planned to alter the statistical analysis of the study. "It's never, ever right to change the final endpoint of a study," especially after all the data is in, said Dr. Kastelein. "It is statistically not good and it gives the wrong impression to the outside world." Dr. Kastelein said he breathed a "sigh of relief" when the companies told him they were reversing their decision.

140. Merck and Schering-Plough abandoned their plan to change the study endpoint but, having seen the criticism the notion engendered, attempted to shift the blame to the expert panel for the proposed change. In an interview with *Forbes*, Peter Kim, head researcher for Merck, stated, "While we greatly respect this expert panel, . . . we are not going to change the primary endpoint for the study."

141. Kim's false sentiment was later echoed by Schering-Plough spokesperson Lee Davies, according to a Bloomberg update on December 12, 2007. Davies said the company decided not to follow the advice of its own expert panel to change the study's goal after getting a second opinion from heart doctors.

142. Like Kim's statement, Davies' statement was false. Both knew that Defendants, not the panel, recommended changing the primary endpoint. Defendants' knowledge of the impropriety of their attempted conduct is revealed by their public attempt to shift responsibility to the panel.

L. Merck And Schering-Plough Doctor The Minutes Of The "Expert Panel" Meeting

143. Among the documents requested from Defendants by the FDA were the minutes of the meeting of the "expert panel" meeting on November 16, 2007. In fact, the "minutes" were not contemporaneous minutes of the meeting but instead were fabricated later, after the FDA asked for them.

144. The companies claimed in a letter to Congress that the minutes were created on December 7, 2007. However, an initial draft of the minutes was not circulated to the expert panelists until December 19, 2007.

145. This timing was suspicious; only a week earlier the companies had been forced, by a hailstorm of criticism, controversy, and looming Congressional investigations, to retreat from their plan to change the primary endpoint of the ENHANCE study.

146. The draft minutes declared:

> The common carotid artery (CCA) provides the most reliable and consistent measurements in IMT studies with the least level of missingness or implausible readings. Therefore, the CCA is now commonly considered the most reliable endpoint. Thus the CCA should be elevated to become the primary study endpoint.

147. Dr. Stein sent his first reply about the draft minutes to Dr. John Strony at SPRI via email on December 21, 2007. As to the CCA discussion that the "minutes" purported to reflect, Dr. Stein wrote:

> This was *not* a conclusion of the meeting. We stated that in regard to this (ENHANCE's) specific data set, with its imaging and measurement problems, the measurements of the CCA are the most valid segmental measurements. In this content [sic], "valid" means most likely to reflect the scientific truth—the real measurements of the carotid IMT. We said the company could "consider" making the CCA measurement the primary endpoint.

(Emphasis added.)

148. The draft minutes further tried to manipulate the expert panel into concluding that the ENHANCE data was problematic and unreliable. The draft minutes for the panel meeting on November 16, 2007, stated that "the Panel members were granted unrestricted access to the blinded image data base."

149. As to that sentence in the minutes, Dr. Stein observed in his December 21, 2007 email:

> I believe that this sentence is an overstatement. We had approximately 6 hours to work so the number of images we were able to review was limited. They may have been "available" but they could not be reviewed meaningfully because of time constraints. We reviewed, at most 50-75 images [out of approximately 40,000 images] and those only were images that the company chose to show us. I recall that I and Dr. Evans added the qualification that ***our conclusions were based on the images we saw, and they were not a randomly selected set of images, thus they were potentially biased because they were selected by the company to illustrate certain points***. Therefore, we can't exclude the possibility that we'd have different conclusions if we saw the rest of the images. (emphasis added)

150. Dr. Stein also noted that the panel "did not vote" on the points set forth in the draft minutes as panel recommendations. As Dr. Stein wrote, the panel "had a divergence of opinions on several" of the issues discussed at the meeting and any conclusions that were reached "were made by the companies, not by us [the panel]."

151. Similar comments from Dr. Stein appeared on every page of the draft minutes (in what Dr. Stein called "MS Word's commenting feature"). These comments reflected that Merck and Schering-Plough – who had many representatives at the November 16, 2007 meeting – knowingly distorted the panel's conclusions and tried to use fabricated after-the-fact "minutes" to hide and protect the companies' attempts to cover up the ENHANCE results.

152. Merck and Schering-Plough circulated a later draft of the minutes on January 3, 2008, but failed to reform the minutes to reflect the changes Dr. Stein had asked for in December 2007.

153. The revised minutes, which included many of the same inaccuracies Dr. Stein had already challenged and tried to fix, stated: "The Panel was unanimous in their opinion that it was reasonable to elevate the common carotid to the primary endpoint."

154. In a pointed response to the supposedly "revised" minutes, Dr. Stein noted that several of his earlier comments were not incorporated, and he again disputed the accuracy of the minutes:

> As stated in my 12-21-2007 comments, "This really overstates our recommendations. We did not vote on this. You asked each of us our opinions, the strength of which varied from complete comfort to a lukewarm feeling that it was 'reasonable.' The tone here implies that we strongly recommended this when in reality, we just advised you on what the scientifically valid approaches would be. **It was the decision of the company to change the endpoint.** (emphasis added.)

155. Dr. Stein concluded in his January 3 email that he could not call what Merck and Schering-Plough had created "minutes", "[s]ince there was no audio or written transcription of the meeting." Dr. Stein wrote that "at best they are an incomplete summary of what transpired at the meeting."[10]

156. In anticipation of the imminent release of the ENHANCE study, Fred Hassan, Schering-Plough's CEO, continued to downplay the importance of the study. At Morgan Stanley's "Pharmaceutical CEOs Unplugged" conference on January 3, 2008, he said that ENHANCE is "not a large trial," and is "in a very, very special population with very, very high doses . . . I don't know why this would have any impact on mainstream use."

M. <u>The ENHANCE Study Results Are Partially Released on January 14, 2008</u>

157. Defendants finally released the results of the ENHANCE on January 14, 2008, and then did so only in a partial press release rather than completely in a medical or scientific journal.

[10] Merck's and Schering-Plough's distortions of the expert panel's discussions were not revealed until April 2008, in connection with Congress's investigation into ENHANCE.

158. In that press release, Defendants finally admitted that ENHANCE proved that the Vytorin group did *not* have a lower CA IMT than the Zocor-alone group. In fact, the Vytorin group's CA IMT was *thicker* than the Zocor-alone group.

159. Defendants' press release asserted that no statistically significant difference existed between treatment groups on the primary endpoint. However, the group treated with statins alone showed a mean carotid IMT of 0.0058 mm, while the group treated with Zetia and statins showed a mean carotid IMT of almost *double* that of the statins monotherapy group: 0.0111 mm. The carotid arterial plaque of those who had taken Vytorin had grown *twice as fast* as for those taking Zocor alone.

160. Dr. Steven Nissen, a renowned cardiologist and chairman of the world-famous Cleveland Clinic's cardiology department, as well as a widely published researcher and senior consulting editor to the Journal of the American College of Cardiology, called the ENHANCE results "shocking." In a *Dow Jones* interview, Dr. Nissen stated that the ENHANCE patients were the ones "you'd most expect the drug to work in" and that "if it doesn't work in this population it's not going to work in anyone" in retarding atherosclerosis.

161. A January 15, 2008 *New York Times* article quoted Dr. Nissen as follows: "This [the ENHANCE results] is as bad a result for the drug as anybody could have feared." Dr. Nissen told the *New York Times*, "Cholesterol lowering with [Zetia] might not provide the same benefits as statins for the same degree of cholesterol reduction."

162. On January 15, 2008, Dr. Nissen also told WebMD that the ENHANCE results are "a stunning reversal for Zetia and Vytorin."

163. Dr. Nissen further stated that millions of patients may be taking a drug that does not benefit them, raising their risk of heart attacks and exposing them to potential side effects.

He recommended that patients not be given prescriptions for Zetia unless all other cholesterol drugs have failed.

164. Echoing Dr. Nissen, Dr. Harlan Krumholz, a prominent Yale University cardiologist, stated: "People may have been on this drug without the ability to know that there was additional data that may have thrown into question its effectiveness . . . . That's extremely unfortunate, and that's an understatement."

165. Another cardiologist also stated, "Statins have diverse effects beyond simple LDL cholesterol lowering, such as potent anti-inflammatory actions." The cardiologist added, "There has yet to be a clinical trial to show that ezetimibe [Zetia] improves clinical outcomes."

N. Congress Investigates Defendants' Conduct

166. Congress immediately took notice of the ENHANCE results. Congress had been asking about the delayed results "since October 2007", according to Representative Stupak.

167. Representatives Stupak and Dingell issued a press release on January 14, 2008, succinctly summarizing Defendants' conduct:

> Today's announcement that the ENHANCE study failed to find any positive benefit from the addition of Zetia to a common, inexpensive, generic therapy raises concerns that attempts were made to mask the minimal value of this new drug. Additionally, Merck's and Schering-Plough's delay in releasing study results, as well as their attempt to manipulate the data is, quite frankly, suspicious.

168. Convinced that Defendants had purposely sat on ENHANCE's results, Representative Stupak stated in a January 17, 2008 *Newsweek* article: "Do I think they knew about it and attempted to put lipstick on the pig, so to speak? Yes. They knew about it. This was their blockbuster drug . . . . These allegations are very serious . . . [W]e have enough information to go for a hearing now."

169. Representatives Dingell and Stupak wrote to Merck and Schering-Plough on January 16 and January 22, 2008, requesting documents concerning the ENHANCE study and the marketing of Vytorin.

170. Senator Charles Grassley, ranking member of the Senate Finance Committee, is also investigating Defendants' conduct in delaying the release of the ENHANCE results and in its marketing of Zetia and Vytorin.

171. The New York Attorney General's office announced on January 26, 2008 that it had subpoenaed documents concerning the ENHANCE study, the marketing of Vytorin, and sales of Defendants' stocks. Other states, including Oregon and Connecticut, have also opened investigations into Defendants' conduct.

O. The Full Results of ENHANCE Are Finally Presented on March 30, 2008

172. The full results of the ENHANCE trial were not presented until the American Cardiology Conference ("ACC") in Chicago on March 30, 2008, and the study was published online in the *New England Journal of Medicine*. Dr. Kastelein, the principal investigator of the study, presented the data to a panel of prominent cardiologists.

173. Dr. Kastelein told the panel and the conference attendees that Vytorin had "no result – zilch. In no subgroup, in no segment, was there any added benefit" in reducing plaque. "Whatever way you look at it," he said, the addition of Zetia offered no benefit to statins.

174. The panel responded with unanimity: Zetia and Vytorin should be used only as a last resort. Dr. Harlan Krumholz, who served on the ACC panel, offered succinct advice to physicians: "Go back to statins. They work." He called Vytorin an "expensive placebo."

175. In connection with the ACC conference, Dr. W. Douglas Weaver, a cardiologist and president-elect of the ACC, gave his assessment of Zetia and Vytorin: "What this tells us is that we have had far too many patients on these drugs than the science supports."

176. Following the presentation of the full ENHANCE results, the ACC released a statement on April 1, 2008, stating that the study "reinforces the need to adhere to current American College of Cardiology/American Heart Association Guidelines which recommend statins to the maximally tolerated dose to goal as first line treatment for patients with coronary artery disease."

177. Two editorials published as companion pieces to the ENHANCE study in the *New England Journal of Medicine* echoed that recommendation: Zetia and Vytorin are drugs of last resort.

P. Even After Learning Of The ENHANCE Results By April 2006 At The Latest, And Even While Suppressing Those Results, Defendants Continued To Market Vytorin And Zetia As Before, Touting Their Relative Efficacy And Not Disclosing Any Of The Health Risks

178. As discussed above, from at latest April 2006 (and likely earlier, in late 2005) to the present, Defendants were aware that Zetia and Vytorin, compared to Zocor alone, failed to slow – and may even have contributed to – plaque formation in the arteries of those with high cholesterol.

179. From the time that the ENHANCE study was completed in April 2006, Defendants continued unabated their intensive marketing of Zetia and Vytorin on television, radio, and in print media, spending more than $200 million on direct-to-consumer advertising through the first three quarters of 2006. Defendants pushed their same messages of the superior efficacy of Vytorin as a combined statin and non-statin, at the same time Defendants were suppressing the ENHANCE study results showing that Vytorin was no more effective than statins alone and posed health concerns, including with respect to hardening of the artery walls.

180. During the two years that Defendants delayed and suppressed release of the ENHANCE study results, they continued their aggressive marketing and promotion and

advertising campaigns touting the supposed benefits of the statin plus non-statin combination in Vytorin. But all the while they knew that such statements were false and misleading and subjected Vytorin-users and Zetia-users to health risks. Neither the Zetia nor the Vytorin website explained that the "different" or distinct ways they work produces no cardiovascular benefits for the patients taking them. Defendants uniformly omitted all mention, let alone analysis, of the ENHANCE study, which would have negated their claims about the purported benefits of Zetia and Vytorin.

181. Defendants continuously and heavily promoted Zetia's 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, throughout 2006, 2007, and well into 2008, notwithstanding the materially contrary (and conceded) results of ENHANCE, in a continuous stream of print ads distributed nationally through the mails, in magazines, and continuously over the wires on Defendants' websites.

182. Mr. Hassan, the Schering-Plough CEO, gave an interview to the *New York Times* on April 14, 2007, one year after Schering-Plough became aware of the ENHANCE results. In that interview, he was asked, "How does your drug Zetia attack the cholesterol problem?" He answered:

> Cholesterol, including L.D.L.'s, are manufactured in the liver. Statins, which came into the market in 1987, work by interfering with that process in the liver. But Zetia, which was a major advance we achieved in 2002, prevents the absorption of bad cholesterol in the gastrointestinal tract. It's a separate mode of action. That's helpful for a whole bunch of people who don't tolerate statins very well.

Mr. Hassan said nothing about the ENHANCE study, which had been completed a year previously, and revealed that Zetia and Vytorin were no better than statins in combating the effects of bad cholesterol.

183. At the Merrill Lynch Global Pharmaceutical, Biotech & Medtech Conference in London, England on September 19, 2007, Alex Kelly, Schering-Plough's Vice President of Investor Relations, stated:

> [S]o far, in 2007—this is through August 2007—VYTORIN and ZETIA are the only two major brands to be growing market share. In fact, we're picking up just short of about a tenth of a share point a month on an average basis so far this year.
>
> So what's driving it? Number one, we have a very strong profile for the products. VYTORIN AND ZETIA are unique. The offer a dual mechanism of treating cholesterol. Because ZETIA inhibits cholesterol absorption in the intestines, it works different than other statins. When you combine ZETIA with simvastatin to make VYTORIN, you get this dual mechanism that no other product has. So that's number one. The science is favoring VYTORIN and ZETIA.

184. In fact, the science was *not* favoring Vytorin and Zetia. Kelly's statements were false and misleading, because, among other things, Defendants were aware that:

(1) ENHANCE's results demonstrating no additional benefit from "dual inhibition" (Zetia's intestinal function and simvastatin's liver function) or from treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE's results proved that any benefits from taking Vytorin could be achieved by taking much cheaper generic simvastatin, or another statin, alone;

(3) Vytorin's promotional materials and sales scripts were "misleading" because claims of Vytorin's comparative superiority over single-action statins failed to disclose crucial material additional information that no proof existed to show Vytorin reduced arterial plaque, or the risk of major cardiovascular events in patients; and

(4) Vytorin provided no clinical benefits to cardiovascular health, and actually has a negative effect on arterial wall thickness, compared to statins alone.

185. Similarly, on October 22, 2007, Schering-Plough issued a press release announcing its financial results for the third quarter of 2007. Later that day, Schering-Plough held a conference call with securities analysts. During the scripted portion of the conference

call, Mr. Hassan continued falsely and misleadingly to highlight Vytorin's supposed benefits, while managing to say nothing about what ENHANCE had already told Defendants:

> **Hassan**: VYTORIN and ZETIA are the only major brands that have continued to grow their market share during the disruption that began in December '06 that was caused by multi-source generics. The lower is better story continues. Evolving medical science continues to find that reaching lower and lower goals for LDL is better for patients and VYTORIN and ZETIA provides very good options.

186. Mr. Hassan's October 22, 2007 statements were false and misleading, and willfully so, for the same reasons that Mr. Kelly's September 19, 2007, statements were false and misleading.

187. Even after the ENHANCE results were released in March 2008, Defendants continued their deceptive promotion and marketing. Ignoring the medical consensus reflected in statements from the American College of Cardiology, American Heart Association, and prominent cardiologists across the country, Defendants pressed ahead with deceptive marketing of Zetia and Vytorin. For example, a Schering-Plough spokesman said after the Spring 2008 ACC conference, "We feel that nothing's changed."

188. Neither the Vytorin nor the Zetia website initially contained any reference to the results of the ENHANCE study, even after its results were released. Eventually, by approximately April 2008, a link on each website entitled "Information About the ENHANCE Trial" was added. This linked to a series of press releases from Defendants, but the site itself featured no statement on the study, and no direct link to the study itself, or to independent parties' statements on the study. The Vytorin and Zetia websites linked (not from the front page) to "Statements from Select Independent Medical Societies on ENHANCE," which itself linked to no statement later than January 17, 2008. Even after the full ENHANCE results were presented, it did not link to the American Cardiology Conference's April 1, 2008 statement on

Vytorin, which stated 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." By the time of the filing of this complaint, even those mentions of the ENHANCE study, several levels into each website, had been removed from the Vytorin and Zetia websites.

189. In a two-page advertisement taken out in the January 20, 2008 *New York Times* and re-run on January 23, 2008, Defendants acknowledged but did not reveal the results of the ENHANCE study. 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.

190. On January 22, 2008, Merck and Schering-Plough finally announced that they were suspending television advertising for Vytorin and Zetia.

191. Defendant Schering-Plough's latest 10-K filing continues to make the same misleading claims about Vytorin's health benefits as the Zetia and Vytorin websites do. After noting that the ENHANCE trial showed that Vytorin had demonstrated effectiveness in lowering LDL levels, the company states,

> Medical experts and health advisory groups have long recognized high LDL cholesterol as a significant cardiovascular risk factor and recommended increasingly aggressive treatment of high cholesterol for certain patients. Lowering LDL cholesterol, along with a healthy diet and lifestyle changes, remains the cornerstone of lipid treatment for patients at risk for heart disease. Clinical studies have demonstrated that VYTORIN lowers patients' LDL cholesterol more than rosuvastatin, atorvastatin and simvastatin at the doses studied and was able to get more patients to their LDL cholesterol goals (as defined by ATP III).

192. Since the release of the ENHANCE trial results, prescriptions for Zetia and Vytorin have plummeted and continue to drop. Schering-Plough's most recent filing with the Securities and Exchange Commission, dated May 28, 2008, reports that prescriptions for Vytorin are down 23% since January 2008, and prescriptions for Zetia are down 22% since then.

193. One of the thousands of patients whose doctors stopped prescribing Vytorin after the ENHANCE trial results' release was Senator John McCain, whose internist told reporters that he had switched Senator McCain to simvastatin alone.

FRAUDULENT CONCEALMENT AND TOLLING OF STATUTES OF LIMITATIONS

194. Plaintiffs were not and could not have been aware of Defendants' misconduct before Defendants released the results of the ENHANCE study on January 14, 2008. Defendants concealed the nature of their representations and omissions concerning Zetia and Vytorin by implementing their scheme to suppress the results of the study – resulting in delay in release of the results until nearly two years after its conclusion. Because of these and other acts of concealment, Plaintiffs could not have discovered the scheme alleged herein in the exercise of reasonable diligence.

195. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and Class Members have been kept in ignorance of vital information essential to the pursuit of these clams, without

any fault or lack of diligence on their part. Plaintiffs and Class Members could not reasonably have discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendants are estopped from relying on any statute of limitations to defeat any of Plaintiffs' or the Classes' claims.

DEFENDANTS' MOTIVE AND FRAUDULENT INTENT

196. Defendants' motive in creating and operating the fraudulent scheme and RICO Enterprise described below was to exploit the cholesterol market for maximum profit and to obtain additional revenues from the marketing and sale of Zetia and Vytorin. The initial scheme was designed and implemented for the purpose of effectively extending the patent life of Zocor and to obtain billions of dollars from the sale of Zetia and Vytorin. Defendants' scheme to hide the results of the ENHANCE study was further rooted in calamitous legal, regulatory and economic challenges the two companies were facing.

Q. Merck's Legal And Regulatory Problems Motivated It To Hide ENHANCE's Results

197. In the spring of 2006, when ENHANCE was being completed, Merck was under scrutiny from the financial markets as a result of 10,000 personal injury lawsuits filed in the wake of disclosures of the dangers of Vioxx, another misleadingly promoted Merck drug.

198. Contemporaneously with the market scrutiny of the Vioxx problem, analysts were publicly concerned that Merck would lose a significant portion of its revenue stream when Zocor went off-patent in June 2006.

199. Merck and its joint venture partner, Schering-Plough, positioned Vytorin as the moneymaking substitute for Zocor once Merck lost exclusive primary patent protection for Zocor. Dr. Steven Nissen, the prominent Cleveland Clinic cardiologist said as much when the

FDA approved Vytorin: "Ezetimibe [Zetia] and Vytorin are just marketing tools, a way to evergreen the patent on Zocor."

200. Defendants made no secret of Vytorin's role as a financial replacement for Zocor. A July 24, 2004 *New York Times* article stated: "Merck said it planned to persuade doctors to switch patients to Vytorin before 2006, when generic competition starts in the United States for Zocor, the company's biggest drug."

201. In light of Vytorin's centrality to Merck's post-Zocor survival plans, and with Merck's Vioxx woes on front pages seemingly daily in 2006, Merck could not afford to disclose that ENHANCE had shown that Vytorin was no better than cheap generic statins such as simvastatin, and that it was more dangerous.

R. Schering-Plough's Financial Motive To Hide ENHANCE's Results

202. Zetia and Vytorin were also crucial to Schering-Plough's business. Schering-Plough's recent 10-K filing with the Securities and Exchange Commission, filed on March 3, 2008, stated, "Schering-Plough's ability to generate profits and operating cash flow is largely dependent upon the continued profitability of Schering-Plough's cholesterol franchise, consisting of VYTORIN and ZETIA."

203. During the ENHANCE study and its aftermath, Schering-Plough was under fierce competitive fire and under resulting severe financial pressure. Schering-Plough's $3 billion-per-year product, Claritin, had recently gone off-patent and was losing market share rapidly to generic versions of the drug. Schering-Plough itself lamented its "severe cash flow pressures" and emphasized the company's "urgent need to upgrade [its] infrastructure in many areas."

204. Schering-Plough's situation was dire enough that its Board of Directors hired turnaround specialist Fred Hassan as CEO to replace Mr. Kogen and put Mr. Hassan on the Board as Director on April 22, 2003.

205. A *Wall Street Journal* article, dated April 15, 2003, underscored the crucial importance of Zetia to Schering-Plough's viability in describing Mr. Hassan's move to Schering: "Mr. Hassan's success may depend on his ability to hawk Zetia."

206. Yet another article, from October 2003, clearly described Zetia's and Vytorin's make-or-break importance to Schering-Plough:

> The company's greatest hope for reviving earnings is new cholesterol drug Zetia and a pill containing Zetia and Merck & Co.'s Zocor. The partners later this year plan to ask U.S. regulators to approve the combination cholesterol drug.
>
> "Zetia and the Zetia/Zocor combination is the big savior. That could drive a lot of earnings growth for them," said [A.G. Edwards analyst Albert] Rauch, who projects $1 Billion in Zetia sales next year.

207. Still further confirmation of the Zetia/Vytorin salvation plan for Schering-Plough came from Mr. Hassan himself. Schering-Plough had no new "blockbuster" or even big-seller drugs in the offing to replace Claritin and other drugs that had lost patent protection and whose sales had evaporated. That made Zetia and Vytorin even more important to Schering-Plough's financial salvation. As Mr. Hassan said, Schering-Plough had "late-stage pipeline gap" as a result of its lack of blockbuster drugs ready to market.

S. Schering-Plough's Legal and Regulatory Woes Motivated It To Hide ENHANCE's Results

208. Numerous other non-economic factors motivated Schering-Plough to conceal the results of ENHANCE for as long as possible.

209. Schering-Plough was under legal siege in early 2003. The FDA had just fined Schering-Plough $500 million – a record – for Schering-Plough's substandard manufacturing practices. Further, the FDA compelled Schering-Plough to operate its plants under a consent decree that Schering-Plough itself called "unprecedented in the scope of remediation and

revalidation requirements." The SEC was investigating meetings Schering-Plough's former CEO, Richard Jay Kogen, had conducted with selected and apparently favored investors.

210. Schering-Plough was also facing charges of illegal drug promotion in 2006. The Department of Justice, through the U.S. Attorney for the District of Massachusetts, filed a Criminal Information ("Information") dated August 29, 2006, against Schering Sales Corporation ("SSC"). SSC was a wholly-owned subsidiary of Schering Corporation, itself a wholly-owned subsidiary of Schering-Plough Corporation.

211. The Information charged that SSC conspired to make false statements to government agencies.

212. First, the Information charged that SSC conspired to make false statements to the Health Care Finance Administration concerning the best price for certain medications, resulting in the non-payment of approximately $4,392,000 in rebates owed to state Medicaid programs.

213. Second, according to the Information, SSC conspired to make false statements to the FDA to avoid FDA scrutiny of SSC's far-reaching and illegal scheme of off-label promotion of two cancer drugs, Temodar and Intron-A. These drugs had very limited markets. Rather than perform the necessary time-consuming and expensive clinical trials to demonstrate the safety and efficacy of these two drugs for other indications, as required under FDA regulations, SSC took an illegal shortcut. It simply promoted the drugs to doctors for uses other than those for which it had been approved by the FDA, all the while knowing that no required clinical studies supported the claims that Temodar and Intron-A were efficacious and safe for those additional uses. The Information charged that this illegal promotion generated some $124,179,000 in pre-tax profits for SSC.

214. On August 25, 2006, four days *before* the date of the Information, SSC entered a Plea Agreement with the United States. Under that Agreement, it "expressly and unequivocally admits that it knowingly, intentionally and willfully committed" the charged crime: "that, from in or about April 1998 through August, 2001, Schering Sales violated 18 U.S.C. § 371 by conspiring with others to knowingly and willfully make false statements to the government, to wit (a) to the Health Care Financing Administration ('HCFA') regarding the best price for Claritin Redi-Tabs, and (b) to the Food and Drug Administration ('FDA') to avoid scrutiny of its off-label marketing of Temodar and Intron-A."

215. In pleading guilty, SSC agreed, and was sentenced, to pay, a criminal fine of $180,000,000. In addition, SSC and Schering-Plough agreed to pay $255,025,089.60 plus interest to settle civil claims for violation of the False Claims Act.

216. Schering-Plough faced, and vigorously opposed, the threat, in connection with the sentencing, of an enormous restitution order requiring Schering-Plough to compensate numerous TPPs who had been duped into paying for off-label prescriptions.

217. At SSC's sentencing hearing, the Court severely reprimanded SSC and lamented the difficulty of ordering restitution to TPPs, saying, among other things:

> In fact, it's been upsetting to me how many of the big pharmaceutical companies have engaged in what I view as clearly illegal behavior in terms of off-label marketing . . . [I]t is against the law to market if it's not an FDA-approved indication. I do not accept that there is a First Amendment right to market something that does not get FDA approval . . . (Transcript of Sentencing Hearing, Jan. 17, 2007, Exhibit E at 20)
>
> [I]f it's ever been unclear, to Schering or anyone else, you cannot market for indications that the FDA has not approved or has rejected. It can't happen. And I saw . . . it here. I mean, the enormous frustration I have felt having seen so much of this is, once it ends up in the civil fraud arena, all the issues that I tried to work through in the restitution come to the front. And how do you prove the nexus? How do you prove that it's based on the fraudulent marketing? And I think the pharmaceutical companies take advantage of this. They know, just based on aggregate marketing data, that they bump up or boost up the sales. But in a civil

> case, it can take you five years to unravel this stuff; and if I could have found an appropriate vehicle to have ordered restitution to the third-party payors, I would have done it. (Exhibit E at 21)
>
> . . . Yes, why buy the cow when you can get the milk for free? And that's even much better put. So, the question is, you can't thumb your nose at the FDA. Maybe it's too slow sometimes. Maybe it's in some ways not aggressive enough in enforcing its own rules sometimes, but at the end of the day, you can't market off-label. So I don't know how further to send this message . . .but it's wrong. And I think that this is a stiff fine and an appropriate civil settlement. (Exhibit E at 22)

218. As the Court's statements at the January 17, 2007 criminal sentencing hearing demonstrate, Schering-Plough, like Merck, was already subject in 2006 to bad publicity and legal tribulations arising out of its marketing and promotional practices.

219. Schering-Plough, like Merck, had every reason in 2006 not to disclose the results of ENHANCE, which directly contradicted Defendants' public claims of Vytorin's purported superiority over other cholesterol drugs. As a result, Schering-Plough, like Merck, actively concealed the truth that Vytorin was not only more expensive but also less efficacious and less safe than the much cheaper, safer generic statins alone, all the while saying just the opposite in marketing to consumers, doctors, PBMs and TPPs.

220. Defendants' fraudulent and misleading statements, by omission and commission, were designed to, and did, cause consumers and TPPs to pay for Zetia and Vytorin prescriptions for cholesterol management when safer and effective treatments were available.

221. Absent Defendants' false and misleading statements and conduct, Plaintiffs and those similarly situated to them would not have paid for such Zetia and Vytorin prescriptions.

USE OF THE MAILS AND WIRES

222. During the Class Period, Defendants used thousands of mail and interstate wire communications to create, execute, and manage their fraudulent scheme, as described above. Defendants' fraudulent scheme involved the active suppression of the results of the ENHANCE

study for a period of almost two years, and national marketing and sales plans and programs, and the scheme encompassed physicians and victims across the country.

223. Defendants' use of the mails and wires to execute their fraud involved Defendants' dissemination of thousands of communications throughout the Class period, via email, telephone, television, magazines, and other print media sent through the U.S. mails and over the Internet, including communications concerning the fraudulent suppression of the ENHANCE results, marketing and advertising materials touting the effectiveness of Zetia and Vytorin that were sent to physicians and media outlets throughout the country, as well as communications with health insurers and patients, including Plaintiffs and the Classes, inducing payments for Zetia and Vytorin to be made in reliance on misrepresentations concerning the safety and effectiveness of Zetia and Vytorin.

224. In addition, employees of Defendants have communicated by United States mail, telephone, and facsimile with numerous physicians and consumers across the country in furtherance of Defendants' scheme.

CONSPIRACY AND CONCERT OF ACTION

225. 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, without limitation, to suppress 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.

CLASS ACTION ALLEGATIONS

226. Under Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs bring this action on behalf of themselves and a Class defined as:

> All individuals and entities in the United States and its territories (other than state governmental entities) who, for purposes other than resale, purchased, reimbursed and/or paid for Vytorin or Zetia, during the period from August 1, 2004, through the date of the class certification order (the "Class Period"). For purposes of the Class definition, individuals and entities "purchased" Vytorin or Zetia if they paid made a non-flat co-payment for some or all of the purchase price.

227. Excluded from the Class are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from the Class are any judge or justice to whom this action is assigned, together with any relative of such judge or justice within the third degree of relationship, and the spouse of any such person.

228. The individual consumer Plaintiffs bring this action on behalf of themselves and a Consumer Subclass, defined as:

> All individuals persons in the United States and its territories who, for purposes other than resale, purchased, and/or paid for Vytorin or Zetia during the period from August 1, 2004, through the date of entry of the class certification order (the "Class Period"). For purposes of the SubClass definition, individuals "purchased" Vytorin or Zetia if they paid or made a non-flat copayment pursuant to the terms of a health insurance plan for some or all of the purchase price.

229. Excluded from the Consumer Subclass are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from the Consumer Subclass are any judicial officers to whom this action is assigned, together with any relative of such judicial officers within the third degree of relationship, and the spouse of any such person.

230. The TPP Plaintiffs bring this action on behalf of a Third Party Payor Subclass, defined as:

> All entities in the United States and its territories (other than state governmental entitles) that, for purposes other than resale, purchased, reimbursed and/or paid for all or part of the cost of Vytorin or Zetia from August 1, 2004, through the date of entry of the class certification order (the "Class Period"). Such entities include, but are not limited to, insurance companies, union health and welfare benefit plans, entities with self-funded plans and private entities paid by any governmental entity (including a state Medicaid program) to provide prescription drug benefits on a capitated basis.

231. Excluded from the Third Party Payor Subclass are (a) Defendants and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors, and (b) any co-conspirators. Also excluded from the Third Party Payor Subclass are any judicial officers to whom this action is assigned, together with any relative of such judicial officers within the third degree of relationship, and the spouse of any such person.

232. The Class and its Subclasses consists of large numbers of individuals and entities in the United States, making individual joinder impractical, as required by Rule 23(a)(1). The disposition of the claims of the members of the Class and its Subclasses in a single class action will provide substantial benefits to all parties and to the Court.

233. The claims of the representative Plaintiffs are typical of the claims of the Class and Subclasses they seek to represent, as required by Rule 23(a)(3), in that the representative Plaintiffs are persons or entities who, like all members of the Class and Subclasses, purchased, reimbursed, and/or paid or co-paid for Zetia or Vytorin. Such representative Plaintiffs, like all members of the Class and Subclasses, have been damaged by Defendants' misconduct, in that, among other things, they paid for Zetia or Vytorin as Defendants misrepresented the safety and efficacy of Zetia or Vytorin relative to the use of statins alone.

234. The factual and legal bases of Defendants' misconduct are common to all members of the Class and Subclasses and represent a unifying and common plan of fraud and other misconduct resulting in injury to Plaintiffs and all members of the Class and Subclasses.

235. Numerous questions of law and fact exist that are common to Plaintiffs and the Class and Subclasses. Those common questions predominate over any questions that may affect individual members of the Class and Subclasses, within the meaning of Rule 23(a)(2) and 23(b)(3). Common questions of law and fact include, but are not limited to, the following:

a. Whether Defendants concealed material information from Plaintiff, members of the Class and Subclasses, physicians, and the general public concerning the efficacy and safety of Zetia and Vytorin, including without limitation the results of the ENHANCE study;

b. Whether Defendants concealed material information from Plaintiff, members of the Class and Subclasses, physicians, and the general public as part of a centrally orchestrated scheme of deception;

c. Whether Defendants engaged in a fraudulent and/or deceptive scheme of marketing and selling Zetia and Vytorin for treating high cholesterol and associated risk factors for heart attacks, such as atherosclerosis;

d. Whether it was the policy and practice of Defendants to prepare, fund, and publish materials which contained false information and misrepresentations regarding the safety and efficacy of Zetia and Vytorin;

e. Whether Defendants are liable to members of the Class and Subclasses for damages for conduct actionable under the RICO statute;

f. Whether Defendants are liable to the members of the Class and Subclasses for damages for conduct actionable under the New Jersey Consumer Fraud Act or other applicable state laws;

g. Whether Defendants unjustly enriched themselves at the expense of the members of the Class and Subclasses;

h. Whether Defendants engaged in a pattern or practice that directly caused Plaintiffs and members of the Class and Subclasses to pay for Zetia and Vytorin prescriptions that were ineffective relative to other, cheaper alternatives;

i. Whether members of the Class and Subclasses are entitled to compensatory damages and, if so, the nature and extent of such damages;

j. Whether members of the Class and Subclasses are entitled to punitive damages and if so, the extent of such damages.

236. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class and Subclasses, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience in the prosecution of nationwide class actions. Plaintiffs and their counsel are committed to the vigorous prosecution of this action on behalf of the Class and its Subclasses and have the financial resources to do so. Neither Plaintiffs nor counsel have any interests adverse to those of the Class or its Subclasses.

237. Plaintiffs and members of the Class and Subclasses have suffered, and will continue to suffer, economic harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy under Rule 23(b)(3). Absent a class action, most members of the Class and its Subclasses likely would find the cost of litigating their claims to be prohibitive, and

would thus have no effective access to the courts or remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication.

238. Plaintiffs seek the certification of a nationwide Class and Subclasses on the civil RICO counts, asserted for violations of 18 U.S.C. §§ 1962(c) and 1962(d) in this Complaint. Plaintiffs additionally seek the nationwide certification, under New Jersey law, of the THIRD COUNT (for violations of the New Jersey Consumer Fraud Act) and the NINTH COUNT (for unjust enrichment). To the extent this Court determines not to certify a nationwide class, under New Jersey law, on one or both of these claims, Plaintiffs seek the statewide certification of the claims asserted in the THIRD through NINTH COUNTS of this Complaint, for consumers and TPPs who are citizens of these respective states. Plaintiffs allege that nationwide class certification, under a single state's law, is superior to all other available methods for the fair and efficient adjudication of this action; and that, in the absence of such nationwide class certification, statewide class certification, as requested herein, is superior to the individualized litigation of such claims, and will enable this Court to adjudicate exemplar states' claims, in an MDL classwide trial, that will inform and instruct the parties and the courts with respect to the remaining claims, and facilitate their just, speedy, and inexpensive adjudication or resolution.

239. This case presents common issues of fact and law that are appropriate for issue-class certification under Rule 23(c)(4); and the management of this action may be facilitated through the certification of additional subclasses under Rule 23(c)(5), if necessary and appropriate.

FIRST COUNT

VIOLATION OF 18 U.S.C. § 1962(C)
(AGAINST ALL DEFENDANTS)
(ON BEHALF OF ALL PLAINTIFFS)

240. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege, against Defendants Merck and Schering-Plough, or, alternatively, against all Defendants, as follows:

241. Defendants are "persons" within the meaning of 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).

242. This Complaint alleges, in the alternative, two enterprises within the meaning of 18 U.S.C. § 1961(4).

243. First, there is MSP as an "enterprise" within the meaning of RICO. MSP is a joint partnership formed, controlled, and conducted by Defendants Merck and Schering-Plough. Defendants Merck and Schering-Plough are named as defendants for purposes of this first enterprise.

244. Defendants Merck and Schering-Plough created and used MSP as a separate entity and tool to effectuate their pattern of racketeering activity.

245. Second, in the alternative, there is the association-in-fact of all three Defendants for the purposes of developing, marketing, and selling Vytorin and Zetia as an "enterprise" within the meaning of RICO (the "Association-in-Fact Enterprise"). The Associatin-in-Fact Enterprise was created, controlled and conducted by all three Defendants to develop, market and sell Zetia and Vytorin. All three Defendants are defendants for purposes of this second RICO enterprise.

246. Defendants Merck, Schering-Plough and MSP created and used the Vytorin/Zetia Marketing Enterprise as a separate entity and tool to effectuate their pattern of racketeering activity.

247. Each Enterprise is an ongoing organization that functions as a continuing unit. Hereafter in this Complaint, both enterprises are referred to as the "Enterprises".

248. As is set forth in detail above, the Enterprises engaged in and affected interstate commerce, because, *inter alia*, they marketed, sold, and provided Zetia and Vytorin to thousands of individuals throughout the United States.

249. Defendants Merck and Schering-Plough have exerted ongoing and continuous control over MSP, and they have participated in the operation or management of the affairs of MSP, through the following actions:

a. Defendants Merck and Schering-Plough have asserted direct control over the information and content disseminated to Plaintiffs, members of the Classes, and physicians regarding the efficacy of Zetia and Vytorin;

b. Defendants Merck and Schering-Plough have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Plaintiffs, Class Members, and physicians throughout the United States; and

c. Defendants Merck and Schering-Plough have placed their own employees and agents in positions of authority and control in MSP.

250. Alternatively, all Defendants have exerted ongoing and continuous control over the Association-In-Fact Enterprise, and they have participated in the operation or management of the affairs of the Association-In-Fact Enterprise, through the following actions:

a. Defendants have asserted direct control over the information and content disseminated to Plaintiffs, members of the Classes, and physicians regarding the efficacy of Zetia and Vytorin;

b. Defendants have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Plaintiffs, Class Members, and physicians throughout the United States; and

c. Defendants have placed their own employees and agents in positions of authority and control in the Association-In-Fact Enterprise.

251. 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:

a. Defendants fraudulently promoted Zetia and Vytorin throughout the November 1, 2002-present Class Period, 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.

b. Notwithstanding their knowledge of the ENHANCE study's results in April 2006, Defendants delayed the release of this study until January 14, 2008, while con-

tinuing 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.

c. 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.

d. 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.

e. 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 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."

f. In a two-page advertisement taken out in the January 20, 2008 *New York Times* and re-run on 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 or 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.

252. In implementing their fraudulent scheme, Defendants were aware that Plaintiffs and Class Members depended on the Defendants' honesty in representing the safety and medical efficacy of Zetia and Vytorin.

253. 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 Plaintiffs, Class 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 of the ENHANCE study were concealed, suppressed, or omitted from such materials.

254. The unlawful predicate acts of racketeering activity committed by Defendants throughout the Class Period (from August 1, 2004 through the present) number in the thousands, had a common purpose, were related, had continuity throughout, and continue to the present. During the Class Period, 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 throughout the Class Period, 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 during the Class Period.

255. Defendants further used mail and interstate wire communications to suppress the results of the ENHANCE study. Defendants used interstate wire communications to

communicate with Dr. Kastelein 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 Dr. Bots 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, the events referenced in paragraphs 75-86 and 95-115 above.

256. 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 in, *inter alia*, paragraphs 9, 11, 40, 51, 72-115, 137-138, 189 and 251 of this Complaint, 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 throughout the class period, 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.

257. 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 payers, 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 <u>different</u> 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.

258. 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 prescriptions 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 simvastatin, 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.

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

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

261. Each of Defendants' fraudulent mailings 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).

262. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiffs and the Classes.

263. The above described racketeering activities amounted to a common course of conduct intended to deceive Plaintiffs and the Class and Subclasses. Defendants' criminal acts of racketeering had the same pattern and similar purpose of defrauding Plaintiffs and the Classes. 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 Plaintiffs and the members of the Classes. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiffs and Class Members.

264. 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.

265. Plaintiffs and members of the Class and Subclasses have been injured in their business and property by reason of these violations in that they have made billions of dollars in payments for Zetia and Vytorin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

266. Plaintiffs' and members of the Classes' and Subclass' injuries to their business and property were directly and proximately caused by Defendants' racketeering activity as described above.

267. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs and the members of the Class and Subclasses for three times the

damages Plaintiffs and Class and Subclass Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

SECOND COUNT

VIOLATION OF 18 U.S.C. § 1962(d)
BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c)
(AGAINST ALL DEFENDANTS)
(ON BEHALF OF ALL PLAINTIFFS)

268. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege, against Defendants Merck and Schering-Plough or, alternatively, against all Defendants:

269. 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."

270. 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 previously in Count I, 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 knew that these acts were part of a pattern of racketeering activity.

271. 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 Plaintiffs and the Classes of money.

272. 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.

273. 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), Plaintiffs and Class Members have been and are continuing to be injured in their business or property as set forth more fully above.

THIRD COUNT

VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT, N.J.S.A. 56:8-1 ET SEQ. (AGAINST ALL DEFENDANTS) (ON BEHALF OF ALL PLAINTIFFS)

274. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege, against all Defendants:

275. This claim is asserted by Plaintiffs on their own behalf and on behalf of all other similarly situated members of the Class against all Defendants.

276. The actions and failures to act of Defendants in suppressing the results of the ENHANCE study, including the false and misleading representations, concealment, and omissions of material facts regarding the safety and efficacy of Zetia and Vytorin, and the above described course of fraudulent conduct and fraudulent concealment, constitute acts, uses, or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts regarding the efficacy, value, standard, characteristics, and benefits of Zetia and Vytorin,

with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*

277. The unlawful acts and practices of Defendants have directly, foreseeably, and proximately caused or will cause damages and injury to Plaintiffs and the members of the Class.

278. As a direct and proximate result of Defendants' wrongful conduct, all Plaintiffs, Class, and Subclass Members are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit under the New Jersey Consumer Fraud Act.

FOURTH COUNT

VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW
(BY THE CALIFORNIA SUBCLASSES)
(AGAINST ALL DEFENDANTS)

279. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein. This Count is pleaded in the alternative, in the event the Court does not agree that New Jersey law applies to a nationwide class.

280. This claim is brought by TPP plaintiff GEHA and consumer plaintiffs Helen Aronis, Kenneth Bever, and Glenda Morgan (collectively, the "California Subclass Representatives") on behalf of the California Third Party Payor Subclass and the California Consumer Subclass (collectively, the "California Subclasses"), respectively.

281. By failing to timely release the results of the ENHANCE trial, and by continuing to conceal these results, which demonstrate that Zetia does not reduce or slow the buildup of arterial plaque, while marketing and selling these drugs to California citizens, Defendants committed unfair and deceptive business acts or practices in violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.*, causing the California Subclass Representatives and California Subclasses to suffer injury in fact by expending 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.

282. Defendants' violations of the California Consumer Legal Remedies Act, as set forth in the Fifth Count of this Complaint, constitute unlawful business practices in violation of California's Unfair Competition Law.

283. Defendants acquired tens or hundreds of millions of dollars in revenue from the sales of Zetia and Vytorin to the California Subclasses as a result of these violations. Pursuant to Cal. Bus. & Prof. Code § 17203, the California Subclass Representatives and California Subclasses seek disgorgement by Defendants of this revenue; and restitution of the amounts they paid for Zetia and Vytorin during the Class Period.

FIFTH COUNT

VIOLATION OF CALIFORNIA CONSUMER LEGAL REMEDIES ACT (BY THE CALIFORNIA SUBCLASSES AGAINST ALL DEFENDANTS)

284. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein. This Count is pleaded in the alternative, in the event the Court does not agree that New Jersey law applies to a nationwide class.

285. The California Subclass Representatives assert this claim for violations of the California Legal Remedies Act, Cal. Civ. Code § 1750, *et seq*. (the "CLRA"), which declares unlawful "[r]epresenting that goods . . . have sponsorship, approval, characteristics, . . . uses, [or] benefits . . . that they do not have," on behalf of the California Consumer Subclass.

286. Defendants engaged in unfair, deceptive, and unlawful acts or practices in violation of the CLRA by, *inter alia*, (a) withholding the results of the ENHANCE study for almost two years; (b) thereby deliberately misrepresenting the efficacy of Zetia and Vytorin

relative to the use of statins alone; and and (c) actively concealing, and causing others to conceal, information about the true safety and efficacy of Vytorin or Zetia.

287. The members of the California Subclasses suffered actual damages as a direct and proximate result of Defendants' violations of the CLRA.

288. On January 29, 2008, Plaintiff Claudia Edwards, who subsequently filed a CLRA action that is a component of these MDL proceedings, served the pre-filing notice required by Cal. Civ. Code § 1782(a) by certified mail, return receipt requested, demanding that Defendants refund to all California consumers and/or their respective insurers all amounts paid for Vytorin, or Zetia prescribed in conjunction with a statin, since April 1, 2006. On February 8, 2008, counsel for all Defendants responded that Defendants would not comply with the demands set forth in the notice.

289. For Defendants' violations of the CLRA the California Consumer Subclasses seek actual damages and punitive damages.

290. The members of the California Consumer Subclass who are over 65 years of age have suffered substantial economic damage resulting from Defendants' violations of the CLRA, and seek the additional damages awardable to senior citizens pursuant to Cal. Civ. Code § 1780(b). Defendants knew or should have known that their misconduct would cause one or more such persons to suffer damage, as Zetia and Vytorin were heavily marketed and promoted to, and prescribed for, the senior citizen patient population.

SIXTH COUNT

VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT
(BY THE FLORIDA SUBCLASSES)
(AGAINST ALL DEFENDANTS)

291. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein. This cause of action is pleaded in the alternative, in the event the Court does not agree that New Jersey law applies to a nationwide class.

292. Plaintiffs Roy Cosgrove and Charles Miller assert this claim for violations of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et. seq*., (the "FDUTPA") on behalf of themselves and on behalf of the Florida Consumer Subclass. Plaintiff GEHA asserts this claim on behalf of itself and the Florida TPP Subclass. The Florida Consumer Subclass and Florida TPP Subclass are hereinafter referred to collectively as the "Florida Subclasses."

293. Plaintiffs Cosgrove, Miller, and GEHA, and members of the Florida Subclasses are consumers within the meaning of the FDUTPA. Fla. Stat. § 501.203(7).

294. The FDUTPA declares unlawful "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practice of any trade or commerce." Fla. Stat. § 501.204(1).

295. Defendants engaged in unfair, deceptive, and unconscionable acts or practices in violation of the FDUTPA by, *inter alia*, (a) withholding the results of the ENHANCE study for almost two years; (b) thereby deliberately misrepresenting the efficacy of Zetia and Vytorin relative to the use of statins alone; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Vytorin or Zetia.

296. Defendants' actions and failures to act, including the false and misleading representations, concealment, and omissions of material facts regarding the safety and efficacy of Zetia and Vytorin, the above described course of fraudulent conduct and fraudulent concealment,

the concealment, suppression or omission of material facts regarding the efficacy, value, standard, characteristics, and benefits of Zetia and Vytorin constituted an unconscionable course of action within the meaning of FDUTPA, Fla. Stat. § 501.204(1).

297. The false, misleading, and deceptive acts and practices and unconscionable course of action of Defendants were a producing cause of damages and injury to Plaintiffs and the members of the Florida Subclasses. Plaintiffs and members of the Florida Subclasses suffered economic damages by making purchases of Vytorin and Zetia that Plaintiff and members of the Florida Subclasses would not have made absent Defendants' violations of the FDUTPA.

298. Plaintiffs and the members of the Florida Subclasses are entitled to actual damages, attorneys' fees and costs of suit, and any other relief that the Court deems proper.

SEVENTH COUNT

VIOLATION OF TEXAS DECEPTIVE TRADE PRACTICES ACT
(BY THE TEXAS SUBCLASSES)
(AGAINST ALL DEFENDANTS)

299. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein. This Count is pleaded in the alternative, in the event the Court does not agree that New Jersey law applies to a nationwide class.

300. Plaintiffs Robert Love and Donald Varino assert this claim for violations of the Texas Deceptive Trade Practices Act ("DTPA") on behalf of themselves and on behalf of the Texas Consumer Subclass. Plaintiff GEHA and FPSA asserts this claim on behalf of themselves and on behalf of the Texas TPP Subclass. The Texas Consumer Subclass and the Texas TPP Subclass are hereinafter referred to collectively as the "Texas Subclasses."

301. Plaintiffs and members of the Texas Subclasses are consumers within the meaning of the DTPA. Tex. Bus. Com. Cd. § 17.45(4).

302. On January 22, 2008, Plaintiffs served the notice required by Tex. Bus. Com. Cd. § 17.505 by certified or registered mail, return receipt requested, addressed to Defendants' principal places of business within Texas, advising Defendants of Plaintiff's specific complaint. As of the date of the filing of this Complaint, Plaintiff has not received the amount of economic damages claimed or expenses incurred in asserting the claim against Defendants contemplated by Tex. Bus. Cd. § 17.506(d).

303. Defendants engaged in false, misleading, and deceptive acts or practices declared unlawful by the DTPA by, *inter alia*, (a) withholding the results of the ENHANCE study for almost two years; (b) thereby deliberately misrepresenting the efficacy of Zetia and Vytorin relative to the use of statins alone; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Vytorin or Zetia.

304. Defendants' actions and failures to act, including the false and misleading representations, concealment, and omissions of material facts regarding the safety and efficacy of Zetia and Vytorin, the above described course of fraudulent conduct and fraudulent concealment, the concealment, suppression or omission of material facts regarding the efficacy, value, standard, characteristics, and benefits of Zetia and Vytorin constituted an unconscionable course of action within the meaning of the DTPA, Tex. Com. Bus. Cd. § 17.50(a)(3).

305. The false, misleading, and deceptive acts and practices and unconscionable course of action of Defendants were a producing cause of damages and injury to Plaintiffs and the members of the Texas Subclasses. Plaintiffs and members of the Texas Subclasses suffered economic damages by making purchases of Vytorin and Zetia that Plaintiff and members of the Texas Subclasses would not have made absent Defendants' violations of the DTPA.

306. Plaintiffs and the members of the Texas Subclasses are entitled to actual damages, attorneys' fees and costs of suit, and any other relief that the Court deems proper.

EIGHTH COUNT

VIOLATION OF MASSACHUSETTS GENERAL LAWS CHAPTER 93A (BY THE MASSACHUSETTS SUBCLASSES) (AGAINST ALL DEFENDANTS)

307. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein. This Count is pleaded in the alternative, in the event the Court does not agree that New Jersey law applies to a nationwide class.

308. Plaintiffs Local 537 and Teamsters assert this claim on behalf of the Massachusetts TPP Subclass.

309. At all relevant times, Defendants were engaged in trade and/or commerce.

310. Pursuant to Chapter 93A, Defendants have a statutory duty to refrain from unfair or deceptive acts or practices in the promotion and sale of its prescription drug products. *See* G.L. c. 93A. Defendants have failed to refrain from such conduct, and engaged in unfair and deceptive conduct in connection with the promotion and sale of Vytorin and Zetia.

311. Defendants have engaged in unfair or deceptive acts or practices declared in violation of the Massachusetts Consumer Protection Act, Mass. Gen. L. Ch. 93A, *et seq.* These unfair or deceptive acts include, but are not limited to: (a) withholding the results of the ENHANCE study for almost two years; (b) thereby deliberately misrepresenting the efficacy of Zetia and Vytorin relative to the use of statins alone; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Vytorin or Zetia.

312. The actions and failures to act of Defendants, including the false and misleading representations, concealment, and omissions of material facts regarding the safety and efficacy of Zetia and Vytorin, and the above described course of fraudulent conduct and fraudulent

concealment, constitute unfair or deceptive practices, in violation of Massachusetts General Laws Chapter 93A.

313. As a result of Defendants' unrair and deceptive acts and practices, Plaintiffs Local 537 and Teamsters sustained injuries, including paying for Vytorin and Zetia prescriptions they would not otherwise have purchased. These injuries to Plaintiffs Local 537 and Teamsters are a forseeable consequence of Defendants' unlawful scheme. Defendants' use of these unfair and deceptive acts and practices have directly, foreseeably, and proximately caused, and continues to cause damages and injury to Plaintiffs and the members of the Subclass.

314. Defendants' use of these unfair and deceptive acts and practices were a direct and proximate cause of Plaintiffs' injuries, and all Plaintiffs, Class and Subclass Members are entitled to actual damages, treble damages, attorney's fees and costs of suit.

NINTH COUNT

UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

315. Plaintiffs incorporate by reference the previous allegations as if they were set fully set forth herein.

316. This claim is asserted by Plaintiffs on their own behalf and on behalf of all other similarly situated members of the Class and its Subclasses against Defendants.

317. As the intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments Plaintiffs and Class Members made for Zetia and Vytorin.

318. In exchange for the payments they made for Zetia and Vytorin, and at the time they made these payments, Plaintiffs and the Classes expected that the drug was a safe and

medically effective treatment for the condition, illness, disease, disorder, or symptom for which it was prescribed.

319. Defendants have voluntarily accepted and retained these payments, with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and the Classes paid for Zetia and Vytorin when they otherwise would not have done so. By its improper and wrongful conduct described herein, Defendants were unjustly enriched at the expense of Plaintiffs and the members of the Classes.

320. It would be inequitable for Defendants to retain the profits, benefits, and other compensation it obtained through its wrongful acts. Plaintiffs and the Classes are 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.

WHEREFORE, Plaintiffs and members of the Class and its Subclasses demand judgment against Defendants in each claim for relief, jointly and severally, as follows:

1. On the RICO claims, three times the damages Plaintiffs and members of the Class and its Subclasses have sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

2. On the New Jersey Consumer Fraud Act claim, refunds pursuant to N.J.S.A. 56:8-2.12, compensatory damages, three times the damages Plaintiffs and members of the Class and its Subclasses have sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

3. On claims arising under the consumer protection laws of States specified in the Complaint (as an alternative to certification of a nationwide class under the New Jersey Consu-

mer Fraud Act), all measures of damages allowable under such statutes, such amount to be determined at trial, plus Plaintiffs' and the Class members' costs in this suit, including attorneys' fees;

4. On the claim for unjust enrichment, recovery in the amount of payments by Plaintiffs members of the Class and its Subclasses for Zetia and Vytorin, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including all reasonable attorneys' fees;

5. Awarding Plaintiffs and members of the Class and Subclasses other appropriate equitable relief;

6. Awarding Plaintiffs and members of the Class and Subclasses their costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

7. Awarding Plaintiffs and members of the Class and Subclasses such other and further relief as may be just and proper under the circumstances.

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
Co-Liaison Counsel for Plaintffs and Member of
Executive Committee of Plaintiffs' Steering
Committee

By: /s/James E. Cecchi
JAMES E. CECCHI

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By: /s/ Stephen A. Weiss
STEPHEN A. WEISS

Dated: September 25, 2008

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DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all claims and issues so triable.

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