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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GENESEE COUNTY EMPLOYEES' RETIREMENT SYSTEM, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. MERCK & CO., INC. and RICHARD T. CLARK, Defendants.	Civil Action No.: 2:08cv2177 (DMC) (MF)
MAYER HORWITZ and PHILIPPE HOFMANS, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. MERCK & CO., INC. and RICHARD T. CLARK, Defendants.	Civil Action No.: 2:08cv2260 (DMC) (MF)

CONSOLIDATED CLASS ACTION COMPLAINT
FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

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Stichting Pensioenfonds ABP ("ABP"), International Fund Management, S.A. (Luxemburg) ("IFM"), Deka International (Ireland) Limited ("Deka Ireland"), the Jacksonville Police and Fire Retirement System ("Jacksonville") and the General Retirement System of the City of Detroit ("Detroit") (collectively referred to as "Lead Plaintiffs" or the "Plaintiffs"), individually and on behalf of all other persons and entities who purchased or otherwise acquired securities issued by Merck & Co., Inc. ("Merck" or the "Company"), between May 1, 2006 and March 28, 2008, inclusive (the "Class Period"), by their undersigned attorneys, bring this action against Merck, Merck/Schering-Plough Pharmaceuticals Company, LLC ("M/S-P"), Richard T. Clark, Peter S. Kim, Judy C. Lewent, Deepak Khanna, and Wendy L. Yarno (collectively, "Defendants"). The allegations against Defendants are based on personal knowledge as to Lead Plaintiffs' own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of their counsel ("Lead Counsel"), which included, among other things: (i) review and analysis of Merck's public filings with the U.S. Securities and Exchange Commission ("SEC"); (ii) review and analysis of medical journals and other publicly-available materials concerning a clinical trial entitled "Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression," more commonly known as "ENHANCE"; (iii) review and analysis of other publicly-available information concerning Merck, including documents uncovered by ongoing investigations of Merck and Schering-Plough Corporation ("Schering-Plough" or "S-P") by the United States Senate Committee on Finance (the "Senate Finance Committee") and the United States House of Representatives Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations (the "House Oversight Subcommittee") into the delayed release of the ENHANCE results; (iv) interviews with former Merck and Schering-Plough employees and

other persons with knowledge of the matters alleged herein, some of whom have provided information in confidence (these confidential witnesses ("CWs") will be identified herein by number (CW 1, CW 2, etc.)); and (v) analyses of Merck executives' trading in Merck securities. Lead Plaintiffs believe that substantial additional evidentiary support will exist for their allegations after a reasonable opportunity for discovery. For their Consolidated Class Action Complaint (the "Complaint"), Lead Plaintiffs allege the following:

I. NATURE OF THE ACTION AND SUMMARY OF ALLEGATIONS

1. This is a federal securities class action brought on behalf of all persons and entities who purchased or otherwise acquired Merck securities during the Class Period, asserting claims under the Securities Exchange Act of 1934 (the "Exchange Act").

2. This action alleges that Defendants concealed material information and made false and misleading statements relating to Merck's multi-billion dollar blockbuster drugs Vytorin and Zetia, which had the effect of artificially inflating the price of Merck securities during the Class Period. In particular, Merck improperly withheld the results of the ENHANCE clinical trial, which showed that patients taking Vytorin (a drug combining Zocor (simvastatin) and Zetia (ezetimibe)), failed to show any improvement in the progression of atherosclerosis over patients taking Zocor (simvastatin), a drug that sells for a fraction of the price.

3. Researchers for the ENHANCE trial began enrolling patients in 2004 and while the trial was underway (but prior to its completion in April 2006) Merck touted the importance of ENHANCE to investors. In Merck's own words, ENHANCE was a "major," "large-scale" trial, and Merck expected data derived from ENHANCE "to drive future growth" by "demonstrate[ing] additional benefits of Vytorin." By December of 2005, however, ENHANCE largely disappeared from Merck's public statements and presentations concerning Vytorin. Investors would learn only years later why this was so: ENHANCE was an abject failure

because its data showed Vytorin to be no better than generic simvastatin (i.e., Zocor) at improving cardiovascular health. This called into serious question Vytorin's and Zetia's continued blockbuster sales to patients, doctors and managed care organizations. Thus, when ENHANCE was completed in April 2006, Merck, along with its marketing and joint venture partner Schering-Plough, failed to disclose the results of the study. Merck tried in vain to mine or recast the data in a positive light with the end result that the ENHANCE findings were not disclosed to investors until nearly two years later, and only after articles in the financial press and Congressional inquiries called Merck and Schering-Plough to task by questioning the legitimacy of the long delay and criticizing the companies' motives.

4. By the time Merck released the preliminary "top line" results of ENHANCE in January 2008, amid public pressure, Vytorin and Zetia had contributed hundreds of millions of dollars to Merck's profits each quarter, and had resulted in massive quarterly growth in Merck's cholesterol franchise. The belatedly-disclosed ENHANCE results, however, shocked the market. Upon the January 14, 2008 partial "top-line" disclosure of the ENHANCE results, Merck's stock price, which closed at $60.55 per share on Friday, January 11, 2008, fell sharply to close at $58.18 per share on Tuesday, January 15, 2008. As criticisms of the Company and its lack of scientific and moral ethics reached a fever pitch, Merck's stock price continued to drop over a series of days, closing at $47.79 per share on January 25, 2008. When the full ENHANCE results were released on Sunday, March 30, 2008, Merck's stock price fell from $44.51 on March 28, 2008 to a close of $37.95 on March 31, 2008 (the next trading day), a one-day decline of approximately 15%. In sum, as a consequence of these disclosures, Merck investors lost more than $47 billion in market capitalization in less than three months.

5. Merck is one of the largest pharmaceutical companies in the world. Over the past few years, Merck has enjoyed strong profit growth, reflected in a growing stock price that peaked at $60 per share during the Class Period, for total market capitalization of $130.2 billion. Merck was able to achieve this strong growth despite the fact that it was embroiled in another large legal scandal involving its painkiller drug Vioxx. Like here, Merck's Vioxx troubles are largely attributable to its suppression of negative clinical data.

6. Vytorin is a cholesterol-lowering medication that is a combination of two drugs, Zetia (a.k.a. ezetimibe) and Zocor (a.k.a. simvastatin). Zocor is a statin, developed by Merck, which reduces low-density lipoprotein ("LDL") cholesterol by interfering with an enzyme in the liver that synthesizes and produces LDL cholesterol. Zetia is not a statin, but a different type of drug that works in the digestive tract by stopping the intestines from absorbing cholesterol found in food. Zetia was developed by Schering-Plough and was approved by the U.S. Food and Drug Administration ("FDA") in October 2002.

7. As Zocor approached the end of its patent protection in June 2005, Merck knew, from its recent experience with declining revenues as a result of losing patent exclusivity for some of its other drugs, that Zocor sales would likewise plunge once that drug lost its patent protection and faced generic competition. A December 9, 2004 *Wall Street Journal* article entitled "Merck's 2005 Profit to Miss Estimate – Embattled Drug Maker Says Sales of Zocor Will Decline Amid Stiffer Competition," reported that Merck "expects sales of its flagship cholesterol drug Zocor to fall next year amid generic competition overseas and new competition in the U.S. Declining sales of Zocor will contribute to lower-than-expected earnings in 2005, the company said." Indeed, the Company said it expected Zocor sales to drop to between $4.1 billion and $4.4 billion in 2005, and later (in 2005) the Company publicly forecasted that Zocor

sales would slump to only $600 million to $900 million for 2006, as generic drugmakers crowded the market with cheaper alternatives.

8. In an effort to soften the loss of patent exclusivity for Zocor and to retain its foothold in the multi-billion dollar cholesterol drug market, Merck teamed up with Schering-Plough to combine Zocor with Schering's Zetia, a name-brand drug that was still under patent and to thereby create a "new" drug that could be patented. In this way, Merck hoped to recoup at least some of the lost profits from Zocor's loss of patent exclusivity, while it attempted to rush to market other cholesterol/atherosclerosis drugs still in the early stages of Merck's research pipeline. The combination of Zocor and Zetia was marketed as Vytorin in the U.S. and became Merck's bid to retain its market share for cholesterol management drugs. As *The New York Times* explained in a July 22, 2004 article: "Zocor loses patent protection in the United States in 2006. So a successful introduction of Vytorin is crucial for Merck to retain its standing in the market for cholesterol drugs, probably the industry's single biggest category."

9. Vytorin is co-marketed by Merck and Schering-Plough through the M/S-P joint venture (collectively, the "Companies"). Merck, M/S-P, and the other defendants named herein, falsely represented to the investing public that Vytorin's ability to lower LDL cholesterol provided significant health benefits and was therefore superior to other drugs (a marketing slogan commonly known as "lower is better") when they knew this was false, and misleadingly touted Vytorin's unique "dual inhibition" function as providing health benefits superior to competing drugs, when Merck and others knew it was little more than a marketing ploy. With ENHANCE, Merck knew that "lower" was not "better" for Vytorin because Vytorin's ability to lower LDL cholesterol levels in patients did not translate into actual health benefits compared to patients taking simvastatin alone. While the Companies made their "lower is better" and similar

statements and marketing claims recklessly prior to completion of the ENHANCE study, by the time the ENHANCE results were in hand at the start of the Class Period, Defendants made these statements and false claims when they (but not the Class) had evidence to the contrary. Defendants thus knew these statements were unsupported, knew that ENHANCE further undermined their veracity, and so they concealed the results of ENHANCE from the public while at the same time pouring hundreds of millions of dollars into a false and misleading campaign bent on driving sales.

10. The Companies had designed ENHANCE to test whether the Zetia and Zocor combination in Vytorin was more effective than Zocor alone in preventing the progression of atherosclerosis (plaque buildup) in the carotid artery, a major risk factor for heart attacks and strokes. The study, completed in April 2006, was specifically designed to test the effectiveness of Vytorin against simvastatin, the generic form of Zocor. Thus, if Vytorin failed to show beneficial changes in carotid artery thickness versus Zocor, the commercial viability of Zetia and Vytorin was at a substantial risk of significant decline. As *The New York Times* observed in December 2007, the results of ENHANCE were of great public interest and highly anticipated: "[i]ndependent scientists have viewed ENHANCE as crucial because it is the first trial that would answer whether Zetia's ability to lower cholesterol has real biological benefits for patients."

11. The website www.cafepharma.com features a chatroom "blog" for pharmaceutical sales professionals. On July 19, 2007, six months before Defendants released the partial ENHANCE results to the public, a thread about ENHANCE appeared on the Merck board on Café Pharma, titled: "ENHANCE - Zetia 10/Simva 80 NOT better than simva 80/placebo!!!" Like other postings, this one concerned facts which Merck and S-P would not disclose until early

2008. The July 19th post concerned the ENHANCE results showing that the combination of 10 mg of Zetia with 80 mg of simvastatin produced no additional benefits in reducing atherosclerosis over 80 mg of simvastatin combined with a placebo. The author of the post stated:

> Now we know why this was pulled from ACC!!! [the American College of Cardiology Conference held on March 24-27, 2007 in New Orleans] We've been living off the LDL lower is better story versus statins alone since launch. This is the first trial with a clinically meaningful end[p]oint (carotid IMT) and shows that ***adding Zetia to high dose [simvastatin] provides no real benefit***. By inference, it suggests that Vytorin is really no better than the simva component alone, too. Based on this, it's easy to predict that IMPROVE-IT may very well be a bust as well. The only saving grace of that trial is that [it] is so large (10,000 pts) that even very small differences may still be statistically significant-but not really clinically significant. Economically-speaking, generic simva is so cheap now (and getting cheaper) that adding Zetia or using Vytorin will have to provide a wide margin of benefit in order to make up for cost differences. ***ENHANCE shows us that there is and will be no wide margin of benefit***. We're screwed once MCOs [managed care organizations] and PBMs [pharmacy benefit managers] figure this out. Better get those rebates ready!

(Emphasis added). In addition to correctly stating (as Merck and S-P would disclose much later) that there was no statistically significant difference between the treatment groups in ENHANCE, the post correctly discussed the study being "pulled from ACC," referring to how the ENHANCE results were intended to be presented at the American College of Cardiology Conference in March of 2007, but were removed at the last minute. Further, the statement that "We've been living off the LDL lower is better story" referred to the Merck marketing message that lowering LDL cholesterol by Vytorin is key to improving cardiac health, although ENHANCE shows that not all means for reducing LDL levels provide the same increased health benefits and outcomes. However, Merck and S-P continued their marketing refrain that "lower is

better," even after the Companies knew that ENHANCE called that hypothesis into question, and demonstrated that ***lower was not better with respect to Vytorin***.

12. Yet another post would reveal additional wholly-accurate and detailed information about the ENHANCE drug trial. On September 19, 2007, a new thread appeared on the S-P board, entitled "ENHANCE." The author wrote: "I feel for everyone waiting for this trial to come out. I heard today things are not looking good for you guys. I really hope you all can pull your butts out of the fire when that thing comes out." A reply post on September 20, 2007 revealed some very specific details:

> One of my docs is a very good friend of the study PI [primary investigator] overseas. I'm told that the study ***IS negative in that there is absolutely no difference in carotid IMT between simva 80 + placebo vs simva 80 + Zetia 10. Although Zetia did lower LDL-C as expected, it did nothing else of any value. So much for "lower is better!" Apparently, the PI and the company have been arguing back and forth about how/when to release the info. PI wants to report, but company keeps blocking/delaying.*** We're pretty well screwed if what is essentially max dose Vytorin is no better than max dose generic simva!!

(Emphasis added).

13. On January 14, 2008, as a result of mounting public scrutiny, the Companies finally released "top-line" results of the ENHANCE study. These results shocked the market: They showed that Vytorin failed to reduce the buildup of arterial plaque any more than less expensive generic simvastatin alone. After the Companies had repeatedly missed their own deadlines for reporting the results, and after Congress, the media and cardiologists around the world had wondered why the results were delayed, the Companies finally disclosed the reason: the results showed that the drug offered no real benefits to users. On Sunday, March 30, 2008, the Companies disclosed the full ENHANCE results to the market. The *New England Journal of Medicine ("NEJM")*, which published the ENHANCE results, took the extraordinary step of also

printing two editorials which recommended, based on the ENHANCE results, that doctors should only turn to Zetia and Vytorin after they had exhausted all other options. Additionally, a panel of experts issued a strong statement calling on cardiologists to rein in the use of Zetia and Vytorin, and urged doctors to turn back to statins like Lipitor or generic simvastatin.

14. The published results were damaging to Vytorin and Zetia because they demonstrated that adding Zetia to a statin, such as Zocor in the Vytorin mix, was no more effective then generic simvastatin (Zocor) alone in preventing progression of atherosclerosis in the carotid artery. Worse still, the ENHANCE results seemed to show that patients on Vytorin suffered *more* plaque buildup than those taking generic simvastatin alone. Doctors had been prescribing Vytorin, or Zetia in combination with other statins, on the theory that the drugs would halt or reduce atherosclerosis more than generic drugs, or other statins, thereby justifying Vytorin and Zetia's hefty price premium. The ENHANCE study left doctors with no reason to prescribe Vytorin over generic cholesterol drugs, such as simvastatin, that sell for a third or less of the cost, and no reason to add Zetia in combination with other statin therapy since there was no proven benefit. Equally important, the ENHANCE study sent a clear message to managed care organizations that Vytorin and Zetia had no place on drug formularies and should not be reimbursed given that superior results could be obtained through the use of generic simvastatin.

15. In the aftermath of the release of the ENHANCE results, it soon became clear that the unusually long delay in the release was purposeful and undertaken to avoid releasing negative clinical data that would threaten the growing sales of Vytorin and Zetia, and the hundreds of millions of dollars in profits being reaped by the Companies. According to an article appearing in *Forbes* on September 3, 2008, "[t]he lead investigator of [the ENHANCE study] has said that the results [of the ENHANCE study] might have been out a year earlier had

the companies left the decision to analyze the data up to him." In an email described by U.S. Senator Chuck Grassley on March 31, 2008, the frustration of Dr. Kastelein, on account of what he perceived to be the delayed disclosure of adverse results, was palpable. Dr. Kastelein angrily wrote to a Schering executive in July 2007, regarding the proposed further delay of the results: "I can tell you that if this is the case, our collaboration is over. This starts smelling like extending the publication [of the study] for no other [than] political reasons and I cannot live with that." The next day in another email, Dr. Kastelein wrote that as a result of the delay, "you will be seen as a company that tries to hide something and I will be perceived as being in bed with you!"

16. The Companies received "initial data checks" from ENHANCE beginning in late 2005. By the close of the ENHANCE trial at the end of April 2006, Defendants were aware of the negative results of ENHANCE, but continued to make false statements to the investing public that "lower is better" when it comes to Vytorin, and that because Vytorin lowered LDL cholesterol levels more than its competitors (namely generic Zocor, Pfizer's Lipitor, and AstraZeneca's Crestor), it was the superior product for cardiovascular health. In addition, the Companies, despite their knowledge that the Vytorin and Zetia franchise would face significant and substantial declines if the negative ENHANCE results were made public (thereby threatening billions of dollars in expected revenues), continued to tout the commercial success of Vytorin and Zetia while falsely conveying the belief (known as of at least May 1, 2006 to be false) that Vytorin and Zetia would continue to deliver strong growth and increased sales.

17. Merck not only influenced investors' views on Vytorin through SEC filings, investor and analyst communications, and through other public statements, but it did so through a massive false and misleading advertising campaign. Merck's direct-to-consumer ("DTC")

advertising concerning Vytorin was substantial. As reported by the *NEJM*, Merck and S-P spent over $200 million in 2007 on direct-to-consumer advertising for Vytorin alone in the United States. The Vytorin DTC advertising campaign was also effective. As the March 30, 2008 *NEJM* article noted, use of Zetia and Vytorin soared in the United States (going from a 0.1% share of lipid-lowering agents in 2002 to 15.2% in 2006), but climbed only minimally in Canada (going from 0.2% share in 2003 to 3.4% in 2006) where advertising drugs to consumers is not allowed. The article stated that the $200 million marketing campaign "probably had an effect on U.S. sales of [Zetia and Vytorin]."

18. As Representative Stupak stated in a January 17, 2008 *Newsweek* article, the ads purchased by the Companies supported an "assumption . . . that lower cholesterol means reduced plaque means reduced risk of heart attack and stroke," but ENHANCE showed that Vytorin failed to produce those benefits.

19. On or about January 23, 2008, shortly after Merck's release of the preliminary ENHANCE results, the FDA contacted Merck by letter to inform it that its DTC marketing materials and its product claim materials directed to healthcare providers were false and misleading. Among other things, the FDA pointed out that it was misleading for Merck to suggest that the two-drug combination in Vytorin provided a cardiovascular benefit because while "one of the drug components in Vytorin [Zocor], reduces the risk of heart attack, heart-related death, stroke, or heart procedures," the other component (Zetia) "has not been shown to prevent any of these cardiovascular outcomes. Furthermore, using the combination . . . product, Vytorin, has not shown any additional cardiovascular benefit compared to using [Zocor] alone." The FDA then went on to state that Merck should promptly change its misleading advertisements, as follows:

> Therefore . . . we are informing Merck that the Vytorin product claim promotional materials would be misleading because the pieces do not include contextual information disclosing a limitation to the efficacy of Vytorin regarding clinical outcome benefits.
>
> Consequently, we recommend revising any DTC Vytorin product claim promotional material, by adding context, in consumer-friendly language, communicating not only that Vytorin contains two medicines (Zocor and Zetia), but also by conveying that ***taking the combination drug Vytorin has not been shown to provide any additional cardiovascular outcome benefits compared to using Zocor alone***.

(Emphasis added).

20. Presently, the circumstances surrounding the delay of the release of the ENHANCE study results are being investigated by several state Attorneys General, including New York's and Connecticut's, as well as Representatives on the federal House Committee on Energy and Commerce and Senators from the Senate Finance Committee.

II. JURISDICTION AND VENUE

21. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

23. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). The Company is incorporated and headquartered in this District, and many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

24. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not

limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

III. PARTIES

A. LEAD PLAINTIFFS

1. Stichting Pensioenfonds ABP

25. ABP is an entity established under the laws of the Kingdom of the Netherlands. With assets amounting to more than 200 billion Euros, ABP is one of the three largest pension funds in the world. Its assets represent around 35% of total Dutch pension fund assets, and its client base totals some 2.2 million participants and retirees, including civil servants, teachers, university professors, policemen and firemen. ABP purchased shares of Merck securities during the Class Period and was injured as a result.

2. International Fund Management, S.A. Luxemburg

26. IFM is organized and incorporated under the laws of the principality of Luxemburg and has its corporate offices in Luxemburg. IFM is part of the Deka Bank group of investment companies, which manage more than 160 billion Euros in assets through mutual funds and special funds. IFM purchased shares of Merck securities during the Class Period and was injured as a result.

3. Deka International (Ireland) Limited

27. Deka Ireland is organized and incorporated under the laws of Ireland and has its corporate offices in Dublin. Deka Ireland is part of the Deka Bank group of investment companies, which manage more than 160 billion Euros in assets through mutual funds and special funds. Deka Ireland purchased shares of Merck securities during the Class Period and was injured as a result.

4. The Jacksonville Police and Fire Retirement System

28. Jacksonville is a public pension plan established for the benefit of the full-time police officers and fire fighters of the City of Jacksonville, Florida. The fund was created in 1937 and is structured as an independent agency of the City of Jacksonville. Jacksonville has over $1 billion in assets under management. Jacksonville purchased shares of Merck securities during the Class Period and was injured as a result.

5. The General Retirement System of the City of Detroit

29. Detroit is a public pension plan in Detroit, Michigan and organized for the benefit of the current and retired employees of the City of Detroit. Detroit is responsible for managing the benefits of approximately 20,000 members and has over $3 billion in assets under management. Detroit purchased shares of Merck securities during the Class Period and was injured as a result.

B. NAMED PLAINTIFF

30. Named Plaintiff Genesee County Employees' Retirement System ("Genesee") is headquartered in Flint, Michigan. Genesee purchased shares of Merck securities at artificially inflated prices during the Class Period and was injured as a result.

C. DEFENDANTS

1. Merck & Co., Inc.

31. Defendant Merck is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. According to Merck public filings, the Company is a global research-driven pharmaceutical company. During the Class Period, Merck issued false and misleading statements to investors.

2. Merck/Schering-Plough Pharmaceuticals Company, LLC

32. Defendant M/S-P is a joint venture between Schering and Merck with its headquarters located at 351 N. Sumneytown Pike, North Wales, Pennsylvania 19454, premises owned and/or leased by defendant Merck. Schering and Merck formed M/S-P in May 2000 to jointly develop and market in the United States new prescription medicines in cholesterol management, including Vytorin. During the Class Period, M/S-P issued false and misleading statements to investors.

3. Richard T. Clark

33. Defendant Richard T. Clark ("Clark") is, and was at all relevant times, Chairman, President and Chief Executive Officer ("CEO") of Merck.

4. Peter S. Kim

34. Defendant Peter S. Kim, M.D. ("Kim") is, and was at all relevant times, President of Merck Research Laboratories.

5. Judy C. Lewent

35. Defendant Judy C. Lewent was Executive Vice President and Chief Financial Officer ("CFO") of Merck until 2007.

6. Deepak Khanna

36. Defendant Deepak Khanna ("Khanna") is, and was at all relevant times, Senior Vice President of Merck and General Manager of defendant M/S-P.

7. Wendy L. Yarno

37. Wendy L. Yarno is, and was at all relevant times, Chief Marketing Officer of Merck.

38. Defendants Clark, Kim, Lewent, Khanna and Yarno are herein referred to as the "Individual Defendants." During the Class Period, the Individual Defendants, by virtue of their

senior executive positions at Merck, were privy to confidential and proprietary information concerning Merck, its operations, finances, financial condition and present and future business prospects relating to Zetia and Vytorin. The Individual Defendants also had access to materially adverse non-public information concerning Vytorin and Zetia, as discussed in detail below. Because of their positions within Merck, the Individual Defendants had access to non-public information about its business, finances, products (including Zetia and Vytorin), markets and present and future business prospects via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof and via reports and other information provided to him in connection therewith. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

39. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants were "controlling persons" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Merck's business.

40. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to securities analysts and through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports, press releases, advertisements and marketing materials alleged herein to be misleading, prior to or shortly after their issuance

and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

41. As senior executives and controlling persons of a publicly traded company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was, and is, traded on the NYSE and governed by the federal securities laws, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with respect to Merck's financial condition and performance, growth, operations, financial statements reflecting data for Vytorin and Zetia, business, products, markets, management, earnings and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Merck's common stock would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

42. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Merck's common stock by disseminating materially false and misleading statements and/or concealing material adverse facts concerning Vytorin and Zetia. The scheme: (i) deceived the investing public regarding the results of the ENHANCE trial, its failure to show a medically advantageous difference between Vytorin and other less expensive drugs, and the business, operations and management and intrinsic value of Merck's securities; and (ii) caused Lead Plaintiffs and members of the Class to purchase Merck's common stock at artificially inflated prices, which declined dramatically when the truth was disclosed.

IV. SUBSTANTIVE ALLEGATIONS

A. THE HISTORY AND SCIENCE BEHIND STATINS

43. Atherosclerosis occurs when LDL or "bad" cholesterol, inflammatory cells, and fibrous tissue form an area of plaque in an artery wall which, if ruptured, can block blood flow to the brain or heart leading to a stroke or heart attack. "Good" cholesterol, known as high-density lipoprotein ("HDL") cholesterol, is believed to help clean out those fatty plaque deposits, thereby reducing the risk of developing atherosclerosis or having a heart attack or stroke.

44. Statins are drugs that lower LDL cholesterol by interfering with an enzyme in the liver that synthesizes and produces LDL cholesterol. Statins are established as the most effective drugs at preventing heart attacks and strokes. Merck introduced the first statin, Mevacor, in 1987. Bristol-Myers Squibb followed with Pravachol in 1991. In 1992, Merck's Zocor became the first "super-statin" and brought greater cholesterol-reducing power, only to be surpassed in potency by Pfizer's Lipitor in 1997.

45. The FDA approved Zetia in October 2002. Zetia works in the digestive tract by stopping the intestines and liver from absorbing cholesterol found in food. Zetia thereby works differently from Zocor and other statins which reduce cholesterol by interfering with liver enzymes. Zetia soon gained a foothold in the cholesterol-reduction market as an add-on drug to use in combination with a statin, typically when statin therapy alone failed to get the patient to his or her LDL cholesterol goal.

46. Because of the massive market for cholesterol lowering drugs, by 2003, Lipitor was the most successful drug ever with annual sales of $9.2 billion and growing. Merck's Zocor was itself a multi-billion dollar drug, achieving annual sales of $4.4 billion in 2005, and was second to only Lipitor in terms of market share and sales prior to losing its patent protection.

47. September 2003 brought another challenger to the market dominated by Lipitor and Zocor when AstraZeneca launched Crestor. Lipitor, Crestor, and Zocor all battled for market share into mid-2004, just ahead of Vytorin's entry to the market, but on account of the massive size of the cholesterol-lowering drug market, each drug was a multi-billion dollar, blockbuster drug for its respective company.

48. Prior to the commencement of the ENHANCE trial, there were decades of research into statins that demonstrated a link between high LDL cholesterol levels and the formation of plaque and the onset of atherosclerosis. Extensive research on statin drugs had confirmed that "lower is better" in terms of lowering LDL cholesterol through the use of these drugs because it would slow or stop the buildup of arterial plaque, stop the onset of atherosclerosis, and reduce the risk of major cardiac events such as heart attack and stroke. As reported by *CNN Money* in an article dated February 6, 2008, "most medical experts" had assumed for the last thirty years that lowered LDL cholesterol through statin therapy, or other means, slowed the buildup of arterial plaque and prevented heart disease. Thus, by the time Vytorin first hit the market in July 2004, the "lower is better" mantra was universally accepted, largely based upon studies involving statins.

49. By August 2004, the American Heart Association ("AHA"), the American College of Cardiology ("ACC") and the FDA each had adopted the "lower is better" position with respect to LDL cholesterol largely based on the growing body of scientific research into statins. The AHA, ACC and FDA assumed, based on various clinical studies, that a lower LDL level resulted in a reduction in arterial plaque and therefore a reduction in the risk of suffering adverse cardiac events such as heart attacks and strokes, but they closely watched "outcome studies" of statins that tested and tried to prove that the lower LDL levels being achieved through

statin therapy were leading to better clinical "outcomes," namely, reduced arterial plaque, and a decrease of adverse cardiovascular events, like heart attacks, strokes and deaths.[1] ENHANCE was one such study that researchers and physicians looked to for guidance on the therapeutic benefits of Zetia and Vytorin.

B. THE MERCK/S-P JOINT VENTURE

1. Merck And S-P Formed A Joint Venture To Market And Sell Vytorin And Zetia And Shared Its Revenues

50. In 2000, Merck and S-P formed M/S-P, a joint venture to develop and market new prescription medicines in cholesterol management. Pursuant to the joint venture agreement, M/S-P was to develop and market a once-daily fixed combination tablet of S-P's ezetimibe (Zetia), and Merck's statin, Zocor. In a *PR Newswire* release on May 23, 2000, Merck CEO Ray Gilmartin praised the joint venture, stating "[This] agreement exemplif[ies] Merck's strategy of seeking innovative collaborations to increase shareholder value. By investing in our internal research program and complementing our pipeline through external collaborations, such as this, we will continue to remain a leader in an increasingly competitive marketplace." As S-P Chairman and CEO Richard Jay Kogan explained in a letter to S-P shareholders dated February 16, 2001 (and included in S-P's 2000 Annual Report), M/S-P also sought to market ezetimibe as a drug to be co-administered with other statins and alone as monotherapy. Additionally, according to an October 17, 2002 M/S-P press release, the "partnership" was expanded in December 2001 to develop and market worldwide (excluding Japan) new prescription medicines in cholesterol management.

[1] Many of the clinical trials on statins involve the use of "surrogate markers" for determining whether the tested drug reduced the progression of atherosclerosis. A "surrogate marker" is a laboratory measurement or physical sign used as a substitute for a clinically meaningful endpoint when the surrogate is "reasonably likely" to predict an actual clinical benefit or outcome. In the realm of cardiovascular health, the build-up of arterial plaque is a commonly used surrogate marker for endpoint outcomes such as heart attacks and strokes.

51. According to the joint venture agreement, Merck and S-P equally share M/S-P's costs, expenses, revenues and profits associated with sales of drugs developed by the partnership. In particular, starting before and throughout the Class Period, Merck and S-P shared all costs, expenses, revenues and profits related to the development, marketing and sale of Vytorin and Zetia.

2. Merck Combines Its Zocor Drug With S-P's Zetia In A Bid To Retain Its Share Of The Cholesterol Management Drugs

52. Despite its past success with Mevacor and its huge sales of Zocor, Merck was under pressure to develop another blockbuster drug. Its 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. As a result of declining revenues from these and other drugs going off patent, Merck's net income for the second quarter ended June 30, 2004 fell to $1.77 billion, compared to $1.87 billion in the period a year earlier. This, combined with legal risks related to Merck's Vioxx debacle, caused its stock price to plummet and caused a change in executive management.

53. As Zocor was approaching the end of its patent protection, Merck knew, from its experience with declining revenues resulting from generic competition to its drugs once they went off patent, that Zocor sales would likewise plunge once that drug lost patent protection. A December 9, 2004 *Wall Street Journal* article entitled "Merck's 2005 Profit to Miss Estimate – Embattled Drug Maker Says Sales of Zocor Will Decline Amid Stiffer Competition," reported that Merck "expects sales of its flagship cholesterol drug Zocor to fall next year amid generic competition overseas and new competition in the U.S. Declining sales of Zocor will contribute to lower-than-expected earnings in 2005, the company said." Indeed, the Company stated it expected Zocor sales to drop to between $4.1 billion and $4.4 billion in 2005, and later (in 2005)

the Company publicly forecasted that Zocor sales would slump to only $600 million to $900 million for 2006, as generic drugmakers crowded Zocor out of the market with cheaper alternatives.

54. To help Merck retain its share of the massive cholesterol drug market despite its pending loss of Zocor's patent exclusivity, the Company sought to use M/S-P to combine Zocor with a name-brand drug still under patent and thereby create a "new" drug that could likewise be patented. In this way, Merck sought to save its blockbuster molecule Zocor (simvastatin) from total loss of patent exclusivity and competition from manufacturers of generic simvastatin. The new partner for Zocor was M/S-P's Zetia, also known as ezetimibe. The combination of Zocor and Zetia was marketed as Vytorin (in the U.S.) and became Merck's bid to retain its market share and leadership role in the area of cholesterol management drugs. As *The New York Times* explained in its July 22, 2004 article: "Zocor loses patent protection in the United States in 2006. So a successful introduction of Vytorin is crucial for Merck to retain its standing in the market for cholesterol drugs, probably the industry's single biggest category."

55. Vytorin is a combination drug consisting of Zocor and Zetia in a single pill. It was approved by the FDA in July 2004 based on its ability to lower LDL cholesterol levels by up to 20% over use of simvastatin (or Zocor) alone. Vytorin was not approved based on any evidence that the drug decreased the risk of suffering heart attacks or strokes or the drug's ability to reduce the rate of atherosclerosis or reverse arterial plaque buildup.

56. Vytorin was critical to Merck's future and success, just as it was critical to the future and success of its marketing partner S-P. As reported on April 1, 2008 by *The Wall Street Journal*, "analysts estimate the [M/S-P] joint venture accounts for about 15% of Merck's profit." According to Merck's CEO Clark, speaking at a Merck presentation during the Morgan Stanley

Pharmaceutical CEOs Unplugged Conference, in January 2006, Vytorin's success was "critical" to Merck so it was assigning its "best people" to work at M/S-P:

> RICHARD CLARK: Well certainly from a Merck standpoint, we believe we have an excellent relationship with our joint venture partner, that ***both Vytorin and Zetia are critical to our future***. They are excellent products, as you – I'm assuming you heard from Fred this morning how well those products are doing and the position that they have, particularly with managed care. From a general management standpoint with the Merck people that are in the joint venture, ***we are putting our best people there***. ***We know how important it is to our success and their success, so it's really critical that we continue to support it and be successful with it moving forward and making sure that we continue to put those aspects into place. So I look at [it] as an important part of our future, and therefore, we need to be aligned with it.***
>
> * * *
>
> The whole market is such a huge market from a market expansion standpoint. So Vytorin is a critical part of now for us it will be a critical product in the future with its dual mechanism of action. So I just think the expansion of HDL raising and triglycerides is important and Vytorin is such a – has outstanding outcomes that there's room enough for both products and that we will make sure that Vytorin is extremely successful It's critical to our future that Vytorin is successful.

(Emphasis added).

57. Defendant Clark echoed the belief that Vytorin was critical to both Merck's and S-P's success during Merck's Q4 2005 Earnings Conference Call on January 31, 2006, by responding to an analyst's questioning as follows:

> As you know, we're focusing our attention, both from a Merck standpoint and a Schering-Plough standpoint, on Vytorin and Zetia. They're very important to both of our companies moving forward, and for our success. So our focus is on the ability to continue to be successful with those 2 products. And the common objective that we all have is to maximize Vytorin and maximize Zetia.

58. Consistent with the importance of Vytorin and Zetia and the success of M/S-P to Merck's profits, Merck was intimately involved in the operation of M/S-P and contributed some of its top employees to the enterprise. Indeed, the head of M/S-P, defendant Khanna, was a Merck employee, as was M/S-P's general manager at the time of Vytorin's launch, who, according to a July 2004 article appearing in *Barron's* (dated June 14, 2004), was Merck's Adam H. Schechter. In addition, priori to the public release of the ENHANCE data, all of the following Merck employees played some role in analyzing ENHANCE: John Irvin, M.D., Senior V.P., Global Research & Development; Tom Musliner, M.D., Executive Director, Cardiovascular Disease, Clinical Research, Merck Research Laboratories; Scott Korn, M.D., Executive Director, Worldwide Regulatory Affairs; Andrew Tersakovec, M.D., Clinical Development, U.S. Human Health; and Michael Stepanavage, Ph.D, Merck Research Laboratories.

59. The employees that Merck and S-P contributed to the joint venture were intimately involved in the operations of M/S-P, including heavy, hands-on involvement in managing the clinical trials relating to Vytorin and Zetia. Many, if not all, of the researchers and statisticians at M/S-P who managed the ENHANCE study data were employees of Merck or S-P. Moreover, unlike many clinical trials where the data is collected by the lead or primary investigator (i.e., the primary physician or scientist in charge of the study), the data from the ENHANCE trial was collected and managed directly by Defendant M/S-P which controlled and had direct access to the computerized ENHANCE database.

C. MERCK AND S-P'S EFFORT TO MAKE VYTORIN INTO A BLOCKBUSTER

1. Intense Competition In The Statin Field

60. Because of the tens of billions of dollars at stake in the vast (and still growing) cholesterol drug market, competition was fierce among the Companies, AstraZeneca and Pfizer to gain market share for their respective cholesterol management medicines. In order to

demonstrate the superiority of their statins, AstraZeneca and Pfizer each had commissioned studies comparing the efficacy of their statins against those of competitors. The data from such trials was used in marketing the drugs to physicians, managed care organizations, and consumers. The data was also watched closely by securities analysts and investors, because perceived marketing advantages and disadvantages could cause tens or hundreds of millions of dollars to shift from one company to another in relatively short order.

61. In 1997, for example, Pfizer commenced the ASAP trial (otherwise known as the Atorvastatin versus Simvastatin on Atherosclerosis Progression trial) comparing high-dose Lipitor with moderate-dose Zocor. The ASAP trial began in the Netherlands, and its study population had the same familial hypercholesterolemia condition that would later be studied in the ENHANCE trial. Dr. John J.P. Kastelein, a doctor in the Netherlands who would later lead the ENHANCE trial, also participated in the ASAP trial, although not as the lead investigator.

62. In the ASAP trial, patients taking Lipitor had a greater reduction in LDL levels and greater regression in the thickness of their arterial plaque than patients taking Zocor. In fact, the patients on Zocor actually showed an increase in plaque build up. The results were published in the British medical journal *The Lancet* in 2001, among other publications, and led researchers to posit that aggressive lowering of LDL levels would show a corresponding decrease in arterial plaque.

63. By 2002, Pfizer commenced another study designed to compare the ability of Lipitor to halt progression of atherosclerosis more than Pravachol. This study was called Reversing Atherosclerosis with Aggressive Lipid Lowering ("REVERSAL"). On November 12, 2003, Pfizer announced the results of its REVERSAL study, reporting that patients taking Lipitor

experienced a greater reduction in the progression of atherosclerosis compared to patients taking Pravachol.

64. Soon, Pfizer announced it was commencing another study, called Incremental Decrease in End Points Through Aggressive Lipid Lowering ("IDEAL") to measure whether patients who had a previous heart attack and took Lipitor to further lower their LDL cholesterol levels experienced a reduction in the amount of cardiovascular events, including heart attacks, strokes and revascularization procedures, compared to patients taking Zocor.

65. Separately, beginning in 2002, AstraZeneca commenced its own long-term clinical studies to measure whether the company's Crestor statin could reduce the risk of major cardiovascular events by reversing plaque buildup in coronary arteries. These studies were part of AstraZeneca's "GALAXY" program to increase sales of its Crestor statin, and included:

- The JUPITER study (Justification for the Use of Statins in Primary Prevention: an Intervention Trial Evaluating Rosuvastatin), which investigated whether long-term treatment with Crestor compared to a placebo would decrease the rate of adverse cardiac events among certain types of individuals;

- The METEOR study (Measuring Effects on intima media Thickness: an Evaluation Of Rosuvastatin), to evaluate Crestor on the progression of carotid atherosclerosis by measuring CA IMT in hypercholesterolemic patients with thickened carotid artery walls;

- The ASTEROID study (A Study To evaluate the Effect of Rosuvastatin On Intravascular ultrasound-Derived coronary atheroma burden), to assess the effects of Crestor in the regression of atherosclerosis in patients with coronary artery disease who require coronary angiography;

- The AURORA study (A study to evaluate the Use of Rosuvastatin in subjects On Regular hemodialysis: an Assessment of survival and cardiovascular events), designed to examine the role of statin therapy in patients with end-stage renal disease undergoing chronic hemodialysis treatment; and

- The ORION study, investigating whether hypercholesterolemic patients taking Crestor experienced any reduction in their CA IMT measurements.

66. The clinical trials in AstraZeneca's GALAXY were presented at the Thirteenth International Symposium on Atherosclerosis on September 29, 2003, and discussed in various publications, including an April 20, 2003 article in *Heart Disease Weekly*, an October 25, 2003 article in *The Lancet*, and an article in *Atherosclerosis Supplements* in March 2003 by Dr. Kastelein, among others.

2. Merck and S-P Design The ENHANCE Study To Demonstrate Vytorin's Ability To Reduce Arterial Plaque

67. Even before the FDA's approval of Vytorin, Merck and S-P recognized that their competitors had begun to plan (and/or begin) studies that potentially could have significant negative consequences for the success of Vytorin. Thus, beginning in 2002, Merck researchers, along with their counterparts at S-P, and M/S-P, designed a study which they hoped would prove that Vytorin's combination of Zetia and Zocor would stop or reduce the growth of fatty arterial plaque more than Zocor alone. This study, called the Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atheroscleratic Process in Patients with Heterozygous Familial Hypercholesterolemia ("ENHANCE"), isolated the carotid artery as the place where plaque buildup would be measured to determine whether the Zetia/Zocor mix in Vytorin was more effective at reducing plaque than Zocor alone.

68. An article published in February 2005 in the *American Heart Journal*, and written by, among others, the lead investigator for the ENHANCE study, described the design, rationale and methods used in the ENHANCE study in detail. The article's authors were Dr. John J.P. Kastelein, who served as the principal investigator of the ENHANCE study and a member of the Department of Vascular Medicine, Academic Medical Center, Amsterdam, the Netherlands; Dr. Eric de Groot, also a member of that Department of Vascular Medicine; and Drs. Philip T. Sager and Enrico Veltri of the S-P Research Institute in Kenilworth, New Jersey.

69. As discussed in the article, the ENHANCE study addressed "whether a regimen that uses drugs with different mechanisms of action [e.g., Vytorin] will be of further benefit in terms of atherosclerosis reduction compared to statin monotherapy [simvastatin]." Merck, S-P and their researchers had to prove that treatment of both sources of cholesterol – absorption in the intestine of biliary and dietary cholesterol, and production in the liver and peripheral tissues – would likely result in lower cholesterol levels and, in turn, a reduction in the amount of plaque buildup in the arteries and a reduction in the risk of heart attack and stroke.

70. The ENHANCE study was funded by Merck and S-P. Merck's participation in the ENHANCE study was personally spearheaded by Merck's then-CEO Raymond V. Gilmartin. The test subjects were a group of 720 patients with a rare condition, called heterozygous familial hypercholesterolemia ("HeFH"), genetically predisposing them to high cholesterol levels.

71. The authors explained how they would measure the relative effectiveness of Vytorin and Zocor on reducing plaque: changes in carotid artery intima-media thickness ("CA IMT" or "CIMT") would be a "surrogate measure" to assess the progression of atherosclerosis.

72. The predetermined primary outcome, or "primary end point," of the trial was the change from the baseline in the mean 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 (at "baseline") and at 6, 12, 18 and 24 month intervals. According to the *American Health Journal* article, 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.

73. The authors of the *American Health Journal* article emphasized that the measurements and analysis of the ultrasound images would be very precise: specific instruments (an "Acusan 128XP instrument . . . equipped with a 7.5-10-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 a prespecified 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 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.

74. The participants in the study were "recruited at 18 highly experienced lipid centers in eight countries (Netherlands, Norway, Canada, Sweden, South Africa, Spain, Denmark, and the United States) where the study was conducted. As Dr. Kastelein (and others) explained in an March 30, 2008, article in the *NEJM* 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.

75. An April 2007 article on the FDA website entitled "The Advancement of Controlled Clinical Trials," explained why it is necessary to establish the endpoints or goals for a clinical study in advance and not engage in "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."

76. Merck and S-P attempted to comply with these requirements by describing in advance the ENHANCE protocols and primary endpoints. Additionally, the companies described the goal of their study to measure whether Vytorin reduced CA IMT more than simvastatin alone.

77. In the *American Health Journal* article, Dr. Kastelein and his co-authors also explained why Merck and S-P funded ENHANCE:

> 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.

In other words, Merck and S-P sponsored ENHANCE because they believed that the test would show that Vytorin was more effective than simvastatin alone in reducing arterial plaque. Of

course, a positive outcome in ENHANCE was critical to Merck and S-P because if adding Zetia to Zocor (i.e. using Vytorin) produced no clinical benefit beyond that of generic Zocor alone, then the marketability of Zetia and Vytorin would be dramatically undermined. Patients would not pay huge premium prices for Zetia and Vytorin if they did not have any proven benefits over and above a generic.

3. Immediately Upon Its Introduction, Vytorin Is Subject To Strong Competition From Lipitor

78. Immediately upon its approval by the FDA in 2004, Vytorin began the long-anticipated (since at least 2002) battle with Pfizer's Lipitor. As *The New York Times* stated in a July 22, 2004 article:

> [T]he biggest competitor for Vytorin is expected to be Pfizer's Lipitor, which is the best-selling statin. "It will be one of the most classical marketing and scientific battles in the history of the pharmaceutical industry," the analyst, Mr. [Neil B.] Sweig [of Fulcrum Partners in New York] said. "Pfizer has tremendous marketing clout and almost infinite financial resources."

79. Just prior to the FDA approval of Vytorin in July 2004, an article appeared in *Barron's* (dated June 14, 2004), titled "Drug War: Who Wins and Loses in the Brawl Over Cholesterol-Lowering Medications," in which the author quoted Adam H. Schechter, the then General Manager of the M/S-P joint venture, as stating that "[w]e believe that Vytorin can compete with all statins in the marketplace, if approved, including Lipitor and Zocor…[and] [w]e're planning to support it as we would support a blockbuster product." In the article, Pfizer's medical and regulatory vice president, Gary Palmer, openly challenged the efficacy of Lipitor's rivals, Crestor and Vytorin, stating that "[w]e don't think that a statin is a statin is a statin" and noting that while Crestor and Vytorin may reduce LDL cholesterol levels, "the drugs haven't yet completed trials that show they reduce deaths, heart attacks and strokes."

80. At the beginning of August 2004, as reported by both *The Wall Street Journal* and *The Times* (London) newspaper, Pfizer gained a key marketing advantage against its competition when the FDA ruled that Pfizer could claim that Lipitor, at the time the world's best-selling medicine, "saves lives by helping to prevent heart attacks, angina and the need for surgery to open clogged arteries." Prior to this time, Pfizer had been limited in marketing the drugs to "its ability to lower cholesterol." According to *The Times*, "[a]nalysts said that this would give Pfizer an edge over AstraZeneca's Crestor and Vytorin" in terms of marketing, and the article quoted Greg Duncan, Vice President of Marketing of U.S. Pharmaceuticals at Pfizer, who said: "I think it's fair to say we will continue to aggressively promote Lipitor as a terrific drug. This new label gives us a strong point of differentiation against Crestor and Vytorin, neither of which has been proven in the way that Lipitor has." According to *The Times* article, a Crestor marketing spokeswoman responded that the Lipitor label change was "unlikely to impact" Crestor, because "[w]e expect the benefits of Crestor in reducing cardiovascular disease to be demonstrated in (later) studies."

81. By July 2004, there was no data showing that lower LDL cholesterol levels achieved by the use of Zetia or the supposed "dual inhibition" functions of Vytorin had any effect on arterial plaque, and some experts even questioned whether Vytorin's cholesterol reducing power would translate into better patient outcomes (i.e., reduced arterial plaque and reduced incidence or risk of heart attacks and strokes). On July 26, 2004, Dr. Nissen told *heartwire.org* that he would be "reluctant to use" Vytorin because there was no scientific evidence that it reduces clinical events. Dr. Nissen further stated, "Yes, it lowers LDL, but it has not been showed to do any more than that . . . we don't know whether [the benefits of lowering LDL alone are] equivalent to [the benefits of] high-dose statins." Vytorin and Zetia, therefore,

from the time of the initial launch of Vytorin and M/S-P, were faced with an ever-widening marketing gap versus their competitors. In the face of this growing positive clinical evidence from their competitors, M/S-P had to come up with positive data or marketing tactics to compete, and ENHANCE was the first trial in the M/S-P pipeline intended to show clinical health benefits beyond simply lowering cholesterol.

82. Merck recognized the connection between cholesterol and arterial plaque, and made the "cause and effect" connection between LDL cholesterol, arterial plaque, and heart attacks and strokes clear in its initial Vytorin package insert, approved July 2004, as follows:

> What should I know about high cholesterol?
>
> Cholesterol is a type of fat found in your blood. Cholesterol comes from two sources. It is produced by your body and it comes from the food you eat. Your total cholesterol is made up of both LDL and HDL cholesterol.
>
> LDL cholesterol is called "bad" cholesterol because it can build up in the wall of your ***arteries*** and form ***plaque***. Over time, ***plaque*** build-up can cause a narrowing of the ***arteries***. This narrowing can slow or block blood flow to your heart, brain, and other organs. High LDL cholesterol is a major cause of ***heart disease*** and ***stroke***.

(Emphasis added).

4. The "Lower Is Better" Marketing Message

83. In an effort to drive sales of Vytorin and Zetia, despite the lack of any trials demonstrating that Vytorin or Zetia actually provided cardiovascular benefits to their users, the Companies devised a massive marketing campaign aimed at consumers, physicians, managed care organizations, and analysts and investors. According to the Companies' joint marketing campaign, Vytorin was intended to produce some key advantages over statins (such as Zocor, Lipitor and Crestor) alone. First, Vytorin was pitched as having a unique "dual inhibition function" – it was the only drug to stop bad cholesterol from both of its possible sources:

absorption from food in the intestines (Zetia) and genetics, meaning natural production and synthesis of cholesterol in the liver (Zocor). As a result of this dual inhibition function, Vytorin (according to the Companies) allowed a patient to take a lower dose of a statin and receive the same or better reduction in LDL cholesterol than would result from a higher statin dose. Merck and S-P saw this as an important marketing advantage due to the mounting data showing dangerous or troubling side effects associated with high dose statins, particularly with Crestor.

84. In support of their marketing message, Merck and S-P touted the results of studies showing that Vytorin reduced LDL cholesterol more than the use of a statin alone. In mid-2004, Merck and S-P received the results of a separate study on the effectiveness of ezetimibe (Zetia), when used with one of a number of statins (including simvastatin), in reducing LDL cholesterol. That trial, called Ezetimibe Add-On to Statin for Effectiveness or "EASE" and sponsored by Merck and S-P (through their joint venture), included over three thousand patients on a stable dose of a statin, but not yet at their LDL cholesterol goal as set by the National Cholesterol and Education Program Adult Treatment Panel III ("NCEP ATP"). The results were presented in March 2004, at the annual American College of Cardiology conference. As explained in a paper distributed at the conference, the EASE trial showed that patients who continued on their current statin and also received a 10 mg dose of ezetimibe obtained a 23% reduction in LDL levels over patients who took a statin and a placebo. (Of course, this study provides no analysis of whether simvastatin actually reduced plaque in the arteries).

85. Merck highlighted the EASE results at scientific symposia held August 28 through September 9, 2004 in Munich, Germany. A white paper/newsletter published by Merck in September 2004 titled "Reduction in Cardiovascular Risk – Lower is Better Through Dual Inhibition" discussed highlights from the symposia, including the discussion of "exciting new

data on the anti-atherogenic benefits of Dual Inhibition." The white paper/newsletter stated that "[s]tatins have been widely prescribed for atherosclerosis" but "[c]oadministering ezetimibe with a statin in patients can consistently provide much greater reductions in LDL-C and improvements in goal attainment."

86. The white paper/newsletter also discussed the results of several studies of "Dual Inhibition" which "suggest that ezetimibe together with a statin will be a valuable therapeutic option to help the more aggressive LDL-C treatment recommendations driving towards 'lower is better' through Dual Inhibition." Merck misleadingly drew the connection between lower cholesterol and patient outcomes in its "Conclusions" by stating "Available clinical outcomes evidence suggests that 'lower is better' to further improve the cardiovascular benefits of LDL-C lowering therapy." Additionally, Merck noted in its newsletter that "surrogate and clinical cardiovascular endpoint trials are currently underway with ezetimibe together with simvastatin to determine the impact of Dual Inhibition on patient outcomes."

87. In its white paper/newsletter, Merck stated that the "summer of 2004 heralded a major change in the treatment paradigm for patients with hypercholesterolemia" with "[n]ew clinical trial evidence and treatment guidelines suggest[ing] that 'lower is better' to optimize cardiovascular benefits of [LDL cholesterol] lowering therapy." Merck queried "how can we achieve these aggressive targets when many patients were already failing to reach their current LDL-C goals?" Merck's answer was through "dual inhibition" and the Company then went on to "summarize[] the compelling clinical evidence in support of Dual Inhibition . . . [while] captur[ing] exciting new data on the anti-atherogenic benefits of Dual Inhibition" in certain patient populations.

88. Among other things, Merck's September 2004 white paper/newsletter further cited to Dr. Kastelein as stating that the data suggested that combining Zetia with a statin "will be a valuable therapeutic option to help meet the more aggressive LDL-C treatment recommendations driving towards 'lower is better' through Dual Inhibition." The white paper/newsletter further touted "surrogate and clinical cardiovascular endpoint trials are currently underway with [Zetia] together with simvastatin to determine the impact of Dual Inhibition on patient outcomes." But Merck summarized and concluded that adding Zetia to a statin consistently worked, and that "[a]vailable clinical outcomes evidence suggests that 'lower is better' to further improve the cardiovascular benefits of LDL-C lowering therapy."

89. In short, Merck was trumpeting the ability of the ezetimibe-simvastatin combination in lowering LDL cholesterol more than simvastatin (or any other statin) alone. It was repeating the "lower is better" mantra as a means to reach "maximum risk reduction in major cardiovascular events." And it was reminding its audience that its ENHANCE trial was underway.

90. While Merck had evidence that Vytorin was better than simvastatin alone in reducing LDL levels, it needed to respond to its competitors' announcements about the benefits of their competing statins. Merck needed ENHANCE to show that Vytorin was better than simvastatin alone by reducing arterial plaque buildup, and thereby reducing the risk of "major cardiovascular events" such as heart attacks and strokes.

91. However, until the ENHANCE trial, Merck had no data even addressing that issue. Nor did S-P. As Merck's and S-P's competitive disadvantage grew, they became more desperate to provide a counter marketing message promoting Vytorin. They co-opted the "lower

is better" mantra and morphed it into a powerful, but false and misleading, marketing ploy for Vytorin.

92. According to Merck and S-P, because Vytorin lowered LDL cholesterol more than their competitors (which was true), it was a better drug for cardiac health than competing statins (which was false, and for which neither Merck nor S-P had any support). The Companies' claim that Vytorin provided superior health benefits to statins alone (because it reduced both sources of cholesterol through its "dual inhibition" approach) had no support and, as ENHANCE showed, was false.

93. Merck's and S-P's claims that the "dual inhibition" function of Vytorin provided superior "anti-atherogenic benefits" and that "lower is better" with respect to Vytorin were made without any support. After Merck and S-P knew the results of the ENHANCE study, they knew that their claims were false, that the "dual inhibition" properties of Vytorin was false because Vytorin was no better than generic Zocor, and that the Companies' entire "lower is better" marketing campaign and public relations pitch on Vytorin were false and misleading.

5. While It Is Underway, Merck Touts The ENHANCE Study

94. Since they did not yet have the clinical data to level the marketing playing field with competitors like Pfizer and Crestor, Merck relied heavily on pushing and promoting its own *pending* outcomes studies in its marketing of Vytorin and Zetia. On November 9, 2004, Merck proudly announced an outcomes test for Vytorin called IMPROVE-IT, the purpose of which was "to evaluate the potential incremental impact of Vytorin versus simvastatin alone in reducing mortality and morbidity in high risk patients with [acute coronary syndromes] by dramatically lowering LDL cholesterol through dual inhibition." In connection with Merck's news release related to IMPROVE-IT, it referenced specifically that this would be the fourth "large-scale" clinical outcome trial being conducted by M/S-P on Vytorin, and then went on to describe

SHARP, SEAS, and ENHANCE. With respect to ENHANCE, Merck announced that it was examining the impact of Vytorin versus Zocor alone in "reversing the atherosclerotic thickening of the carotid artery in patients with high cholesterol."

95. Merck heavily touted the ENHANCE trial, as well as other clinical outcome trials on Vytorin, directly to analysts and investors. For ENHANCE, it appears from Merck's disclosures and its sudden non-disclosures, that Merck touted it right up until the point at which Merck began to realize that the preliminary results were negative, and that Vytorin would therefore fail miserably in its first significant clinical study designed to prove some health benefit beyond merely lowering cholesterol.

96. In this regard, while the ENHANCE study was in full swing during 2003 and 2004, Merck's senior management highlighted ENHANCE in Merck's widely-communicated "Annual Business Briefings," which were released by Merck as part of its Form 8-K SEC filings just prior to the fiscal year end. In Merck's December 9, 2003 Annual Business Briefing, for instance, Merck stated that Vytorin represented a "Significant Franchise Growth Opportunity" and identified the ENHANCE study (along with other pending outcome studies on Vytorin) as an event that would provide "Significant New Data Expected to Drive Continued Growth" at Merck.

97. The following year's disclosures regarding ENHANCE were similar. In Merck's December 14, 2004 Annual Business Briefing, Merck again touted its pending outcome studies on Vytorin, including ENHANCE. Merck stated that the completion of ENHANCE was anticipated in 2006, and that the data from ENHANCE and other outcome studies was "Expected to Drive Future Growth." Merck boasted that ENHANCE was targeted at showing "[a]therosclerotic regression" and listed ENHANCE among the "[n]ew outcome studies [that]

will demonstrate additional benefits of Vytorin." Merck stated that its sales force was redeployed to capitalize on the opportunities with Vytorin, specifically to further support the launch and to promote the expected "additional clinical data."

98. The significance of favorable outcomes from ENHANCE and other studies to the success of Vytorin was critical. By January 2005, according to an article appearing in *The Wall Street Journal* titled "Merck, Schering-Plough Drug Gets Mixed Views on Early Sales," some analysts (such as Richard Evans of Sanford Bernstein) had backed off their growth estimates for the Vytorin and Zetia franchise because "the drug essentially stopped gaining any [market] share." Proving that Vytorin resulted in better clinical outcomes for patients was always the key to its growth and profitability, but Merck and Schering-Plough did not yet have that type of data. According to an article appearing on *TheStreet.com*, titled "High Hopes for Merck, Schering-Plough," dated March 16, 2005, which interviewed and quoted several Merck and Schering-Plough investment analysts, proof of positive patient outcomes through clinical trials was critical to Vytorin, since its ability to lower LDL cholesterol was already a given:

> How far can Vytorin go? A lot will depend on whether several more years of patients' experience and more clinical trials produce outcomes that propelled sales of the market leaders [i.e. Lipitor and Crestor]. It also will depend on whether doctors believe there's a difference between Vytorin and the statin class of cholesterol drugs such as Lipitor and Crestor….
>
> Clearly the bar for Vytorin has been set higher. That's why investors yawned last week when Schering-Plough and Merck presented a study showing Vytorin did a better job of lowering cholesterol than did Lipitor at different doses. The reason: Analysts said they had already seen similar data.
>
> As with Crestor, Vytorin now must show analysts and doctors that it can improve clinical outcomes; ***lowering cholesterol is no longer enough***.
>
> What may capture their attention is several clinical trials sponsored by Merck and Schering-Plough…[including ENHANCE, which]

> will compare Vytorin vs. Zocor to see if the combination pill does a better job in reversing the plaque-related thickening of the carotid arteries in patients with high-cholesterol.

(Emphasis added).

6. Merck Tries To Twist Its Competitors' Studies To Support Vytorin

99. The pressure on Merck to obtain favorable test results from ENHANCE intensified during the term of the ENHANCE study. First, Merck suffered a serious setback on September 30, 2004, when the Company withdrew its widely popular arthritis drug Vioxx from the market. That day, Merck's stock price fell $12.07, from $45.07 to $33.00, its lowest close in the previous eight years, reducing Merck's market capitalization by nearly $27 billion. On October 21, 2004, Merck reported that its third quarter profit fell 29%, and net income dropped to $1.33 billion, compared to $1.86 billion a year earlier, due to costs of customer returns of Vioxx and write-offs of inventory. Merck needed a blockbuster drug to fill the earnings hole left by the withdrawal of Vioxx.

100. Merck turned to Vytorin and Zetia, assigning some of its top executives to manage M/S-P, redeploying its sales force, and devoting tens of millions of dollars to a massive advertising and promotion campaign. Ramping up Vytorin and Zetia, and pinning its hopes on turning these drugs into blockbusters was urgent not only because Merck had recently lost billions in Vioxx revenues, but also because it would soon lose billions more when its top selling drug, Zocor, went off patent.

101. Merck's plan to quickly ramp up Vytorin and Zetia sales through an aggressive marketing campaign quickly came under pressure as Pfizer and AstraZeneca began releasing more and more positive results from clinical trials involving their respective statins. Pfizer had already announced at the end of 2003 the results of REVERSAL, which showed that patients

taking Lipitor experienced a greater reduction in the progression of atherosclerosis compared to patients on the statin Pravachol. Then on November 15, 2005, Pfizer announced the results of the IDEAL (Incremental Decrease in Endpoints Through Lipid Lowering) study, which compared Lipitor to Zocor. Pfizer reported that "[p]atients who had a previous heart attack and took . . . Lipitor . . . to further lower their LDL or 'bad' cholesterol levels had significantly fewer cardiovascular events including heart attacks, strokes and revascularization procedures, than patients taking Zocor (simvastatin)." Later, on May 16, 2006, according to an article that day on the *Medical News Today* website, Pfizer announced at the American Heart Association Quality of Care and Outcomes Research Meeting in Washington, D.C. that a new economic analysis of the results of the IDEAL study "showed that one out of every six heart attacks, strokes or cardiovascular procedures could be avoided for coronary heart disease patients treated with intensive Lipitor therapy above and beyond those treated with Zocor over 4.8 years," providing "a cost savings for payors in long-term hospitalizations and surgical costs."

102. Just after Pfizer's announcement of the results of the IDEAL study in November 2005, the FDA ruled that Pfizer could claim that Lipitor saved lives by helping to prevent heart attacks, angina and the need for surgery to open clogged arteries. Prior to the FDA ruling, Pfizer had been limited in marketing Lipitor to trumpeting the drug's ability to lower cholesterol. Analysts at that time said that the FDA ruling permitting Pfizer to broaden its marketing message would give Pfizer a competitive edge over Vytorin.

103. A few months later, on March 14, 2006, the *New York Times* reported that a study (Crestor's ASTEROID trial) demonstrated that Crestor actually *reversed* the buildup of plaque in coronary arteries. The patients in the study, called ASTEROID, were given a 40-milligram dose of Crestor over a two-year period, and the study was heralded as demonstrating a statin's ability

to unclog arteries and thereby decrease the risks of suffering adverse cardiac events. A March 14, 2006 *Wall Street Journal* article entitled "Statin Use May Reverse Course of Heart Disease" stated that after two years on the 40 mg dose of Crestor, "the patients not only achieved extraordinarily low levels of LDL, researchers said, but the volume of heart-attack-inducing fatty deposits inside their coronary arteries fell 7% to 9%." The article also stated that "[t]he findings [from the Crestor trial] are among the most provocative yet to support the notion that lower is better when it comes to LDL, or bad cholesterol."

104. Pfizer responded that its REVERSAL trial, although not deemed statistically significant, resulted in a 5.9% plaque reduction through Lipitor treatment versus Pravachol, while alluding to the fact that it believed Crestor's ASTEROID trial was not designed "in a well-controlled manner." *World Markets Analysis*, "March 2006 ACC Meeting: Key Takeaways for Lipitor and Vytorin," Mar. 14, 2006.

105. These clinical results for Lipitor and Crestor put Vytorin at a serious competitive disadvantage. The pressure on Merck to obtain equally compelling support for Vytorin and Zetia grew.

106. By March 2006, both Pfizer and AstraZeneca were armed with studies showing that their cholesterol drugs provided clear health benefits beyond lowering cholesterol, and they were permitted to market these study results by truthfully asserting that Vytorin could make no such claims, at least beyond those health benefits attributable to Zocor alone. The results of this marketing advantage were immediate. As an AstraZeneca spokeswoman said (as reported in a May 8, 2006 *Dow Jones* article), there was "strong growth for Crestor prior to and after the release" of the March study. That article also noted that "Steve Nissen, head of Cardiovascular

Medicine at the Cleveland Clinic, noted that there had been no data directly linking Vytorin to cardiovascular outcomes, while Lipitor has such data."

107. Likewise, Dr. Michael Berelowitz, a senior vice president at Pfizer, stated in a June 23, 2006 *New York Times* article that there were no studies showing that Vytorin could reduce heart disease as effectively as Lipitor. In Dr. Berelowitz's words: "Other agents come in and all they can talk about is that they lower cholesterol and LDL. . . . They have none of the evidence of cardiovascular risk reduction and mortality risk reduction." A March 26, 2007 *Dow Jones* article similarly summarized: "Zetia, either alone or with a statin, hasn't been proven to prevent heart disease or heart attacks. Also, Vytorin hasn't been proven to have a benefit beyond simvastatin (generic Zocor) on cardiovascular outcomes."

108. For Vytorin, however, its clinical outcomes data was not yet available. By March of 2006, Merck and S-P clearly felt the pressure to return positive outcome trial data for Vytorin as securities analysts felt that "[c]learly, there are major shortcomings in clinical data relating to wider-held assumptions relating to cholesterol therapies… However, these trials will play a crucial role in both the positioning of Crestor, Lipitor and Vytorin on the formularies of Medicare Part D and their subsequent acceptance among physicians." *Id.*

109. In an effort to close the marketing gap and fill the void of positive clinical data, one tactic used by Merck and S-P to counter-market against Lipitor and Crestor despite their complete lack of clinical trial outcomes data, was to attempt to turn the positive outcome trials of their competitors, into positive results for Vytorin. M/S-P did this by pushing its "lower is better" marketing message, even in the face of the contrary data coming in from ENHANCE. For instance, immediately after the positive ASTEROID trial results for Crestor were released, Merck sprung into action in an effort to spin the ASTEROID results into a positive for Vytorin.

As reported in the May 8, 2006 *Dow Jones* article, a "Merck spokeswoman said there is mounting evidence that large decreases in bad cholesterol levels reduce the risk of cardiovascular events, and a study has shown Vytorin can provide greater reduction than Lipitor." Thus, Defendants continued to proclaim that "lower is better," and that, solely based on this rationale, Vytorin was better at reducing the risks of cardiovascular events. Defendants did so with extreme recklessness as, at a minimum, they had absolutely no data to support their statements and, at worst, they had received enough information from the ENHANCE study to know that such statements were false.

110. According to analysts, the Companies' tactics were successful, as analysts accepted the M/S-P spin as truth. According to analysts at Bear Stearns, for instance, the ASTEROID test results did not exactly thrust Crestor into a position of market dominance or threaten to undermine Vytorin's commercial success: "Rather [ASTEROID] reaffirms a growing body of evidence that says lower LDL cholesterol levels are better. To that end, Vytorin should benefit handsomely." Indeed, Bear Stearns analysts believed Vytorin would benefit *even more than Crestor* from ASTEROID, because of its belief that Crestor would continue to be dogged by "the negative perception of the drug's safety. Vytorin lowers LDL as well as Crestor, yet has no safety issues," Bear Stearns analysts wrote, parroting the M/S-P marketing message.

111. According to *Reuters*, moreover, who interviewed analyst Tim Anderson of Prudential Equity regarding the positive ASTEROID trial on Crestor, Merck and Schering-Plough were "already on the counter-attack and were briefing physicians on a head-to-head study comparing their drug Vytorin to Crestor, even though [the study] has yet to be published."

112. Merck and Schering-Plough employed similar tactics when marketing Vytorin against Lipitor. For example, in an article dated May 8, 2006, appearing on *Dow Jones*

Newswires titled "Pfizer's '06 Sales Target Seen As Difficult," the author wrote that Vytorin's primary weakness was its relative lack of clinical data which Vytorin's competitors were seizing upon in their counter-marketing: "As for Vytorin, some experts agree with Pfizer's assertion that [Vytorin's] clinical data are weaker than that for Lipitor. Dr. Nissen, head of cardiovascular medicine at the Cleveland Clinic, noted there has been no data directly linking Vytorin to cardiovascular outcomes, while Lipitor has such data." According to the article, a Merck spokeswoman countered with the Merck marketing mantra that ***"there is mounting evidence that large decreases in bad cholesterol levels reduce the risk of cardiovascular events, and a study has shown Vytorin can provide greater reduction than Lipitor."*** (Emphasis added). These statements were made by Merck even though by May 2006, the ENHANCE data showed Vytorin was no better, and actually worse, than drugs like Lipitor, because even though Vytorin drove down LDL cholesterol levels, there was no proof it had any positive effect on reducing "the risk of cardiovascular events."

113. Merck, therefore, desperately needed a study to show that Vytorin's dual inhibition function lowered cholesterol *and* reduced atherosclerosis and a patient's risk of adverse cardiac events – Merck needed scientific data showing that the "lower" cholesterol levels produced by Vytorin was indeed "better."

114. Merck had another reason to commence a study – it knew that its patent on Zocor would expire in June 2006, and it needed to find a reason for physicians to prescribe, and patients to buy, Vytorin at prices which Merck knew would far exceed the price of generic simvastatin.

115. As the *New Jersey Star Ledger* later reported on March 30, 2006, a 10-milligram tablet of Vytorin and other brand name statins typically costs more than $2, while generic Zocor

(simvastatin) was "expected to cost about 35 cents." Similarly, *The New York Times* remarked on November 21, 2007 that at that time, "Merck's Zocor [was] subject to cheap competition from generic simvastatin that costs pennies a day. But Merck can continue to command name-brand prices through Zetia and Vytorin, which both cost about $3 a day. . . ."

7. Vytorin And Zetia Quickly Become Blockbuster Drugs

116. To promote the growth of Vytorin and Zetia through the "lower is better" and "dual inhibition" marketing campaigns, Merck spent enormous sums on advertising concerning Vytorin. The *NEJM* reported that Merck and S-P spent over $200 million in 2007 on direct-to-consumer advertising for Vytorin alone in the United States.

117. The advertising campaign was effective – as the March 30, 2008 *NEJM* article noted, use of Zetia and Vytorin soared in the United States (increasing from a 0.1% share of lipid-lowering agents in 2002 to 15.2% in 2006), but climbed only minimally in Canada (increasing from 0.2% share in 2003 to 3.4% in 2006) where the advertising of drugs to consumers is not allowed. The article stated that the $200 million marketing campaign "probably had an effect on U.S. sales of [Zetia and Vytorin]."

118. As Representative Stupak stated in a January 17, 2008 *Newsweek* article, the advertisements purchased by the Companies supported an "assumption . . . that lower cholesterol means reduced plaque means reduced risk of heart attack and stroke," but the results of the ENHANCE study, as Defendants well knew by the beginning of the Class Period, showed that Vytorin failed to produce those benefits. Nevertheless, throughout the Class Period, the Companies continued to press their marketing claims even though as a result of ENHANCE they knew those claims were false and misleading.

119. The marketing message crafted by Merck and adopted by S-P worked. Analysts quickly predicted blockbuster sales for the combination drug. According to a July 24, 2004

article in *The New York Times*, David Moskowitz, an analyst at Friedman, Billings, Ramsey & Company, forecasted annual worldwide sales of Vytorin to reach $3.5 billion by 2008. The article also reported that:

> 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. … Schering-Plough turned to Merck in a marketing agreement to help persuade doctors that Zetia has advantages over medicines like Lipitor [from Pfizer] and Crestor from AstraZeneca.

Their repeated proclamations that "lower is better' and that Vytorin had a "dual inhibition" function drove sales of Vytorin ever higher. Indeed, Vytorin quickly reached blockbuster status following its July 2004 launch. By October 2005, it was the third best-selling cholesterol-lowering drug (according to an October 12, 2005 *AP Financial Wire* report), and by the end of January 2006, it was used as a first-line therapy in 46% of new prescriptions (according to a World Markets Research Centre report, dated January 31, 2006). It was outpacing sales of rival statins Pravachol and Crestor.

120. As Merck and analysts predicted, once Merck lost patent exclusivity in Zocor, sales of that brand-name drug plummeted as doctors and pharmacy-benefit managers shifted patients to generic versions of the drug. A July 25, 2006 *Wall Street Journal* article noted that a company in India had already captured 65% of the market for generic simvastatin. However, many Zocor patients were switching to Vytorin. Al Rauch, analyst for A.G. Edwards, succinctly stated that "Vytorin looks like it's actually cannibalizing Zocor and Pravachol," and he noted that Zocor patients were leaving that drug behind in favor of Vytorin. In 2006, U.S. sales of Vytorin topped $2 billion, making up for more than $1 billion in sales lost after generic forms of Zocor were released in June 2006.

121. Analysts were encouraged by the dramatic rise in sales of Vytorin, and raised their targets for Merck's earnings and stock price. On July 24, 2006, a Natixis Bleichroeder Inc. analyst report increased the target price for Merck to $41 nearly 8%, based in part on predicted increased sales "mostly due to the higher contribution from the Zetia/Vytorin JV." On September 28, 2006, Natixis Bleichroeder issued another analyst report which described "continued strength in Vytorin" and increased estimates for sales of the drug and Merck's earnings coming from M/S-P. About three weeks later Natixis Bleichroeder issued another report increasing its target price for Merck stock to $52 (from its previous estimate of $41) based in part on "strong sales of Vytorin as part of the cholesterol JV [joint venture] with Schering-Plough."

122. Other analysts similarly recommended investing in Merck due to the Company's success with Vytorin. On October 12, 2006, Prudential Equity Group, LLC predicted that "Vytorin/Zetia sales will continue to grow" as "volume in the U.S. for both Vytorin and Zetia [was continuing] to grow at a double-digit pace from quarter to quarter." Hilliard Lyons analyst reports in 2006 repeatedly referred to Vytorin as "a key component in Merck's strategy to offset the 2006 loss of patent protection for Zocor in the United States." A December 12, 2006 Credit Suisse report rated Merck an "Outlook Solid" and emphasized "Vytorin's importance" and Credit Suisse's "view that this franchise is strategically important." A.G. Edwards & Sons, Inc. issued a report on December 19, 2006 stating that "the outlook for [Merck] will continue to improve over the next several years with the growth of the Zetia/Vytorin franchise."

123. Analysts continued their positive recommendations of Merck into 2007 as sales of Vytorin continued to surge while Merck and S-P continued to withhold publication of the results

of ENHANCE – results that the Companies well knew threatened to undermine the commercial viability of Vytorin and Zetia.

124. A January 3, 2007 Bear Stearns analyst report upgraded Merck to "Outperform" from "Peer Perform" stating ***"[t]he cholesterol [joint venture] accounts for 22%/27% of MRK's [Merck's] pretax income in '07/'10***. Lower-priced generic simvastatin is a risk to the statin class; but appears to have had a limited impact on Vytorin based on 1) robust LDL-lowering, 2) safety vs. high-dose statins, 3) 27% discount to high dose Lipitor; & 4) ease of shifting uncontrolled generic Zocor users. Vytorin is the primary choice for generic Zocor users needing stronger LDL-lowering." (Emphasis added).

125. A January 26, 2007 Prudential Equity Group, LLC report predicted that the "Vytorin/Zetia joint venture with marketing partner Schering-Plough" should be a "key" contributor to performance. A.G. Edwards & Sons, Inc.'s July 23, 2007 report characterized Vytorin as one of Merck's "key in-line franchises" and predicted " improvement in [Merck's] operating leverage… is something that we anticipate will continue to improve over the next several years."

126. In July 2007, Verispan LLC, a market research company, reported that Vytorin prescriptions had jumped 20% in the previous twelve months, and sales rose in the face of a 90% increase in prescriptions for generic versions of Zocor, fueled by insurance companies pressing doctors to use cheaper medicines. Craig Maxwell, a J.P. Morgan Securities LTD analyst, noted that Vytorin's sales had risen 90% between 2005 and 2006, and predicted that the drug could reach $4.6 billion in sales by 2012.

127. On September 7, 2007, Deutsche Bank issued its report on Merck, characterizing it as a "Top Pick." On November 27, 2007, Bear Stearns issued a report in which it raised its

sales and earnings estimates for Merck, as well as its target price for Merck's stock. Deutsche Bank continued its upbeat prognosis on Merck in its November 29, 2007 "Company Alert" when it recommended buying Merck stock and raised its price target to $70 from $62. In a December 4, 2007 conference call, Peter Kellogg boasted that "[t]he income contribution related to Merck Schering-Plough is expected to increase in 2008 based on the continued growth of Zetia and Vytorin in the U.S. and in Europe."

128. On December 11, 2007, Credit Suisse noted that "all is well" with Merck. The next day, December 12, 2007, Cowen & Co. said in its report that Merck's "momentum [was] poised to continue." Deutsche Bank said the same in its December 12, 2007 report, recommending a "buy" on Merck stock.

129. While Defendants continued to conceal the damaging results of the ENHANCE study, sales of the hugely profitable Zetia and Vytorin increased rapidly, making the Merck/S-P cholesterol franchise the second largest in the world. The tables below illustrate the global sales of Zetia and Vytorin by quarter (in millions, rounded) as well as the relative increases in sales:

Zetia	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	Full Year
2006	415	474	501	535	1,925
2007	544	605	606	680	2,436
% Change (2007 vs. 2006)	+31%	+28%	+21%	+27%	+27%

Vytorin	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	Full Year
2006	371	491	517	554	1,933
2007	616	683	684	778	2,761
% Change (2007 vs. 2006)	+66%	+39%	+32%	+40%	+43%

D. MERCK KNEW THAT THE ENHANCE RESULTS WERE BAD FOR VYTORIN LONG BEFORE THOSE RESULTS WERE MADE PUBLIC

1. Merck And S-P Begin Receiving ENHANCE Test Results In 2005

130. The ENHANCE study commenced in August 2002 with the screening and randomization process for eligible patients. As Dr. Kastelein reported in various articles, the CA IMT measurements were made at various intervals over two years; accordingly, preliminary data (for the early interval measurements) was available for the early entrants by the beginning of 2004, and the last measurements on early entrants had been made by the fall of 2004. The data was sent to Merck and S-P (through the M/S-P joint venture), and those companies then forwarded the data to Dr. Kastelein and other researchers. The schedule for ENHANCE was to evaluate the last patient in April 2006, "unblind" the data in the summer and send the results back to Dr. Kastelein for analysis, and he would present the findings at a national meeting of cardiologists in the fall of 2006. However, Defendants changed this schedule once they were able to determine from their early reviews of the data in 2005, that the combination of Zetia and Zocor produced no additional benefits in terms of reducing arterial plaque.

131. Representatives of the Companies admitted (in a *Wall Street Journal* article appearing years later, on March 24, 2008), that "Dr. Kastelein's team began sending complete measurements from the first group of patients" in "late 2005" following which statisticians "began routine checks to make sure the data were in order." Those initial checks failed to show the benefit that the Companies hoped for and the market expected. The test results showed no statistically significant difference in CA IMT measurements between the two groups of patients in the study. In other words, early results showed no benefit in taking Vytorin over simvastatin alone.

132. In response to these initial results showing that ENHANCE was not providing the results that they had expected, toward the end of 2005, Merck officials began to eliminate public references to the study. From 2002 through 2004, Merck had constantly touted the ENHANCE study and the benefits it would provide to the commercial success of Vytorin. *See supra* Section IV.C.5. Beginning, however, with Merck's Annual Business Briefing at the end of 2005, ENHANCE was dropped as a topic of conversation. On December 15, 2005, with ENHANCE just months away from completion and with Merck and S-P having already begun the process of analyzing the preliminary ENHANCE data, Merck for the first time in years omitted any reference whatsoever to ENHANCE in its Annual Business Briefing. No longer did Merck tout ENHANCE to the investment community and shareholders as a trial "expected to drive future growth," nor did Merck state that ENHANCE would "demonstrate additional benefits of Vytorin." Instead, Merck's management avoided any reference to ENHANCE or any outcome studies at all relating to Vytorin. Even the following year, in Merck's December 2006 Annual Business Briefing, Merck made only a single, veiled reference to "endpoint studies" which it hoped to "complete and promote" but again made no reference whatsoever to ENHANCE.

133. Thus, by late 2005, Defendants knew they had a problem. The study the Companies had sponsored, and which they hoped would substantiate their message that "lower is better" with respect to Vytorin and that Vytorin's "dual inhibition" feature made it a superior drug to traditional statins, instead showed just the opposite. Defendants desperately sought a way to manage, or outright reject the data that they knew did not, and would not, show that Vytorin stopped or reduced arterial plaque more than simvastatin alone.

134. Despite the care taken in establishing the ENHANCE test protocols, selecting the measuring apparatus and software, and finding certified sonographers, beginning in late

2005/early 2006, following the initial reviews of the test results, the Companies began to question Dr. Kastelein on the accuracy of the data. The Companies, troubled by the test results, pointed out what they alleged were problems:

> The companies [Merck, S-P, and M/S-P] began sending what became a constant flow of inquiries to Dr. Kastelein asking him and his lab to check and clarify data and re-read images in a bid to resolve the problems. Early in 2006, the companies' committee proposed a different approach to reading the still-blinded data, and pitted Dr. Kastelein's lab against an outside research team to see whether one would be more accurate. There was no meaningful difference and Dr. Kastelein's team was kept on the case, spending the second half of 2006 re-reading most of the 40,000 images taken in the study, according to the companies.

Wall Street Journal (March 24, 2008).

135. Clearly, Merck was concerned that the results it had received at that time showed such small, statistically insignificant differences between the test groups that there would be no data supporting the use of Vytorin over simvastatin alone. Indeed, the March 24, 2008 *Wall Street Journal* article included a criticism levied by Allen Taylor, Chief of Cardiology Service at Walter Reed Medical Center, Washington, D.C. and an expert in imaging neck arteries, who remarked on Merck's belated challenges, stating that "It's very atypical for a trial to go through this sort of scrutiny." The article also noted that "Dr. Kastelein . . . grew frustrated by the companies' demands and repeatedly tried to reassure the sponsor about the data and its readiness."

2. The Companies Try To Challenge The Test Results

136. Having failed in their initial attempt to challenge and shape the test results, the Companies tried again in January 2007. At that time, Merck and S-P (through their M/S-P joint venture) retained 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" to provide advice and a written report on purported problems with CA IMT measurements in the ENHANCE trial.

137. Dr. Bots provided the Companies with his report on or about January 26, 2007. He concluded that there were no problems with the ENHANCE data that would justify any delay in releasing the test results. However, it was not until April 11, 2008 that the Bots Report was made public, when Representatives John Dingell (Chairmen of the Committee on Energy and Commerce) and Bart Stupak sent a letter to defendant Richard Clark and S-P CEO Fred Hassan attaching the report and asking, among other things:

> What was the purpose of hiring an independent consultant to review ENHANCE data, and why did Merck/Schering-Plough not proceed with data analysis after Dr. Bots' independent consultation report indicated that the ENHANCE data were, in his own words, "fine?"

138. As the Bots Report obtained by Congress explains, Merck and S-P set up three meetings in Amsterdam at the Core Echo Laboratory to address the Companies' purported concerns – one on January 16, 2007 and two on January 18, 2007. The Report defined Dr. Bots' 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."

139. 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 study team, Dr. Bots concluded that the CA IMT measurements "were indeed done in a manner that was described in the protocol." Emphatically, twice more in his report he stated: "[t]he CIMT measurements seem to be done according to the procedures outlined in the protocol." On this issue, he concluded that "[t]he 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."

140. On the purported issue of "outliers," Dr. Bots again found no problems with the ENHANCE data. He noted that "[t]he 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 found that:

> [the] data are well in line with the studies that have been published in the literature. ***Based on these findings there seems to be little concern regarding the validity and precision of the data.***

(Emphasis added). In evaluating "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." Accordingly, Dr. Bots concluded that the "variability due to imaging and reading" was "excellent."

141. In his Report, Dr. Bots also addressed the issue of missing data. As the Report stated, "[o]f 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." He further rejected any concerns by explaining that:

> 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.

142. Thus, Dr. Bots found the purported concerns unjustified, and stated in his "Conclusions" section of the Report that "the evidence to me is sufficient to indicate that the data are fine." In his "Summary" he likewise stated: "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." As the *Wall Street Journal* later reported on March 24, 2008, "[i]n January 2007, an independent consultant told the companies that the quality of the ENHANCE data was similar to what was found in other comparable trials."

143. Despite Dr. Bots's emphatic conclusions, Merck and S-P pressed for ways to change the results by, for instance, changing the way CIMT was measured through selection of images, or changing the parameters used to define outliers. However, Dr. Bots found that such proposals would have only modest effects writing:

> [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, randomisation protects against bias the estimate of the difference between treatment arms.

144. In short, Dr. Bots concluded in his Report that there were no issues or problems in following the protocols for the ENHANCE trial, taking and recording the CIMT measurements, dealing with outliers, or addressing missing data. The Bots Report demonstrated that there was no excuse to delay release and publication of the ENHANCE results. Merck's Dr. Musliner later attempted to defend his Company's actions, stating: "It wasn't that the study looked like it was totally inadequate . . . . The more you can reduce your variability, the greater your chances of showing the significance of smaller differences."

145. Although there was no excuse to delay publication of the results, Merck and S-P still kept them a secret, and engaged in additional attempts (set forth below) to change the test

results in an effort to obtain data that showed Vytorin to be what it was not – more effective at counteracting plaque buildup than generic Zocor.

3. The ENHANCE Trial Results Are Published On The Café Pharma Website Beginning In March 2007

146. Café Pharma (www.cafepharma.com) is a website which provides "discussion boards" which serve as a reference source for pharmaceutical sales professionals, office staff, and others interested in the pharmaceutical industry and a place for those individuals to post information particular to their industry. These professionals frequent Café Pharma to review and exchange information about pharmaceutical companies and the products they sell, their competitors, and other developments affecting people who work in the industry. The website features individual pharmaceutical company boards, which range from Aai Pharma to Zygogenetics, that function like virtual bulletin boards, allowing visitors to the website to visit any company's board, read comments posted on the board, or post their own comments on it anonymously.

147. Specific results of the ENHANCE study were publicly posted on the Café Pharma website on both the S-P and Merck boards a full year before the companies officially released the full study results in March of 2008. Because the information in the postings was both detailed and accurate, and fully corroborated by the ENHANCE study results later released by the companies, it is indisputable that Merck and S-P company insiders – those who would in fact have known of the study results and been in a position to post the results on Café Pharma – knew about the ENHANCE study results at the time they were posted, a full year prior to their public release.

148. Starting in March 2007, dozens of posts about the ENHANCE trial began appearing on the S-P and Merck boards at Café Pharma. Some of those posts revealed specific,

credible details about the ENHANCE study results that only Merck and S-P insiders and study investigators would have known at the time. This demonstrates that the results were either un-blinded much earlier than Merck and S-P claimed, or that the results were identifiable without being un-blinded and the Defendants knew the results.

149. The specific information posted on the Café Pharma website concerning ENHANCE throughout 2007 did not give investors reason to investigate further because the anonymous nature of the posts, without concomitant confirmation of their accuracy by Merck, S-P or other independent, reliable third-party sources, called into question their validity at the time. That changed, however, when Merck and S-P disclosed the actual results of the ENHANCE study in early 2008, and those results confirmed that the leaks posted on the Café Pharma discussion boards were accurate. Moreover, while the Café Pharma posts were not sufficiently reliable at the time of their posting to be material to public investors, they could not have been ignored by insiders at Merck and S-P charged with overseeing and managing the ENHANCE study.

150. Lead Plaintiffs have communicated with multiple confidential witnesses, including former Merck and S-P employees and consultants, who report that employees at those companies, including upper management, were familiar with Café Pharma and visited the boards on a regular basis.

151. Confidential Witness #4 ("CW 4") confirms that personnel at Merck visited Café Pharma. This source was a sales representative for Merck from February 2007 through May 2008 who was familiar with Café Pharma and read postings on the site. Confidential Witness #11 ("CW 11") was a Merck sales representative from January 2002 until July 2008. CW 11

reported that sales representatives were told posting on the site was a violation of Merck policy, which confirms that Merck management knew about and monitored the Café Pharma site.

152. Personnel at S-P visited Café Pharma as well. Confidential Witness #2 ("CW 2"), a District Sales Manager with S-P from before 2002 until early 2007, knew about and visited Café Pharma. This source believes that senior management at S-P, at least up to the national sales director level, also visited Café Pharma. CW 2 recalled hearing the national sales director commenting, in connection with a corporate acquisition by S-P, "You should have seen what was posted on Café Pharma today." Confidential Witness #9 ("CW 9") was a sales representative for S-P from March 2004 to early 2007 responsible for selling Zetia and Vytorin. This source reported familiarity with the site, frequenting it to find background information on pharmaceutical companies. CW 9 said that the site provides a place for internal company employees and sales representatives to "vent." CW 9 believes that while outside individuals occasionally will post about a company in which they are interested, generally the postings are by employees internal or networked throughout the company in question. Confidential Witness #7 ("CW 7") was a former regional Sales Director at S-P from 2004 to early 2008. CW 7 estimates that 95% of the people whom the source respected the most in the pharmaceuticals business, including mentors, used the site as a source for information. CW 7 knew that management at S-P monitored the site because CW 7's managers mentioned postings in conversation. In sum, these various confidential sources consistently state that personnel at their respective companies (Merck and S-P), including upper management, knew about and visited the Café Pharma website for a variety of reasons.

4. The Café Pharma Postings Show That Insiders At Merck And S-P Knew About The Dismal Test Results Long Before The Results Were Formally And Publicly Disclosed

153. Numerous postings on Café Pharma discussion boards beginning in March 2007 contained information about the ENHANCE study results that was consistent with the actual test results disclosed by Merck and S-P the following year, demonstrating the Companies' knowledge of the test results long before the results were formally announced in 2008.

154. On March 7, 2007, under the subject heading "ENHANCE," the following thread appeared on the S-P board at Café Pharma: "Hey, whatever happened to the ENHANCE study for Zetia that was supposed to be at ACC [The American College of Cardiology Conference in March 2007]? One of my docs told me that it wasn't anywhere on the agenda at the meeting, but METEOR (Crestor) was. Is there some problem?" On March 9, 2007, a reply post in the March 3, 2007 ENHANCE thread appeared: ". . . One of my docs told me that he had heard from someone at SPRI [Schering-Plough Research Institute] that there was no difference between the Zetia and placebo groups in terms of carotid thickness."

155. A subsequent reply to the March 7, 2007 posting identified further specific information about the ENHANCE study results. On March 13, 2007, a new post declared: "have a buddy at SPRI. He says that the study is a bust. Adding Zetia to already maxed-out statin is useless." These various postings on Café Pharma demonstrate that personnel at Merck and S-P were aware of and discussing the results of the ENHANCE study, or recklessly disregarding those facts, by March 7, 2007 or no later than March 13, 2007 – each more than one year before the Companies released the full results.

156. Other revealing posts appeared throughout 2007 on the Café Pharma boards, providing details on the ENHANCE study results. On June 3, 2007, a new thread appeared on Café Pharma entitled, "Re: What happened to ENHANCE?" One post complained: "Still not

released! Heard it crashed and burned!" The next day, on June 4, 2007, a reply post on the thread provided the following highly detailed information about the ENHANCE study results: "NO difference in the primary endpoint (change in CIMT baseline) between simva+zetia and simva+placebo, and there were higher rates of liver problems in the simva+zetia group." This post is remarkably accurate in stating (as Merck and S-P would disclose a year later) that there was no difference in CIMT measurements between the Vytorin (Zetia plus simvastatin) and simvastatin-only study groups.

157. On July 19, 2007, yet another new thread about ENHANCE appeared on Café Pharma, this one on the Merck board, and entitled: "ENHANCE - Zetia 10/Simva 80 NOT better than simva 80/placebo!!!" Like other postings, this one concerned facts which Merck and S-P would not disclose until early 2008. The July 19 post concerned the ENHANCE results showing that the combination of 10 mg of Zetia with 80 mg of simvastatin produced no additional benefits in reducing atherosclerosis over 80 mg of simvastatin combined with a placebo. The author of the post stated:

> Now we know why this was pulled from ACC!!! [the American College of Cardiology Conference held on March 24-27, 2007 in New Orleans] We've been living off the LDL lower is better story versus statins alone since launch. This is the first trial with a clinically meaningful end[p]oint (carotid IMT) and shows that ***adding Zetia to high dose [simvastatin] provides no real benefit***. By inference, it suggests that Vytorin is really no better than the simva component alone, too. Based on this, it's easy to predict that IMPROVE-IT may very well be a bust as well. The only saving grace of that trial is that [it] is so large (10,000 pts) that even very small differences may still be statistically significant-but not really clinically significant. Economically-speaking, generic simva is so cheap now (and getting cheaper) that adding Zetia or using Vytorin will have to provide a wide margin of benefit in order to make up for cost differences. ***ENHANCE shows us that there is and will be no wide margin of benefit***. We're screwed once MCOs [managed care organizations] and PBMs [pharmacy benefit managers] figure this out. Better get those rebates ready!

(Emphasis added). In addition to correctly stating (as Merck and S-P would disclose much later) that there was no statistically significant difference between the treatment groups in the ENHANCE study, the post correctly discussed the study being "pulled from ACC," referring to how the ENHANCE results were intended to be presented at the American College of Cardiology Conference in March of 2007 but removed at the last minute. Further, the statement that "We've been living off the LDL lower is better story" referred to the Merck marketing message that lowering LDL cholesterol by any means is key to improving cardiac health, although ENHANCE shows that not all means for reducing LDL levels provide the same increased health benefits and outcomes. However, Merck and S-P continued their marketing refrain that "lower is better," even after the Companies knew that ENHANCE flatly contradicted that claim.

158. Several days later, on July 24, 2007, another post on Café Pharma responded to the original July 19, 2007 post, foreshadowing tactics Merck and S-P would later use to challenge and manipulate the ENHANCE test results:

> I think the time delay is because they are stalling in order to do 2 things: 1) datamine the trial to try to find some secondary or tertiary endpoint analysis that looks positive to some degree to offset the primary endpoint not being met, and 2) develop a counter-strategy to spin the results and/or discredit/disavow the trial (i.e. point out limitations in study design, the endpoint, etc). By itself, this trial won't torpedo the whole thing because there are too many people who think that carotid IMT isn't an ideal endpoint, and they'll come out with some BS about "having to wait until the results of IMPROVE-IT before we have the definitive answer". [They] should be shitting bricks over in R&D and Marketing, [because] the ARBITER-1 trial (an IMT study) perfectly predicted both the REVERSAL and PROVE-IT trials. IMPROVE-IT is 10,000 patients – any trial requiring that large of an N indicates that the absolute difference between the 2 comparators is expected to be quite small. If ENHANCE indeed is negative, and I have heard from sources close that it is, then IMPROVE-IT is definitely at risk. ENHANCE will hurt, and it

> may slow us down, but IMPROVE-IT may cause the whole thing to start a backslide.

This post, like many prior ones, accurately notes that the ENHANCE study results were "negative." The post also accurately discusses the attempts by Merck and S-P to change the primary endpoint of the study (the Companies' highly unusual break from scientific protocol in November 2007 which drew intense criticism), and the companies' subsequent "spin" to discount the importance of the ENHANCE study, where Merck and S-P claimed that any results achieved with this small specialized population would not be applicable to the population as a whole, and directed the public's attention to another study in progress called IMPROVE-IT.

159. News about ENHANCE's failure began to appear more frequently on the message boards in the late summer and fall of 2007. On August 19, 2007, a thread appeared on the Merck board entitled, "Vytorin ENHANCE Dinner Programs." The poster complains: "This [is] so stupid for us to do these programs with 'late breaking news' only to try and overcome that our ENHANCE study bombed! My manager actually thinks that our docs are going to come out to our programs just to [hear] that Vytorin is no better than simva . . ." A reply to the August 19, 2007 thread appeared a day later in a post that declared, ". . . ENHANCE shows nothing but we are going to SELL that we can do something we can't . . ."

160. A month later, yet another post reveals additional, accurate, detailed information about the drug trial. On September 19, 2007, a new thread appeared on the S-P board, entitled "ENHANCE." The author wrote: "I feel for everyone waiting for this trial to come out. I heard today things [are] not looking good for you guys. I really hope you all can pull your butts out of the fire when that thing comes out." A reply post on September 20, 2007 revealed some very specific details:

> One of my docs is a very good friend of the study PI [primary investigator] overseas. I'm told that the *study* ***IS negative in that***

> ***there is absolutely no difference in carotid IMT between simva 80 + placebo vs simva 80 + Zetia 10. Although Zetia did lower LDL-C as expected, it did nothing else of any value. So much for "lower is better"! Apparently, the PI and the company have been arguing back and forth about how/when to release the info. PI wants to report, but company keeps blocking/delaying.*** We're pretty well-screwed if what is essentially max dose Vytorin is no better than max dose generic simva!!

(Emphasis added).

161. This post revealed material information, none of which can be disputed, that would not be disclosed or verified by the Companies for months. First, the information about the study being negative and the medication dosages for the treatment arms is completely accurate, as corroborated by the study results released by Merck and S-P in 2008. Second, the Zetia treatment arm did lower LDL cholesterol levels as expected, but there was no further value to the medication at all, as there was no statistically significant effect on atherosclerosis from the addition of Zetia to simvastatin, as evidenced by the CA IMT measurements in the study. Finally, the author accurately described the ongoing dispute between Merck and S-P and the "PI" (principal investigator), Dr. John Kastelein, who was (and is) located in the Netherlands, "overseas." It would be almost eight months later when in the course of a Congressional inquiry e-mails were publicly disclosed which illustrated the companies' struggle with Dr. Kastelein, including back-and-forth arguments between them highlighting Dr. Kastelein's frustration with the companies' refusal to publish the ENHANCE study results and their ongoing delay tactics. Based on all of the accurate, detailed information regarding the ENHANCE study results that was posted on the well-known Café Pharma internet chat site, Defendants cannot disavow knowledge of that information, especially since it was the Companies, not the researchers, who had control of the data.

162. On November 14, 2007, yet another post indicated that the ENHANCE investigators running the trial and studying the data had already discussed the negative study results:

> ***[W]ord of mouth from investigators in running the trial is that it is a negative study***. We [S-P] and Merck both talked up this study publicly a bunch before the results were known internally, now both are stone cold silent. The study was first supposed to be presented at AHA [the American Heart Association meeting in] 2006, then ACC 2007, and now both ESC and AHA are passed this year with not a peep. You do the math.

(Emphasis added). While Merck and S-P publicly announced that the study remained blinded until December 31, 2007, the post shows that people within the Companies knew the results months, if not years, before the study was "formally" un-blinded.

163. These Café Pharma postings included accurate, detailed descriptions of the study results, which apparently were passed along through personal networks from both SPRI personnel and the study investigators. The numerous and accurate postings demonstrate that decision makers within Merck and S-P knew or recklessly disregarded the results of the ENHANCE study long before the results were formally announced. The posts also reflect consternation and disappointment among Company insiders that disclosure of the results was delayed for so long, and show that the Companies were actively seeking any way to put a positive "spin" on the results before formally presenting them.

5. Merck Has A Long-Standing Practice Of Hiding Information Regarding Adverse Drug Trials And Did So With ENHANCE

164. On May 31, 2005, *The New York Times*, in an article entitled "Despite Vow, Drug Makers Still Withhold Data," reported:

> Within the drug industry, companies are sharply divided about how much information to reveal, both about new studies and completed studies for drugs already being sold. The split is unusual in the

> industry, where companies generally take similar stands on regulatory issues.
>
> Eli Lilly and some other companies have posted hundreds of trial results on the Web, and pledged to disclose all results for all drugs they sell. ***But other drug makers, including Merck . . . , release less information and are reluctant to add more, citing competitive pressures.***
>
> ***[T]he companies can hide negative trial results by refusing to publish studies, or by cherry-picking and highlighting the most favorable data from studies they do publish.***
>
> *** * ***
>
> Lilly has also posted the results of many completed studies to clinicalstudyresults.org, the website created last September by PhRMA. That site now contains some information on nearly 80 drugs that are already on the market. ***Both Lilly and Glaxo have posted detailed summaries of hundreds of studies . . . . Merck has posted none.***

(Emphasis added).

165. The next day, June 1, 2005, *The New York Times*, in an article entitled "Hiding the Data on Drug Trials," reported further details concerning certain pharmaceutical companies' efforts to hide negative trial results from the public:

> By law, the companies are supposed to register important trials with a government Web site. Most manufacturers are complying, but the three big obfuscators – [including] Merck [ ] – are often getting around the requirement by not naming the drugs they are testing, instead using phrases like "an investigational drug." ***Merck was the worst offender, failing to provide a drug's name some 90 percent of the time***.

166. Merck's Vioxx-related legal troubles were quite similar to its shenanigans here, in that it involved Merck's efforts to suppress and spin negative clinical trial results. With Vioxx, Merck "voluntarily" withdrew its drug from the market in 2004 after Merck claimed that data from a new study showed Vioxx was increasing the risks of heart attacks and strokes. According to independent researchers writing in the British medical journal *The Lancet*, however, who

analyzed data from 29 prior clinical trials of Vioxx, including unpublished results, this so-called revelation was nothing "new" to Merck. According to the *Lancet* researchers, Merck knew as early as 2000 that Vioxx had links to heart attacks and strokes, but it suppressed and twisted this data in an effort to hide or minimize the risk while it collected billions in profits. Among other things, the *Lancet* report heavily criticized Merck's spin of earlier data from studies that clearly showed Vioxx's adverse effects on the heart.

167. The *Lancet's* scientific expose of Vioxx was followed up by two *Wall Street Journal* reports. The first report, on October 5, 2004, stated that Vioxx was responsible for more than 27,000 heart attacks and sudden cardiac deaths before Merck decided to recall the drug. The second report, on November 1, 2004, claimed that documents existed showing that Merck hid or denied evidence for years that its blockbuster arthritis drug Vioxx causes heart problems, and it detailed specific emails and correspondence showing that Merck executives clearly knew about the increased risks of heart attack and stroke. These documents included a March 9, 2000 e-mail from Merck research director Edward Scolnick to colleagues conceding an elevated risk of heart attack and stroke was "clearly there," and a training document from Merck that listed potentially difficult questions about Vioxx's heart risks and stated in capital letters, "DODGE!"

168. Merck's practice of hiding information regarding its drug testing from the public, fully evident with respect to Vioxx, also occurred with ENHANCE. Strangely, Merck also failed to appoint a steering committee. Confidential Witness #8 ("CW 8"), a Merck research director through August 2008, said s/he was shocked when s/he learned that Merck had had results of the ENHANCE study for almost two years before publication and stated s/he did not know why there was no steering committee for the study.

169. Confidential Witness #1 ("CW 1"), a Merck senior manager in marketing for years, noted that it made absolutely no sense not to have a steering committee in ENHANCE, because such a committee is a vital component in any pharmaceutical study. In brief, a steering committee is made up of "key opinion leaders" who are not employees of the funding company, such as Merck, who lend objectivity when advising on how the study is run and how the results are compiled and distributed. Asked if the damage related to the release of the ENHANCE study might have been averted had a steering committee been in place for guidance, CW 1 said, "I think so, yes, absolutely."

170. The principal investigator for ENHANCE, Dr. Kastelein, shared these concerns. On March 31, 2008 a *Wall Street Journal* blog entitled "Hard Lessons from Vytorin's 'Trial out of Hell '" tackled the steering committee question:

> First, I'm never going to do another trial on my own, [Dr. Kastelein] said. I would really have loved to have had a steering committee next to me. Independent committees can provide a buffer between clinical trial leaders and companies sponsoring trials to handle scientific disputes; none was appointed for Enhance. Second, it's never good to wait too long for the results of trial, he said. From all points of view, it's always better once the last patient is out (and evaluated) that the results are rapidly known.

6. E-mails Between S-P And Dr. Kastelein Confirm That Merck And S-P Knew The Study Results Months Before Their Publication

171. As outlined in various posts on Café Pharma, Merck and S-P not only knew that the study results were negative at least a year before the full results were finally published, the Companies were in a battle with the principal investigator over publication. The ENHANCE results were originally set to be disclosed at a conference to take place at the end of 2006. That release date was adjourned. Then, Dr. Kastelein was prepared to publish in early 2007, but the Companies continued to block and delay disclosure of the results. The struggle between the

Companies and Dr. Kastelein was documented in a series of back-and-forth e-mails, which were not revealed to the public until they were unearthed in April 2008 through a Congressional inquiry.

172. During the summer of 2007, Dr. Kastelein communicated with senior S-P researchers, including researchers at Schering-Plough Research Institute ("SPRI") declaring that there was no good reason to delay publication of the study results. On July 6, 2007, Dr. Kastelein sent the following email regarding the ENHANCE study:

> ***[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.
>
> John

(Emphasis added).

173. In response, Dr. Strony offered the following explanation for the delay:

> 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…

174. Attempting again to push for publication of the data, Dr. Kastelein e-mailed a reply to Dr. Strony on July 7, 2007, now including 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***
>
> John

(Emphasis added).

175. Dr. Veltri responded this time, offering yet another rationalization for the delay. Not content with Dr. Veltri's response, 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 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.***
>
> Regards, John

(Emphasis added).

176. Confidential witnesses have provided statements supporting what Dr. Kastelein wrote, in particular, that Merck and S-P were in control of the ENHANCE data. Confidential Witness #5 ("CW 5") was a consultant for the M/S-P joint venture on the ENHANCE trial who worked directly with researchers in Amsterdam for approximately four to five years on a variety of tasks, including quality control of the ultrasound imaging. Although this source had expertise in measuring, examining and interpreting ENHANCE study data, this person did not have direct access to any of the databases, and when information was needed on how individual sonographers or readers were performing, CW 5 was forced to request the relevant data from Dr. Strony, saying that CW 5 frequently e-mailed and participated in conference calls with Dr. Strony, who was intimately involved in analyzing the ENHANCE data. According to CW 5, Merck and S-P were in control of the ENHANCE study database from at least as early as 2006, stating that Schering had the code and the data in 2006 and performed the analysis.

E. MERCK AND S-P TRY TO MINIMIZE THE RESULTS OF THE ENHANCE STUDY

1. Merck And S-P Continue To Delay Release Of ENHANCE And Attempt To Change The Primary Endpoint In An Effort To Manipulate The Test Data Into A Favorable Result

177. Merck and S-P (through M/S-P) had commissioned Dr. Michiel Bots, an expert in CA IMT imaging, to review the ENHANCE study data just months after the trial ended. But after Dr. Bots concluded in January 2007 that the study data were "fine," Merck and S-P sought another way to undermine and discredit the negative results. Throughout the summer of 2007, as

detailed in numerous e-mails between the ENHANCE study primary investigator, Dr. Kastelein, and Merck and S-P executives, Dr. Kastelein pressed the Companies to be forthright and report the ENHANCE study, even threatening to end their collaboration over the "political" delays. However, the Companies refused to release the results, as they knew such disclosure would hinder their ability to sell Vytorin and Zetia.

178. Merck's and S-P's suppression of the ENHANCE study results had their desired effect – sales of Vytorin continued to surge, while those of competitors' statins declined. As reported in *The Record* of Bergen County, New Jersey on July 22, 2007:

> Sales are surging for Vytorin . . . . Vytorin prescriptions have jumped 20% in the last 12 months . . . [and] sales rose in the face of a 90 percent increase in prescriptions for generic versions of Merck's Zocor….

The article noted that Vytorin's "double-barreled" attack on cholesterol was proving popular, and "boosted by consumer ads, contributed to the 12 percent decline in the last year in prescriptions for Pfizer's Lipitor."

179. Seven months after the Bots Report was issued, and after Dr. Kastelein had been continually stonewalled, on August 20, 2007, Dr. Kastelein met with Merck and S-P executives to discuss releasing the ENHANCE results. Merck and S-P demanded that the test data be reviewed yet again and Dr. Kastelein acceded to their request to convene an expert panel to further consider those Companies' trumped-up issues with the data.

180. Merck and S-P continued to delay, failing to even convene the independent expert panel until mid-November 2007, which further frustrated Dr. Kastelein. The Companies may have planned to stall even longer, but there was growing public interest in the ENHANCE trial, which made further delays problematic. Allegations of negative study results began appearing on the popular pharmaceutical discussion website Café Pharma, and there was growing

speculation that Merck and S-P were blocking publication of the ENHANCE results to maintain their lucrative Vytorin sales. Further, the Companies knew that *Forbes* was working on a story about the publishing delay, as the author had communicated with executives at both Merck and S-P and Dr. Kastelein in preparing the article (which was later published on November 19, 2007).

181. Finally, on November 16, 2007, months after the data had been examined by Dr. Bots and proclaimed "fine," Merck and S-P convened the independent expert panel to discuss what the companies alleged were problems with the ENHANCE data. One of the Companies' goals of convening the panel was to have the panel consent to changing the primary endpoint of the ENHANCE study, an abject violation of scientific protocols but a change the Companies believed was necessary in order to obtain favorable test results.

182. The expert panel consisted of J. Robin 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. Michiel Bots, of the University of Utrecht, Netherlands, and author of the aforementioned Bots Report. Additionally, twelve Merck and S-P employees were also in attendance at the November 16 meeting, including 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.

183. Dr. Kastelein did not attend the panel meeting. The panelists were told that Dr. Kastelein was not in attendance so the experts would not feel constrained, and could freely offer

their honest opinions. In this same vein, the experts were also informed that no meeting minutes would be taken. However, Dr. Kastelein's exclusion from a crucial meeting intended to examine the study he ostensibly led was highly unusual, and drew pointed criticism from industry experts in later months.

184. As reported in a January 11, 2008 *Forbes* article entitled "Inside Schering and Merck's Secret Panel," 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."

185. As would later be disclosed, Merck and S-P could not risk having Dr. Kastelein present at the meeting because the Companies knew he would oppose the Companies' request to change the primary endpoint of the study. Merck and S-P intended to push the panel into recommending that very change, and did not want to give Dr. Kastelein an opportunity to oppose their efforts. Additionally, Merck and S-P also found it necessary to later fabricate a record of what they wished had transpired at the meeting.

186. The use of the expert panel by Merck and S-P drew widespread criticism. First, the panel was criticized as a means for the Companies to challenge data that had already been reviewed and which had been gathered according to strict protocols established in advance and strictly followed during the trial. In short, there was no reason for the panel. Second, the panel was criticized as a means for Merck and S-P to completely change the goal, or primary endpoint, of the ENHANCE study, in a post-hoc attempt to cherry-pick data and obtain more favorable test results. That would be a breach of established scientific test protocols. Third, Merck & S-P attempted to steer the panel into a finding that the data gathered during the ENHANCE trial was

flawed. That was an improper attempt to influence the panel. Finally, Merck and S-P later attempted to fabricate the panel's recommendations by creating versions of "minutes" of the panel's meeting which completely misrepresented what transpired at the meeting. As would later be revealed in documents gathered by the FDA and Congress, in stark contrast to the public representations by Merck and S-P, the panel never recommended changing the primary endpoint of the ENHANCE study.

2. There Was No Need For The Expert Panel

187. Merck and S-P convened the panel to revisit a purported issue that had been twice previously resolved. While the Companies claimed that there may be problems with the data in ENHANCE, they had carefully selected the instruments, software and personnel employed to make the CA IMT measurements, as well as the protocol employed during the trial. Additionally, they had asked Dr. Kastelein in early 2006 to review the images in order to resolve purported problems, and later retained Dr. Bots to provide a written report on supposed problems with CA IMT measurements. In both cases, the conclusion was that the protocols were followed and the data were fine – there were no problems or any reason to reject or revisit the data.

188. As there was absolutely no reason to convene the panel in November 2007, people inside Merck and S-P, as well as outsiders, were surprised by the development. CW 5, a consultant for the M/S-P joint venture, worked directly with researchers in Amsterdam for approximately four to five years in quality control for the ENHANCE trial. CW 5 was surprised upon learning in September 2007 about the plans to convene an expert panel, and explained being "stunned" that the Companies believed that to be necessary. CW 5 had reviewed literature from scores of studies funded by the federal government and international non-profit organizations and had concluded that the quality control data CW 5 reviewed for the ENHANCE study was of similar quality to the other studies. According to CW 5, great care was taken to

ensure that the ENHANCE data was valid and reproducible, "as tight as any in the world." This observation was corroborated by the Bots Report and statements by Dr. Kastelein.

3. Merck And S-P Receive Widespread Criticism For Their Attempt To Change The Primary Endpoint

189. Three days after the expert panel meeting, on November 19, 2007, Merck and S-P (through their joint venture) issued a press release announcing that the Companies had convened an independent expert panel to offer advice regarding the "prospective analysis" of the ENHANCE trial. The Companies stated that the panel recommended changing the primary endpoint, the main measure established before the trial for how the drugs would be evaluated. The study's primary endpoint, or result, was the average of ultrasound measurements of carotid artery wall thickness at three locations – the common carotid arteries, the carotid bulbs and the internal carotid arteries – to be taken at the beginning of the study ("baseline"), at interim points throughout the study, and again after two years. The change, if any, would be measured by comparing the baseline images to the final images for each patient. The November 19 press release stated that the primary endpoint would be changed to only the common carotid artery.

190. The Companies claimed that this unorthodox change was needed "to expedite the reporting of the study findings." The Companies also noted that the study remained blinded. Thus, the Companies suggested in their announcement that the data had not yet been analyzed and the Companies did not know the results, although the postings on Café Pharma and the Kastelein emails demonstrated the opposite. Further, Merck and S-P attempted to dodge responsibility for changing the study endpoint, a highly controversial and unorthodox move, by making it appear as if the expert panel strongly supported the change. Later, in documents first revealed to Congressional investigators, panelists would refute that they ever made such a

recommendation (although they did discuss it), insisting that the decision to change the primary endpoint originated with Merck and S-P.

191. When the scientific community learned of Merck's and S-P's plan for a post-hoc redefinition of the ENHANCE study, they were outraged and demanded that the companies abide by established scientific guidelines. As reported in *The New York Times* on November 21, 2007 in an article entitled "After A Trial, Silence":

> [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 to the data the trial has actually produced.
>
> ***"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."***

(Emphasis added). According to a January 11, 2008 *Forbes* article, Dr. Psaty further noted, "You just don't change a primary endpoint in a major importance trial part way through."

192. Indeed, what the Companies were proposing was akin to going to a poker table, having ten cards dealt to you, and deciding which five cards you want in your hand. The Companies wanted to decide which data to choose after all the cards are on the table.

193. Confidential Witness #6 ("CW 6") addressed the propriety of changing the endpoint. This source is a physician who worked at S-P for over ten years through early 2007 in the Division for Medical Science Liaisons ("MSLs"). MSLs are a resource for physicians across the country, and often educate physicians about ongoing studies to which the sales people do not have access. According to CW 6, from a scientific point of view, it is a violation of protocol to change the primary endpoint of a study: "If a study is not a good study, then it is just not a good study and you have to explain why the results were seen."

194. As reported in the *NEJM* on March 30, 2008, of the three measurement sites in each carotid artery that were initially defined as comprising the primary endpoint for the study, two sites showed an actual increase in the artery wall thickness, proof that not only is Vytorin not effective in terms of an anti-atherosclerotic health benefit, but rather Vytorin demonstrated adverse health effects. The common carotid artery – the new proposed endpoint – was the only site of the three that showed less of an increase in artery wall thickness for treatment with Vytorin compared to treatment with just simvastatin. In contrast, the other measurement sites that were included in the initial definition of the primary endpoint (carotid bulbs and internal carotid artery) showed greater increases in artery wall thickness for Vytorin treatment compared to simvastatin-only treatment. The proposal by Merck and S-P to change the study's primary endpoint to reflect only information showing a slight decrease in artery wall thickness for Vytorin treatment (information favorable to Merck and S-P), while excluding all negative information, raises a strong inference that officials at those companies already knew or recklessly disregarded the study's unfavorable results even before the November 16, 2007 expert panel meeting. However, the test results and the fact that the change in primary endpoint would yield results more favorable to Merck and S-P, were facts not known by outside cardiologists or commentators, who criticized the companies for their attempt to change the primary endpoint, nor known by investors.

195. In addition to the firestorm of criticism over the announced change in the primary endpoint, Merck and S-P were criticized for their continual delay in releasing the ENHANCE results. 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…." As *Forbes* reported in a November 19, 2007 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." Of course, no one but Merck and S-P insiders and the ENHANCE investigators knew the actual results until the findings from ENHANCE were publicly released.

196. Dr. Allen J. Taylor, head of cardiology at Walter Reed Army Medical Center and quoted in the *Forbes* article, worried that Merck and S-P may have had an incentive to delay as long as possible in the hope that better data might emerge from another study. He remarked: "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."

197. The WebMD article explained why cardiologists, the press and investors were anxiously awaiting release of the ENHANCE results: "the 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 atherosclerotic plaque are seen as a reliable surrogate and normally predict whether a drug will be effective in lowering cardiac events." A November 26, 2007 article on the blog *Junkfood Science* further 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."

198. The November 19, 2007 *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." Likewise, a November 21, 2007 *New York Times* 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.

199. Dr. Kastelein was equally frustrated with the delays. He told *The New York Times* on November 21, 2007 that the delay was the result of Merck and S-P controlling the raw data and raising questions about its accuracy. "There was friction and tension," he said.

200. In the November 19 *Forbes* article, Dr. Kastelein attempted to explain the delay by "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." Nevertheless, Merck and S-P continued to delay and search for ways to challenge data which they knew showed that the addition of Zetia to simvastatin produced no additional cardiovascular benefit. As those companies knew, once the results were disclosed, sales of Vytorin would plummet. Indeed, the November 19, 2007 *Forbes* article quoted Dr. Paul Thompson, director of cardiology at Hartford Hospital in Connecticut, as predicting that a bad result would cause Pfizer and AstraZeneca sales representatives to turn up at every hospital in the country "within milliseconds."

201. *Forbes* also reported that Merck and S-P had not registered the ENHANCE trial or its results on the government website clinicaltrials.gov, where all clinical trials are required to be listed even before they begin, and where the study designs are required to be clearly defined. On October 23, 2007, *Forbes* emailed an M/S-P spokesperson to ask why the ENHANCE study was absent from the website. As reported in an April 3, 2008 *Forbes* article, M/S-P subsequently listed the study on October 31, according to the website's track-changes function.

202. The November 19 *Forbes* article also pointed out "[a]nother source of suspicion" with the ENHANCE study – while top clinical experts recommended that outside researchers conducting the study (not the company) have control over the raw study data and computerized database created to analyze study results, here the information and database were held by the Companies. That fact was referenced in the aforementioned July 13, 2007 email from Dr. Kastelein to Dr. Veltri.

4. The FDA And Congress Launch Investigations Into ENHANCE Prompting Merck And S-P To Reverse Their Decision To Change The Primary Endpoint

203. On November 20, 2007, amid a blitz of criticism over the delays in releasing the ENHANCE results and over the announced endpoint change, the FDA launched an investigation regarding ENHANCE, and specifically requested minutes from the November 16 expert panel meeting.

204. On December 11, 2007, Representative John D. Dingell, Chairman of the Committee on Energy and Commerce, and Representative Bart Stupak, Chairman of the Subcommittee on Oversight and Investigations, wrote Merck and S-P about the delays in disclosing the ENHANCE study results. Beyond the issue of delays, the Representatives expressed concern that the study's endpoint now "appeare[d] to differ from the endpoint described in the initial study" and that Merck and S-P had engaged in "apparent manipulation of

trial data." Additionally, the Representatives requested that Merck and S-P preserve and provide information concerning the ENHANCE study, including all data and the names of any outside panel members that recommended changing the study's endpoint.

205. Under mounting criticism and investigations by the FDA and Congress, Merck and S-P reversed their decision to change the primary endpoint for the ENHANCE study on the same day, December 11, 2007. This reversal was reported by *Forbes* in an article entitled, "Merck and Schering Backtrack," in which defendant Peter Kim stated, "We held two other consultant meetings and had internal discussions. We have made the decision that, while we greatly respect this expert panel, that we are not going to change the primary endpoint for the study." The reversal was also addressed on a Frequently Asked Questions posting on S-P's website, where in a response to the question "Why didn't you change the primary endpoint?" S-P 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-Plough 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.

(Emphasis added). S-P again falsely attributed, and Merck recklessly allowed S-P to attribute, to the expert panel the initial decision to change the primary endpoint, although it was the decision of the Companies to change the endpoint, and the Companies failed to disclose that the change was designed to produce more favorable test results.

206. Though he was excluded from the panel, Dr. Kastelein was quoted in the November 19, 2007 joint venture press release as initially going along with the endpoint change, stating: "We view the experts panel's recommendation to narrow the primary endpoint to the common carotid artery as helpful . . . ." However, Dr. Kastelein had earlier expressed outrage when he learned of the proposal to manipulate the ENHANCE study. On July 6, 2007, in an e-mail 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.

(Emphasis added).

207. The *Wall Street Journal* reported on December 17, 2007 that Dr. Kastelein regretted "not standing up" to Merck and S-P when they told him in November 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 are in, said Dr. Kastelein. "It is statistically not good and it gives the wrong impression to the outside world." He said he breathed a "sigh of relief" when the Companies told him they were reversing their decision.

208. Merck and S-P reversed the decision to change the study endpoint, but still attempted to divert responsibility for changing the endpoint to the expert panel. In an interview with *Forbes* magazine, defendant 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." This was later echoed by S-P spokesperson Lee Davies, according to a *Bloomberg* update on

December 12, 2007. Davies said the company decided to go against the advice of its own expert panel to change the study's goal after getting a second opinion from heart doctors. However, this was false, because (as Merck and S-P knew), it was the Companies, and not the panel, which recommended changing the primary endpoint.

5. Merck And S-P Fabricate Minutes Of The Panel Meeting

209. In an attempt to dodge criticism from their decision to change the primary endpoint of the ENHANCE study, Merck and S-P attempted to create a post-hoc record of the panel meeting to satisfy requests by congressional investigators. These purported "minutes" were allegedly created on December 7, 2007, according to a letter the Companies sent to Congress, but an initial draft of the carefully contrived minutes was not circulated to the expert panelists until December 19, 2007. This timing was suspicious, because a week earlier the companies were forced to rescind their decision to change the primary endpoint of the ENHANCE study amid a flurry of controversy and the launch of Congressional investigations.

210. As would first be revealed months later during the Congressional investigation, Merck and S-P circulated the first draft of the purported minutes on December 19, 2007, asking panelists to comment. Dr. Stein sent his first reply to Dr. John Strony at SPRI on December 21, 2007 via email. 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.

In response to this, 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). 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]." Comments like this appeared on numerous pages of the draft minutes (in what Dr. Stein called "the MS Word commenting feature"), revealing that Merck and S-P distorted the conclusions of the expert panel, and attempted to use "minutes" created after the fact to retrospectively justify actions taken by the Companies.

211. Dr. Strony circulated a later draft of the minutes on January 3, 2008, but failed to revise the minutes to reflect the changes requested by Dr. Stein in December. The edited minutes, which included many of the same inaccuracies Dr. Stein had previously addressed, stated: "The Panel was unanimous in their opinion that it was reasonable to elevate the common carotid to the primary endpoint." In a heated reply, Dr. Stein noted that several of his earlier comments were not incorporated, and thus 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). Dr. Stein concluded in his January 3 email that he could not call what Merck and S-P had created as "minutes" "[s]ince there was no audio or written transcription of the meeting," and he remarked that "at best they are an incomplete summary of what transpired at the meeting."

212. Physicians, investors and others outside of Merck and S-P were unaware of the misrepresentations by Merck and S-P in their November 19, 2007 press release concerning the expert panel. The misrepresentations came to light for the first time on April 11, 2008, as part of the Congressional investigation. Nor were investors, physicians and others outside of Merck and S-P aware of the results of the ENHANCE study prior to their partial disclosure on January 14, 2008 and full disclosure on March 30, 2008. In fact, even after the December 11, 2007 letter from Representatives Dingell and Stupak, practitioners, investors and analysts remained confident that ENHANCE would provide favorable data demonstrating cardiovascular benefits from Zetia and Vytorin. As the *New York Times* reported on December 12, 2007:

> "Zetia has been proved to lower LDL, or bad, cholesterol by 15 to 20 percent. Every other medicine that lowers LDL also reduces heart attacks, and ***there is no reason to believe Zetia to be an exception,"*** said Dr. Michael Crawford, the interim chief of cardiology at the University of California, San Francisco.

(Emphasis added).

213. As known only by Defendants and S-P, there was one exception to this statement. Merck and S-P had reason to know that Vytorin did not reduce heart attacks. In the case of Vytorin, lower was NOT better.

6. Merck And S-P Attempt To Manipulate The Panel By Providing It With Hand-Picked Data

214. In another deception, Merck and S-P attempted to steer the expert panel into concluding that there were problems with the ENHANCE data. The draft minutes for the November 16 panel meeting included the following claim: "the Panel members were granted unrestricted access to the blinded image data base." However, in reality, Merck and S-P handpicked some of the worst images available, and attempted to steer the panel into finding that the data was flawed. This was a bold attempt by Merck and S-P to further discredit the

ENHANCE study and avoid the impact that the negative results would have on their Vytorin sales. In his corrections to the draft minutes, Dr. Stein noted 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 30,000 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).

215. Thus, although Merck and S-P *claimed* the panel was intended to gather independent expert feedback about the ENHANCE data, in reality Merck and S-P hand-selected a small number (50-75 out of 30,000) of ultrasound images from the ENHANCE study to show the expert panel, and then manipulated the wording of the minutes from the meeting to pretend that the panel was granted "unrestricted access" to the data. In fact, the panel was granted only restricted access to the worst images available. According to CW 5, the Companies selected the 74 most "discrepant" images out of 30,000 to show to the expert panel.

216. The materials prepared for the November 16, 2007 expert panel also painted a skewed picture of the ENHANCE 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 backtracking on the decision to change the primary endpoint.

217. The attempt by Merck and S-P to manipulate the panel by presenting an extremely skewed version of the data demonstrates that these companies knew or recklessly disregarded the results of the ENHANCE study. They selected the "worst" images to show the experts, and used negative "leading" language in the introductory presentation to the panel. Further, Merck and S-P delayed and blocked publication until Congress got involved, and attempted to change the endpoint months after the final data was collected, drawing a backlash from scientists, regulators, and commentators.

F. THE TRUTH ABOUT VYTORIN'S LACK OF EFFECTIVENESS BEGINS TO EMERGE

1. Merck's And S-P's Early Analysis Of Test Data Enabled Those Companies To Conclude That Vytorin Did Not Work As Advertised

218. The detailed and accurate postings on Café Pharma, together with the attempt by Merck and S-P to change the primary endpoint, demonstrate the Companies' knowledge and possession of test data showing no benefit in using Vytorin over simvastatin alone. While these facts also show that the test results were by that time "un-blinded" (meaning that there was disclosure of which patients received which therapy), even if the results were still blinded, that would not prevent the Companies from concluding that the test results were negative.

219. ENHANCE was designed to determine whether the addition of Zetia to Zocor stopped or reduced the thickening of arterial plaque. If there were no differences in the average CA IMT measurements between the test groups, then there would be no demonstrable benefit in the addition of Zetia, and it would not matter which group used Vytorin and which used simvastatin alone. Indeed, when the abridged ENHANCE results were released in January 2008, the Companies concealed that Vytorin produced no additional cardiovascular benefits.

220. Just two days before the release of the full results of the ENHANCE trial, Merck issued a press release demonstrating its ability to draw certain conclusions from still-blinded studies. In its March 28, 2008 release (still posted on Merck's website), Merck said that:

> The academic leadership of the IMPROVE-IT trial recommended increasing the size of the patient population up to 18,000. ….The recommendation from the academic leadership was based on ***recent analyses of the blinded, aggregate event rates in the IMPROVE-IT trial and published data on the relationship between lowering LDL cholesterol*** and clinical benefit that have emerged since the original protocol was prepared. ….The purpose of the trial is to determine whether Vytorin (ezetimibe/simvastatin) 10/40 mg provides incremental reductions in cardiovascular events in patients recovering from acute coronary syndrome in comparison to simvastatin 40 mg alone

(Emphasis added). The fact that Merck and S-P could analyze still-blinded, aggregate data in the IMPROVE-IT trial in order to conclude that more patients were needed to show whether there was any benefit from use of Vytorin raises a strong inference that Merck and S-P likewise were able to determine whether the still-blinded ENHANCE data demonstrated a statistically-significant difference between the treatment arms.

2. Merck And S-P Release Selected Results Of The ENHANCE Study, Revealing That Vytorin Provides No Benefit Over Zocor Alone

221. As *The New York Times* reported on November 21, 2007, there was "a growing chorus of complaints from cardiologists" over Merck's and S-P's ongoing delays in releasing the results of the ENHANCE trial. The article explained:

> Cardiologists have been awaiting the results of the trial, called ENHANCE, to learn how well Zetia and Vytorin work. If they are not as effective as other cholesterol medicines, patients taking them may be putting themselves at unnecessary risk of heart attacks.
>
> There's clearly some rightful interest in what the results are, said Dr. Allen J. Taylor, Chief of Cardiology at Walter Reed Army

> Medical Center. You've got millions of people treated with the drugs….
>
> Dr. Howard Weintraub, the clinical director of the New York University center for the prevention of cardiovascular disease, said cardiologists were especially concerned about the trial's results because Zetia works differently from other cholesterol-lowering medicines like Lipitor or Merck's own Zocor.

A January 11, 2008 *Wall Street Journal* article remarked that "[i]nvestors in Merck continue to fret about the still-unreleased results of a drug study known as Enhance" but "[c]ompany executives ha[d] been downplaying the study lately." No wonder – while it had been two years since the ENHANCE trial was complete, the findings had not been released, as Merck and S-P knew that such disclosure would devastate their efforts to sell Vytorin and Zetia.

222. On January 14, 2008, Merck and S-P, through their joint venture, finally released "top-line" results of the ENHANCE study. These "top-line" results shocked the market: they showed that Vytorin failed to reduce the buildup of arterial plaque any more than less expensive generic simvastatin alone. Merck, S-P and their joint venture, having repeatedly missed their own deadlines for reporting the results, and pressured by Congress, the media and cardiologists around the world wondering why the results were delayed, disclosed the reason – the results were horrible. Among the study population of people at the highest risks of plaque buildup and adverse cardiovascular events and believed to be the choice group to demonstrate a benefit, ENHANCE showed that there was no benefit to using Vytorin over simvastatin alone.

223. Merck and S-P (through their joint venture) stated in a joint press release that not only did Vytorin fail to slow the progression of atherosclerosis, it actually seemed to contribute to plaque formation. ENHANCE showed that the speed with which arteries thickened with plaque almost doubled among those on the two-drug regimen compared to those taking simvastatin alone.

224. As the Companies concluded in the press release:

> There was no statistically significant difference between treatment groups on the primary endpoint. The change from baseline in the mean carotid IMT was 0.0111 mm for the ezetimibe/simvastatin 10/80 mg group versus 0.0058 mm for the simvastatin, 80 mg group (p=0.29). At baseline, the mean carotid IMT measurement for ezetimibe/simvastatin was 0.68 mm and for simvastatin 80 mg was 0.69 mm. There was also no statistically significant difference between the treatment groups for each of the components of the primary endpoint, including the common carotid artery. Key secondary imaging endpoints showed no statistical difference between treatment groups.

These results showed that the CA IMT for the Vytorin group of patients actually increased slightly more than for the simvastatin group, but in an amount which, the Companies claimed, was not statistically significant.

225. Dr. Howard Weintraub, clinical director of the Center for the Prevention of Cardio-Vascular Disease at New York University Medical Center in New York City and clinical associate professor at the NYU School of Medicine, succinctly stated: "ENHANCE found that plaque got slightly worse when the drug combination was used" (as reported in a January 14, 2008 *Business Week* article).

226. Prominent physicians and professors were surprised that Vytorin did not show a benefit among the test group – persons with a rare genetic disease predisposing them to high levels of LDL cholesterol. Dr. Nissen, Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic and a widely published and respected researcher and senior consulting editor to the *Journal of the American College of Cardiology*, stated that "you'd most expect the drug to work in [these types of patients and] if it doesn't work in this population it's not going to work in anyone."

227. A March 31, 2008 *Red Orbit News* article reported Dr. Greg Brown of the University of Washington in Seattle as stating, "[t]he study challenged long-held assumptions

about the value of lowering LDL cholesterol. We've always assumed no matter how you get the LDL down, it's good."

228. In response to the shocking news, Merck's stock price dropped; analysts immediately reduced their ratings on Merck stock; and Congressmen and others claimed that Merck's (and S-P's) delay in releasing the results of the ENHANCE trial was intentional, and fraudulent.

229. Merck's stock price, which closed at $60.55 per share on Friday, January 11, 2008, dropped to close at $58.18 per share on Tuesday, January 15, 2008. In response to the overwhelming criticisms of the Company, Merck's stock price dropped further to close at $47.79 per share on January 25, 2008.

3. Doctors And Congressmen Charge Merck And S-P With Intentionally Withholding The Test Results

230. Representatives Dingell and Stupak of the House Committee on Energy and Commerce quickly charged Merck and S-P with intentionally concealing negative data which the companies knew would be harmful to their efforts to sell Vytorin and Zetia. In a press release issued the same day as the Companies' January 14, 2008 announcement, Congressmen Dingell and Stupak confirmed that their investigation of those companies and their handling of ENHANCE would continue, stating:

> "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 and Schering-Plough's delay in releasing study results, as well as their attempt to manipulate the data is, quite frankly, suspicious," said Dingell . . . .
>
> "In light of today's results, which were released nearly two years after the ENHANCE trial ended, it is easy to conclude that Merck and Schering-Plough intentionally sought to delay the release of this data," said Stupak.

231. Representative Dingell said he (and Stupak) would "continue [their] investigation until these questions are answered." Representative Stupak, Chairman of the Subcommittee on Oversight and Investigations, told *Forbes*: "It is easy to conclude that Merck and Schering-Plough intentionally sought to delay the release of this data." In the same January 15, 2008 *Forbes* article, Dr. Steven Nissen states "This drug doesn't work. Period. It just doesn't work."

232. In a January 17, 2008 *Newsweek* article, Representative Stupak was asked, "Do you think that Schering-Plough and Merck intentionally sought to delay the release of this data?" "Yes," he succinctly responded, explaining that the Companies did so to preserve their profits:

> 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. Take aware $5 billion or more from these companies and man . . . . These allegations are very serious though. We've been on this since October, and we have enough information to go for a hearing now.

233. Editors of medical journals and doctors contended that Merck and S-P had engaged in "selective publication" in which positive trials are submitted quickly for dissemination while negative studies like ENHANCE are delayed or shelved. Philip Greenland, dean for clinical research at Northwestern University's Feinberg School of Medicine, and editor of the journal *Archives of Internal Medicine*, stated that where trial sponsors "put [data] in a drawer and trash it or have the endpoint changed" they "damage the public trust."

234. Dr. Harlan M. Krumholz, a cardiologist at Yale, echoed the same views in a January 15, 2008 *New York Times* article, where he stated that drug companies have a responsibility to release all their trial findings, positive or negative, as quickly as possible, even if the results might hurt sales. He said: "People may have been on this drug without the ability to know that there was additional data that might have thrown into question its effectiveness. . . . That's extremely unfortunate, and that's an understatement." In a subsequent January 26, 2008

Wall Street Journal article, Dr. Krumholz added: "It's in their [Merck and S-P's] great interest to delay this study if there is any possibility that it doesn't come out positive."

235. Dr. Allen Taylor, chief of cardiology service at Walter Reed Army Medical Center in Washington, D.C., similarly suggested to the *Wall Street Journal* that Merck and S-P knew well before their January 14 release that ENHANCE failed to show any benefit for the more expensive Vytorin. He stated: "The timeline shows what an immense effort the companies went to work on the data. . . . The question is, why were you doing all that? People don't spend 18 months jumping through hoops for nothing." The website *Pharmalot.com* remarked in a January 14, 2008 article that the "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." In a January 17, 2008 *Wall Street Journal* article, Dr. Nissen suggested that the delay was engineered to allow Merck and S-P time to earn billions of dollars from sales of Vytorin:

> Here we are, six years after this drug was marketed and promoted with a massive marketing campaign and has become a $5 billion drug . . . . The first trial we have is reported much too late and doesn't show really any evidence of a benefit.

236. Congress and the media had commenced their investigations into whether Merck and S-P had intentionally delayed the release of data they knew would cripple their efforts to sell Vytorin. As those investigations would later disclose, that was, in fact, the reason for the two-year delay.

4. Congress And State Attorneys General Sharpen Their Focus And Demanded Explanations For Merck's and S-P's Concealment Of The ENHANCE Results

237. On January 16, 2008, Representatives Dingell and Stupak sent their second request to Merck and S-P probing those companies' "withholding of clinical trial data that may

significantly affect the medical management of hypercholesterolemia, as well as the use of misleading statements in direct-to-consumer advertisements for prescription medications." The lawmakers expressed their "dismay[ ] at the pace of the release of the ENHANCE study result," noting that while the trial ended in April 2006, as of December 2007 Merck and S-P stated that the results had not been unblinded and were not ready for presentation, but within the next month (following public outcry over the delay), the results were available in a press release. This sequence "raises a number of troubling questions related to apparent manipulation of the study's endpoints," they wrote, which also suggests that the reason for the delay was to garner additional profits from Vytorin sales, rather than to safeguard patients' health:

> Given Vytorin's large market share, we . . . believe that the vast number of patients who have been using Vytorin could have learned of its insignificant benefits earlier than January 2008. In addition, given the frequency of Vytorin advertisements, it concerns us that a study showing that Vytorin provide no increased benefit was not issued for nearly two years while direct-to-consumer advertisements were carried on the airwaves. This situation raises concerns that the drug companies and their advertisement agencies profited at the significant expense of patients' health.

238. The Congressmen also expressed concern that, as they had recently discovered, the advisory panel created to determine whether to change the primary endpoint did not include Dr. Kastelein. The Congressmen requested that Merck and S-P produce several categories of documents, including records of communications between Dr. Kastelein and Merck and S-P and members of the advisory panel, records relating to the January 14, 2008 press release announcing the ENHANCE results, and records relating to advertisements for Vytorin.

239. On January 16, 2008, Representatives Dingell and Stupak sent a separate letter to the FDA, again expressing concerns over the delay in Merck's and S-P's release of the ENHANCE results and requesting "all records relating to any print, radio, television, or internet

advertisements for Vytorin." Separately, the FDA said that the agency "will have to review all data in light of studies to determine if it impacts the labeling and advertising for the drug."

240. On January 22, 2008, amid the controversy surrounding Merck's shocking release of the ENHANCE results, Merck (and S-P) suspended television ads for Vytorin. Television advertisements were also suspended for Zetia.

241. Also on January 22, 2008, Representatives Dingell and Stupak sent another letter to Merck and S-P requesting additional documents, including those related to any outside advisory committees and boards that may have reviewed the ENHANCE trial, and requesting information concerning when senior officers of Merck and S-P first learned of the study results.

242. On or about January 23, 2008, the FDA contacted Merck by letter to inform it that its DTC marketing materials and its product claim materials directed to healthcare providers, were false and misleading. Among other things, the FDA pointed out that it was misleading for Merck to suggest that the two-drug combination in Vytorin provided a cardiovascular benefit because Zetia "has not been shown to prevent any of these cardiovascular outcomes. Furthermore, using the combination . . . product, Vytorin, has not shown any additional cardiovascular benefit compared to using [Zocor] alone." The FDA then went on to state that Merck should promptly change its misleading advertisements, as follows:

> Therefore . . . we are informing Merck that the Vytorin product claim promotional materials would be misleading because the pieces do not include contextual information disclosing a limitation to the efficacy of Vytorin regarding clinical outcome benefits.
>
> Consequently, we recommend revising any DTC Vytorin product claim promotional material, by adding context, in consumer-friendly language, communicating not only that Vytorin contains two medicine (Zocor and Zetia), but also by conveying that ***taking the combination drug Vytorin has not been shown to provide any additional cardiovascular outcome benefits compared to using Zocor alone.***

(Emphasis added).

243. A day later, Representatives Dingell and Stupak announced that their investigation into the delay in releasing the ENHANCE results would be broadened to include an examination of the relationship between the M/S-P joint venture and American College of Cardiology ("ACC") and the AHA. Representative Dingell stated in a news release by the Committee on Energy and Commerce:

> Given the AHA's and ACC's recent statements on Vytorin and the ENHANCE study, our Committee is interested to learn what financial arrangements exist between marketers of Vytorin and these two organizations. . . . The public places great trust in the official views of the AHA and the ACC, so it is important to verify that these views have not been compromised by a financial relationship with the pharmaceutical industry.

Representative Stupak echoed these sentiments, stating that:

> The American Heart Association and the American College of Cardiology are widely perceived as objective and impartial, and are trusted by doctors and patients alike. . . . Our Subcommittee intends to examine exactly how much funding these two organizations received from Merck and Schering-Plough, how they use this funding and any potential conflicts of interest.

The Representatives included in their letter a request for information on Merck's and S-P's financial ties to the ACC and AHA.

244. Also on January 24, 2008, Senator Charles Grassley, ranking member of the Senate Committee on Finance, opened his own probe into Merck's and S-P's conduct, sending a letter to Merck's CEO, Richard Clark, and to S-P's CEO, Hassan, requesting documents and the answers to questions regarding the delay in releasing the results of ENHANCE. Senator Grassley wrote that "there is no apparent gain in health benefits from using Vytorin over the much cheaper generic statin, simvastatin" but the Companies had the study results since April 2006, more than 20 months before releasing them. Senator Grassley also wrote to ACC

President James Dove, AHA CEO M. Cass Wheeler, and SEC Chairman Christopher Cox to express his concerns about the extraordinary delay in releasing the ENHANCE study results.

245. On January 25, 2008, the FDA issued an "Early Communication About An Ongoing Review of Vytorin" in which it informed the public that the agency would review the ENHANCE results, once it received them in final form, and determine whether "any further regulatory action is warranted" against Merck and S-P. The FDA noted that "[t]here are no clinical studies available that demonstrate a reduction in risk of heart attack or stroke when ezetimibe is used or in combination with a statin, including the fix-dosed combination drug of ezetimibe and simvastatin, Vytorin."

246. That day, *Forbes* published an article commenting on the various Congressional inquiries into ENHANCE, noting that "[t]he answers matter to investors." The article quoted Steven Joffe, M.D., M.P.H., a bioethicist and researcher at the Dana-Farber/Harvard Cancer Center, who commented on the delay in releasing the ENHANCE results, stating: "It's hard to see who is helping shape these decisions who has a strong level of independence from the company. Who has seen the data who can take public accountability?"

247. State Attorneys General began their own investigations into whether Merck and S-P intentionally concealed the results of a study that found their brand-name drug was no more effective than a cheaper, generic alternative. The Associated Press reported on January 26, 2008 that New York State Attorney General Andrew Cuomo had issued subpoenas to Merck and S-P to determine if they deliberately concealed the negative results of the ENHANCE study. Mr. Cuomo said he was investigating whether Merck and S-P violated New York consumer protection laws by "aggressively marketing [Vytorin] to unsuspecting patients and doctors" and whether the Companies' statements to investors were accurate. Thus, the subpoenas sought,

among other things, Vytorin-related documents pertaining to marketing and advertising and communications with drug representatives, investors and analysts. Included in the investigation was an inquiry into whether statements by Merck and S-P to investors were accurate. Mr. Cuomo said his action put "[d]rug companies . . . on notice that concealing critical information about lifesaving prescription drugs, profiting at the expense of patients' health, and wasting taxpayer dollars, is simply unacceptable."

248. The next day, Connecticut Attorney General Richard Blumenthal announced that his state was investigating Merck's and S-P's behavior relating to Vytorin. As reported by *The Wall Street Journal* on January 29, 2008, Mr. Blumenthal sought to determine "whether state funds were spent on false assurances about the safety and effectiveness" of Vytorin.

249. As reported by the *Wall Street Journal* and *Business Week* on February 11 and 12, 2008, Representatives Dingell and Stupak broadened their probe yet again, this time to include messages on the Café Pharma pharmaceutical industry website. In a letter to the operators of Cafepharma.com, the Congressmen wrote: "These Web site entries are obviously troubling and raise again the question of whether anyone within Merck or Schering-Plough knew the results of the ENHANCE trial prior to the official release of data in the January 14, 2008, press release." The Congressmen gave Café Pharma two weeks to turn over requested information and ordered them not to destroy or tamper with any records relating to M/S-P and ENHANCE.

250. The Congressmen also wrote to Café Pharma's webmaster, Sarah Palmer, and the chief executive of SoftLayer Technologies, requesting information on identities of those who wrote the posts in question. Ms. Palmer responded, however, that the site does not collect user information for anonymous posts on its message boards.

5. Prior To The Release Of The Full ENHANCE Study Results, Doctors And The Market Remained Optimistic That ENHANCE Results Would Show Some Cardiovascular Benefits For Vytorin

251. The January 14, 2008 release of the partial ENHANCE results did not disclose all the results, or all the details of the trial, leaving doctors and the market optimistic that the full results would demonstrate some cardiovascular benefit to Vytorin (and Zetia). As explained by Prediman K. Shah, a cardiologist at Cedars-Sinai Medical Center in Los Angeles, lowering cholesterol is almost always a good thing, and it would not make "an iota of sense" for Zetia not to work. *See* Matthew Herper, "The Vytorin Question," *Forbes* (Nov. 19, 2007).

252. Indeed, just before the full ENHANCE results were released, *Dow Jones* reported on Friday, March 28, 2008:

> While the top-line study results are already out, doctors are looking for additional information from the study, which will be reviewed by an expert panel of cardiologists [at the American College of Cardiology conference].
>
> Prescription volume for both Vytorin and Zetia has declined since January. ***But the full data could paint a more complicated picture, and one that is potentially favorable for the drugs. . . .***
>
> Also, the study is expected to provide a breakdown of the various measurements of carotid artery thickness, including a site on the artery called the "common carotid." The top-line data were an average of thickness at three different sites on the artery. And doctors expect to learn more about the data quality problems that appeared to arise during the course of the trial, which both Merck and Schering-Plough have said partly accounted for the long delay in releasing trial results.

(Emphasis added).

6. Merck And S-P Release The Complete ENHANCE Results

253. On March 30, 2008, two and a half months after Merck and S-P released their abridged "top-line" results of the ENHANCE trial, the Companies finally released the complete results. Dr. Kastelein presented a full report at a conference held by the ACC in Chicago,

Illinois. According to Dr. Kastelein, the full results confirmed that Vytorin was no better at reducing the progression of atherosclerosis than simvastatin alone. The results showed that Vytorin had "***no result – zilch. In no segment was there any added benefits***" in terms of reducing plaque buildup in the arteries, said Dr. Kastelein. (Emphasis added).

254. The subsequent discussion at the cardiology conference was harsher than expected. A panel of experts was expected to debate how the ENHANCE study should impact the behavior of doctors in prescribing Vytorin, but in a surprise move, they arrived at a consensus before the meeting and issued a unanimous statement calling on cardiologists to rein-in the use of Zetia and Vytorin. As the *Wall Street Journal* explained on March 31, 2008, "[i]ndustry observers had predicted that an open conversation by the experts could temper the negative image of the drug that emerged earlier this year after the study results were made public, but just the opposite occurred."

255. In a panel discussion that followed the presentation, doctors advised that the results showed that Vytorin should be prescribed less often. Dr. Harlan Krumholz of Yale, on behalf of the panel, told thousands of cardiologists in attendance that "the most likely explanation [for the test results] is that in this study the compound did not work." He argued that Zetia is so different from other cholesterol medicines that there is no way to be certain that it is actually safe, and said: "You've just seen a negative trial that should change practice especially the way we in this country have prescribed." He called Vytorin an "expensive placebo" and advised cardiologists to "go back to statins." He also said Vytorin should be used only as a last resort, and stated (as reported in a March 31, 2008 *Business Week* article): "For myself, I would not take the medication, and if I recommend it to anyone, it would be for the highest-risk patient

who couldn't tolerate statins." Dr. Krumholz said his recommendations were based on a consensus reached with the three other panelists who had discussed the data for several weeks.

256. Roger Blumenthal, M.D., a preventative cardiologist at Johns Hopkins Hospital who was not involved in the trial, said that "[t]here are very real concerns whether [Vytorin and Zetia] will have a meaningful impact on cardiovascular risk," as reported in a March 31, 2008 *Wall Street Journal* article. Dr. Blumenthal said that he had been looking for clues for potential benefit to the drugs but found none, calling it "a disappointment."

257. At the conference, Dr. Krumholz said his comments and recommendations were consistent with the views of the ACC and two editorials in the *NEJM*. The *NEJM*, which also published the ENHANCE study results in the journal's April 3, 2008 issue, took the unusual step of releasing the article, along with two editorials early on March 30 to coincide with the Chicago ACC conference.

258. The *NEJM* article was written by Dr. Kastelein and other doctors (each with a Ph.D.) and titled "Simvastatin with or without Ezetimibe in a Familial Hypercholesterolemia." The authors presented and discussed the full ENHANCE study results, and noted that "[l]arge epidemiologic studies have provided strong associations between intima-media thickness and stroke, angina pectoris, and myocardial infarction." They also noted that patients with familial hypercholesterolemia have a greatly increased risk for premature coronary artery disease, and that treatment of such patients with high dose statins has been shown in at least one study "to attenuate the progression of intima-media thickness." However, ENHANCE showed treatment of those patients with a combination of the Zocor statin with Zetia failed to produce any additional benefit. In the "Conclusions" section of the *NEJM* article, the authors wrote:

> In patients with familial hypercholesterolemia, combined therapy with ezetimibe and simvastatin did not result in a significant

> difference in changes in intima-media thickness, as compared with simvastatin alone, despite decreases in levels of LDL cholesterol and C-reactive protein.

In short, the results demonstrated that Vytorin would not produce any benefit in reducing the rate of atherosclerosis or the risk of adverse cardiac events over that of simvastatin alone.

259. The *NEJM* article contained a chart that included the following data concerning the change in CA IMT as an average of the six carotid artery segments (the common carotid artery, carotid bulb, and internal carotid artery in each of the left and right arteries where the measurements were made), and at the sites individually, comparing simvastatin with Vytorin:

Mean intima-media thickness Of carotid artery (mm)	Simvastatin Monotherapy	Simvastatin plus Ezetimibe
Average of six segments	0.0058 +/- 0.0037	0.0111 +/- 0.0038
Common carotid artery	0.0024 +/- 0.0043	0.0019 +/- 0.0044
Carotid bulb	0.0062 +/- 0.0069	0.0144 +/- 0.0070
Internal carotid artery	-0.0007 +/- 0.0064	0.0099 +/- 0.0065

The authors found the above differences between the average CA IMT in the simvastatin monotherapy group and the simvastatin plus ezetimibe groups to be statistically insignificant, thus demonstrating no cardiovascular benefit for treatment with Vytorin over simvastatin alone.

260. The *NEJM* also published that day an editorial based on the study results, calling on doctors to prescribe Zetia (and, by extension, Vytorin) only in selected cases. When diet, exercise and a statin are insufficient to lower a patient's cholesterol to the target level, the editorial advised doctors to consider other drugs, such as niacin and fibrates. Zetia (and Vytorin) should be "reserved for patients who cannot tolerate these agents," the editorial said.

261. In the *NEJM*, on Sunday, March 30, 2008, a separate paper on Vytorin addressed the ENHANCE trial results again and came to the same conclusion – Vytorin did not reduce plaque buildup any more that statin treatment alone in the ENHANCE study group.

> The ENHANCE study by Kastelein, et al. ***did not provide evidence that ezetimibe [Zetia], as an adjunct to simvastatin, reduced the progression of atherosclerosis, as compared to simvastatin alone, even though ezetimibe was associated with the expected additional reduction in LDL cholesterol levels.***

(Emphasis added.)

262. Merck and S-P immediately tried to lessen the damage by attempting to discredit the data as well as the design of the study. The companies claimed that the approach used to measure plaque buildup was too imprecise. On April 2, 2008 *Bloomberg* reported:

> Merck and Schering-Plough, which funded and helped design the earlier Enhance study, have tried to discredit it. The companies wanted to alter the main goal of the trial after it was completed, a scientific faux pas, saying the approach used to measure plaque was too imprecise. They also said years of earlier treatment left patients, who had an inherited condition marked by high cholesterol, with little plaque buildup, making it difficult to detect a benefit from the therapy.

However, that same method – using ultrasound imaging to measure CA IMT – had also been employed in various studies sponsored by Pfizer and AstraZeneca on their respective statins.

263. Merck and S-P also claimed that earlier statin treatment left the patients in the study with little plaque buildup, making it difficult to detect a benefit from the Vytorin therapy. However, doctors and the media rejected this spin. Dr. Allen Taylor was quoted by *Bloomberg* on March 30, 2008 as stating:

> Every single explanation or attempt to discredit the trial based on the standpoint of the sponsors is completely debunked by the data. . . . If it is not the investigator, it's not the data, it's not the endpoint, it must be the drug.

264. Based upon the March 30, 2008 release of the full ENHANCE results and commentary in scholarly publications, researchers and physicians questioned whether there was any reason to prescribe Zetia or Vytorin at all. As summarized by *Forbes* on March 30, 2008, "researchers now wonder whether Zetia may have subtle, negative effects that counteract its LDL-lowering ability."

265. On Monday, March 31, 2008, the first business day after the Chicago conference, Merck stock plummeted, going from $44.51 at the close on Friday, March 28, 2008 to $37.95 per share at the close on March 31, a decline of $6.56 per share, wiping out an additional $14 billion in the Company's market capitalization causing further damage to shareholders. That was the biggest one-day drop in Merck shares since September 30, 2004, when Merck's Vioxx was pulled from the market.

266. The disclosure of the complete ENHANCE results and the subsequent recommendations by cardiologists to prescribe Vytorin only as a last resort caused Wall Street analysts to downgrade their projections on sales of Vytorin and their projections on Merck's future earnings. Catherine Arnold of Credit Suisse lowered her estimate for Vytorin market share, reduced Credit Suisse's 2008 sales forecast for Vytorin (and Zetia) in the U.S. by $302 million and made cuts to Credit Suisse's forecasts for Vytorin sales in later years as well. Credit Suisse cut its forecast for Merck to $3.31 a share from $3.36.

267. The same day, other analysts weighed in on the expert panel discussion of ENHANCE at the ACC. Seamus Fernandez of Leerink Swann, an investment bank specializing in healthcare, stated:

> The expected panel discussion ended up being more of a consensus statement that concluded 1) ENHANCE was a well-conducted, high-quality imaging study; 2) there is ***no evidence from ENHANCE that the combination performs better*** than the same

> dose of statin alone; 3) ***LDL lowering is not an infallible surrogate***; and 4) ***Zetia/Vytorin should be reserved for last-line therapy*** after trying multiple statins and other 'evidence-based' therapies (bile acid resins, fibrates and niacin). Since the panel recommended that Zetia be considered as a 3rd- or even 4th-line therapy, we believe a recovery in prescriptions is unlikely in 2008 and there could be additional negative impact on U.S. prescriptions post-ACC.

(Emphasis added).

268. A March 31, 2008 *Reuters* story reported that Lehman Brothers had cut its price target on Merck by more than 10% based on ENHANCE results. According to the Lehman Brothers report, "[p]ost presentation comments about the trial were surprisingly negative and will likely have a detrimental and material impact on prescription trends." That day alone, Merck lost $14.3 billion in market capitalization.

269. Also on March 31, 2008, Senator Grassley lobbed another round of letters to Merck and S-P, asking the companies to explain their handling of the ENHANCE study results. Senator Grassley released new evidence that the Companies had long known that ENHANCE showed Vytorin was no more effective than simvastatin but withheld that information to pump up sales of Vytorin.

270. Even the researcher who led the crucial ENHANCE study accused Vytorin's makers of withholding negative results to boost sales, Senator Grassley said. The Senator's letter cites testy e-mails from Dr. Kastelein, including one sent on July 6, 2007 to officials at the Merck-S-P joint venture, stating that if the study results would not be presented at an upcoming medical conference, "our collaboration is over . . . . This starts smelling like extending the publication for no other [than] political reasons and I cannot live with that." As Senator Grassley wrote, Dr. Kastelein went further the next day, writing: "you will be seen as a company that tries to hide something and I will be perceived as being in bed with you!" Senator Grassley claimed

that Merck and S-P were "placing marketing interests above science" by, among other things, spending $3.5 million to "wine and dine doctors and convince them to prescribe Vytorin." Senator Grassley requested identification of the key opinion leaders for ENHANCE, Vytorin and/or Zetia and how much each such leader was paid.

7. Disclosures Of Other Test Results Confirm That Vytorin Provides No Cardiovascular Benefits And Is In Fact Harmful

271. While Merck and Schering-Plough were in the midst of defending themselves against the growing tidal wave of criticism being levied by the media, physicians, investors and Congressional investigators on account of their suppression of the negative data on Vytorin from the ENHANCE trial, the safety and efficacy of Vytorin was again called into doubt by another negative clinical trial on Vytorin.

272. On July 21, 2008, Merck and Schering-Plough convened a press conference to pre-release the results of the "SEAS" study (Simvastatin and Ezetimibe in Aortic Stenosis), which investigated the effects of Vytorin in patients with aortic stenosis – a relatively common condition believed to be cholesterol-related involving the partial blockage of the aortic valve in the heart due to plaque buildup. Left untreated aortic stenosis can cause heart failure, cardiac arrest and death, and aortic valve replacement for severe symptoms of aortic stenosis is the second most frequent type of heart surgery. The pre-release of the results of SEAS trial came as a surprise to investors and analysts because the results had not been expected until the American Heart Association 2008 Scientific Sessions (in November 2008), according to a July 21, 2008 article appearing on *TheHeart.org*.

273. The SEAS study involved 173 clinical centers in Europe and 1873 patients with mild to moderate aortic stenosis who had no symptoms of the disease. Patients were given Vytorin or a placebo with the primary endpoint of the study being "major cardiovascular events"

related to aortic stenosis or atherosclerosis. Researchers also hoped to show through SEAS that intensive LDL lipid lowering with Vytorin positively influenced the progression of aortic stenosis by preventing major events such as valve replacement surgery, hospitalization due to heart failure, and death. Like Vytorin's ENHANCE study, however, Vytorin failed the SEAS trial miserably, strongly suggesting that the results of ENHANCE were not anomalous, as the Companies had immediately urged, and not easily explained away by difficulties with the patient population, the size of the trial, or by some other pretextual ground.

274. The SEAS researchers found no significant differences between the Vytorin treatment group and the placebo group for the primary and secondary endpoints of the study. According to the chair of the SEAS steering committee, Dr. Terje Pedersen of Norway, as reported by *TheHeart.org*, "The SEAS study has given a clear-cut answer to the question of whether intensive lipid lowering will influence the course of aortic-stenosis disease. I think we can conclude that it does not." These study results further corroborated that Vytorin was no better than placebo (again) in reducing the major cardiovascular events associated with aortic stenosis. But that was not the end of it; the results were far worse. SEAS also showed a disturbing correlation between Vytorin and the risk of cancer, including the possibility that Vytorin served to hasten a cancer-related death. In addition, the SEAS Study found that cancer patients taking Vytorin had increased rates of "serious" heart events. Thus, not only did SEAS confirm the results of ENHANCE that Vytorin did not work well in improving patient outcomes, but it further demonstrated that Vytorin potentially was dangerous. According to *USA Today*, in an article titled "Heart Drug's Safety Scrutinized," even the lead investigator of the SEAS study thought that Vytorin's link to cancer was "disturbing."

275. According to *The New York Times* article "Trial Intensifies Concerns About Safety of Vytorin," dated July 22, 2008, this increased cancer rate was statistically significant, meaning that there was only a 5% chance that the results were an anomaly. Because of this high increased risk, moreover, the SEAS lead investigator received permission to unblind the data in two larger Vytorin trials involving 20,000 patients: SHARP, testing Vytorin vs. placebo and Zocor in kidney patients, and IMPROVE-IT, which compares Vytorin and Zocor in patients at risk for heart attacks. Although those trials are incomplete, at the time the cancer analysis was done, all studies showed a significantly increased risk of dying from cancer (70% increased cancer death rate in SEAS, and 33% increased cancer death rate in SHARP and IMPROVE-IT), according to *USA Today*.

276. Merck and Schering-Plough spin-doctors went to work again. According to the *Wall Street Journal*, Merck and Schering-Plough hired and funded "an analysis" of the SEAS data by an Oxford University epidemiologist. In their pre-release of the SEAS data, they stated "the observed differences in cancer in the SEAS study…could have occurred as a result of chance" on account of the comparisons – which the Companies themselves encouraged – of the SEAS data to the unblinded data from SHARP and IMPROVE-IT. In a next day (July 22, 2008) open letter to health care professionals about SEAS, Merck again discounted any link between Vytorin and cancer stating that "M/S-P believes the cancer finding in SEAS is likely to be an anomaly that, taken in the light of all the available data, does not support an association with Vytorin." These conclusions, supported by the Companies' hired-gun from Oxford, allowed the Companies to again state through Merck spokesperson Skip Irvine, that "we don't believe that changes in the clinical use of Vytorin are warranted."

277. Numerous physicians and researchers, however, said "not so fast." According to a July 22, 2008 article in *The New York Times*, physicians immediately questioned how looking at the unblinded data from the SHARP and IMPROVE-IT trials could matter given the fact that cancer typically takes time to develop and those trials were only one or two years in at the time the data was unblinded and compared to the *four years* of Vytorin treatment studied in SEAS. *The New York Times* therefore reported that physicians it had interviewed, including Dr. Steven Nissen, a former president of the American College of Cardiology, were not so quick to dismiss the Vytorin link to cancer stating that the SEAS results "will heighten concerns about Vytorin's safety and effectiveness." According to *The New York Times*, even when all three studies (SEAS, SHARP, and IMPROVE-IT) are looked at together, the number of cancer deaths was still alarming with a one-third (1/3) higher risk among those taking Vytorin.

278. According to *Forbes* ("Another Storm Brewing for Vytorin," August 27, 2008), moreover, none of the sixteen (16) medical research experts they interviewed were entirely convinced that Vytorin posed a definitive cancer link but eight (8) thought that it was premature to dismiss any cancer risk as "an anomaly" (as the Companies had attempted) and ten (10) believed there was some possibility that Vytorin increased the risk of death for patients with cancer. *Forbes* also laid out good scientific reasons why Vytorin may pose an increased cancer risk. Although Zocor's safety (in terms of not having links to cancer) was confirmed by decades of research, the *Forbes* article said, SEAS was the "was the biggest and longest study yet conducted for Zetia." Thus, according to *Forbes*, the Zetia component of Vytorin might make cancers more deadly because Zetia is known to block not only the absorption of cholesterol but also plant sterols, which might slow tumor growth. Doctors consulted by *Forbes* stated that, either way, "it [the SEAS results] should push people further away from the use of [Vytorin]."

279. Again, Merck and Schering-Plough were under pressure from the media and from physicians for what appeared to be a blatant attempt at twisting what was clearly negative data on Vytorin from the SEAS study. Experts severely criticized the way the SEAS results were made public by the Companies in a press release and news conference, rather than "appearing first in a medical journal where the results are carefully vetted by anonymous outside experts." Dr. Steven Nissen, for instance, was quoted by *Forbes* in "The Vytorin Saga, Vytorin Study's Ethical Morass" as stating that Merck and Schering-Plough were "trying to spin the results using media relations strategies rather than the proper scientific approach."

280. In addition to ENHANCE and SEAS, Vytorin and Zetia continue to be studies in a larger trial, called IMPROVE-IT, which (among other things) is testing whether Vytorin reduces the incidence of heart attacks and strokes versus generic Zocor alone. That trial, which was commenced in 2005 with an expected enrollment of 10,000 patients has already raised suspicions and red flags among analysts. Merck announced on March 28, 2008, for instance, that the IMPROVE-IT researchers were increasing enrollment by 8,000 patients to a total test population of 18,000, and that they were pushing back the endpoint of the study from 2011 to 2012, at the earliest. Analyst figured that this meant IMPROVE-IT would likewise fail. In an article appearing in Business Week two days after the Merck announcement, on March 31, 2008, titled "A Weak Prognosis for Vytorin and Zetia," Raymond James pharmaceutical analyst Michael Krensavage found that increased enrollment indicates that "early signs from the Improve-It trial are not good." "There is only one way to interpret that [the increased enrollment]. It's negative," Krensavage was quoted. "[A]dding more patients means that the beneficial effects of the drug may be smaller than the Company expected…. To spot an effect, therefore, the trial has to have more patients." The same day, *TheStreet.com* reported that

Merrill Lynch analyst David Risinger "has grown somewhat concerned about [IMPROVE-IT], as well, citing "the trial's increased size in particular." According to Risinger's analyst report on the subject, "Even though it may be attributed to a low rate of events due to better patient care, it also raises concern that the magnitude of the benefit (if any) for Vytorin is small.

G. SALES OF VYTORIN PLUMMET AND ANALYSTS DOWNGRADE THEIR RATINGS ON MERCK

281. The onslaught of investigations and press regarding ENHANCE resulted in a plunge in U.S. prescriptions written for Vytorin and a drop in Merck's stock price. As *The Wall Street Journal* reported on January 23, 2008, prescriptions written for Vytorin in the week ended January 18, 2008 fell about 9.5%. As *Bloomberg* reported on January 25, 2008, in the ten days since the partial results of ENHANCE were released on January 14, 2008, new prescriptions for Vytorin fell 22%, according to James Kelly, analyst with Goldman Sachs Group Inc. Moreover, doctors were starting their new patients on simvastatin alone, which at that time cost three cents per pill compared to about $3 per pill for Vytorin.

282. *The Wall Street Journal* reported on January 26, 2008 that the plunge was continuing – according to the prescription-tracking firm ImpactRx, Vytorin prescriptions dropped by two-thirds in the past week. Deutsche Bank reported in a Merck "Company Alert" on January 25, 2008 that since the January 14 announcement of the ENHANCE results, Merck had suffered a loss in market capitalization of over $27 billion. *Barrons* reported on January 30, 2008 that since January 14, Merck's stock had dropped 23%, and "[a]nalysts ha[d] cut earnings estimates for 2008."

283. Hilliard Lyons published a January 21, 2008 analyst report with a headline reading "Vytorin Concerns Overshadow" Merck's fourth quarter. On January 30, 2008, Natixis Bleichroeder issued a report downgrading its outlook for Merck and lowering its price target,

stating that "[w]hile Merck downplayed the potential that Vytorin and Zetia prescriptions will permanently decline, we now estimate that Zetia and Vytorin sales will fall 22% in 2008." A March 26, 2008 Credit Suisse analyst report argued the outlook for Vytorin and Zetia post ENHANCE was a major controversy that weighed heavily on Merck sales.

284. The Defendants withheld the ENHANCE study results in a desperate effort to preserve their skyrocketing sales as long as possible. Vytorin sales increased rapidly during 2007, showing a 43% increase over 2006. Zetia sales had increased as well. After the damaging study results were finally released, the public reacted strongly. In addition to sharp drops in Merck's stock prices, physicians sharply cut their prescriptions for the drugs. The table below from S-P's 8-K, dated September 22, 2008, illustrates the drop in U.S. prescription rates for both Zetia and Vytorin, while the overall cholesterol management market remained constant:

U.S. Total Prescription Volume (000's)

	Jan 08	**Feb 08**	**Mar 08**	**Apr 08**	**May 08**	**Jun 08**	**Jul 08**	**Aug 08**
Cholesterol Mgmt Market	20,519	19,042	19,788	19,645	19,910	19,403	20,292	19,666
Zetia	1,375	1,183	1,201	1,079	1,067	1,022	1,038	984
Vytorin	1,851	1,607	1,619	1,428	1,412	1,330	1,339	1,249

285. Thus, from January 2008 to August 2008, the number of Zetia prescriptions dropped from 1,375 million per month to 984 million, a decline of 29%, Vytorin prescriptions dropped from 1.851 million to 1.249 million, a decline of 33%, and combined Zetia and Vytorin prescriptions dropped from 3.229 million per month to 2.233 million, a decline of 31%.

V. FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS DURING THE CLASS PERIOD

A. OVERVIEW OF DEFENDANTS' FALSE AND MISLEADING STATEMENTS IN SUPPORT OF THEIR FRAUDULENT SCHEME

286. By July 2004, when Vytorin first hit the market, the "lower is better" mantra with respect to statins was accepted largely based on decades of research into statins. Lowering LDL cholesterol was widely perceived as being clinically beneficial because of the belief, supported by extensive research, that there was a direct linkage between high LDL cholesterol and the formation of arterial plaque and the onset of atherosclerosis. Statin research confirmed that "lower is better" in the sense that lowering LDL cholesterol had been shown to slow or stop the build-up of plaque in the arteries and thus slow or stop the onset of atherosclerosis and major cardiac events. By August 2004, the American Heart Association (AHA), the American College of Cardiology (ACC), and the FDA each had adopted a "lower is better" position with respect to LDL cholesterol based upon this growing body of scientific research mostly focused on into statins.

287. Importantly, by July 2004, there were no tests confirming that "lower" LDL cholesterol was indeed "better" for cardiac health involving Zetia. Thus, whether or not the supposed "dual inhibition" functions of Vytorin or Zetia add-on therapy provided actual cardiovascular health benefits were altogether unproven, and many experts questioned whether Zetia's or Vytorin's cholesterol-reducing power would translate into better patient outcomes (*i.e.*, reduced arterial plaque, heart attacks and/or strokes). These were clinical and marketing disadvantages that Merck well knew, but it had designed and launched surrogate and outcome studies including ENHANCE, SEAS, and IMPROVE-IT, in an effort to overcome these perceived shortcomings. ENHANCE was most critical to Merck, not only because it was the first important surrogate study on the efficacy of Vytorin (begun in 2002), but because it was set

to conclude at around the same time that Zocor lost patent exclusivity (the ENHANCE trial concluded April 2006; Zocor lost patent exclusivity June 2006). Merck ***had*** to prove that Vytorin was better than Zocor alone in order to justify to doctors, patients, and the managed care industry that it was worth paying $3 per pill for Vytorin versus $0.75 per pill for generic Zocor (simvastatin), and the ENHANCE trial was designed to do just that.

288. Until ENHANCE was completed, Merck was at a marketing disadvantage with respect to Vytorin. Its primary competitors, Lipitor and Crestor, began releasing more and more positive outcomes research beginning in 2003, and by March 2006 both AstraZeneca and Pfizer were able to market their drugs as positively affecting arterial plaque build-up, and patient outcomes. Merck, because of Vytorin's relative lack of clinical evidence, could not make such claims. In March of 2006, moreover, AstraZeneca released the results of its ASTEROID trial which proved Crestor could actually reverse the build-up of arterial plaque and thus reverse atherosclerosis. The positive outcome studies being published by Vytorin's competitors caused Vytorin's marketing gap to grow deeper, and Merck and S-P therefore needed a strong message to counter-market its blockbuster drug. As Merck's CEO, defendant Clark, stated in a June 14, 2006 Goldman Sachs Annual Global Healthcare Conference, "Vytorin and Zetia are critical to the future success of Merck [and] are critical to the future of Schering-Plough as well. So we will do everything we must to maximize both of those products at the joint venture." Merck and S-P found their marketing hook for Vytorin by co-opting the "lower is better" mantra from statin research, and by touting Vytorin's "dual inhibition" cholesterol-lowering mix as being superior to competing statins.

289. Merck and S-P did not yet have the clinical data regarding Vytorin's impact on patient outcomes, and thus they did ***not*** know "lower" was in fact "better" when it came to Zetia

(the non-statin part of Vytorin) or the "dual inhibition" mix of Vytorin. Nevertheless, Defendants morphed the "lower is better" mantra from statin research into a powerful marketing ploy for Vytorin and Zetia. According to Defendants, because Vytorin and Zetia lowered cholesterol more than its competitors (which was true), it was a better drug, and more capable of reducing arterial plaque and overall cardiac risks (which was unproven until ENHANCE proved it was false).

290. The Class Period begins on May 1, 2006. By that date, the ENHANCE study was closed and the preliminary results were available to, and seen and discussed by, Merck and S-P scientists, executive members of the M/S-P joint venture, and Merck and S-P executives. Thus, the poor outcome results of Vytorin and Zetia were concealed from the market by Merck beginning on that date, if not before.

291. The ENHANCE study proved that Vytorin's and Zetia's cholesterol reducing capabilities not only failed to produce a positive outcome on arterial plaque, but actually made arterial plaque ***slightly worse***. Thus, the ENHANCE study actually showed that for Vytorin ***lower was actually worse***, and it was false and misleading for Merck (and S-P) to state or imply otherwise, while at the same time suppressing the negative data from the ENHANCE study. Thus, as of at least May 1, 2006, if not sooner, Merck knew that although Vytorin ***was*** a more potent drug at lowering LDL cholesterol compared to competing statins, it ***was not*** "better" than competing statins because Vytorin's cholesterol lowering mix ***was not*** having a positive impact on arterial plaque or on patient outcomes. This potentially groundbreaking news to the medical community, which called into question the notion that "lower is better" when it comes to Vytorin, was concealed by Merck and S-P so that they could continue to compete and continue

to push their blockbuster drugs Vytorin and Zetia using a marketing pitch and public relations campaign that they knew to be false.

292. Merck also knew, at least by May 1, 2006, if not sooner, that the adding Zetia to a statin (like Vytorin in ENHANCE) was ineffective because it ***was not*** having a positive impact on arterial plaque or on patient outcomes making Merck's widely touted "dual inhibition" function of Vytorin misleading. In fact, Merck learned from ENHANCE that adding Zetia to a statin, for whatever reason, appeared to make arterial plaque slightly worse. But Merck concealed this knowledge from doctors, patients, analysts and investors, and instead continued to unabashedly tout Zetia as a powerful add-on drug to statin therapy that would allow patients to achieve superior results ("lower is better") through "dual inhibition."

293. Merck itself recognized the connection between cholesterol and arterial plaque, and made the "cause and effect" connection between LDL cholesterol, arterial plaque, and heart attacks and strokes clear in its Vytorin package insert, as follows:

> What should I know about high cholesterol?
>
> Cholesterol is a type of fat found in your blood. Cholesterol comes from two sources. It is produced by your body and it comes from the food you eat. Your total cholesterol is made up of both LDL and HDL cholesterol.
>
> LDL cholesterol is called "bad" cholesterol because it can build up in the wall of your ***arteries*** and form ***plaque***. Over time, ***plaque*** build-up can cause a narrowing of the ***arteries***. This narrowing can slow or block blood flow to your heart, brain, and other organs. High LDL cholesterol is a major cause of ***heart disease*** and ***stroke***.

(Emphasis added).

294. At the same time Merck was making these "cause and effect" assertions between high LDL cholesterol and the build-up of arterial plaque, heart attacks and strokes, Merck was assuring the public through a massive DTC advertising campaign that Vytorin was better than

competing statins because "only Vytorin helps block the absorption of cholesterol that comes from food and reduces the cholesterol that your body makes naturally." "Cholesterol comes from 2 sources: Food and Family," the typical Merck advertisement stated, and "only" "Vytorin treats both." To analysts and investors, moreover, Vytorin was touted as not only more effective, but as safer than statin therapy. Merck claimed that Vytorin lowered bad cholesterol more than Lipitor and Crestor because of "dual inhibition," and claimed that this was more safe than taking the high dose statin necessary to achieve the same powerful cholesterol-lowering capabilities of Vytorin.

295. After gathering the ENHANCE study results, the Companies not only persisted in their misleading advertising campaign, but they ramped it up, telling their respective marketing and public relations personnel to actually increase the message that "lower is better" in the marketplace. According to a December 2007 "market review" document, unearthed by the Senate investigation of Merck's conduct regarding Zetia and Vytorin, the marketing message became slightly more aggressive. In fact, the internal marketing message for 2008, just weeks ahead of the release of the negative ENHANCE data was "Incorporate 'lower is better' into message flow" and "incorporate switch message – SNAG (simvastatin not at goal)." According to Senator Grassley, when commenting on this document (and others) in a March 31, 2008 letter to Merck and S-P, he was "troubled that M/S-P may be placing marketing interests above science."

296. On or about January 23, 2008, just days after the initial release of the negative ENHANCE study results by Merck, the FDA contacted Merck by letter to inform it that its DTC marketing materials and its product claim materials directed to healthcare providers, were false and misleading. Among other things, the FDA pointed out that it was misleading for Merck to

suggest that the two-drug combination in Vytorin provided a cardiovascular benefit because while "one of the drug components in Vytorin [Zocor], reduces the risk of heart attack, heart-related death, stroke, or heart procedures," the other component (Zetia) "has not been shown to prevent any of these cardiovascular outcomes. Furthermore, using the combination…product, Vytorin, has not shown any additional cardiovascular benefit compared to using [Zocor] alone." The FDA then went on to state that Merck should promptly change its misleading advertisement, as follows:

> Therefore….we are informing Merck that the Vytorin product claim promotional materials would be ***misleading*** because the pieces ***do not include contextual information disclosing a limitation to the efficacy of Vytorin regarding clinical outcome benefits***.
>
> Consequently, we recommend revising any DTC Vytorin product claim promotional material, by adding context, in consumer-friendly language, communicating not only that Vytorin contains two medicines (Zocor and Zetia), but also by conveying that taking the combination drug ***Vytorin has not been shown to provide any additional cardiovascular outcome benefits compared to using Zocor alone***.

(Emphasis added).

297. Both prior to and throughout the Class Period, Defendants and their joint venturers at S-P issued numerous false and misleading statements regarding Vytorin, while at the same time concealing adverse material information from investors regarding the negative ENHANCE study results. Defendants actively suppressed the negative results of the ENHANCE study in order to continue reaping the huge profits from two of Merck's multi-billion dollar, blockbuster drugs Vytorin and Zetia. In this respect, they concealed material information from investors regarding the severe risks to the Company's multi-billion dollar Vytorin and Zetia franchise. But in addition to their deliberate campaign to suppress the negative ENHANCE data

and conceal material information, Defendants also made numerous affirmative misrepresentations to the public that generally fall within one of four categories, as follows:

(1) Defendants made false and misleading statements through a variety of public channels claiming that Vytorin was safe and effective, and *better than* competing drugs, including competing statins, at improving patients' health when they knew, as a result of ENHANCE, that such claims were untrue;

(2) because Defendants knew that the release of the ENHANCE study results would have a material negative impact on the Company's financial results in general, and on the continued success of Merck's Vytorin and Zetia franchise specifically, the Defendants issued numerous false and misleading statements to investors regarding Vytorin's and Zetia's strength, commercial success and projected future commercial success to Merck;

(3) even as Defendants actively concealed the negative ENHANCE data from the public, Defendants made false statements about their allegedly positive progress with ENHANCE and the handling of the ENHANCE data; and,

(4) falsely assured all of Merck's stakeholders, including investors, that Merck (i) put patients before profits, (ii) abided by the highest ethical practices in all of its business and research endeavors, and (iii) was fully transparent with its business, its clinical trials, and its research.

B. DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS REGARDING VYTORIN'S SAFETY AND EFFICACY

1. Merck's False And Misleading Vytorin Marketing Campaign.

298. The Defendants flooded the market with public disclosures relating to the purported powerful efficacy of Vytorin as compared to the statins of its competitors (*e.g.*, Lipitor, Crestor), and as compared to Zocor alone. As set forth in detail below, in its marketing to medical professionals, in its DTC advertising, and in its public statements to the media, analysts and investors, the Companies stated consistently throughout the Class Period that Vytorin was a superior cholesterol-reducing drug because it lowered LDL cholesterol better than the competition, and "lower is better" for patients with high cholesterol and cardiovascular risks.

299. While it is true (and has been scientifically verified) that Vytorin does indeed lower LDL cholesterol to a greater extent than competing cholesterol drugs, Defendants made numerous false and misleading statements during the Class Period by claiming that "lower is better" with respect to Vytorin, and made further false and misleading statements by claiming that Vytorin's "dual inhibition" function provided superior benefits to taking statins alone. Such statements are not true when speaking about Vytorin, but Defendants recklessly made such statements and claims when they were unproven, and continued to make such statements and claims even after they knew the negative results of ENHANCE proved them to be false.

2. Merck's DTC Advertising Was False And Misleading.

300. Merck's DTC advertising campaign was as massive as it was false and misleading. In television commercials, and in magazines and newspapers with local and nationwide distribution, Merck bombarded the public with its marketing message. In its most common print advertisements, which were widely distributed throughout the Class Period in substantially similar or identical fashion thousands of times over -- including, for example, in *Cooking Light*, dated October 1, 2006; *Readers' Digest*, dated August 1, 2006; *Better Homes & Gardens*, dated September 1, 2006; and *U.S. News & World Report*, dated September 4, 2006, and in major newspapers throughout the country – Merck assured the public that Vytorin was better than competing statins because "only Vytorin helps block the absorption of cholesterol that comes from food and reduces the cholesterol that your body makes naturally." "Cholesterol comes from 2 sources: Food and Family," the Merck advertisements stated, and "only" "Vytorin treats both."

301. The foregoing statements and advertising claims were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone;

(3) Vytorin's advertising and promotional materials were false and/or misleading because as a result of ENHANCE, Defendants knew that Vytorin provide no cardiovascular health benefits that are not provided by Zocor (simvastatin) (or other statin drugs), and actually had a slightly negative effect on cardiovascular health as compared to the use of statins alone.

302. In another Merck print advertisement, appearing numerous times in newspapers of local and national distribution during the Class Period, Merck took out full page newspaper ads touting Vytorin's dual inhibition function as being somehow better than Lipitor. For example, on July 9, 2006, in the *Dallas Morning News*, Merck's full-page ad read:

> TAKING LIPITOR?
>
> Then take a look at this. Doctors have switched more patients from Lipitor to Vytorin than to any other branded cholesterol treatment.
>
> It's a fact. You see, doctors know that Vytorin actually treats the 2 sources of cholesterol. ***Only*** Vytorin helps block the cholesterol that comes from food and reduces the cholesterol your body makes naturally, based on your family history. And in a clinical study, Vytorin was proven to lower bad cholesterol (LDL) an average of 53% while Lipitor reduced it an average of 45%.

(Emphasis in original).

303. The foregoing statements and ad claims were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of the ENHANCE study which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) The ENHANCE study proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone;

(3) Vytorin's advertising and promotional materials were false and/or misleading because as a result of ENHANCE, Defendants knew that Vytorin provide no cardiovascular health benefits that were not provided by Zocor (simvastatin) (or other statin drugs), and actually had a slightly negative effect on cardiovascular health as compared to the use of statins alone.

304. Merck's television commercials directed to the public were equally false and misleading. In at least 26,287 sixty-second television commercials, running locally and nationally from as early as January 1, 2007 through March 1, 2008, people dressed to resemble different food items touting the superiority of Vytorin's "dual inhibition" properties and claimed that Vytorin was superior to competing statins. In one example, which appeared at least 5,356 times across the nation from August, 28, 2007 through February 18, 2008, Merck's commercial used the following script:

> Cholesterol, it can come from casserole, creamy tuna and peas. And your Grandmother, Louise. A plate of Mom's lasagna, extra cheesy. And your Pop Petey. A healthy diet is important. When that's not enough, there's Vytorin.
>
> Cholesterol comes from two sources, food and family. Vytorin treats two sources. Vytorin contains two medicines: Zetia and Zocor. Vytorin was also proven in clinical studies to lower cholesterol more than Lipitor or Crestor…. Eat right and stay active, if that's not enough then there is Vytorin [Vytorin treats two sources of cholesterol].

305. In another revised version of the same or substantially similar commercial, Crestor is dropped from the script and the focus is on the market-leader, Lipitor. In addition, the revised version of the same or substantially similar commercial featured an actor writing on a chalkboard the words "ONLY Vytorin" and the word "ONLY" is shown next to "Vytorin" on

the last screen scene with a voice over making the claim "the only medicine that treats the two sources of cholesterol."

306. The foregoing statements and advertising claims were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone;

(3) Vytorin's advertising and promotional materials were false and/or misleading because as a result of ENHANCE, Defendants knew that Vytorin provided no cardiovascular health benefits that were not provided by Zocor (simvastatin) (or other statin drugs), and actually had a slightly negative effect on cardiovascular health as compared to the use of statins alone.

307. In another of Merck's Vytorin television commercials, appearing both locally and nationally in sixty-second spots at least 8,901 times from April 30, 2007 through March 1, 2008, Merck compared what food and family have in common, and used the following script:

> Cholesterol. It can come from that cherry pie, but also from your Grandad Si. From beef off a grill, and your Grandmother, Jill. A healthy diet is important; when that's not enough, adding Vytorin can help. Cholesterol comes from two sources: food and family – Vytorin treats two sources. Only Vytorin blocks the absorption of cholesterol and reduces the cholesterol your body makes naturally. Vytorin was also proven in clinical studies to lower bad cholesterol more than Lipitor alone. More than Crestor alone.
>
> So, eat right, stay active. But if that's not enough, ask your doctor about adding Vytorin – two sources of cholesterol, treat them both with Vytorin.

308. The foregoing statements and ad claims were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE study which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone;

(3) Vytorin's advertising and promotional materials were false and/or misleading because as a result of ENHANCE, Defendants knew that Vytorin provided no cardiovascular health benefits that were not provided by Zocor (simvastatin) (or other statin drugs), and actually had a slightly negative effect on cardiovascular health as compared to the use of statins alone.

309. In a third version of Merck's Vytorin food/family television commercials, appearing both locally and nationally in sixty-second spots at least 12,430 times from January 1, 2007 though January 14, 2008, Merck used the following script:

> Cholesterol. It can come from bowtie pasta, but also from your Grandfather Bo. From a silky pie or your Mom Juliana. When healthy diet is not enough, Vytorin can help. Cholesterol comes from food and family. [Vytorin treats two sources.] [Vytorin contains two medicines: Zetia and Zocor.] It absorbs from food and helps you reduce your naturally produced cholesterol. It is clinically proven to lower bad cholesterol more than [Lipitor] and [Crestor] alone. [ASK YOUR DOCTOR HOW TO TREAT 2 SOURCES OF CHOLESTEROL].

310. The foregoing statements and advertising claims were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone;

(3) Vytorin's advertising and promotional materials were false and/or misleading because as a result of ENHANCE, Defendants knew that Vytorin provided no cardiovascular health benefits that were not provided by Zocor (simvastatin) (or other statin drugs), and actually had a slightly

negative effect on cardiovascular health as compared to the use of statins alone.

3. Merck's Marketing To The Medical Community Was False And Misleading

311. In addition to its false and misleading DTC marketing campaign, Merck also targeted doctors and other medical professionals with its false and misleading marketing message. According to Confidential Witness #3 ("CW 3"), who was a Merck "Executive Specialty Sales Representative" specializing in Merck's cardiovascular drug franchise and who directly sold Vytorin for several years before leaving Merck in mid-2007, Merck salespeople were specifically trained with scripts to pound home the "lower is better" marketing message when providing details to doctors on the benefits of Vytorin. CW 3 said that when his/her doctors asked about Vytorin's efficacy, which was often, s/he would assure them that the results of ENHANCE would be available soon, and assured them it was the best cholesterol drug on the market.

312. Confidential Witness No. 10 ("CW 10"), a Merck sales representative from approximately May 2007 to May 2008 with direct responsibility for selling Vytorin and Zetia, corroborated that they were trained on the "lower is better" Vytorin marketing message for their physician sales visits. Both before and after the publication of the ENHANCE study results, CW 10 was told to tell doctors that Vytorin lowered LDL cholesterol better than any other drug on the market. CW 10 stated that when the ENHANCE study results became public, the sales representatives were in a tough situation, but the doctors were also in a bind because they had to answer to patients who have been spending top dollar on these medicines, "when they could have gone to Target or Wal-Mart and gotten just as effective drugs for a fraction of the price." When CW 10 learned of the ENHANCE results, s/he felt that Merck was being "dishonest by waiting so long to release the results of the ENHANCE study."

313. Confidential Witness No. 12 ("CW 12") was a Merck sales representative from April 2007 to May 2008 with responsibility for selling Vytorin. CW 12 corroborated the marketing message to the physicians, saying that Merck sales representatives detailed doctors regarding Vytorin's efficacy in lowering levels of LDL cholesterol.

314. Merck's marketing statements above were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins; and

(2) Vytorin's advertising and promotional materials were false and/or misleading because as a result of ENHANCE, Defendants knew that Vytorin provided no cardiovascular health benefits that were not provided by Zocor (simvastatin) (or other statin drugs), and actually had a slightly negative effect on cardiovascular health as compared to the use of statins alone.

4. Merck Falsely Touted Vytorin's Superior Safety And Efficacy To Mislead Investors.

315. Merck not only bombarded the public with its false and misleading advertising campaign and blitzed medical professionals with its highly-trained sales force about the purported powerful efficacy and superiority of Vytorin's "dual inhibition" properties and its message that Vytorin was better than competing drugs because it drove LDL cholesterol lower (i.e., "lower is better" when it came to Vytorin), but it would also disseminate its "lower is better" message in response to any marketing challenges, even where Merck knew its claims to superiority were misleading.

316. For example, on March 13, 2006, when AstraZeneca presented the extraordinarily positive results of the ASTEROID clinical trial of Crestor, which proved that Crestor actually ***reversed*** the build-up of plaque in coronary arteries, Merck was quick to respond. ***The same day*** as the release of the Crestor study results, Prudential analyst Timothy Anderson wrote a note to

investors stating that Merck and S-P have clinical data (which they pre-released to him prior to formally announcing their findings to the medical community) that shows their cholesterol drug Vytorin lowers bad LDL cholesterol levels better than Crestor. According to Anderson, Merck had data from a head-to-head study against Crestor which showed Vytorin was superior: "The data show that dose-for-dose, Vytorin is statistically significantly better than Crestor on LDL reduction…[and] both Vytorin and Crestor have been shown to raise HDL more than competing statins." Anderson also added that Merck's Vytorin also beat Crestor in controlling another blood level factor, triglycerides, and that "Vytorin is generally perceived as having an actual safety advantage."

317. In a similar report relating to Crestor's ASTEROID trial results, appearing on March 13, 2006 on *Marketwatch.com*, Bear Stearns analysts are quoted as concluding that Vytorin was actually a benefactor of the ASTEROID trial, while parroting the Merck spin, as follows: "it reaffirms a growing body of evidence that says lower LDL cholesterol levels are better. To that end, Vytorin should benefit handsomely…. Vytorin lowers LDL cholesterol as well as Crestor, yet has no safety issues."

318. Indeed, Merck itself was always quick to trot out its "lower is better" message in response to its competitors' claims of superiority. An article dated May 8, 2006, appearing on *Dow Jones Newswires* and relating to a potential shortfall in Pfizer's 2006 Lipitor sales targets, in part on account of Vytorin's success, is emblematic. In the article, titled "Pfizer's '06 Lipitor Sales Target Seen As Difficult," analyst Peter Loftus commented on the growing challenge that Vytorin posed to Lipitor's market dominance, but stated that Vytorin's primary weakness was its relative lack of clinical data: "As for Vytorin, some experts agree with Pfizer's assertion that [Vytorin's] clinical data are weaker than that for Lipitor. Steve Nissen, head of cardiovascular

medicine at the Cleveland Clinic, noted there has been no data directly linking Vytorin to cardiovascular outcomes, while Lipitor has such data." According to the article, an unnamed Merck spokeswoman countered these perceived weaknesses of Vytorin with the Merck message that ***"there is mounting evidence that large decreases in bad cholesterol levels reduce the risk of cardiovascular events, and a study has shown Vytorin can provide greater reduction than Lipitor."*** (Emphasis added). In other words, even after the ENHANCE data showed Vytorin was no better, and actually worse, than drugs like Lipitor, Merck still claimed that Vytorin brought LDL cholesterol levels lower, and that "lower is better."

319. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone;

(3) Vytorin's promotional materials and sales scripts were false and/or misleading because as a result of ENHANCE. Defendants knew that Vytorin provides no clinical cardiovascular health benefits that are not provided by Zocor (simvastatin), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone.

320. On July 24, 2006, Merck issued a press release announcing earnings results for the second quarter of 2006, ending June 30, 2006. In that release, and its Quarterly Report on Form 10-Q covering the same period, published on August 7, 2006, Merck touted the superiority of Vytorin over its competitors, as follows:

> In the second quarter, Merck/Schering-Plough announced new data from two clinical trials. Data presented at the international Symposium on Atherosclerosis meeting showed that Vytorin was significantly more effective than Crestor in reducing LDL cholesterol across all study dose comparisons and an analysis of

> the data showed that, when averaged across all study doses, Vytorin brought more patients at high risk of cardiovascular disease to LDL cholesterol levels less than 70 mg/dl compared to Crestor. Also in June, new data released at the American Diabetes Association's (ADA) 66th Annual Scientific Sessions showed that at the recommended usual starting doses Vytorin was superior to Lipitor in the lowering of LDL cholesterol in patients with type 2 diabetes.

321. On October 5, 2006, Merck and S-P issued a joint press release announcing that the FDA approved a label change to reflect Vytorin's superiority over Crestor at lowering LDL cholesterol levels. On October 20, 2006, Merck also published a press release announcing earnings results for the third quarter of 2006, ending September 30, 2006, which recounted and reiterated the October 5, 2006, release, as follows:

> On Oct. 5, the Merck/Schering-Plough partnership announced that the FDA had approved the inclusion of new data in the product label showing that Vytorin, a cholesterol-absorption inhibitor combined with simvastatin, is more effective than Crestor at lowering LDL cholesterol at all doses compared, ranging from the usual starting recommended doses (Vytorin 10/20 mg, Crestor 10 mg) to the maximum approved doses (Vytorin 10/80 mg, Crestor 40 mg). Vytorin now has been shown in clinical studies to provide greater LDL cholesterol lowering efficacy versus Lipitor, Crestor and ZOCOR at all study dose comparisons.

322. On November 7, 2006, Merck filed its Form 10-Q for the third quarter of 2006 wherein it published the same information set forth above about Vytorin.

323. In the January 2007 edition of "ProQuest Information and Learning" in an article titled "Success from Two Sources," defendant Deepak Khanna, VP/GM of the Merck/Schering-Plough marketing team stated, "This is a market that is about efficacy, lowering LDL and helping patients achieve their LDL-C goals. When you show them data on how your LDL-lowering gets more patients to goal versus your competitors, that's getting physicians information that is helpful."

324. As reported by *Reuters* on January 3, 2008, less than two weeks before the negative ENHANCE study results were made public, Merck's CEO, defendant Richard Clark, spoke at a Morgan Stanley investor meeting in New York, and stated that Vytorin would likely ***get a sales boost*** "as patients fail to adequately benefit from less-potent but far cheaper generic forms of [Zocor]" regardless of the outcome of ENHANCE. During the Morgan Stanley Conference, Clark stated that "[w]hen you do head-to-head competition with Lipitor and Crestor, [and Zocor], or for LDL lowering, Vytorin wins." Clark further stated that regardless of the outcome of ENHANCE, Vytorin and Zetia get patients to their LDL cholesterol goals "better than other products" and "[the drugs have] been successful for that reason." While Clark declined to provide sales forecasts, he stated that he was "optimistic" that "Vytorin would be helped in the United States as patients now taking generic Zocor fail to drive their levels of 'bad' LDL cholesterol down to recommended levels." Clark stated that even with generic competition, he was "very positive" that Merck's Vytorin franchise was "well positioned" for reimbursement by insurers.

325. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone;

(3) Vytorin provides no clinical cardiovascular health benefits that are not provided by Zocor (simvastatin), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone; and

(4) Vytorin was not well-positioned for reimbursement by insurers given that the ENHANCE data showed that it did not provide any benefit beyond that of generic Zocor.

5. Merck's Joint Venture Marketing Partner – Schering-Plough – Also Heavily Touted Vytorin's Superior Safety And Efficacy To Investors.

326. Because S-P was Merck's marketing partner and joint venturer with respect to Vytorin and Zetia, investors and analysts looked equally to S-P's public statements and guidance regarding the products of the joint venture. When S-P made false and misleading statements concerning Vytorin or Zetia, Merck was aware of such statements, knew that such statements were made to benefit their joint venture, yet failed to correct them. Moreover, analysts looked to statements by Merck, S-P, and/or the joint venture equally when looking for information concerning Vytorin, Zetia, or ENHANCE. Accordingly, the statements made by S-P, and S-P affiliated members of the joint venture, may be attributed to Merck.

327. On July 24, 2006, S-P issued a press release which, among other things, quoted S-P CEO Hassan, who emphasized the purported benefits of Vytorin, as compared to competing branded and generic drugs in the cholesterol-lowering market, as follows:

> ***"While the U.S. cholesterol-lowering market adjusts to the entry of generic Zocor competition, we remain confident in the value proposition afforded by Vytorin and Zetia," said Hassan.*** The company pointed to head-to-head clinical trials versus Crestor, Lipitor and Zocor that have shown Vytorin to be the most effective medicine for lowering cholesterol and getting patients to more aggressive treatment goals. Further, new recommendations from the American Heart Association and the American College of Cardiology are calling for increasingly aggressive treatment of high cholesterol for certain patients. ***"Vytorin and Zetia are valuable tools for doctors seeking to get their patients to goal," Hassan said, "with Vytorin offering the added benefit of being able to get more patients to goal at the initial starting dose."***

(Emphasis added).

328. That same day, S-P held a conference call with securities analysts, in which S-P's CEO Hassan and S-P's Executive Vice President and President of the Global Pharmaceuticals

Business, Carrie Cox, consistently touted the purported superiority of Vytorin, stating during the scripted portion of the earnings call that:

> **Hassan**: "Many of you have asked us about the impact of two recent generic entries, Pravachol and Zocor. ***Doctors tell me that these generics are not as effective as Vytorin because Vytorin can get more patients to goal, on the first try. Doctors also tell me that Vytorin is often sparing their patients the cost and other burdens of additional visits and lab tests that, with a less effective medication, would have been needed to escalate the dose.***"
>
> * * *
>
> **Cox:** "Recently, the American Heart Association and the American College of Cardiology recommended more aggressive LDL management to 70 or below for patients with coronary heart disease. But as Fred [Hassan] mentioned, the majority of patients are still not at today's more challenging treatment goals. Older, lower efficacy statins, still usually don't get the job done, even after titration to a higher dose. ***With lower clearly better, mounting clinical evidence continues to demonstrate that Vytorin provides superior LDL reduction.***"

(Emphasis added).

329. In response to a question posed by a Friedman, Billings and Ramsey analyst, Cox again stressed the purported benefits of Vytorin, stating that ***"[t]he best outcome for patients is to lower their cholesterol as effectively as possible, as soon as possible, and that clearly shows the way towards Vytorin as the most effective therapy out there.***" (Emphasis added).

330. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone; and

(3) As a result of ENHANCE, Defendants knew that Vytorin provides no cardiovascular health benefits that are not provided by Zocor (simvastatin)

> (or other statin drugs), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone.

331. In S-P's earnings conference call of October 20, 2006, S-P's Cox again stressed the purported benefits of Vytorin stating that "Vytorin stands apart from the competition with clear superiority in lowering LDL through the dual inhibition of both sources of cholesterol." Cox also explained that "the continued success of this [cholesterol] franchise comes in the midst of significant uncertainty in the market with the introduction of new generic statins. As we have emphasized from the beginning, the value proposition for Vytorin and Zetia is compelling."

332. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone; and

(3) ENHANCE proved there was no "compelling" "value proposition" for Zetia because adding Zetia to generic Zocor (simvastatin) provided no actual medical benefit; and

(4) As a result of ENHANCE, Defendants knew that Vytorin provided no cardiovascular health benefits that are not provided by Zocor (simvastatin) (or other statin drugs), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone.

333. In S-P's earnings conference call with securities analysts for the fourth quarter and year-end 2006, Hassan in his scripted comments again downplayed the impact that competing generics, such as Zocor, would have on Vytorin's continued market share, stating:

> Six months post the ZOCOR generic, we've seen that Vytorin continued to grow market share, so we feel good that some of the more dire predictions about the impact of generic ZOCOR have not occurred. We have met that challenge.

> ***Now we will see the next wave of change with multiple generics. This is new territory, but we're encouraged because the proposition for Vytorin remains strong as the evolving medical science finds that lower and lower LDL is better and better. . . .***

(Emphasis added).

334. The scripted comments from S-P's Cox focused on Vytorin's dynamic growth in prescription rates on account of its purported medical benefits, specifically comparing Vytorin to competing generics:

> During the quarter total prescription growth for Vytorin in the U.S. remained strong, increasing 54% versus last year, more than triple the growth of the cholesterol market. Vytorin and Zetia continued to grow right through the entry of generic statins.
>
> ***The facts remain the same—older, lower efficacy statins still usually don't get the job done, no matter how low the cost***. Despite a second wave of generics entering the market, we believe that Vytorin will continue to enjoy competitive, second tier access.
>
> ***Lowering LDL remains the cornerstone of lipid management. Vytorin provides superior LDL reduction and gets more patients to goal at the initial starting dose and across the closing range***, more than Lipitor, more than Crestor and more than simvastatin [Zocor].

(Emphasis added).

335. Notably, during the Q&A portion of the earnings call, an analyst with Summer Street Research Partners questioned whether the deceleration of Vytorin's year-over-year growth in new prescriptions (as demonstrated by IMS prescription data) was due to Crestor, generics, or both. In response, S-P's Cox stated:

> [W]e were simply delighted that Vytorin continued to grow so well through the launch of generic simvastatin because it wouldn't have been totally surprising if our growth had flattened out during that phase, given the fact that simvastatin could have been seen as a major competitor to Vytorin more than any other product in the category.

> ***At this point, as Fred [Hassan] mentioned, the data we have demonstrating proven superiority compared to the major statins is so compelling that we feel quite confident that while LDL remains the cornerstone of lipid management, we are very well positioned for future growth***.

(Emphasis added).

336. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone; and

(3) As a result of ENHANCE Defendants knew that Vytorin provides no cardiovascular health benefits that are not provided by Zocor (simvastatin) (or other statin drugs), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone.

337. On April 19, 2007, S-P held a conference call with securities analysts to discuss its financial results for the first quarter of 2007. During the scripted portion of the earnings call, Hassan and Cox continued to stress the still-growing sales of Vytorin and Zetia, notwithstanding a "new wave" of generics:

> Hassan: "Adjusted for our assumed 50% share of Vytorin and Zetia, that is 21% adjusted growth versus the same quarter last year. ***We continue to grow Vytorin and Zetia despite the new wave of generics that has recently entered the market. As we have said before, physicians and their patients are following the evolving medical science; evolving medical science that is indicating that lower LDL cholesterol is better***."
>
> Cox: "In the U.S., new prescription shares for the [Vytorin/Zetia] franchise reached 16.4% with both products continuing to set new market share highs despite the availability of a second wave of generic statins. ***We believe that this further validates the importance of the unique mechanism of Vytorin, which provides***

> ***superior LDL reduction through dual inhibition of the two sources of cholesterol***.
>
> * * *
>
> ***At last month's American College of Cardiology meeting, lowering LDL was again validated as the primary target of lipid therapy and with lower clearly better, we believe this plays right into the strength of our cholesterol franchise. Only Vytorin provides more than a 50% LDL reduction at the usual starting dose and across the closing range. More than Lipitor and more than Crestor.***
>
> ***No other product, branded or generic, delivers this kind of powerful efficacy***. Managed care organizations continue to recognize this compelling value proposition and Vytorin continues to enjoy competitive second-tier access."

(Emphasis added).

338. During the Q&A portion of the earnings call, an analyst with Prudential Equity noted that the results of the ENHANCE study "could be fairly important" to [the] Vytorin franchise," and questioned whether Schering was "worried" about the outcome. In response, Hassan again tried to downplay the importance of ENHANCE, stating that it "is a surrogate market trial in a very special population with very special doses." Instead, Hassan directed the analyst to the IMPROVE-IT trial, which he characterized as "more of an outcomes trial." Notwithstanding his attempt to deflect attention away from ENHANCE, Hassan still emphasized that "[t]he overall regression curve in terms of LDL, lower LDL, is better, is being proven in numerous studies, ***so we are pretty confident about the overall pattern of data for Vytorin***." (Emphasis added).

339. The foregoing statements were false and misleading for at least the following the reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone;

(3) ENHANCE proved adding Zetia to Zocor (simvastatin) provides no actual benefit compared to Zocor (simvastatin) alone; and

(4) As a result of ENHANCE Defendants knew that Vytorin provides no cardiovascular health benefits that are not provided by Zocor (simvastatin) (or other statin drugs), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone

340. On July 23, 2007, S-P issued a press release to announce its financial results for the second quarter of 2007, and later that day, it held an earnings call with securities analysts to discuss S-P's financial results. During the scripted portion of the earnings call, S-P's Cox continued to highlight the purported benefits of Vytorin:

> **Cox:** "[O]ur global cholesterol franchise delivered another impressive quarter with global franchise sales increasing 34% to nearly $1.3 billion. . . . In the U.S., Vytorin and Zetia continue to grow despite the availability of multi-source generics. New prescription growths for the franchise remains strong, increasing 20% versus the prior year, and more than double growth of the entire cholesterol market. Both Vytorin and Zetia set new market share highs and remain the only branded growth products in the LDL category.
>
> As we've anticipated, clinical practice continues to shift towards more aggressive LDL management. ***With lower, clearly better, only Vytorin provides more than a 50% LDL reduction at the usual starting dose through the dual inhibition of both sources of cholesterol. Vytorin simply gets more patients to goal at the initial starting dose and across the dosing range. First line therapy continues to represent the majority of Vytorin business. Vytorin is also the brand of choice for patients needing to upgrade their medication for greater efficacy.***

(Emphasis added).

341. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone; and

(3) As a result of ENHANCE Defendants knew that Vytorin provides no cardiovascular health benefits that are not provided by Zocor (simvastatin) (or other statin drugs), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone.

6. The September 2007 Merrill Lynch Conference

342. On September 19, 2007, Alex Kelly ("Kelly"), Schering's Vice President of Investor Relations, presented at the Merrill Lynch Global Pharmaceutical, Biotech & Medtech Conference held in London, England. In his scripted comments, Kelly emphasized the supposed benefits of Vytorin stating that:

> [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***.

(Emphasis added).

343. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone; and

(3) As a result of ENHANCE Defendants knew Vytorin provides no cardiovascular health benefits that are not provided by Zocor (simvastatin) (or other statin drugs), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone.

344. On October 22, 2007, S-P issued a press release announcing its financial results for the third quarter of 2007, and later that day, it held a conference call with securities analysts. During the scripted portion of the conference call, S-P continued to highlight the purported benefits of Vytorin by emphasizing the "lower is better" mantra, as follows:

> 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.***"

(Emphasis added).

345. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone; and

(3) As a result of ENHANCE Defendants knew that Vytorin provides no cardiovascular health benefits that are not provided by Zocor (simvastatin) (or other statin drugs), and actually has a slightly negative effect on cardiovascular health as compared to the use of statins alone

C. DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS REGARDING VYTORIN'S COMMERCIAL STRENGTH AND SUCCESS, AND ITS PROJECTED FUTURE SUCCESS

346. The Merck Defendants also made false and misleading statements and omissions during the Class Period with respect to Vytorin's commercial strength and success, and its projected future success.

1. Merck's 1Q 2006 Results

347. On May 9, 2006, Merck filed its Form 10-Q with the SEC reporting its quarterly financial results for the 1st Quarter 2006 (period ending March 31, 2006). In its report, Merck touted its strong sales and growth of Vytorin and Zetia, attributing such strength to the unique "dual inhibition" approach to cholesterol management, as follows:

> Global sales of Zetia and Vytorin, as reported by the Merck/Schering-Plough partnership, in the aggregate were $793.2 million for the first quarter and combined new prescriptions reached approximately 15% of the U.S. lipid-lowering market, according to the March 2006 IMS Health data.
>
> Global sales by the Merck/Schering-Plough partnership of Zetia, the cholesterol-absorption inhibitor…reached $414.8 million in the first quarter, an increase of 25% compared with the first quarter of 2005.
>
> Global sales of Vytorin, also developed and marketed by the Merck/Schering Plough partnership, reached 378.4 million in the first quarter. Vytorin…is the first single cholesterol treatment to provide LDL cholesterol lowering through dual inhibition of cholesterol production and absorption.

348. The Company's Form 10-Q filed on May 9, 2006 also contained Sarbanes-Oxley required certifications, signed by defendants Clark and Lewent, who each certified (among other things) the following:

> 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;

> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report…

349. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts stated therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE, which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales was at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from ENHANCE were being improperly delayed because they were negative; and

(4) Defendants misled investors into believing that the Vytorin and Zetia drug franchise was strong and rapidly growing, when it was certain to decline.

2. Merck's 2Q 2006 Results

350. On July 24, 2006, Merck published a press release announcing earnings results for the second quarter of 2006, ending June 30, 2006. Among other things, Merck's 2Q 2006 release contained statements regarding the success of the Company's Vytorin and Zetia product sales, as follows:

> As reported by the Merck/Schering-Plough partnership, global sales of Zetia and Vytorin in the aggregate reached $973 million for the second quarter as compared to $507 million for the same period last year. Combined new prescriptions attained more than

> 15% of the U.S. lipid-lowering market, according to the most recent monthly IMS Health data.
>
> Global sales of Zetia, the cholesterol-absorption inhibitor also marketed as Ezetrol outside the United States, reached $476 million in the second quarter, an increase of 51% compared with the second quarter of 2005. Also in the second quarter, Zetia was approved by the FDA for co-administration with fenofibrate, offering a new treatment alternative for patients with mixed hyperlipidemia. Sales for the first six months were $891 million, an increase of 38% over the comparable 2005 period.
>
> Global sales of Vytorin, also developed and marketed by the Merck/Schering-Plough partnership, reached $497 million in the second quarter. Vytorin, marketed outside the United States as Inegy, is the first single cholesterol treatment to provide LDL cholesterol lowering through dual inhibition of cholesterol production and absorption. Sales for the first six months were $876 million.

351. On August 7, 2006, Merck filed its Form 10-Q for the second quarter of 2006. The Company reiterated the information about Vytorin published in its July 24, 2006 press release.

352. The Company's Form 10-Q filed on August 7, 2006 also contained Sarbanes-Oxley required certifications, signed by defendants Clark and Lewent, who each certified (among other things) the following:

> 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report…

353. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts stated

therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE, which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales was at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from the ENHANCE trial were being improperly delayed because they were negative; and

(4) Defendants misled investors into believing that the Vytorin and Zetia drug franchise was strong and rapidly growing, when it was certain to decline.

3. Merck's 3Q 2006 Results

354. On October 20, 2006, Merck published a press release announcing earnings results for the third quarter of 2006, ending September 30, 2006. The press release touted Merck's strong financial results, again led in part by the performance of Zetia and Vytorin:

> Combined global sales of Zetia and Vytorin, as reported by the Merck/Schering-Plough partnership, exceeded $1.0 billion for the third quarter.
>
> Global sales of Zetia, the cholesterol-absorption inhibitor also marketed as Ezetrol outside the United States, reached $502 million in the third quarter, an increase of 41% compared with the third quarter of 2005. Sales for the first nine months were $1.4 billion, an increase of 39% over the comparable 2005 period.
>
> Global sales of Vytorin, marketed outside the United States as Inegy, reached $527 million in the third quarter. Sales for the first nine months were $1.4 billion. On Oct. 5, the Merck/Schering-Plough partnership announced that the FDA had approved the inclusion of new data in the product label showing that Vytorin, a cholesterol-absorption inhibitor combined with simvastatin, is more effective than Crestor at lowering LDL cholesterol at all doses compared, ranging from the usual starting recommended doses (Vytorin 10/20 mg, Crestor 10 mg) to the maximum

> approved doses (Vytorin 10/80 mg, Crestor 40 mg). Vytorin now has been shown in clinical studies to provide greater LDL cholesterol lowering efficacy versus Lipitor, Crestor and ZOCOR at all study dose comparisons.

355. In the Company's October 22, 2006 earnings conference call, defendant Clark emphasized the importance of Vytorin, saying, "I am pleased to report that Merck's strong performance in 2006 has continued right through the third quarter. Let me take a few moments to review the highlights of the quarter, which are led by the performance of Singulair, Vytorin and Zetia, our vaccines, as well as our ongoing cost management initiatives." Clark added: ***"The combined sales of Zetia and Vytorin topped $1 billion in the third quarter, the first time the combined sales of these products have exceeded that major milestone in one quarter. I should add that the strong growth of both of these products has been consistent through 2006."*** (Emphasis added).

356. On November 7, 2006, Merck filed its Form 10-Q for the third quarter of 2006. The Company reiterated the information about Vytorin published in its October 20, 2006 press release.

357. The Company's Form 10-Q filed on November 7, 2006 also contained Sarbanes-Oxley required certifications, signed by defendants Clark and Lewent, who each certified (among other things) the following:

> 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report…

358. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to

Defendants or recklessly disregarded by them, which were necessary to make the facts stated therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE, which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales was at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from the ENHANCE trial were being improperly delayed because they were negative; and

(4) Defendants misled investors into believing that the Vytorin and Zetia drug franchise was strong and rapidly growing, when it was certain to decline.

4. Merck's 4Q 2006 and 2006 Year-End Results

359. On January 30, 2007, Merck reported full-year and fourth-quarter 2006 earnings results in a press release. Merck stated its financial results "***reflected solid sales growth and strong results from the Merck/Schering-Plough partnership.***" (Emphasis added). Merck again portrayed the Vytorin and Zetia joint venture as highly successful and a growing blockbuster franchise, as follows:

> Combined global sales of Zetia and Vytorin, as reported by the Merck/Schering-Plough partnership, reached $1.1 billion for the fourth quarter, representing growth of 46% over fourth quarter 2005. Sales for the year were $3.9 billion, a 60% increase over full year 2005.
>
> Global sales of Zetia, the cholesterol-absorption inhibitor also marketed as Ezetrol outside the United States, reached $536 million in the fourth quarter, an increase of 37% compared with the fourth quarter of 2005. Sales for the year were $1.93 billion, an increase of 38% over full year 2005.

> Global sales of Vytorin, marketed outside the United States as Inegy, reached $553 million in the fourth quarter, an increase of 56% compared to the fourth quarter of 2005. Sales for the year were $1.96 billion, an increase of 90% over full year 2005.

360. On the Company's January 30, 2007 earnings conference call, defendant Clark again focused on the importance of Vytorin, stating: "I would like to take just a few moments to walk you through some of the highlights. In 2006, our products including Singulair, Vytorin, Zetia and our vaccines delivered impressive sales growth."

361. On February 28, 2007, Merck filed its Form 10-K for fiscal year 2006 and the fourth quarter of 2006, signed by defendant Clark. The Company reiterated the information about Vytorin and Zetia published in its January 30, 2007 press release, and added the following:

> Equity income from affiliates reflects the performance of the Company's joint ventures and partnerships. In 2006 and 2005, the increase in equity income from affiliates reflects the successful performance of *Vytorin* and *Zetia* through the Merck/Schering-Plough partnership.

362. The Company's 4th Quarter 2006 Form 10-Q and its 2006 Year End Form 10-K also contained Sarbanes-Oxley required certifications, signed by defendants Clark and Lewent, who each certified (among other things) the following:

> 1. I have reviewed this quarterly [annual] report on Form 10-Q [10-K] of Merck & Co., Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report…

363. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts stated

therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE, which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales were at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from the ENHANCE trial were being improperly delayed because they were negative; and

(4) Defendants misled investors into believing that the Vytorin and Zytorin drug franchises were strong and rapidly growing, when they were certain to decline.

5. Merck's 1Q 2007 Results

364. On April 19, 2007, Merck reported results for the first quarter of 2007, ending on March 30, 2007. The Company stated in its press release that the performance of key products including Vytorin and Zetia drove its results:

> Combined global sales of Zetia and Vytorin, as reported by the Merck/Schering-Plough partnership, reached $1.2 billion for the first quarter, representing growth of 47% over the first quarter of 2006. Global sales of Zetia, marketed as Ezetrol outside the United States, reached $544 million in the first quarter, an increase of 31% compared with the first quarter of 2006. Global sales of Vytorin, marketed outside the United States as Inegy, reached $624 million in the first quarter, an increase of 65% compared with the first quarter of 2006.

365. On Merck's April 19, 2007 earnings conference call, defendant Clark continued to tout Vytorin's growth and success: "Both Zetia and Vytorin, which we market in partnership with Schering-Plough, also performed very well this past quarter. They posted a combined $1.2 billion in sales, a 47% increase from the first quarter of 2006."

366. On May 8, 2007, Merck filed its Form 10-Q for the first quarter of 2007. The Company reiterated the information about Vytorin published in its April 19, 2007 press release. The Company's Form 10-Q also contained Sarbanes-Oxley required certifications, signed by defendants Clark and Lewent, who each certified (among other things) the following:

> 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report…

367. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts stated therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales was at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from the ENHANCE trial were being improperly delayed because they were negative; and

(4) Defendants misled investors into believing that the Vytorin and Zetia drug franchise was strong and rapidly growing, when it was certain to decline.

6. Merck's 2Q 2007 Results

368. On July 23, 2007, Merck reported results for the second quarter of 2007, ending on June 30, 2007. The Company stated that its results were driven by the continued strong performance of key products including Vytorin:

> Combined global sales of Zetia and Vytorin, as reported by the Merck/Schering-Plough partnership, reached $1.3 billion for the second quarter, representing growth of 30% over second quarter 2006. Global sales of Zetia, marketed as Ezetrol outside the United States, reached $578 million in the second quarter, an increase of 21% compared with the second quarter of 2006. Global sales of Vytorin, marketed outside the United States as Inegy, reached $686 million in the second quarter, an increase of 38% compared with the second quarter of 2006. Both Vytorin and Zetia achieved all-time highs in new and total prescription share during the second quarter.

369. On the July 23, 2007 earnings conference call, defendant Clark commented: "Vytorin and Zetia achieved all-time highs in both new and total prescription share in the quarter, posting combined global sales of $1.3 billion, an increase of 30% compared to the second quarter of 2006."

370. On August 8, 2007, Merck filed its Form 10-Q for the second quarter of 2007. The Company reiterated the information about Vytorin published in its July 23, 2007 press release. The Company's Form 10-Q also contained Sarbanes-Oxley required certifications, signed by defendants Clark and Lewent, who each certified (among other things) the following:

> 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report…

371. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts stated therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales was at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from the ENHANCE trial were being improperly delayed because they were negative; and

(4) Defendants misled investors into believing that the Vytorin and Zetia drug franchise was strong and rapidly growing, when it was certain to decline.

7. Merck's 3Q 2007 Results

372. On October 22, 2007, Merck reported "double-digit revenue and earnings per share growth for the Third-Quarter 2007." In commenting on the results, defendant Clark stated, "Our third-quarter results reflect the continued progress Merck is making to deliver on our strategy. Merck again delivered strong results, including 12 percent sales growth and double-digit earnings-per-share growth, fueled by the performance of Singulair, Januvia, Gardasil, Varwax, Vytorin and Zetia." In discussing the specific financial results of Vytorin, the release issued by the Company stated,

> Combined global sales of Zetia and Vytorin, as reported by the Merck/Schering-Plough partnership, reached $1.3 billion for the third quarter, representing 26 percent growth compared with the third quarter of 2006. Global sales of Zetia, marketed as Ezetrol outside the United States, reached $607 million in the third quarter,

> an increase of 21 percent compared with the third quarter of 2006. Third-quarter global sales of Vytorin, marketed outside the United States as Inegy, reached $693 million, an increase of 32 percent compared with the third quarter of 2006. Both Zetia and Vytorin achieved all-time highs in total prescription share during the third quarter. The Company records the results from its interest in the Merck/Schering-Plough partnership in equity income from affiliates.

373. During the third quarter conference call, held on October 22, 2007, CFO Peter Kellogg provided more specifics regarding the Merck/Schering-Plough partnership, explaining that third quarter revenues of Vytorin were $693 million; and that $526 million of those revenues were in the United States, an increase of 22% over the prior year. Kellogg concluded, "[w]ith our year-to-date performance and our guidance [for the] full year [it] is clear that the products our driving a healthy top-line, despite lapping the ZOCOR expiry. We anticipate continued strong performance from our key franchises in the remainder of this year."

374. On November 1, 2007, Merck filed its Form 10-Q for the third quarter of 2007. The Company reiterated the information about Vytorin published in its October 22, 2007 press release. The Company's Form 10-Q also contained Sarbanes-Oxley required certifications, signed by defendant Clark, who certified (among other things) the following:

> 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report…

375. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts stated

therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales was at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from the ENHANCE trial were being improperly delayed because they were negative; and

(4) Defendants misled investors into believing that the Vytorin and Zetia drug franchise was strong and rapidly growing, when it was certain to decline.

8. Merck's December 2007 Guidance Call

376. On December 4, 2007, Merck provided updated guidance for its results for the full year 2007 and for 2008. The Company reaffirmed its full-year 2007 non-GAAP (Generally Accepted Accounting Principles) earnings per share (EPS) guidance range of $3.08 to $3.14, excluding certain items and anticipated a 2007 GAAP EPS range of $1.45 to $1.51. Subsequently, the Company held a conference call to discuss their updated guidance which defendant Clark stated, "confirms that many of our top-line and productivity goals are making great progress. We remain on track to achieve our 2010 targets." In drawing attention to two specific line items in the 2008 guidance, Clark noted that with respect to product gross margin: "Based on our stated 2008 financial guidance of 77% to 78%, we anticipate returning PGM to pre-ZOCOR levels at 2008, a year earlier that we initially projected." Clark also stated "For 2008, the Company anticipates that many of our in-line and newer franchises will continue their strong performance and that we will further extend the success of Zetia and Vytorin franchises, as well as launch additional new products." Later in the call, Peter Kellogg, Merck's CFO

stated, "The income contribution related to Merck/Schering-Plough is expected to increase in 2008 based on the continued growth of Zetia and Vytorin in the U.S. and in Europe."

377. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts stated therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales was at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from the ENHANCE trial were being improperly delayed because they were negative; and

(4) Defendants misled investors into believing that the Vytorin and Zetia drug franchise was strong and rapidly growing, when it was certain to decline.

9. Merck's December 2007 Annual Business Briefing

378. On December 13, 2007, Merck hosted its Annual Business Briefing. In its slide show presentation to analysts and investors, Merck stated that Vytorin sales year-to-date after the 3rd Quarter had ballooned year-over-year by 34% to over $3.7 billion. Merck further stated:

> Vytorin continues to outpace branded statins in TRx share growth since the availability of generic simvastatin;
>
> Vytorin has unmatched access and is available to more patients at the lowest branded co-pay than other branded statins;
>
> Zetia continues to grow in total prescription share and is the leading non-statin in new and total prescription share in the cholesterol-lowering market.

379. In the same presentation on a separate slide discussing the key drivers to Merck's anticipated 2008 growth, Merck listed "Zetia and Vytorin" as driving "equity income growth."

380. The foregoing statements were materially false and misleading when made because they misrepresented facts, and/or failed to disclose material, adverse facts known to Defendants or recklessly disregarded by them, which were necessary to make the facts stated therein not misleading. These statements were false and misleading in at least the following ways:

(1) Defendants failed to disclose the negative results from ENHANCE which was necessary and material to investors' analysis of Vytorin and Zetia revenues in the context of Merck's business and earnings potential going forward;

(2) Defendants failed to disclose that the valuable income stream from Vytorin and Zetia sales was at risk and in jeopardy, which would have a materially negative effect on the Company's earnings, revenues, and overall business;

(3) Defendants failed to disclose that the results from the ENHANCE trial were being improperly delayed because they were negative;

(4) Defendants misled investors into believing that the Vytorin and Zetia drug franchise was strong and rapidly growing, when it was certain to decline; and

(5) Defendants failed to disclose that as a result of the negative conclusions of ENHANCE, which showed that Vytorin was no better than generic simvastatin because the mixture with Zetia did not work, the prescription trends for Vytorin and Zetia were likely to collapse and patient access was likely to be limited as managed care would no longer pay a high premium for a drug that had proven to be ineffective versus a generic.

D. DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS REGARDING MERCK'S ETHICAL CONDUCT, ITS TRANSPARENCY, AND ITS PURPORTED PATIENTS-FIRST FOCUS

381. At the same time Merck was suppressing the results, and trying to scrub the negative data from ENHANCE, it was assuring investors and all Merck "stakeholders" that it was committed to, and practiced the highest ethical standards, and that its business and its

research were conducted with full transparency. Indeed, Merck had made numerous statements to its investors to make them believe in Merck's ethics and integrity even before the start of the Class Period. At Merck's April 26, 2005 shareholder meeting, for instance, then-CEO Raymond Gilmartin boldly pronounced:

> At Merck, we 'Put Patients First.' And that's not just a slogan; its how we do business. It's how we lead our mission of discovery and developing novel medicines that address unmet medical needs, and that provides demonstrable value to patients, prescribers and payers alike.
>
> We have found that putting the best interests of patients first is also consistent with the long-term best interests of stockholders. These interests are not in conflict. They are closely linked. Putting patients first will drive the future growth and success of our company.
>
> * * *
>
> These two imperatives, always putting patients first and the unending pursuit of scientific excellence are closely linked with a third for which Merck had long been known, a dead rock commitment to the highest standards of ethics and values.

382. Gilmartin's successor, Defendant Richard Clark assured shareholders that he and all others at Merck embraced the same creed. Indeed, on May 5, 2005, the day Clark was announced as Merck's new CEO and President, Clark echoed Gilmartin's remarks stating that "[w]hile we will be open to new and creative approaches to driving shareholder value, we will remain true to what has been and will continue to be the foundation of Merck – our commitment to scientific excellence, through ethics and values, and to putting patients first."

383. On its website during the Class Period, Merck conveyed these sentiments to shareholders. Merck consistently assured investors, among other things, that it was "dedicated to putting patients first" in conducting its business, and that ethics and integrity were the hallmarks of Merck as a corporate enterprise. Merck's website described in detail its "Corporate

Philosophy," announced to the public what it believed to be its "Corporate Responsibility" and set forth a "Mission Statement" detailing, among other things, how Merck was "committed to the highest standards of ethics and integrity." Indeed, Merck's corporate logo (used on its website and elsewhere throughout the Class Period) emphasized its purported "patients-first" philosophy:

1. Merck Specifically Attempted to Influence Investors With Its Statements About Its Commitment to Ethics and Transparency

384. Merck's representations about its ethical conduct and transparency were material to its investors, and Merck itself recognized this on its website disclosures: "We recognize that in our business, ethics and transparency are of critical importance to patients, health care professionals, our employees ***and investors***." (Emphasis added). Merck further professed the belief that

> Acting in a responsible manner over the long term serves the best interests of the people our programs benefit, ***as well as our shareholders***. By doing the right thing, we further enhance our Company's reputation, our ability to play a constructive role in advancing good public policy, customer trust and, as a result the opportunity to achieve our business goals. We recognize that, more than ever before, companies, ***investors***, government and the public are interested in how businesses conduct themselves, and want companies to actively demonstrate their commitment to good corporate citizenship.

(Emphasis added).

385. Merck further highlighted on its website its belief that high ethical standards were

> essential to the success of [Merck's] business endeavors. Thus, the Company will not accept anything less. Like integrity of product, integrity of performance is a Merck standard wherever we do business, and ignorance of that standard is never an acceptable excuse for improper behavior. Improper behavior cannot be rationalized as being the Company's interest. No act of impropriety advances the interests of the Company.

386. Merck was committed to ensuring that its investors were aware of its purported ethical practices and therefore made its internal "Code of Conduct" available to investors in a booklet titled *Our Values and Standards*. During the Class Period, for instance, Merck encouraged its public investors to read about its focus on ethical business practices by posting the following on its website:

> We believe that all of our stakeholders are entitled to know about our business practices. The *Our Values and Standards* booklet is available to the public and can be accessed via our Web site at: www.Merck.com.

387. In Merck's *Our Values and Standards* booklet, President and CEO Clark indicated that he spent a lot of time with Merck employees and "external stakeholders" discussing what is important about Merck, and he stated that "the resounding answer is trust – trust in the science, trust in the product, and trust in the people." Thus, according to Defendant Clark, Merck's mission was "grounded in a philosophy of putting patients first, and conducting our business with integrity" and Merck's "commitment to scientific excellence, ethics and integrity…is the foundation on which all that we do is built." According to Clark, trust, ethics and integrity are what "[Merck] stands for" and are "the basis of [Merck's] success."

388. In its *Our Values and Standards* booklet, Merck also properly recognized that its ethics, values and standards in the way that it conducted its business inspired trust and confidence by the "financial markets" which was "essential to our success." Thus, upon its own initiative, Merck published its *Our Values and Standards* booklet and invited shareholder inspection, specifically so that investors and other financial stakeholders could learn of Merck's purportedly high regard for business ethics and good corporate practices with the express purpose of influencing "financial markets" and investment decisions.

389. Shareholders were assured by Merck, in its *Our Values and Standards* booklet under a heading "Our Shareholders," that Merck "strive[s] to provide honest, accurate and ***timely information*** to our shareholders about our performance and to make clear disclosures in all public reports and communications." (Emphasis added).

2. Merck Attempted to Influence Investors With Its Purported "Corporate Responsibility" and "Mission."

390. Merck also made extensive disclosures on its website under a heading of "Corporate Responsibility" relating to its high ethical standards. According to Merck, its mission entailed something more than developing and delivering medicines and vaccines, because "as a Company, we seek to maintain high ethical standards and a culture that values honesty, integrity and transparency in all that we do." According to Merck's website, "Company decisions are driven by what is right for patients."

391. Thus, Merck assured investors in its published "Mission Statement" that ethics and integrity were one of its five core values as follows:

> ***We are committed to the highest standards of ethics and integrity.*** We are responsible to our customer, to Merck employees and their families, to the environments we inhabit, and to the societies we serve worldwide. In discharging our responsibilities, we do not take professional or ethical shortcuts. Our interactions with all segments of society must reflect the high standards we profess.

(Emphasis added).

392. Merck's also assured investors that "For more than 100 years, Merck has been placing patients first in all that we do…. George W. Merck, our founder's son, believed that placing patients before profits is not only good medicine, but also good business. The values and standards imparted by George W. Merck live on in our company today through our commitment to innovative drug research and discovery, ethical business practices, and ensuring access [sic] medicines for those who need them."

393. To advance its publicly-stated "Mission," Merck put investors further at ease by stating that it had "strong policies and safeguards in place" to foster its ethical standards, and "a long history of adherence to high ethical standards."

394. Merck not only professed this overarching focus on ethics and transparency in its business in general, but it specifically assured its investors that its clinical trials were conducted with the highest regard for ethics pursuant to Merck's own Code of Conduct, which addressed, among other things, "the Company's commitment to publish the results of hypothesis-testing studies, regardless of outcome." Merck further told investors that its clinical studies were "consistent with standards established by the Declaration of Helsinki," which includes, as a "Rule," that negative as well as positive results should be published or otherwise made publicly available.

395. Merck also boasted that its "commitments have long been guided by the vision of George W. Merck, the Company's modern-day founder, who believed in the importance of putting patients first. George Merck's words are reflected in the way we conduct our business: Company decisions are driven by what is right for patients. Merck maintains high ethical standards and a culture that fosters honesty, integrity and transparency - even under the most challenging circumstances."

396. The foregoing statements were materially misstated and omitted to state material facts required therein or necessary to make the statements contained therein not misleading. Each of the statements relating to Merck's purported business ethics, integrity, transparency, and "patients-first focus," were false and misleading in at least the following ways:

(1) Merck improperly suppressed, withheld, attempted to manipulate, and failed to disclose the negative results from ENHANCE;

(2) Merck put profits before patients with respect to ENHANCE because it suppressed, withheld, attempted to manipulate, and failed to disclose the

negative results from the ENHANCE study, which proved, among things, that patients could save enormous sums of money by using generic Zocor (simvastatin), since Vytorin provided no additional benefit;

(3) Merck failed to disclose that the results from ENHANCE were being improperly delayed because they were negative;

(4) Merck misled investors and consumers into believing that the Vytorin's "dual inhibition" function was supported by more advanced science than competing drugs, and therefore capable of producing better clinical results; and

(5) Merck misled investors by falsely claiming that the Vytorin and Zetia drug franchise was rapidly growing, and able to produce consistent revenues, when it was when it was certain to decline.

E. DEFENDANTS' FALSE AND MISLEADING STATEMENTS RELATING TO THE ENHANCE STUDY

397. After almost a year of waiting for the release of the ENHANCE data, securities analysts were growing impatient. By April of 2007, both Merck and S-P were called upon to answer questions about ENHANCE, including a growing chorus of inquiries into the ENHANCE study results. By November 2007, with still no answers on ENHANCE, the chorus of inquiries reached a fever pitch that soon snowballed into a Senate investigation. In an effort to downplay the importance of ENHANCE , and to try to salvage their blockbuster drug franchise, Merck and S-P made numerous false statements relating to the ENHANCE study itself and their handling of the ENHANCE data which further served to artificially inflate Merck's stock price, even as negative information regarding ENHANCE slowly leaked into the market.

1. Merck And Schering-Plough's April 2007 Conference Calls

398. On the April 19, 2007 Merck conference call, the following exchange took place regarding ENHANCE:

George Grofik, Citigroup –*Analyst*

> And secondly, if you can give us an update on the timing and venue of the presentation of enhanced *[sic]* study results for Vytorin? Thank you.
>
> Graeme Bell**,** Merck & Co., Inc. - *Executive Director of IR*
>
> With regard to enhanced *[sic]*, as we have indicated the analysis that's still ongoing, we are going into that information and we will pick an appropriate scientific forum in order to disseminate the enhanced *[sic]* data when we are ready to do that ....

399. The foregoing statements were false and misleading for least the following reasons:

(1) Defendants failed to disclose that the results from ENHANCE were being improperly delayed because they were negative; and

(2) It would be almost a full year, in March 2008, before Defendants would "pick the appropriate forum" to release the ENHANCE data.

2. The November 2007 Joint Press Release

400. On November 19, 2007, M/S-P issued a press release entitled "Merck/Schering-Plough Pharmaceuticals Provides Update on ENHANCE Trial." Specifically, the November 19 press release revealed that an independent expert panel purportedly made a recommendation to change the primary endpoint of the ENHANCE study to "expedite the reporting of the study findings":

> [A]n independent panel of clinical and biostatistics experts was convened on Friday, November 16, 2007 to offer advice about the prospective analysis of the ENHANCE trial. ENHANCE is a multinational, randomized, double-blind, trial that examines the effects of the highest approved dose of Vytorin/Inegy (10 mg ezetimibe + 80 mg simvastatin) versus the highest approved dose of simvastatin 80 mg alone in patients with Heterozygous Familial Hypercholesterolemia (HeFH). Patients with this uncommon genetic condition usually have very high cholesterol levels. HeFH occurs in approximately 0.2 percent of the population.
>
> ***The independent panel recommended focusing the primary endpoint to the common carotid artery to expedite the reporting of the study findings.*** Merck/Schering-Plough now anticipates that

> these results of the ENHANCE study will be presented at the American College of Cardiology meeting in March 2008.
>
> ***While the clinical portion of the ENHANCE study is complete, the study remains blinded and the data are now being analyzed.*** The rigorous study design and analytical process specified in the study protocol require examination of more than 40,000 scans of the arterial intima-media thickness (IMT) of the carotid and femoral arteries collected in eighteen multi-national study sites. This has been time consuming and taken longer than originally anticipated because during the analysis, observations of variability in some of the data were detected as part of the validation/data review procedures. ***Such potentially confounding observations are not unusual in studies of this kind.***
>
> The primary objective of the ENHANCE trial is to measure the change in the intima media thickness at three points of the carotid artery (the internal carotid, carotid bulb and the common carotid), at the beginning of the study and at two years. The ENHANCE trial employs a novel non-invasive methodology to assess the intima-media thickness using digital single-frame ultrasound imagery of the arteries. This technique was pioneered by Professor John Kastelein, the lead investigator of the ENHANCE study.
>
> "It is critically important for researchers to take the appropriate time and rigor to conduct clinical trials, analyze data and report study results. The ENHANCE trial is complex and is being conducted with great care," said John Kastelein, M.D., Ph.D., professor of medicine and chairman, Department of Vascular Medicine, Academic Medical Center, Amsterdam, Netherlands. "We view the experts panel's recommendation to narrow the primary endpoint to the common carotid artery as helpful, and we will continue to expedite the completion of ENHANCE and reporting of its results, while ensuring the integrity of the data." Kastelein added, "We anticipate that results of the ENHANCE study will be presented at the American College of Cardiology meeting in 2008, dependent upon successful completion of the data analysis."

(Emphasis added).

401. The foregoing statements in April and November 2007, were false and misleading because they falsely attributed to the expert panel (rather than Defendants) the decision to change the primary endpoint of ENHANCE, and falsely described the variability of the data in the

ENHANCE as only "potentially confounding," when in fact S-P and Merck knew the ENHANCE data, including its variability, would not demonstrate a statistically-significant benefit of Zetia and Vytorin, and further knew that even according to its independent expert who was hired in the hopes of finding just such problems with the data, concluded the data were "fine" and adequate for publication.

402. Two days later, on November 21, 2007 *The New York Times* ran a story in response to the M/S-P press release, titled "After a Trial, Silence," and reported that the delay in releasing the results of ENHANCE has "led to a growing chorus of complaints from cardiologists," prompting Merck and Schering-Plough to promise to publish a portion of the results in March 2008. Dr. Allen J. Taylor, chief of cardiology at Walter Reed Army Medical Center, who was quoted in the article, said: "There's clearly some rightful interest in what the results are. You've got millions of people treated with the drugs." As noted in the article, together, "Zetia and Vytorin have grabbed nearly 20 percent of the American market for cholesterol-lowering drugs, because of aggressive marketing from Merck and Schering-Plough that highlights Zetia's uniqueness among cholesterol medicines."

3. Merck's December 11, 2007 Conference Call

403. On December 11, 2007, in a conference call with securities analysts, Merck's executive vice president, Ken Frazier, stated the following:

> Vytorin and Zetia are very strong success stories, even in a cholesterol market that has not grown as quickly as it has in prior years. But it's still large and growing. These are essentially the only branded agents that are now growing after the advent of generic simvastatin, after managed care has incented positions to use generic simvastatin widely. These drugs continue to have an important place in that market because not all patients are the right patients for generic simvastatin.
>
> There are a lot of patients who are appropriate first line for a higher efficacy statin. And there are also patients who start with

> generic simvastatin and don't get to goal who are candidates either for Vytorin or for Zetia being added on. So we continue to believe that these are drugs that have very, very compelling profiles. And our job is to help physicians identify the profile of those patients who are the appropriate Zetia patients and the appropriate Vytorin patients going forward.

404. Frazier was asked pointedly "what is your counter-detailing message if the ENHANCE trial is negative?" And, secondly, what are you doing to accelerate market share growth of Vytorin?" Frazier falsely told the questioner "we don't know what the [ENHANCE] study will show" but, Frazier said hypothetically, if "the study doesn't show that Vytorin has that specific benefit" then "we have to keep in mind … that that [arterial plaque] imaging trial is a surrogate for the actual outcome. I think it's clear in this marketplace there's enough data out there that shows that lowering LDL and the more you can lower it for certain patients, the better off the patient is."

405. The foregoing statements were false and misleading because they falsely imply that the ENHANCE results were unknown, and falsely imply that regardless of Vytorin's effect on arterial plaque, that Vytorin is still the better drug.

4. The January 3, 2008 Morgan Stanley "Pharmaceutical CEOs Unplugged" Conference

406. On January 3, 2008, both Merck's CEO Clark and S-P's CEO Hassan spoke at an analyst event in New York called the "Morgan Stanley Pharmaceutical CEOs Unplugged Conference." As reported by the *Wall Street Journal* Healthblog, Schering-Plough's CEO Hassan, spoke for 45 minutes, 35 minutes of which was devoted to the controversy around the lack of disclosure of the ENHANCE trial results. Hassan downplayed the importance of the trial, stating "[it is] not a large trial" and that it 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."

407. The statements made at the analyst conference were false and misleading because the Company did not act in good faith and the delay in the results occurred because the Defendants knew the results were bad. Moreover, the fact that the results were blinded does not mean that the researchers could not tell whether the study was a success because the point of the study was to show statistical significance between the treatment and non-treatment arm. Thus, researchers could know that the study was a failure if there were no statistical differences in the data, without knowing which data went with the treatment or non-treatment arm, and it was misleading for the Company to represent that it was impossible to know the study results before they were unblinded.

408. After the long delay, on January 14, 2008, Merck and Schering-Plough finally announced the top-line results of ENHANCE. The release disclosed that the primary endpoint was the mean change in the IMT measured at three sites in the carotid arteries between patients treated with Vytorin (ezetimibe/simvastatin) versus patients treated with Zocor (simvastatin) alone over a two-year period. The finding was that there was no statistically significant difference between treatment groups on the primary endpoint. Additionally, the overall incidence rates of treatment-related adverse events were similar. The release announced that the full results would be presented at the March 2008 ACC meeting.

409. Also on January 14, 2008, the ACC issued a release regarding its interpretation of the ENHANCE trial top-line results, advising that "major clinical decision" not be based on the ENHANCE data alone, though the "study deserve serious thought and follow-up," concluding, "there should be no reason for patients to panic."

410. In response to this partial disclosure of the ENHANCE results (the underlying statistical information and other details were not released at that time), the price of Merck stock

decreased from $59.26 to $57.67. The price continued to fall over the next week, hitting a low during trading on January 25, 2008 of $42.32.

5. Merck's 4Q 2007

411. On January 30, 2008, Merck issued 2007 fourth quarter earnings which also temporarily stemmed the decrease in the Merck stock price by making additional misrepresentations. In the release, the Company reported the following:

> Combined global sales of Zetia and Vytorin, as reported by the Merck/Schering-Plough partnership, reached $1.5 billion for the fourth quarter of 2007, representing 34 percent growth compared with the fourth quarter of 2006. Combined annual worldwide sales during 2007 were $5.2 billion, an increase of 34 percent compared with the prior year. Global sales of Zetia, marketed as Ezetrol outside the United States, reached $679 million in the fourth quarter, an increase of 27 percent compared with the fourth quarter of 2006. Sales for the year were $2.4 billion, an increase of 25 percent over full-year 2006. Fourth-quarter and full-year 2007 global sales of Vytorin, marketed outside the United States as Inegy, reached $776 million and $2.8 billion, an increase of 40 percent and 42 percent, respectively, compared with similar periods in 2006. The Company records the results from its interest in the Merck/Schering-Plough partnership, which totaled $538 million and $1.8 billion in the fourth quarter and full year of 2007, respectively, in equity income from affiliates.

412. Also on January 30, 2008, in addressing the ENHANCE trial, defendant Clark represented that the Company had acted in good faith, attempted to minimized the importance of ENHANCE**,** and stated that the full results would be discussed in a scientific context at the March 2008 meeting of the ACC:

> As we said, we plan to discuss the ENHANCE data in a proper scientific context at the American College of Cardiology Meeting in March. Again, let me emphasize that operating with the highest standard of ethics and scientific integrity are the utmost personal importance to me, and are the foundation of this company. We will continue to work hard to respond to any allegations to the contrary. At the same time, Merck will not for a second lose focus of our overarching message and that is improving [inaudible].

413. The foregoing statements were false and misleading for at least the following reasons:

(1) Merck failed to disclose the negative results of ENHANCE which showed that there was no added benefit to "dual inhibition" or to treating "both sources of cholesterol" as opposed to just treating one with statins;

(2) ENHANCE proved "dual inhibition" provided no actual medical benefit and thus any benefits from taking Vytorin could be achieved by taking generic Zocor, or another statin, alone; and

(3) As a result of ENHANCE Defendants knew that Vytorin provided no cardiovascular health benefits that are not provided by Zocor (simvastatin) (or other statin drugs), and actually had a slightly negative effect on cardiovascular health as compared to the use of statins alone.

VI. SCIENTER

414. As alleged herein, the facts support a strong inference that Defendants knew that the public documents and statements issued or disseminated in the name of the Company concerning Vytorin were materially false and misleading; knew that such statements or documents concerning Vytorin would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Vytorin, their control over, and/or receipt and/or modification of Merck's allegedly materially misleading misstatements and/or their associations with the Company that made them privy to confidential proprietary information concerning Vytorin, participated in the fraudulent scheme alleged herein.

415. Defendants were personally motivated to engage in the wrongdoing alleged herein in order to sell their personally-held Merck stock at prices that were artificially inflated by Merck's false statements concerning Vytorin. Defendant Clark sold $2 million of his Merck

shares in May 2007 and he did not have any previous selling activity since 2002. Defendant Lewent sold $10 million of her shares in July and August 2007. In total, insiders grossed $26 million worth of shares during the Class Period.

A. ALLEGATIONS OF SCIENTER

416. The Defendants were active, culpable, and primary participants in the fraud by virtue of (i) their receipt of information regarding the ENHANCE findings years before the information was made public and their failure to alert the public that, with regard to Vytorin, a lower LDL does not translate to better clinical outcomes; (ii) their actual issuance and control over Merck's false and misleading statements; (iii) Merck's failure to correct any false statements made by S-P, and Merck's participation in the S-P false statements through the M/S-P joint venture; (iv) their supervision over employees and marketing partners that encouraged and promoted the fraud; and (v) their association with the joint venture between Merck and S-P that made them privy to confidential information concerning the ENHANCE.

417. The lack of disclosure of material adverse information concerning the lack of cardiovascular benefit of Vytorin that threatened Vytorin's medical and commercial viability was a top-down strategy perpetuated by the Individual Defendants, other senior managers at Merck, personnel at M/S-P, and senior managers at S-P. This knowing or reckless disregard of the truth concerning Vytorin caused Merck's financial results and future growth prospects to be materially misleading.

418. As a result of having reviewed or having access to the results of ENHANCE months before the investing public, the Defendants engaged in a pattern of deceit by failing to disclose the material adverse information. The Defendants also attempted to manipulate the ENHANCE data, hidden behind a veneer of respectability through the November 2007 "independent expert panel." This scheme failed due, in part, to investigations by both Congress

and the FDA. Ultimately, amid public outcry, Merck/S-P abandoned its efforts to manipulate the study data and returned to the original study endpoint. Accordingly, the Defendants intentionally and/or recklessly engaged in a scheme to defraud and engaged in a practice that operated as a fraud on Plaintiffs and the investing public.

419. ENHANCE demonstrated that while Vytorin lowered LDL as well as or better than other statins on the market, the drug did nothing whatsoever to halt or reverse the growth of atherosclerosis. In fact, patients on Vytorin experienced slight plaque growth. Despite knowing these results, for years Defendants continued pounding home the "lower is better" message, all the while knowing or willfully ignoring the fact that for Vytorin, lower was ***not*** any better at all. Physicians and patients were lulled into a false sense of security, believing that patients on Vytorin would experience reduced cardiac events, while Defendants concealed the adverse information in order to boost Merck's revenue.

420. Throughout the Class Period, Defendants knew or recklessly disregarded the materially false and misleading nature of the information they caused to be disseminated to the investing public. The Defendants knew or recklessly disregarded the fact Vytorin was proven useless against atherosclerosis, and failed to release highly relevant study results, which caused Merck's financial statements to be materially false and misleading. These false and misleading statements adversely affected the integrity of the market for the Company's common stock causing the price of the Company's common stock to be artificially inflated.

B. DEFENDANTS INTENTIONALLY WITHHELD THE ENHANCE RESULTS

1. Merck Had Access To All Relevant Information By Virtue Of The Joint Venture Agreement

421. The Defendants had access to, control over, and a duty to monitor all relevant information concerning Vytorin, including information at Schering-Plough. Vytorin was sold by

M/S-P, a joint venture company created by Merck and Schering-Plough. According to the "Cholesterol Governance Agreement," which outlines the joint venture arrangement between the two Companies, Merck had the sole authority to designate one of its employees to serve as the general manager of the Cholesterol Business and Cholesterol Products who is fully dedicated to the Cholesterol Business ("Cholesterol Business" and "Cholesterol Products" defined as including Vytorin and Merck/Schering-Plough Pharmaceuticals). Thus, aside from Merck's own actions in concealing the ENHANCE study results, attempting to manipulate the endpoint, and making false and misleading statements, Merck also had control of M/S-P. Indeed, Defendant Deepak Khanna, a Senior Vice President at Merck, functioned as General Manager of M/S-P. Information known by Schering-Plough was known by Merck as well because Merck had representatives on the following M/S-P committees: i) a Vytorin development committee; ii) a Vytorin marketing committee; and iii) a Vytorin finance committee. By virtue of this control, and the joint venture agreement between the Companies, any knowledge Schering-Plough had of adverse results of ENHANCE can be imputed to the Defendants.

2. Defendants Improperly Withheld The ENHANCE Study Results And Lied About Not Knowing The Results

422. Defendants failed to release ENHANCE results until 2008, and claimed that the study was not "un-blinded" until December 31, 2007, inferring that Company executives were unaware of the negative results until that time. However, the Defendants knew the study was going poorly as early as 2005, years before the Company revealed the startling results to the investing public.

423. The last ENHANCE patient completed treatment in April 2006. However, ENHANCE began enrolling patients for a two-year course of treatment in 2002. As a result, the ultrasound images and other relevant data for hundreds of participants had been collected and

researchers were able to analyze the data for early enrollers as early as 2005. Representatives of Merck and S-P admitted (in a *Wall Street Journal* article appearing on March 24, 2008), that "Dr. Kastelein's team began sending complete measurements from the first group of patients" in "late 2005" following which statisticians made "routine checks … to make sure the data were in order." Those initial checks failed to show the benefit that the Companies hoped for and the market expected – the test results showed no statistically significant difference in CA IMT measurements between the two groups of patients in the study. In short, early results showed no benefit in taking Vytorin over simvastatin alone.

424. Thus, in 2005, the Defendants were already ***examining the early study data***, and found that there were no significant differences between the study groups. Due to the financial impact the product had on Merck and S-P, the Defendants were highly motivated to delay the release of ENHANCE and certainly had the opportunity to do so, blaming purported data problems as the reason for nearly two years after the study was completed.

425. Merck's "Annual Business Briefing" presentation in December 2005 further reflects that by that time Merck knew ENHANCE was a bust. That is because ENHANCE is conspicuous by its absence in the presentation. In years prior, while ENHANCE was in its early stages, the ENHANCE trial was highly touted to analysts and investors in Merck's Annual Business Briefings. In Merck's December 2003 Annual Business Briefing, Merck touted ENHANCE as an event that would provide "Significant New Data Expected to Drive Continued Growth." In Merck's December 2004 Briefing, Merck again boasted about its pending studies on Vytorin, including ENHANCE, stating that ENHANCE was anticipated to be complete in 2006, and that the data from ENHANCE (and other outcome studies) was "Expected to Drive Future Growth." Merck explained that ENHANCE was targeted at showing "[a]therosclerotic

regression" – the gold standard of trials for cholesterol drugs at the time – and listed ENHANCE among the "[n]ew outcome studies [that] will demonstrate additional benefits of Vytorin." By the Annual Business Briefing presentation of December 2005, however, Merck consciously avoided any mention of ENHANCE, and that is because it knew the results were poor.

426. Thus, the Defendants knew by at least early 2006 that ENHANCE would not be beneficial to them, yet the Defendants knowingly misrepresented and/or failed to disclose this materially significant information to the Plaintiffs and the investing public during the Class Period.

3. Café Pharma Postings Demonstrate That The Defendants Were Well Aware Of The Study Results At Least A Year Before The Full Results Were Publicly Revealed

427. As discussed previously, Café Pharma (www.cafepharma.com) is a website which provides "discussion boards" which serve as a reference source by pharmaceutical sales professionals, office staff, and others interested in the pharmaceutical industry and a place for those individuals to post information particular to their industry.

428. Specific results of the ENHANCE study were publicly posted on the Café Pharma website on both the Merck and S-P boards a full year before the companies officially released the full study results in March of 2008. Starting in March 2007, dozens of posts about the ENHANCE trial began appearing on the boards at Café Pharma. Some of those posts revealed specific, credible details about the ENHANCE study results that only company insiders and study investigators would have known at the time. Without corroboration of this information by the Companies, however, investors could not have appreciated their importance.

429. Lead Plaintiffs have communicated with multiple confidential witnesses, including former Merck and S-P employees and consultants, who report that senior managers at Merck were familiar with Café Pharma and visited the boards on a regular basis for a variety of

reasons. The Café Pharma messages demonstrate that specific information about ENHANCE was known by Merck and S-P which demonstrates the Defendants knew the ENHANCE results, either because analyses were performed on blinded data that demonstrated the lack of a statistical difference between the two groups of patients or because the ENHANCE results had been un-blinded (or at least partially un-blinded) within the Company. The actual ENHANCE results reported in 2008, when read together with the earlier Café Pharma posts, demonstrate that the ENHANCE results were known within Merck long before they were publicly disclosed and that the Café Pharma posts were more than just speculation.

430. The relevant posts included the following information:

> March 9, 2007: "One of my docs told me that he heard from someone at SPRI [S-P Research Institute] that there was no difference between Zetia and placebo groups in terms of carotid thickness."
>
> March 13, 2007: "Have a buddy at SPRI. He says that the study is a bust. Adding Zetia to already maxed-out statin is useless."
>
> June 3, 2007: "[ENHANCE] Still not released! Heard it crashed and burned!"
>
> June 4, 2007: "NO difference in the primary endpoint (change in CIMT + baseline) between simva+zetia and simva+placebo, and there were higher rates of liver problems in the simva+zetia group."
>
> July 19, 2007: "ENHANCE – Zetia10/Simva 80 NOT better than simva 80/placebo!!! Now we know why this was pulled from the ACC!!! We've been living off the LDL lower is better story versus statins alone since launch. This is the first trial with a clinically meaningful end[p]oint (carotid IMT) and shows that adding Zetia to high dose [simvastatin] provides no real benefit . . . ENHANCE shows us that there is and will be no wide margin of benefit. We're screwed once the MCOs [managed care organizations] and PBMs [pharmacy benefit managers] figure this out. . ."
>
> September 20, 2007: "One of my docs is a very good friend of the study PI [primary investigator] overseas. I'm told that the study IS negative in that there is absolutely no difference in carotid IMT

> between simva 80 + placebo vs simva 80 + Zetia 10. Although Zetia did lower LDL-C as expected, it did nothing else of any value. So much for "lower is better!" Apparently, the PI and company have been arguing back and forth about how/when to release the info. PI wants to report, but company keeps blocking/delaying. We're pretty well screwed if what is essentially max dose Vytorin is no better than max dose generic simva!!"
>
> November 14, 2007: "[W]ord of mouth from investigators in running the trial is that it is a negative study. We and Merck both talked up this study publicly a bunch before the results were known internally, now both are stone cold silent . . . You do the math."

431. When these posts are read together, in light of Merck's subsequent disclosures of the actual ENHANCE results as well as disclosure of the tension between the Companies and Dr. Kastelein, it is readily apparent that these posts are more than just speculation. The Café Pharma messages included accurate, detailed descriptions of the study results, which were passed along through personal networks from both SPRI personnel and the study investigators. The numerous and accurate postings demonstrate that decision makers within Merck knew or recklessly disregarded the results of ENHANCE long before the results were formally announced.

4. E-mails between Representatives of the Joint Venture and Dr. Kastelein Confirm That Merck Knew the Study Results Years Before Their Publication

432. Merck not only knew that the study results were negative long before the full results were finally published, the Companies were in a battle with the principal investigator over publication. Dr. Kastelein was prepared to publish in early 2007, but the Companies continued to block and delay disclosure of the results. The struggle between the Companies and Dr. Kastelein was documented in a series of back-and-forth e-mails, which were not revealed to the public until they were unearthed in April 2008 through Congressional inquiries. The e-mails raise a strong inference of scienter on the part of Defendants, as it is clear that the principal

investigator of ENHANCE was ready and willing to publish the results at least a year before their eventual release.

433. During the summer of 2007, Dr. Kastelein communicated with senior 2006 joint venture researchers, declaring that there was no good reason to delay publication of the study results. On July 6, 2007, Dr. Kastelein sent the following email regarding ENHANCE to Dr. John Strony at S-P:

> 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.
>
> John

(Emphasis added).

434. In response, Dr. Strony offered the following explanation for the delay:

> 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…

435. Attempting again to push for publication of the data, Dr. Kastelein e-mailed a reply to Dr. Strony on July 7, 2007, now including 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***
>
> John

(Emphasis added).

436. Dr. Veltri responded this time, offering yet another rationalization for the delay. Not content with Dr. Veltri's response, 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 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.***
>
> Regards, John

(Emphasis added).

437. While Defendants continually delayed publication in 2007 by inventing problems with the data, eventually hiring an independent expert panel to perform yet another review, Dr. Kastelein was prepared to publish in early 2007. The fact that the Companies were able to publish preliminary results just days after backing down on their decision to change the primary endpoint, using the very data they claimed was flawed, demonstrates a strong inference of scienter. The Defendants knew that the study results were negative, and were desperately trying to delay publication and discredit the data in order to avoid the inevitable crash in sales when the public learned the truth.

5. Merck Had Unfettered Access To All Of The Raw Data, And ENHANCE Researchers Had To "Request" Study Data From The Defendants, Giving Rise To A Strong Inference That Defendants Were Able To Ascertain The Results Years In Advance Of Publication

438. *The New York Times* reported on November 21, 2007 that the delay in the release of the ENHANCE study results had led to "a growing chorus of complaints from cardiologists." As the article stated:

> In June 2006, a S-P executive told investors that the Enhance data would be ***ready*** by year-end, although it might not be publicly presented until 2007. ***At the latest***, doctors had expected the results by the American College of Cardiology conference in March 2007. In an interview yesterday morning, Dr. Kastelein, the study's leader, said he had hoped to present the results of the trial at the March 2007 conference. But ***S-P and Merck controlled the raw data and raised questions about its accuracy***, resulting in long delays, he said. "***There was friction and tension***," he said.

(Emphasis added).

439. This is corroborated by a statement from Confidential Witness #5 ("CW 5"), who was a consultant on ENHANCE, working directly with researchers in Amsterdam for approximately four to five years. CW 5 was responsible for quality control of the ultrasound imaging, among other things, and his/her expertise concerned how to measure, examine and interpret data. CW 5 primarily spoke to the people directly responsible for the ultrasound and image readings at the center in Holland and frequently e-mailed and participated in conference calls with Dr. Strony. CW 5 reports that s/he did not have direct access to any of the databases, and when information was needed on how individual sonographers or readers were performing, the relevant data needed to be requested from Dr. Strony. Indeed, according to CW 5: S-P was in control over the ENHANCE database from at least as early as 2006; and "S-P had the code and the data in 2006 and performed the analysis."

440. The fact that Merck and S-P controlled the data, coupled with their attempts to discredit and/or manipulate the endpoints, creates a strong inference of scienter.

C. MERCK ATTEMPTED TO DISCREDIT THE ENHANCE STUDY RESULTS, GIVING RISE TO A STRONG INFERENCE OF SCIENTER

441. Despite the care taken in establishing the ENHANCE test protocols, selecting the measuring apparatus and software, and finding certified sonographers, following the initial reviews of the test results Merck and S-P began to question Dr. Kastelein on the accuracy of the data. The Companies, knowing the results were unfavorable, pointed out what they alleged were problems in a desperate attempt to discredit or bury the study. The March 24, 2008 *Wall Street Journal* article stated:

> The companies [Merck and S-P] began sending what became a constant flow of inquiries to Dr. Kastelein . . . and pitted Dr. Kastelein's lab against an outside research team to see whether one would be more accurate. There was no meaningful difference and

> Dr. Kastelein's team was kept on the case, spending the second half of 2006 re-reading most of the 40,000 images taken in the study, according to the companies.

442. Defendants were concerned that the results they had received at that time showed such small, statistically insignificant differences between the test groups that there would be no data supporting the use of Vytorin over simvastatin alone. The March 24, 2008 *Wall Street Journal* article included a criticism levied by Allen Taylor, Chief of Cardiology Service at Walter Reed Medical Center, Washington, D.C. and an expert in imaging neck arteries, who remarked on Merck's belated challenges, stating that "It's very atypical for a trial to go through this sort of scrutiny." The article also noted that "Dr. Kastelein . . . grew frustrated by the companies' demands and repeatedly tried to reassure the sponsor about the data and its readiness."

1. The Bots Report

443. Having failed in their initial attempt to challenge the test results, Merck and S-P tried again in January 2007. At that time, the Companies retained 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" to provide advice and a written report on purported problems with CA IMT measurements in the ENHANCE trial.

444. Dr. Bots provided Merck and S-P with his report on or about January 26, 2007. He concluded that there were no problems with the ENHANCE data that would justify any delay in releasing the test results. However, the Companies refused to publish the ENHANCE results, presumably because such disclosure would severely curb their lucrative Vytorin revenues. The fact that Merck and S-P completely ignored the advice of Dr. Kastelein, their own lead investigator, and later Dr. Bots, the expert they hired, gives rise to a strong inference of scienter.

445. The pertinent findings of the Bots Report include the following:

> Dr. Bots' objectives were defined 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."

446. Dr. Bots concluded that the CA IMT measurements "were indeed done in a manner that was described in the protocol." Emphatically, twice more in his report he stated: "[t]he CIMT measurements seem to be done according to the procedures outlined in the protocol." On this issue, he concluded that "[t]he 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."

447. On the purported issue of "outliers," Dr. Bots found that with respect to the "mean absolute CIMT difference and the standard deviations, 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*.** (Emphasis added).

448. Dr. Bots also addressed the issue of missing data. The Report stated, "[o]f 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." He further rejected any concerns by explaining that 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.

449. In short, Dr. Bots found all purported concerns unjustified, and stated in his "Conclusions" section of the Report that "the evidence to me is sufficient to indicate that the data are fine." In his "Summary" he likewise stated: "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."

450. Despite Dr. Bots' emphatic conclusions, Defendants pressed for ways to change the results by, for instance, changing the way CA IMT was measured through selection of images, or changing the parameters used to define outliers. However, Dr. Bots found that such proposals would have no effect, writing:

> [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 the estimate of the difference between treatment arms.

451. The Bots Report demonstrated that there was no valid basis to delay the publication of the ENHANCE results. Defendants' attempts to discredit the study had again failed, and their insistence on disregarding the Bots Report gives rise to a strong inference of scienter.

2. The Independent Expert Panel is Convened

452. On August 20, 2007, several months after the Bots Report was issued, and after Dr. Kastelein had been continually stonewalled, Dr. Kastelein met with Merck and S-P executives to discuss finally releasing the ENHANCE results. Knowing that releasing ENHANCE would be disastrous for sales, Merck and S-P demanded that the test data be reviewed yet again and Dr. Kastelein acceded to their request to convene an expert panel to further consider the Companies' trumped-up issues with the data.

453. Holding this panel would provide a means for the Companies to suggest an alternate, more favorable endpoint, and cloak the change in legitimacy by running it through the panel. Merck and S-P continued to delay, failing to even convene the independent expert panel until mid-November 2007, which further frustrated Dr. Kastelein. Allegations of negative study results were appearing on Café Pharma, and there was growing speculation that Merck and S-P were blocking publication of the ENHANCE results to maintain their lucrative Vytorin sales. Further, the Companies knew that *Forbes* was working on a story about the publishing delay, as the author had communicated with executives at both Companies and Dr. Kastelein in preparing the article (which was later published on November 19, 2007).

3. Defendants Attempted To Manipulate The ENHANCE Study Results To Make Them Appear More Favorable, Supporting A Strong Inference Of Scienter

454. One of Merck's goals of convening the panel was to have the panel consent to changing the primary endpoint of the ENHANCE study, an abject violation of scientific protocol, but a change the Companies believed was necessary in order to mitigate the damage of the test results. Dr. Kastelein failed to attend the panel meeting. As would later be discovered, Merck intended to push the panel into recommending a change to the primary endpoint of the study.

455. The use of the expert panel by Merck drew widespread criticism. First, the panel was criticized as a means by the Companies to challenge data that had been already been reviewed and which had been gathered according to protocols established in advance and strictly followed during the trial. In short, there was no reason for the panel. Second, the panel was criticized as a means for Merck to completely change the goal, or primary endpoint, of ENHANCE, in a post-hoc attempt to cherry-pick data and obtain more favorable test results. That would be a breach of established scientific test protocols. Third, Merck and S-P attempted

to steer the panel into a finding that the data gathered during the ENHANCE trial was flawed. That was an improper attempt to influence the panel. Finally, Merck later attempted to fabricate the panel's recommendations by creating versions of minutes of the panel's meeting which completely misrepresented what transpired at the meeting. As would later be revealed in documents gathered by the FDA and Congress, in stark contrast to the public representations by Merck and S-P, the panel never recommended changing the primary endpoint of the ENHANCE study.

456. Over one month after the expert meeting, on December 19, 2007, Merck and S-P circulated to participants purported "minutes" of the November 16, 2007 expert meeting, although the Companies had represented to the meeting participants at the start of the meeting that there would be no meeting minutes or transcript. The comments on the draft "minutes" by one of the meeting's panel members and attendees, Dr. Stein, of the Division of Cardiovascular Medicine at the University of Wisconsin, demonstrate three points: (i) that the Companies hand-selected the data that the experts viewed; (ii) that they tried to conceal this fact; and (iii) that they tried to attribute a conclusion to the panel that the panel did not reach, namely, that the Companies should change the primary endpoint of the study. These revelations, coupled with the fact that Merck and S-P attempted to change the endpoint to the one measurement that was MOST favorable to Vytorin, give rise to a strong inference of scienter.

457. Dr. Stein's comments on the draft minutes were revealing. Regarding an entry in the draft minutes that stated: "the Panel members were granted unrestricted access to the blinded image data base," Stein vehemently disagreed. "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 30,000 images] and those only were images that the company chose to show us." (Emphasis added).

458. Thus, in what was supposed to be an effort to obtain neutral, expert feedback about the ENHANCE data (eleven months after it had already received such feedback from Dr. Bots), the Companies hand-selected "50-75" out of 30,000 ultrasound images to show the expert panel, and then attempted to misstate the minutes from the meeting to suggest that the panel was granted "unrestricted access" to the data. In fact, the panel was granted only restricted access to the ***worst data***. According to CW 5, who was a consultant for M/S-P in the Netherlands, the Companies selected the 74 most "discrepant" images out of 30,000 to show to the expert panel.

459. The draft minutes also stated that, "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." The CCA measurement is the one that proved to be most favorable to Vytorin. Dr. Stein again disagreed with the minutes, stating, "***This was not a conclusion of the meeting***." Dr. Stein further noted, "[T]he tone of these conclusions makes it seem as [if] these were strong, unanimous, scientific recommendations, rather than opinions with varying degrees of enthusiasm from panel members and varying degrees of scientific justification. ***Indeed, the conclusions were made by the companies, not by us***." (Emphasis added).

460. The Company apparently ignored Dr. Stein's comments on the minutes, although he provided them in two separate readings of the minutes, as the meeting summary was finalized without correcting the objectionable material.

461. In addition to fabricating the minutes, Merck also attempted to improperly influence the supposedly "independent" panel. Materials prepared for the November 16, 2007 meeting by Merck and S-P also presented to the independent panel a skewed picture of the ENHANCE data in an apparent effort to further delay or modify the release of the results. One slide included the statement: "Existing data is not statistically analyzable," and under the heading "Statistical Issues," another slide stated, "There is [a] tremendous risk analyzing this data." The veracity of these statements, however, is severely undermined by the fact that Merck released preliminary top-line results of ENHANCE (based on this same data) a short time later, about a month after Defendants reversed the decision to change the endpoint.

462. Defendants' conduct with regard to the November 16, 2007 expert panel further demonstrates that the Company knew or recklessly disregarded the results of ENHANCE, sought further delay, and attempted to alter the study's primary endpoint (an unprecedented violation of scientific protocol for which it sought cover in the form of an expert panel that it manipulated), giving rise to a strong inference of scienter.

4. Defendants Attempted to Change the ENHANCE Primary Endpoint to One That Would Have Most Benefited the Company

463. After the expert panel meeting, Merck announced the highly unorthodox step of changing the primary endpoint of ENHANCE, purportedly based on the expert panel's conclusions. On November 19, 2007, Merck issued a press release announcing that, "an independent panel of clinical and biostatistics experts was convened on Friday, November 16, 2007 to offer advice about the prospective analysis of the ENHANCE trial." The release added that "The independent panel recommended focusing the primary endpoint to the common carotid artery to expedite the reporting of the study findings."

464. The November 19, 2007 press release stated that: "We view ***the experts panel's recommendation*** to narrow the primary endpoint to the common carotid artery as helpful." (Emphasis added). Moreover, the assertion that "[a] panel of outside scientists recommended the change" was repeated in a November 21, 2007 *New York Times* article. These statements, however, were false and misleading, because Merck and S-P, and not the expert panel, recommended the primary endpoint change.

465. Merck's announced change to the ENHANCE primary endpoint received immediate criticism from the scientific community. As *The New York Times* reported on November 21, 2007:

> [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.
>
> ***"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."***

(Emphasis added).

466. Worse, the modified endpoint was also the endpoint most favorable to Vytorin according to the final ENHANCE results. Specifically, the ENHANCE results, as subsequently reported in the *NEJM* on March 30, 2008, showed that, of the several measurement sites that initially comprised the primary endpoint of ENHANCE (common carotid artery, carotid bulb, and internal carotid artery), the common carotid artery was the only site of the three that showed ***less of an increase*** in artery wall thickness for Vytorin treatment than for generic simvastatin treatment. By contrast, both the carotid bulb and internal carotid artery measurement sites showed ***greater increases*** in artery wall thickness for the Vytorin treatment.

467. The fact that changing the ENHANCE primary endpoint was raised by Merck and S-P officials during the expert panel meeting, combined with the suspicious benefit to Merck in using the most favorable measurement as the new modified endpoint further raises a strong inference that Merck in fact knew or recklessly disregarded the negative ENHANCE results long before they were finally published.

5. Defendants Suddenly Reversed Their Position, Deciding Against The Proposed Change in the ENHANCE Endpoint

468. On December 11, 2007, only days after announcing that they were changing the primary endpoint of ENHANCE, and on the same date they received the first letter from Congress questioning their actions, Defendants reversed course and announced that they would in fact not change the endpoint. Defendants still attempted to divert responsibility for changing the endpoint to the expert panel. In an interview with Forbes magazine, defendant 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."

469. On December 17, 2007, The *Wall Street Journal* reported that Dr. Kastelein "breathed a sigh of relief" when Merck and S-P advised him the previous week that they were reversing course and not changing the primary endpoint. *The Wall Street Journal* reported that Dr. Kastelein said "***he regrets not standing up to Merck & Co. and S-P Corp.*** when they first told him last month that ***they planned to alter the statistical analysis*** of their jointly sponsored trial." (Emphasis added). As the article reported:

> ***"It's never, ever right to change the primary endpoint of a study,"*** especially after all the data are in, [Dr. Kastelein] says. "It is statistically not good and it gives the wrong impression to the outside world." He says he initially went along with the plan but now regrets not firmly resisting it from the outset. ***He says the episode was the culmination of a long-running battle over the conduct of the trial and the companies' worries that some***

> ***deficiencies in the data would jeopardize a good result. He says the concerns were unnecessary.***

(Emphasis added). Therefore, according to the principal investigator of ENHANCE it was the manufactured concerns of Merck and S-P, rather than the expert panel recommendations or "deficiencies in the data" that led to the delays in the release of the ENHANCE results and the proposed change in endpoint.

470. The fact that Defendants attempted to manipulate the panel, falsely attributed the decision to change the ENHANCE endpoint to the panel, and then quickly screeched into reverse when Congress launched an inquiry into their decision to change the endpoint gives rise to a strong inference of scienter.

D. MERCK KNOWINGLY AND/OR RECKLESSLY SPREAD FALSE MARKETING MESSAGES REGARDING VYTORIN TO INCREASE PROFITS, DESPITE HAVING PROOF THAT VYTORIN WAS INEFFECTIVE

471. Merck and S-P also planned to tweak their marketing message in preparation for the release of the ENHANCE results. According to an internal Merck/S-P marketing document entitled "Merck/S-P Pharmaceuticals WWOC Review," dated December 17, 2007, the Companies intended to pound physicians with the only message they could, namely, that Vytorin still lowered LDL more than its competitors. Regardless of the fact that, in regards to Vytorin, ENHANCE showed that lowering LDL was most likely useless in preventing cardiovascular events, it was their only means of damage control. Specifically, the document stated: "Incorporate 'lower is better' into message flow" and "incorporate switch message – SNAG (simvastatin not at goal)."

472. By this point, with all of the messages posted on Café Pharma, the repeated attempts to discredit the study or to manipulate the endpoint, and the repeated attempts to delay publication of the study, it is clear that the Defendants knew the ENHANCE results would be

negative. According to multiple Confidential Witnesses, the Companies continued to push the "lower is better" message throughout the Class Period, despite having clear evidence that lower is not better with regard to Vytorin. The Companies' tenacity in planning a marketing push based on the one demonstrated effect of Vytorin – the ability to lower cholesterol better than a statin alone, regardless of the lack of effect on cardiovascular outcomes – supports a strong inference of scienter.

E. THE PURPORTED "DATA ISSUES" WERE A MERE PRETEXT TO DELAY DISCLOSURE OF NEGATIVE RESULTS

473. As *The New York Times* reported on January 15, 2008: "the drug companies blamed the complexity of the data for the delay. Now, barely a month after news articles noted the delay and Congress pressured the companies to disclose the study's findings, the results are out." As Dr. Harlan Krumholz, a cardiologist at Yale University, stated in *The New York Times*, drug companies have a responsibility to release all their trial findings, positive or negative, as quickly as possible – even if the results might hurt sales: ***"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."*** (Emphasis added).

474. As *The New* York *Times* further reported on January 16, 2008:

> There have long been suspicions, but it was still very disturbing to learn this week that a heavily promoted cholesterol-lowering drug had flunked a clinical trial of its effectiveness in reducing fatty deposits in arteries. The two companies that reap billions from the drug had been ***cynically sitting on the results for more than a year***.

(Emphasis added).

475. In a January 17, 2008 *Newsweek* article, in response to the question, "Do you think that S-P and Merck intentionally sought to delay the release of this data?", Representative

Stupak stated: "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. Take away $5 billion or more from these companies, and man… These allegations are very serious though. We've been on this since October, and we have enough information to go for a hearing now." (Emphasis added).

476. On January 25, 2008, *Forbes* printed an article discussing the release of the partial ENHANCE results. The story reported that Dr. Harlan Krumholz of Yale University was concerned the delays were caused by commercial – not scientific – concerns. "By the [S]ummer of 2005, their marketing division is so successful that it already is a blockbuster drug. There was only downside [to analyzing the results]." Dr. Allen Taylor of the Walter Reed Army Medical Center found that spending so long purportedly trying to clean up the data was not appropriate: "It's not liking the answer and hoping that if you do it again you'll get a better answer … The fact that they never found a good solution validates the point: The data are the data."

477. On January 26, 2008, the *Wall Street Journal* reported on continued suspicions in the medical community concerning the companies' delayed release of the ENHANCE results. In the article, Dr. Krumholz of Yale University stated: ***"It's in their great interest to delay this study if there is any possibility that it doesn't come out positive."*** (Emphasis added).

F. VYTORIN'S LACK OF EFFICACY WAS APPARENT TO RESEARCHERS EVEN BEFORE THE DATA WAS UN-BLINDED

478. Clinical trials to compare medications are typically "blinded," meaning that neither the participating patients nor those evaluating their medical outcomes know which study treatment was received by an individual. Blinding helps to avoid bias in treatment assignment and outcome evaluation, and has become a key feature of modern clinical trials. Significant, dispositive information about current and anticipated trial results may, however, be obtained

even while an analysis is blinded. Well-accepted statistical methods available to Defendants provided them with the ability (even on the basis of blinded, or partially blinded, data) to determine whether the ENHANCE data would show a statistically-significant change.

479. Several useful analyses of study data may be performed without unblinding by examining pooled data without knowledge of which treatment was received by a particular patient. Even with this limitation, analysis can extract important information about the likelihood the study will come to a clear conclusion.

480. The primary outcome measure for ENHANCE was the change in CIMT from baseline to patient follow-up at two years. For ENHANCE, CIMT was defined as the average thickness of the carotid arterial wall at three main locations, the common carotid arteries, carotid bulbs, and internal carotid arteries. In ENHANCE, CA IMT was in the range of 0.6-0.8 millimeters (0.024-0.031 inches). The average change in carotid artery IMT over two years of ENHANCE patient follow-up was 0.0058 mm. in 320 patients receiving only simvastatin and 0.0111 mm. in 322 patients receiving simvastatin plus ezetimibe or Vytorin. As part of the final analysis, ENHANCE compared the change in CIMT between the two study groups with statistical adjustment for study center (there were 18 centers involved) and the CIMT at baseline. The difference between the two study groups was statistically non-significant, however, the Vytorin/Group experienced slightly higher plaque growth.

481. Standard deviation may be monitored while a study is underway, without un-blinding. With two study groups, assuming the two standard deviations are roughly the same, an estimate of their common standard deviation value depends upon the means in each group since each standard deviation is based on differences from that group's mean. If the study remains blinded, these means are unknown. However, technical methods exist to obtain a summary

estimate of the standard deviation despite the limitation of unknown group means. This method is characterized as an "internal pilot study" since it uses early information, with no need to unblind, to project the study's ability to find a statistically-significant treatment effect. In ENHANCE, this approach could have been used repeatedly.

482. Partial unblinding, requiring only a relabeling of the study groups as A and B, is another, simpler approach. If one group were clearly superior, the study would be progressing satisfactorily although the analyst would not know which group was the better one. Conversely, a partially unblinded comparison with a highly non-significant effect might be detected.

483. On February 11, 2008, in the Second Senate Letter, Senator Grassley wrote to Hassan that ENHANCE statisticians would not have needed to have unblinded the ENHANCE data to know that the study had failed to show a statistically-significant difference between treatment arms:

> It has come to my attention that S-P and Merck would not need to unblind the data to understand that Vytorin performed no better than generic simvastatin. The ENHANCE trial is a non-inferiority study. These studies try to detect a statistically significant difference between treatment groups on the primary endpoint. Once the results are recorded, the study is then unblinded to determine which drug is the better performer. ***However, if the drugs performed the same, meaning there is no statistically significant difference in the treatments, then this information is apparent before the study has been unblinded***.

(Emphasis added).

484. The Defendants had the ability (even based on blinded preliminary data) to determine whether the Company's studies around provide statistically-significant results. For instance, on March 28, 2008 (two days before the release of the final ENHANCE results), Merck disclosed that it was adding approximately 5,500 patients to IMPROVE-IT, the Company's ongoing outcomes trial designed to test whether Vytorin can reduce heart attacks more than

treatment with simvastatin monotherapy. As *Dow Jones* reported on March 28, 2008, researchers were expanding the trial's enrollment to as many as 18,000 patients from the previous target of 12,500 because:

> The researchers said they determined that more patients were needed in order to detect whether or not Vytorin could provide a statistically significant reduction in risk of heart problems compared with one of its component drugs, simvastatin. … The doctors said the increase in the Improve-It study was based on "ongoing evaluation of ***blinded, aggregate cardiovascular event rates*** in the trial …" Blinded typically means not knowing which patient is getting which therapy. All trial participants and leaders remain blinded to which treatment the patients are receiving, the doctors said.

(Emphasis added). Defendants' ability to analyze blinded, aggregate data in IMPROVE-IT to draw a conclusion regarding the trial's capacity to show a statistically-significant benefit of Vytorin over simvastatin raises a strong inference that researchers determined, even based on blinded data, that ENHANCE would not demonstrate a statistically-significant difference between treatment arms.

485. The facts set forth above, viewed collectively, give rise to a strong inference that the Defendants acted knowingly, or at least recklessly, when they concealed from the market the material negative results of ENHANCE, which, when they were disclosed, had a significant, negative impact on Merck's sales of Vytorin, the price of Merck securities, and Merck's business as a whole.

G. THE SCIENTER OF THE INDIVIDUAL DEFENDANTS

1. The Individual Defendants Were In Positions Of Actual Control And/Or Supervision of Merck's Manipulative Practices

486. Defendants Clark, Kim, Lewent, Khanna and Yarno (collectively, the "Individual Defendants") acted with scienter in that they directed, knew about or recklessly disregarded the fraudulent practices implemented under their watch. As officers of the Company, the Individual

Defendants each knew, through direct knowledge learned through the supervisory nature of their positions or recklessly disregarded and failed to disclose, material adverse information; were involved in the decisions concerning Vytorin made at the Companies, and, made false and misleading statements of material fact. Each of the Individual Defendants is liable as a participant in a fraudulent scheme and course of dealings that operated as a fraud or deceit on purchasers of Merck securities by issuing materially false and misleading statements, failing to correct the misstatements of others participating in the Merck/S-P joint venture and/or concealing material adverse facts regarding the failure of ENHANCE to demonstrate any real cardiovascular benefit of Vytorin, while continuing to promote product superiority.

487. In addition to the foregoing facts, all of which support a strong inference of scienter on the part of the Individual Defendants, the Individual Defendants also had the motive and opportunity to withhold the ENHANCE study results. These Defendants were the senior management of the Company, and thus at all times were the individuals with principal responsibility for ensuring that the Company's statements were accurate and truthful.

a. Richard T. Clark

488. Defendant Clark took over as Merck's President and CEO after Raymond Gilmartin resigned on May 4, 2005, and led Merck's operations with regard to Vytorin. Prior to his role as CEO, Clark served as President of Merck's Manufacturing Division. In April 2007, he was named Chairman of Merck's Board of Directors.

489. Clark knew or recklessly disregarded information known to Merck that Vytorin was practically useless in preventing cardiovascular events, which is the ultimate goal of patients who take the drug. Further, he knew that Merck was wrongfully withholding this information from the investing public by concealing the results of ENHANCE, and that Vytorin earnings reported during the Class Period were based entirely upon a drug that the Defendants, including

Clark, knew was ineffective. The Company admitted that initial data checks were conducted in 2005 in the ENHANCE study, which would have shown that Vytorin was not performing as expected.

490. Clark played an active role in Merck's deception. As CEO, Clark stated at a June 14, 2006 Goldman Sachs Annual Global Healthcare Conference that "Vytorin and Zetia are critical to the future success of Merck, are critical to the future of Schering-Plough as well. So we will do everything we must to maximize both of those products at the joint venture." CW #1 confirmed that Clark participated in Vytorin status meetings.

491. As reported by *Reuters* on January 3, 2008, ***less than two weeks*** before the negative ENHANCE study results were made public, Clark spoke at a Morgan Stanley investor meeting in New York, and stated that Vytorin would likely *get a sales boost* "as patients fail to adequately benefit from less-potent but far cheaper generic forms of [Zocor]" regardless of the outcome of ENHANCE. During the Morgan Stanley Conference, Clark stated that "[w]hen you do head-to-head competition with Lipitor and Crestor, [and Zocor], or for LDL lowering, Vytorin wins." Clark further stated that *regardless of the outcome of ENHANCE* Vytorin and Zetia get patients to their LDL cholesterol goals "better than other products" and "it has been successful for that reason."

492. Further, Clark consistently highlighted the blockbuster success of Vytorin in press releases and quarterly earnings announcements, all through 2006 and into 2007. He pointed out Vytorin's "impressive sales growth" and touted the success of the "Merck/Schering-Plough partnership." On July 23, 2007, in an earnings report and related investor conference call, Clark announced that Vytorin achieved all-time highs in both new and total prescription share.

493. Clark was highly motivated to downplay the significance of ENHANCE and make false statements about Vytorin. His promotion to CEO in May of 2005 not only catapulted his salary over the million-dollar mark, but he also received ***millions*** in bonus payouts and stock options. By March 2007, due in part to Merck's astronomical success with blockbuster drugs like Vytorin, Clark's salary had ballooned to $1,700,000, and his total compensation in 2007 including salary, bonus and other incentive awards was almost twenty million dollars. In addition to this sudden infusion of wealth, Clark enjoyed the perks of leading a large company like Merck, including a company paid automobile with a full-time chauffeur, personal security, home security installation and monitoring, and access to the Company jet for personal use. In May 2007, long after the ENHANCE results were known internally, Clark sold 83% of his Merck stock shares for over two million dollars.

b. Peter S. Kim

494. Defendant Kim is President of Merck Research Laboratories. He joined Merck and became an executive officer in February 2001. While Merck was desperately trying to either suppress the ENHANCE results or manipulate the study findings to place Vytorin in a better light, Kim acted with scienter and was a direct participant in the deception. Kim fraudulently attempted to attribute the Company's controversial decision to change the endpoint in ENHANCE to the independent expert panel after the media explosion when the proposed change was announced. On December 11, 2007 in a *Forbes* article entitled, "Merck and Schering Backtrack," when explaining Merck's decision to revert to the original endpoint on the same day Congress launched an inquiry, Kim stated, "We held two other consultant meetings and had internal discussions [regarding the endpoints]. We have made the decision that, while we greatly respect this expert panel, that we are not going to change the primary endpoint for the study."

495. Kim knew or recklessly disregarded information known to Merck that raised serious questions about Vytorin's ability to impact atherosclerosis, and therefore was unlikely to prevent cardiovascular events, which is the ultimate goal of patients who take the drug. Further, he knew that Merck was wrongfully withholding this information from the investing public by concealing the results of ENHANCE, and that Vytorin earnings reported during the Class Period were based entirely upon a drug that the Defendants, including Kim, knew was ineffective.

496. Kim was a direct and substantial participant in the fraud who received substantial revenue-based bonuses and other compensation during the Class Period that was artificially increased by the wrongful conduct set forth herein. In addition to his substantial salary, bonus, and stock options, Kim was grandfathered in under an executive incentive program, no longer legal due to executive compensation reform laws, in which the Company gave Kim a half million dollar interest-free "loan", which was rapidly "forgiven" over the next five years. Kim's salary also hit the million dollar mark in August 2007, weeks before the negative ENHANCE results would be revealed, for his "proven leadership, contributions and performance."

c. Judy C. Lewent

497. Defendant Lewent was Executive Vice President and CFO for Merck, a position she held for about eighteen years until late 2007 when she resigned. Defendant Lewent was intimately familiar with the Company's financial position, and prior to the announcement of Clark as Gilmartin's successor, Lewent was in line for Gilmartin's position. Lewent needed Vytorin to be a blockbuster drug to advance within the Company.

498. Lewent knew or recklessly disregarded information known to Merck about Vytorin was practically useless in preventing cardiovascular events, which is the ultimate goal of patients who take the drug. Further, she knew that Merck was wrongfully withholding this information from the investing public by concealing the results of ENHANCE, and that Vytorin

earnings reported during the Class Period were based entirely upon a drug that the Defendants, including Lewent, knew was ineffective.

499. As Merck's Executive Vice President and Chief Financial Officer, Lewent was responsible for ensuring the Merck's financial performance met analyst's expectations each quarter during the Class Period. Lewent was clearly aware of the impact the negative ENHANCE results would have on the market for Merck Securities. In July and August of 2007, she sold nearly 50% of her Merck stock holdings, in sales exceeding five million dollars.

d. Deepak Khanna

500. Defendant Khanna is a Senior Vice President at Merck and General Manager of M/S-P. According to the Cholesterol Governance Agreement, the president of the joint venture between the two companies, M/S-P, is appointed by Merck, and is involved in ***every aspect*** of the cholesterol business. Thus, Khanna and Merck were also intimately involved, and aware of what was going on at all times with ENHANCE.

501. Khanna was also a participant in the Merck fraud, and acted with scienter. In the January 2007 edition of "ProQuest Information and Learning" in an article titled "Success from Two Sources," Khanna stated, "This is a market that is about efficacy, lowering LDL and helping patients achieve their LDL-C goals. When you show them data on how your LDL-lowering gets more patients to goal versus your competitors, that's getting physicians information that is helpful."

502. At a hearing before a House subcommittee investigating Merck for its actions surrounding ENHANCE, Khanna pointed out that Merck had suspended its Vytorin broadcast advertising in January 2008, stating, "[w]e took this action in anticipation of the confusion that could be created by our release of the results of the ENHANCE trial." In other words, Merck knew that it would take a huge public relations hit from the revelation that it had been hiding the

negative results for almost two years. Further, Khanna attempted to discredit the ENHANCE trial in retrospect, saying the trial was relatively small with a "unique" patient population.

e. Wendy L. Yarno

503. Defendant Yarno is Merck's Chief Marketing Officer. It was her responsibility to figure out some way to put a positive spin on the negative ENHANCE study results. CW 1, a former senior marketing executive in the Global Marketing Department, alleges that the very senior Merck executives kept the ENHANCE study information secret, which compromised the Company's credibility and trustworthiness. However, CW 1 learned in the early part of fourth quarter of 2007 that one of her upcoming projects was to "somehow market" the results of ENHANCE, but they never received the materials they needed to move forward. Instead, the marketing department simply "stayed on message" about Vytorin and "lower is better."

504. Yarno was clearly worried about the impact that the negative ENHANCE study would have on Merck's stock price. In March 2007 and again in October 2007, Yarno exercised stock options that were not set to expire for another six to eight years, selling ten million dollars worth of Merck stock. The timing is highly suspicious, considering that Yarno didn't exercise any options in 2005 or 2006.

2. Merck's Bonus Structure Incentivized Defendants To Perpetrate The Fraud

505. The huge salaries that Merck paid to its top executives were only a small portion of their overall compensation. In addition to base salary and benefits, Merck executives are eligible for substantial annual cash awards (which can be millions) under Merck's "Executive Incentive Plan (EIP)," as well as long term incentives in the form of stock options and stock awards. Up to 70% of these bonus incentives are tied to the fiscal performance of the Company, as well as Merck's stock price. The Individual Defendants had enormous amounts of money on

the line, which gave them tremendous incentive to suppress the negative results of ENHANCE and keep Vytorin profits as high as possible.

	Year	Salary	EIP Bonus	Stock Awards	Option Awards	Other Bonus	Pension/ Deferred Comp	"Other" Comp	Total
Clark	2007	1,616,670	4,311,059	5,846,754	2,946,722		4,860,602	310,055	19,891,862
	2006	1,183,334	1,800,000	2,359,616	2,475,584		2,257,670	210,536	10,236,740
Lewent	2007	569,026	0	714,370	963,987	1,000,000	642,410	61,273	3,951,066
	2006	828,130	875,000	735,135	966,444		673,032	101,053	4,178,794
Kim	2007	922,560	1,395,554	3,016,933	641,709		253,899	267,133	6,497,788
	2006	821,334	900,000	1,697,749	860,070		147,507	319,240	4,745,900

506. As alleged herein, the Individual Defendants acted with scienter in that, among other things: (1) they had access to internal data concerning ENHANCE; (2) they knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of the Companies were materially false, incomplete or misleading; (3) they knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and (4) they knowingly or recklessly participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws.

507. Each of the Individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, products, growth, and financial condition, as alleged herein. The Individual Defendants were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

VII. LOSS CAUSATION

508. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Lead Plaintiffs and the Class.

509. During the Class Period, Lead Plaintiffs and the Class purchased Merck securities at artificially inflated prices and were damaged when the price of Merck securities stock declined when the truth was revealed to, and/or the information alleged herein to have been concealed from the market were revealed, causing investors' losses. Specifically, Merck's stock began to decline on January 14, 2008, with the release of the top-line ENHANCE results, continued to decline as the market digested the news and the uproar surrounding the news, and then declined dramatically on March 31, 2008, when the full ENHANCE results were released.

510. Throughout the Class Period, the Defendants' false and misleading statements and omissions concerning the success of Vytorin inflated Merck's stock price. Had the Defendants revealed the ENHANCE study results and been truthful about the efficacy of Vytorin, instead of concealing the negative results and falsely telling physicians, patients and investors that "lower is better" with regard to Vytorin, the Lead Plaintiffs and the Class would not have purchased Merck's securities, or would not have purchased them at the artificially inflated prices at which they were offered.

511. As a direct result of the Defendants' misrepresentations, and omissions of material facts, the price of Merck's common stock was artificially inflated throughout the Class Period. Because of the Defendants' misstatements and omissions, Merck's common stock closed at an average price of $48.46 per share during the Class Period, reaching a Class Period high of $60.77 per share on December 10, 2007.

512. Merck attempted to "walk the market down" by issuing a press release before the open of the markets on Monday January 14, 2008, revealing for the first time an abridged version

of the ENHANCE study results. Up until that time, based on Defendants' continued misrepresentations, investors had held out hope that the study results might be positive. Over the following two weeks, Merck's stock price plummeted as the market absorbed the information contained in the press release and as investors reacted to news that lawmakers were asking for probes regarding Merck's advertising of Vytorin, not to mention news that medical expert Dr. Nissen (the head of cardiology at the Cleveland Clinic in Ohio) stated that he did not see a "compelling reason" to use Vytorin. During this 2-week time period, Merck's stock declined $12.76 per share or over 21%, from $60.55 per share on Friday January 11, 2008 to $47.79 per share on January 25, 2008 -- wiping out well over $25 billion of the Company's market capitalization.

513. Full ENHANCE results were released Friday March 30, 2008 at the American Conference of Cardiology (ACC) held in Chicago, Illinois, and for the first time, the investing public found out the extent of Defendants' deception. Investors' reaction was swift and drastic as Merck's stock price experienced a one-day decline of $6.56 per share or 15% from $44.51 per share on Friday March 28, 2008 to $37.95 per share on Monday March 31, 2008. This one-day decline, on extremely heavy trading volume of over 81 million shares traded, wiped out an additional $14 billion in the Company's market capitalization.

514. On March 31, 2008, the Dow Jones Industrial Average rose 46.5 points and the S&P 500 rose 7.5 points. Media accounts stated that the drop in Merck's stock price was caused by the disclosure of the full ENHANCE trial results. For example, *Bloomberg* reported that Merck "sank in New York trading after heart doctors said millions of people taking the cholesterol pills Vytorin and Zetia should switch to older, cheaper drugs that work as well," and that the 15% decline was "the biggest drop since Sept. 30, 2004, when it withdrew its painkiller

Vioxx." *Marketwatch.com* reported that shares of Merck "hit the skids on Monday, retreating in the wake of the release of additional clinical data that showed their cholesterol drug Vytorin was not any more effective in battling heart disease than a cheaper generic."

515. In total, from its Class Period high of $60.77 per share on December 10, 2007 to its closing price of $37.95 per share on March 31, 2008, Merck's share price declined $22.82 per share or 38%. In addition, from January 11, 2008, Merck's last closing price prior to the January 14 partial results press release, to March 31, 2008, the Company's stock price dropped a similar 37%, wiping out nearly $48 billion in market capitalization and deflating the Company's stock price.

VIII. CLASS ACTION ALLEGATIONS

516. Lead Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Merck publicly traded securities during the Class Period May 1, 2006 through and including March 28, 2008 (the "Class"). Excluded from the Class are (a) Defendants; (b) members of the immediate families of the Individual Defendants; (c) the subsidiaries and affiliates of Defendants; (d) any person or entity who is a partner, executive officer, director or controlling person of Merck, M/S-P or S-P (including any of their subsidiaries or affiliates) or any other Defendant; (e) any entity in which any Defendant has a controlling interest; (f) Defendants' directors and officers' liability insurance carriers, and any affiliates or subsidiaries thereof; and (g) the legal representative, heirs, successors and assigns of any such excluded party.

517. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Merck has over 2 billion shares of common stock outstanding, owned

by thousands of persons, with on average daily trading volume in excess of 1 million shares during the Class Period.

518. There is a well-defined commonality in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(1) whether the 1934 Act was violated by Defendants;

(2) whether Defendants omitted and/or misrepresented material facts;

(3) whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(4) whether Defendants knew or deliberately disregarded that their statements were false and misleading**;**

(5) whether the prices of Merck's publicly traded securities were artificially inflated; and

(6) the extent of damage sustained by Class members and the appropriate measure of damages.

519. Lead Plaintiffs' claims are typical of those of the Class because Lead Plaintiffs and the Class sustained damages from Defendants' wrongful conduct.

520. Lead Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class.

521. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

IX. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

522. At all relevant times, the market for Merck's common stock was an efficient market for the following reasons, among others:

(1) Merck common stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(2) As a regulated issuer, Merck filed periodic public reports with the SEC and the NYSE;

(3) Merck regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(4) Merck was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

523. As a result of the foregoing, the market for Merck common stock promptly digested current information regarding Merck from all publicly available sources and reflected such information in the prices of the stock. Under these circumstances, all purchasers of Merck common stock during the Class Period suffered similar injury through their purchase of Merck common stock at artificially inflated prices and a presumption of reliance applies.

X. NO SAFE HARBOR

524. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the particular speaker knew that the particular

forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Merck who knew that those statements were false when made.

COUNT I

VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10(b)-5 PROMULGATED THEREUNDER AGAINST ALL DEFENDANTS

525. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

526. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

527. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period. Defendants herein are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

528. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Merck, as specified herein. In particular, Defendants engaged and participated in a continuous course of conduct to conceal adverse material information

regarding the ineffectiveness of Zetia and Vytorin in ENHANCE. Defendants concealed the negative ENHANCE results, thereby concealing the fact that Zetia and Vytorin had no impact on the reduction of arterial plaque or on cardiac health when combined with generic statin therapy. In addition, Defendants concealed and further failed to disclose that Zetia and Vytorin, as a result of ENHANCE, actually had demonstrated a negative impact on cardiac health when compared to generic statin therapy alone.

529. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct involving false and misleading statements, as specified herein, to mislead and defraud analysts, investors, and the public. In particular, Defendants made numerous affirmative misrepresentations during the Class Period, as specified herein, that generally fall within the following categories:

(1) Defendants made false and misleading statements claiming that Vytorin was safe and effective, and *better than* competing drugs, including competing statins, at improving patients' health when they knew or recklessly disregarded, as a result of ENHANCE, that such claims were untrue;

(2) Defendants made false and misleading statements regarding Vytorin's and Zetia's commercial strength, commercial success and projected future commercial success to Merck, when they knew or recklessly disregarded, as a result of ENHANCE, that such statements were untrue;

(3) Defendants falsely assured Merck investors that Merck (i) put patients before profits, (ii) abided by the highest ethical practices in all of its business and research endeavors, and (iii) was fully transparent with its business, its clinical trials, and its research, when they knew or recklessly disregarded, as a result of ENHANCE, that such statements were untrue.

530. The allegations set forth above establish a strong inference that the Defendants acted with scienter throughout the Class Period in that they had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless

disregard for the truth in that they failed to ascertain and disclose such facts. Defendants' material misrepresentations and/or omissions were done knowingly or with recklessness for the purpose and effect of concealing Merck's present and future business prospects from the investing public and supporting the artificially inflated price of Merck's securities.

531. As a result of the Defendants' dissemination of the materially false and misleading information and failure to disclose material facts, as set forth herein, the Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Merck common stock. Plaintiffs and the Class would not have purchased Merck common stock at the prices they paid, would have paid less, or would not have purchased Merck common stock at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' fraudulent scheme, misleading statements and material omissions.

532. At the time of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth herein, the Plaintiffs and the Class were ignorant of the falsity of the statements and were ignorant of the omissions.

533. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Cass suffered economic damages in connection with their purchases of Merck common stock during the Class Period when the truth was disclosed, causing the value of Merck's stock to decline dramatically.

COUNT II

VIOLATION OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

534. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

535. During the Class Period, the Individual Defendants, by virtue of their senior executive positions in Merck, were privy to confidential and proprietary information concerning Merck, its operations, finances, financial condition and present and future business prospects relating to Zetia and Vytorin. The Individual Defendants also had access to materially adverse non-public information concerning Vytorin and Zetia. Because of their positions within Merck, the Individual Defendants had access to non-public information about its business, finances, products (including Zetia and Vytorin), markets and present and future business prospects via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof and via reports and other information provided to him in connection therewith. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

536. The Individual Defendants were "controlling persons" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Merck's business.

537. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to securities analysts and through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports, press releases, advertisements and marketing materials alleged herein to be misleading, prior to or shortly after their issuance

and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

538. As senior executives and controlling persons of a publicly traded company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was, and is, traded on the NYSE and governed by the federal securities laws, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with respect to Merck's financial condition and performance, growth, operations, financial statements reflecting data for Vytorin and Zetia, business, products, markets, management, earnings and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Merck's common stock would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

539. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Merck's common stock by disseminating materially false and misleading statements and/or concealing material adverse facts concerning Vytorin and Zetia. The scheme: (i) deceived the investing public regarding the results of the ENHANCE trial, its failure to show a medically advantageous difference between Vytorin and other less expensive drugs, and the business, operations and management and intrinsic value of Merck's securities; and (ii) caused Lead Plaintiffs and members of the Class to purchase Merck's common stock at artificially inflated prices, which declined dramatically when the truth was disclosed.

540. As set forth above, the Individual Defendants and Merck each violated Section 10(b) and Rule 10b-5 by their acts and omissions. By virtue of their positions as controlling persons, the Individual Defendants are liable under Section 20(a) of the Exchange Act.

541. As a direct and proximate result of Defendants wrongful conduct, Plaintiffs and the Class suffered damages in connection with their purchases of the Company's stock during the Class Period.

COUNT III

VIOLATION OF SECTION 20A OF THE EXCHANGE ACT AGAINST INDIVIDUAL DEFENDANTS CLARK, LEWENT, AND YARNO

542. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

543. This claim is asserted pursuant to Section 20A of the Exchange Act against Defendants Clark, Lewent, and Yarno (the "20A Defendants"), by Lead Plaintiffs, on behalf of themselves and other class members who purchased shares of Merck stock contemporaneously with the sale of Merck stock by the 20A Defendants while the 20A Defendants were in possession of material, non-public, adverse information that artificially inflated the value of those Merck securities.

544. The 20A Defendants, as set forth in detail above, violated the Exchange Act by trading on inside information because each 20A Defendant at the time of his or her stock sales concealed the results of ENHANCE from the market, and/or made false and misleading statements or claims relating to Vytorin and Zetia, and/or acted as a "control person" within the meaning of Section 20(a) of the Exchange Act, with control over persons or entities otherwise violated the Exchange Act.

545. The Lead Plaintiffs made stock purchases contemporaneous to the stock sales of the 20A Defendants named in this Count. On the same day that Lewent sold 5,100 shares Merck stock (August 6, 2007) at $51.51 per share while in possession of material inside information, for example, Lead Plaintiff Detroit purchased 5,300 shares of Merck stock at $51.11 per share. Lewent also made contemporaneous sales of Merck when, on August 2, 2007, she sold 10,000 shares of her Merck holdings at $52.02 per share, because the following day, on August 3, 2007, Lead Plaintiff ABP purchased 5,287 Merck shares at $51.36 per share.

546. In total, Lewent sold nearly 50% of her Merck stock holdings during a two week period in late July and early August 2007 while concealing non-public, adverse information regarding ENHANCE and misleading the market with false and misleading statements regarding the commercial viability of Vytorin and Zetia. Lewent gained nearly $10 million by selling her Merck shares in July and August 2007.

547. Defendant Yarno also sold Merck stock contemporaneously with purchases by plaintiffs while Yarno was in possession of material non-public information. On April 25, 2007, for instance, Yarno sold 40,332 shares of Merck stock for $51.56 per share. At about the same time, on April 27, 2007, Lead Plaintiff Deka Ireland purchased 82,340 shares of Merck stock at a cost of $51.79 per share. Later during the Class Period, on October 26, 2007, Lead Plaintiff ABP purchased 24,000 shares of Merck stock at $57.41 per share, and plaintiff IFM purchased 80,000 shares for $57.40 per share. That same day, Yarno sold 147,174 shares at $57.37 per share.

548. In total, Yarno made insider stock sales valued at $10,523,030 in 2007, while concealing non-public, adverse information regarding ENHANCE and leading a false and misleading marketing effort relating to the drugs Vytorin and Zetia. These 2007 stock sales represented a sale of *all* of Yarno's Merck stockholdings, and she finally cashed out just months

before the negative ENHANCE data was released to the market causing Merck's stock to plummet.

549. Defendant Clark is also liable for violating Section 20A because he too made sales of Merck securities contemporaneous to purchases by Lead Plaintiff ABP. On April 30, 2007, for instance, Lead Plaintiff ABP bought 832,491 shares of Merck stock at a cost of $51.48 per share. Just days later, on May 3, 2007, ABP bought another 2,125 Merck shares at a cost of $51.36 per share. On May 4, 2007, while defendant Clark was in possession of material non-public information, Clark contemporaneously sold 41,050 shares of his Merck holdings at $52.02 per share. Likewise, Lead Plaintiff Detroit made contemporaneous purchases of Merck stock with Defendant Clark by purchasing 5,600 on May 11, 2007, just days after Clark's May 7 sell off.

550. In May 2007, long after the ENHANCE results were known internally, and during the Class Period while the results were concealed, Clark sold 83% of his Merck stock shares for over two million dollars. Defendant Clark sold $2 million of his Merck shares in May 2007 despite not having had any previous selling activity since 2002.

551. In addition to the Lead Plaintiffs' contemporaneous purchases with the 20A Defendants' insider sales, Class members also purchased Merck common stock on the dates that the 20A Defendants made insider sales.

552. Defendant Merck, through its officers, agents and employees, is liable pursuant to Sections 20(a) and 20A(c) of the Exchange Act for communicating material, non-public, adverse information to each of the 20A Defendants, thereby enabling them to trade on such information and damaging the Lead Plaintiffs and other members of the Class who purchased Merck securities.

553. As a direct and proximate result of the wrongful conduct alleged herein against Merck and the 20A Defendants, the Lead Plaintiffs and members of the Class have been damaged, and (among other damages) seek disgorgement of the 20A Defendants profits, or losses avoided, on account of the insider transactions listed above.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray for relief and judgment, as follows:

A. Determining that this action is a proper class action and certifying Lead Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure and Lead Plaintiffs' counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Lead Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

Dated: October 6, 2008

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JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury as to all issues so triable.

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By: /s/ James R. Banko
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Dated: October 6, 2008

CERTIFICATE OF SERVICE

The foregoing Consolidated Complaint was served on all counsel in the manner specified below:

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