



## INTRODUCTION AND OVERVIEW

1. Lead Plaintiff, the Pipefitters Union Local 537 Pension Fund and named plaintiff City of Livonia Employees' Retirement System (collectively referred to as "plaintiffs"), on behalf of themselves and all other persons similarly situated, allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys.

## NATURE OF THE ACTION

2. This is a federal securities class action brought against Wyeth (or the "Company") and certain of its officers for violations of the Securities Exchange Act of 1934 (the "Exchange Act"). This action is brought on behalf of all purchasers of Wyeth securities during the period June 26, 2006 through July 24, 2007 (the "Class Period") who were damaged as a result of the violations of federal securities laws.

### **Pristiq and VMS**

3. This action concerns defendants' false statements and omissions regarding the development of the drug Pristiq and Wyeth's New Drug Application ("NDA") for the use of Pristiq in the treatment of post-menopausal vasomotor symptoms ("VMS"). Pristiq, also known as desvenlafaxine succinate or DVS-233, is an antidepressant of the serotonin-norepinephrine reuptake inhibitor ("SNRI") class.

4. Pristiq is closely related to another drug franchise marketed by Wyeth, Effexor and Effexor XR ("XR" denotes the Extended Release Formulation). Pristiq is a "salt" of the active metabolite of Effexor and Effexor XR. Many drugs are converted or metabolized by chemical activity into other chemicals. This metabolism of a drug may result in production of one or more metabolites of the original drug. When a metabolite of a drug produces a therapeutic effect it is considered an active metabolite. An estimated one-half of all drug molecules used in medicine are

administered as salts; this is because they are often more stable, or because they offer better absorption or distribution within the body, among other various reasons. For instance, when a person takes the drug Effexor, the body converts it to desvenlafaxine (*i.e.*, Pristiq), which is the actual substance intended to cause the desired therapeutic effect.

5. Wyeth intended to market Pristiq in the U.S. for various uses, all of which would require approval from the Federal Food and Drug Administration (“FDA”). In order to gain approval for marketing from the FDA, drugs go through a monitored clinical trial process of increasing scrutiny, which culminates in Phase 3 trials in human patients.

6. Prior to the Class Period, defendants conducted three Phase 3 trials of Pristiq’s safety and efficacy in treating VMS, also known as “hot flashes” or “hot flushes.” By the time Wyeth completed the Phase 3 VMS clinical trials, the Company had invested several years and tens, if not hundreds, of millions of dollars to develop the drug and prepare it for marketing.

7. The market for therapies which treat VMS is massive in scale. In the United States alone nearly 23 million women suffer from VMS. Prior to 2002, the first-line treatment for VMS was hormone therapy – usually through a treatment of estrogen. In July 2002, however, the Women’s Health Initiative Hormone Program (“WHI”), published a 15-year study that examined the risks and benefits of taking supplemental hormones after menopause, including the hormonal therapies sold by Wyeth, Premarin and Prempro. The WHI study found that Premarin increased the risks of stroke and blood clots and that Prempro caused an increased risk of breast cancer, heart disease, stroke, blood clots and urinary incontinence. Wyeth’s sales of Premarin and Prempro plummeted from \$4.4 billion in 2001 to under \$880 million in 2004 as a result of the increased risks identified in the WHI study. Two of Wyeth’s more profitable drugs were suddenly disfavored and

the Company desperately needed a way to tap into the lucrative women's health market. Pristiq, purported to be the first non-hormonal therapy for VMS, was touted as the answer.

8. Drugs which have the potential to effectively treat chronic common health problems like post-menopausal symptoms are especially important for pharmaceutical companies from a business standpoint. As a result of their massive market potential and ability to generate revenues in excess of \$1 billion per year, such products are referred to as "blockbuster" drugs. Because of the huge market demand and the results of the WHI studies, Wyeth championed Pristiq as an alternative to the standard hormone-based treatment for VMS.

#### **Approval of Pristiq Was Vitally Important to Wyeth**

9. Wyeth, like other pharmaceutical companies, is a research-driven company and its business model depends on the development and regulatory approval of new, patent-protected products to replace other brand-name drugs as they come off patent. This series of drugs in development is referred to as the "pipeline." Indeed, the drug pipeline is critical to pharmaceutical companies' financial success and important to investors because new drug products are necessary to sustain growth and profitability. Many research-driven pharmaceutical companies have had difficulty maintaining a full pipeline in the last decade and have seen their valuation tumble or resorted to alternatives to development to fill the gaps. Alternatives include buying new drugs for the pipeline through purchase of whole pharmaceutical and biotech companies or licensing promising or already approved drugs. For instance, Wyeth made two massive biotech purchases when they bought Immunex in 1994 and a majority stake in Genetics Institute in 1996. Wyeth has also made more than 100 collaborative agreements with small biotech companies and other partners.

10. By the beginning of the Class Period, however, Wyeth and other research-driven pharmaceutical companies were operating in a climate where markedly fewer drugs had been approved in the past five years as compared to the five years prior, and far more drugs were being

rejected in the later stages of development than ever before. This phenomenon is well known, has been widely discussed in the media and has been a major issue for all pharmaceutical companies, including Wyeth. In the industry, it is most often referred to as the “pipeline problem.” In addition, the number of alternatives to development were drying up as the massive pharmaceutical companies used their financial resources to acquire the vast majority of promising small developers and therapies.

11. At the same time as its pipeline was drying up, Wyeth faced the loss of income from drugs set to go off-patent. Once a drug goes off-patent, competitors can market generic versions, which can be sold at a fraction of the cost of brand-name drugs because the sellers of generics do not have to recoup R&D and marketing costs. A drug which was worth several billion dollars in revenue per year under patent may be worth only a few million per year once there are generic competitors. Of particular importance to Pristiq, the U.S. patent protection for Wyeth’s drug Effexor expired in 2006 and generic versions of the active ingredient in Effexor were already “cannibalizing” Wyeth’s revenue streams by August 2006. Even more daunting for Wyeth, the patent protection for Effexor XR was set to expire in 2008 and generic versions of the drug were expected to launch in June 2010.

12. Wyeth’s combined 2007 sales of Effexor and Effexor XR were approximately \$3.7 billion, which represented 17% of the Company’s 2007 net revenue. The generic drug manufacturer Teva’s August 2006 launch of generic Effexor, however, quickly captured 96% of all Effexor prescriptions and Wyeth faced a similar, massive decline in its sales of Effexor XR beginning in July 2010.

13. Pristiq was one of a series of drug products that Wyeth was desperately trying to develop in order to replace the revenue streams from Effexor and Effexor XR as their patents

expired and went generic. Particularly, as the FDA became more cautious in its approach to approving new drugs, thus reducing competition for those drugs that are approved, Wyeth's ability to bring Pristiq to market was essential to the future growth of the Company.

14. If approved by the FDA, Pristiq would have another advantage for Wyeth. Because the active ingredient in Pristiq is so closely related to that contained in Effexor, Wyeth had a head start in the development of Pristiq. Indeed, as it would not be necessary for Wyeth to spend as much time and resources developing a novel compound, the Company had the potential of experiencing a longer than normal period of marketing "exclusivity." While most drugs have five to ten years of patent protection after obtaining FDA approval, Pristiq, if approved in 2007, would have had 15 years of patent protection.

15. Because Pristiq and Effexor are so closely related, however, Wyeth needed to create a material distinction between the two drugs to gain FDA approval and, ultimately, to encourage physicians to prescribe Pristiq. Initially, in conjunction with disclosures about the use of Pristiq for major depressive disorder ("MDD"), defendants asserted that Pristiq was superior to Effexor XR because it had, *inter alia*, equivalent or better efficacy, improved tolerability and did not require a different dosage than Effexor XR. Phase 3 testing of Pristiq for the treatment of MDD, however, showed that Pristiq did not differentiate with respect to efficacy or tolerability. While this did not stop Wyeth from seeking FDA approval for Pristiq for MDD, it caused analysts and investors to question the value of this "me-too" drug for MDD. In essence, why would a doctor prescribe Pristiq for MDD when it was no better than generic Effexor?

16. In an effort to distinguish Pristiq and promote Wyeth's drug pipeline, defendants increasingly focused on Pristiq as a treatment for VMS and other women's health issues. Defendants set the stage for their intention to market Pristiq under the same brand name for both

VMS and depression during the February 9, 2006 Merrill Lynch Global Pharmaceutical, Biotechnology & Medical Device Conference. During the conference, defendant Kenneth Martin (Wyeth's former Chief Financial Officer and Vice President) told investors and securities analysts:

[Pristiq], as most of you know and as I mentioned, was filed for depression indications at the end of 2005. We also are working on and plan to file for use in addressing [VMS] for postmenopausal women.

*This would be the first nonhormonal treatment for those symptoms.* We know from our work with Premarin how big that market is. In fact, until recently Premarin was the most prescribed drug in the pharmaceutical industry. . . .

The opportunity clearly is there. The market clearly is there. And if the profile of the product is where we hope it be, we think this is a – this could be a very big opportunity. . . . This is a drug that we're very optimistic about.

17. During the Class Period, defendants continued to emphasize the critical importance of Pristiq to Wyeth. For example, at Wyeth's October 5, 2006 annual conference with investors and securities analysts, defendant Robert Essner (Wyeth's Chairman and former Chief Executive Officer) stated:

*[W]e are creating a natural position for Pristiq . . . which we believe[] gives the drug multi-billion dollar potential* and which will allow it to coexist successfully with Effexor XR, in the minds of our customers and in the hands of our sales representatives.

18. During the same conference, defendant Joseph Mahady (Wyeth's Senior Vice President and President of Global Business, Wyeth Pharmaceuticals) added:

[Pristiq] begins to really differentiate itself with its ability to reduce the frequency and severity of moderate to severe [sic] vasomotor symptoms associated with . . . menopause.

\* \* \*

*[W]e predict that Pristiq has the potential to exceed \$2 billion in peak sales,* and that's the cost of the two indications that we've spoken about, MDD and VMS.

19. During a November 15, 2006 conference with investors and securities analysts, defendant Robert Ruffolo (Wyeth's Senior Vice President and President of Wyeth Research) reiterated the positioning of Pristiq as a drug primarily targeted on the women's health field:

*Our intent for Pristiq is to be used first-line.*

\* \* \*

*We think that [Pristiq] will also be important for the vasomotor indication where – it would obviously be our intent for this drug to be used as another option for women who are suffering from vasomotor symptoms, which is the number one reason women will go to the doctor to seek treatment.*

\* \* \*

*In fact, the way Pristiq looks like it's positioning itself right now, it's a drug primarily for women's health.*

20. During the Class Period, Wyeth was also trying to overcome the negative image associated with the Company's manufacturing facilities. Not only had Wyeth been forced to pay fines totaling more than \$30 million in 2000 as a result of failing to correct drug manufacturing problems that had existed at certain U.S. plants beginning in 1995, but the Company's Guyana-Puerto Rico manufacturing facility, where Pristiq was to be made, had become the subject of an FDA inquiry. In November 2005, the FDA identified phenol contamination in birth control pills, hormone replacement therapy, headache medicines, depression medicines, and other drugs at the Puerto Rico facility. Focusing attention on the purported benefits of Pristiq, and hiding known side effects associated with the drug, further served to divert attention from the problems with Wyeth's Puerto Rican manufacturing facilities.

#### **Serious Adverse Effects Associated with Pristiq Were Discovered by Defendants by 2005**

21. As of the start of the Class Period, Pristiq was one of only a couple of drugs in Wyeth's development pipeline with "blockbuster" potential and a chance to obtain FDA approval in time to offset both the declining revenues the Company faced as Effexor XR went generic and the

market's reaction to the WHI studies. As a result, investors and analysts were highly focused on Pristiq and defendants expressed confidence that Pristiq would launch in the United States in 2007.

22. While defendants were touting the benefits of Pristiq – both for women with VMS and for Wyeth's corporate coffers – and expressing their confidence in a timely launch of Pristiq in 2007, they knew that a significant number of women taking Pristiq had already suffered serious adverse events (“SAEs”) during Phase 3 clinical trials. Had defendants fully disclosed this information during the Class Period, it would have had disastrous consequences for Wyeth. Not only would it have undermined defendants' claims that Pristiq was safe for treating VMS, it would have cast serious doubt on the chances of FDA approval of the VMS NDA and damaged the Pristiq-franchise for all uses. In light of the marginal, if any, benefit Pristiq provided over generic Effexor for MDD, and the understandable reluctance of physicians to prescribe any drugs with reported safety issues, disclosure of the SAEs associated with the VMS clinical trials would have doomed Pristiq.

23. Wyeth's Study 315 commenced in December 2003 and review of the study data was completed in May 2005. The study was a randomized, double-blind study conducted in 37 locations across the United States. The purpose of this Wyeth-sponsored study was to test the efficacy, safety and tolerability of Pristiq in women for the treatment of VMS. Of 1169 women screened, 707 between the age of 37 and 78 years were randomly assigned to receive a placebo, or a 50, 100, 150 or 200-mg dose of Pristiq per day.

24. Study 315's safety and tolerability data was compiled over the course of a 52-week period during which patients were on active treatment (“during therapy”) and in the 15-days following active treatment (“post-therapy”). Wyeth's biostatistics group carried out the statistical analysis of Pristiq's efficacy, safety, and tolerability data gathered during both the therapy and post-

therapy periods. In addition, the biostatistics group received reports on all incidences of SAEs immediately from the site at which they occurred and was responsible for reporting those events within Wyeth and to the FDA through MedWatch, a global adverse event reporting system that every pharmaceutical company in the U.S. uses to report SAEs to the FDA.

25. The safety data associated with Study 315, which defendants submitted to the FDA in June 2006 along with the Pristiq NDA for the VMS indication, was dire. The data showed that the use of Pristiq for treatment of VMS could cause serious hepatic (liver damage) and cardiovascular (heart attacks, partial or complete obstruction of the coronary artery, and hypertension) side effects. In fact, during the course of Study 315, 27 women suffered SAEs, including three coronary occlusions and two heart attacks. Perhaps the most startling adverse events suffered by the women in Study 315 was that of increased high blood pressure – a major health problem for post-menopausal women. Study 315 demonstrated that women on a regimen of Pristiq were 353% to 508% more likely to suffer hypertension, depending on dosage level, in comparison to women on a placebo.

26. The safety results further showed that not a single women being treated with placebo suffered an SAE during Study 315. The relative significance of the SAEs, and all other adverse events for that matter, was only heightened as the study revealed that more women on a regimen of Pristiq who suffered from an adverse event discontinued treatment in comparison to the number of women taking placebo who discontinued their participation in the study.

27. The Study 315 SAEs, which occurred in 2003 and 2004, were handled with great urgency at Wyeth. Wyeth, as the study's sponsor, received notification of all SAEs via email within 24 hours of occurrence. Additionally, Wyeth was responsible for reporting the Pristiq SAEs to the FDA through MedWatch. Wyeth was required to report all Study 315 SAEs to the FDA within

seven days after their occurrence and, thereafter, was required to submit a follow-up report to the FDA within 14 days of the SAE's occurrence to include any further information obtained from the particular study site where the SAE occurred.

28. In addition to the negative safety data, the results of Study 315 indicated that Pristiq's effectiveness in treating VMS was only marginally better than placebo. Given the modest efficacy results, defendants knew that the SAEs uncovered during the clinical trial would dramatically reduce, if not eliminate, the likelihood of FDA approval of the drug as an indication for VMS. Indeed, the cardiovascular side effects associated with Pristiq would be of particular concern to the FDA and any physician, because the intended patient population of women who would use the drug as a non-hormonal treatment for VMS generally suffered from elevated risk of heart disease due to their age and post-menopausal status.

29. As defendants knew, Pristiq, as a treatment for VMS, would be reviewed by a different division of the FDA than the division that reviewed Pristiq for the treatment of MDD. Typically, the FDA's risk-benefit analysis of a drug compound depends on a number of factors, including the intended condition and patient population to be treated. In other words, for the treatment of a condition with serious and often fatal consequences, such as MDD in adults of all ages, the FDA will be more tolerant of side effects compared to what would be allowed in a drug marketed for treatment of a condition with less severe consequences, such as VMS in post-menopausal women. Accordingly, defendants were on notice that the FDA would apply a stricter standard to Wyeth's VMS application compared to that for MDD.

30. After receiving notice of the SAEs associated with Study 315 and prior to submitting the VMS NDA to the FDA, defendants initiated two additional studies of Pristiq – Studies 319 and 321. Consistent with Study 315, Study 319 was intended to assess the efficacy and safety of Pristiq

in treatment of moderate-to-severe VMS in comparison to placebo and Study 321 was designed to assess the efficacy and safety of Pristiq in treatment of VMS in general in comparison to placebo. Notably, however, the later studies specifically excluded patients with a history of heart attack, chest pains, elevated blood pressure and blood clots. These exclusions were not made with respect to Study 315 and the exclusions were added to reduce the likelihood of additional SAEs. By adding the exclusions, however, Wyeth was simply manipulating the study data rather than investigating further the link between Pristiq and cardiovascular and hepatic side effects.

31. Nevertheless, prior to the Class Period, defendants announced their intention to submit a NDA for Pristiq for the VMS indication and later touted Wyeth as “a leader and innovator in women’s health.” Despite submitting the Study 315 data to the FDA, defendants failed to disclose publicly the negative safety results of the study or reveal the existence or nature of the SAEs, which all indicated that Pristiq posed a real and serious risk to patients. Indeed, throughout the Class Period, defendants continued to discuss with analysts and investors the results of the Pristiq clinical studies, and the purported safety and benefits of Pristiq, but failed to disclose the known cardiovascular and hepatic side effects.

### **The Pristiq NDA and Defendants’ False Statements and Omissions**

32. By June 26, 2006, the beginning of the Class Period, defendants were well aware of or recklessly disregarded the SAEs reported during Study 315, including the hepatic and cardiovascular side effects associated with the use of Pristiq for the treatment of VMS. Nevertheless, defendants publicly discussed the purported benefits of Pristiq and submitted a NDA to the FDA for marketing approval of Pristiq for the VMS indication. The NDA included data from the Pristiq clinical trials, including data from Study 315, which was not made available to investors or the public.

33. Rather than disclose the critical information about the SAEs associated with Pristiq to investors and risk the sudden decline in the price of Wyeth's stock that would ensue, following the submission of the Pristiq VMS application, defendants continued to issue false and misleading statements in press releases, SEC filings and during conference calls. Defendants' statements reassured investors that Pristiq was safe and effective, would fill the unmet needs of millions of women suffering from both VMS and depression, would replace the revenue stream from Effexor and could generate billions of dollars in revenue for Wyeth.

34. Throughout the Class Period, defendants told investors that Pristiq would be the first FDA-approved non-hormonal treatment for VMS, “[p]roviding [s]pecific [b]enefits for [o]ver 35 [m]illion [w]omen.” During Wyeth's October 5, 2006 annual conference with investor and securities analysts, defendants declared Pristiq to be the “*first and only SNRI proven to effectively address the distinctive symptoms and therapeutic needs of women with depression associated with menopause [and] vasomotor symptoms,*” “*giv[ing] the drug multi-billion dollar potential.*” Securities analysts following Wyeth repeated defendants' misleading statements and omissions, emphasizing that Pristiq would be the “first non-hormonal treatment of moderate-to-severe vasomotor symptoms (VMS) associated with menopause” and confirming the Company's expectation of annual sales of \$2 billion or more for the drug.

35. Defendants also told investors that Pristiq was at least as effective as its number one selling anti-depressant Effexor, and would create an enhanced market opportunity for the Company given the product's ability to treat both depression and VMS, but never disclosed the serious hepatic and cardiovascular side effects associated with the drug. Securities analysts following Wyeth repeated defendants' statements and emphasized to the market the importance of Pristiq for Wyeth's

stock, given the loss of Effexor XR revenue by mid-2010 and projected sales for Pristiq in the billions of dollars.

36. Despite knowing about the SAEs reported during Study 315, defendants repeatedly assured the market about the prospects for FDA approval of Pristiq for VMS. Defendants' false statements included: "*we think we have a package that could warrant approvability by FDA*"; "*I think it's fair to say that our regulatory and clinical teams, however, remain pretty optimistic that the current filing can result in favorable action by April 23rd*"; "*[w]e think the package that we filed is an approvable one*"; and "*[w]e're optimistic about approval . . . [f]ollowing FDA approval we'll be prepared to launch Pristiq in the U.S. as the first FDA approved non-hormonal therapy for the treatment of moderate to severe vasomotor symptoms in menopause.*"

37. During numerous conference calls defendants also gave investors assurances that Pristiq was safe and effective, stating that Pristiq "*possesses much of the proven SNRI clinical profile with respect to safety and safety, efficacy, and tolerability*" and Pristiq had a well established cardiovascular safety profile, "*[p]roviding [s]pecific [b]enefit for [o]ver 35 [m]illion [w]omen.*" In a May 9, 2007 press release, when Wyeth discussed clinical trial results evaluating Pristiq's safety and efficacy for the treatment of VMS, defendants failed to disclose the severity and impact of SAEs discovered during Study 315, instead assuring investors, the market and potential patients that the "*most common side effect in all three studies was nausea.*"

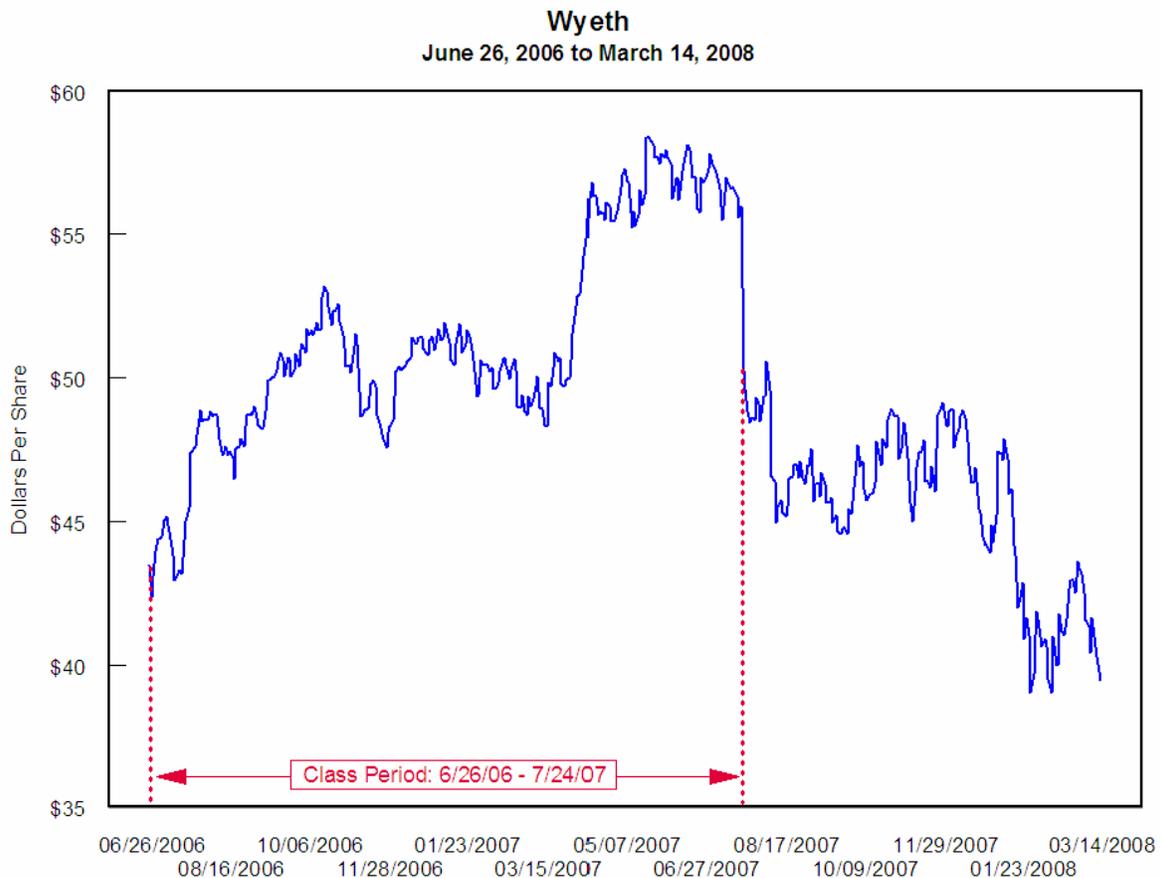
38. Less than a week before the end of the Class Period, on July 19, 2007, when asked by an analyst to summarize Pristiq's cardiovascular profile, defendants again failed to disclose the serious cardiovascular risks reported in Study 315. Rather than disclosing the truth about the known side effects, defendant Bernard Poussot (Wyeth's President and Chief Operating Officer) stated that

*“[o]n the cardiovascular profile, we stand by the safety of the product” and “we believe we have a very safe product and stand by that.”*

39. Defendants’ statements throughout the Class Period were false and misleading and concealed the SAEs and safety issues uncovered during the Pristiq clinical trials for VMS. Specifically, defendants failed to disclose that Study 315 identified SAEs, including liver damage, cardiovascular events and hypertension, associated with the use of Pristiq for VMS.

40. Defendants’ misstatements and omissions were well-timed and calculated to deceive shareholders and inflate the value of Wyeth’s stock. Indeed, in a series of coordinated sales during the Class Period, defendants Essner, Mahady, Martin, Poussot and Ruffolo dumped more than 1.55 million shares of their Wyeth stock for insider trading proceeds of \$83.82 million.

41. The following chart illustrates the artificial inflation of Wyeth’s stock during the Class Period and its dramatic decline upon the FDA’s announcement of its concerns about Pristiq’s safety profile for the treatment of VMS and the need for additional, long-term studies to evaluate the previously undisclosed cardiovascular and hepatic safety issues.



### **The Truth Is Uncovered and the FDA Requires Additional Studies of the SAEs**

42. On July 24, 2007, defendants issued a press release stating that the Company failed to gain FDA approval for Pristiq for the treatment of VMS until it received additional information concerning potentially serious liver damage and cardiovascular side effects associated with the use of the drug. Defendants further disclosed that the FDA demanded that Wyeth conduct additional clinical research – including at least one Phase 3 trial to be conducted over the course of at least one year in a population of post-menopausal women – before the agency would consider approving the drug for the VMS indication.

43. The July 24, 2007 disclosures were essentially a rejection of Pristiq as a VMS treatment and posed a serious threat to the Company's drug pipeline. Barbara Ryan, an equity analyst for Deutsche Bank Securities, reported on July 24, 2007:

This blow to Pristiq will intensify the company's exposure to Effexor generics in 2010 . . . .

\* \* \*

In our view, the fact that Pristiq would be a "non-hormonal" treatment for [VMS], was the only visible commercial hook for this "me too" SNRI. *For all intents and purposes, this indication is dead . . . [and] will intensify the company's exposure to Effexor [XR] generics in 2010 . . . .*

44. Within two months of announcing the Pristiq-VMS setback, in August 2007, Wyeth announced that it had terminated a Phase 3 study of Pristiq as a treatment for fibromyalgia. In addition, in August 2007, Wyeth cancelled its Study 407 (Pristiq as a treatment for breast cancer survivors) as a result of the FDAs refusal to approve Pristiq for VMS due to safety concerns.

45. Then, on March 12, 2008, Wyeth announced that it was withdrawing its application for European Marketing Authorization for Pristiq as a treatment for VMS. Like the FDA in July 2007, the European Medicines Agency ("EMA") had concerns about the drug's association with serious hepatic and cardiovascular side effects. In response to the EMA's concerns, Wyeth stated that "planned" clinical trials, including a 12-month study to be initiated in early 2008, would address the EMA's questions about the drug's safety.

46. As of March 12, 2008, however, Wyeth had not enrolled any patients in the 12-month Pristiq safety study to address the FDA and EMA's concerns with the hepatic and cardiovascular side effects.

### **Wyeth's Stock Drops Sharply as a Result of the July 24, 2007 Disclosures**

47. As a result of the July 24, 2007 disclosures, Wyeth's stock price dropped more than 10%, \$5.70 per share, on extremely heavy volume. Within three trading days, Wyeth's stock was trading below \$49.00 per share – near where it was at the start of the Class Period.

48. The dramatic drop in Wyeth's stock price reflected investor and analyst estimates of far lower earnings due to the cardiovascular and hepatic side effects associated with Pristiq and the FDA demand for additional studies. Credit Suisse analyst Catherine Arnold reported that, as a result of the July 24, 2007 disclosures, estimates for Pristiq's future earnings were reduced from \$2.6 billion to only \$378 million, *a \$2.2 billion reduction*, by 2011. Another analyst, Jon LeCroy, M.D., of Natixis Bleichroeder, Inc. confirmed that the disclosure of the safety issues associated with Pristiq “suggests that Pristiq will have extreme difficulty replacing Effexor XR lost sales, implying that *Wyeth will face an extremely large earnings cliff in 2011.*”

### **THE PARTIES**

#### **Lead Plaintiff**

49. By Court Order dated February 26, 2008, the Pipefitters Union Local 537 Pension Fund (or the “Fund”) was appointed as Lead Plaintiff in this action. The Pipefitters Union Local 537 Pension Fund is a joint employee-employer Taft-Hartley pension fund managed and administered in Alston, Massachusetts. The Fund was organized for the benefit of current and retired members of Pipefitters Local 537. As set forth in the Certification the Pipefitters Union Local 537 Pension Fund filed in connection with its motion to be appointed Lead Plaintiff, the Fund purchased Wyeth securities during the Class Period and, as a result of the defendants' conduct detailed herein, suffered damages in connection with the purchase of Wyeth securities.

**Additional Named Plaintiff**

50. The City of Livonia Employees' Retirement System (or the "Retirement System") filed one of the original complaints in this action and remains in this action as a named plaintiff and a proposed Class Representative. The City of Livonia Employees' Retirement System is based in Livonia, Michigan, the eighth largest city in the state, and was organized for the benefit of current and retired public employees of the City of Livonia. As set forth in the Certification the City of Livonia Employees' Retirement System filed with their original complaint in this action, the Retirement System purchased Wyeth securities during the Class Period and, as a result of the defendants' conduct detailed herein, suffered damages in connection with the purchase of Wyeth securities.

**Defendants**

51. Wyeth develops, produces and markets pharmaceuticals, as well as over-the-counter treatments, nutritional supplements and animal vaccines. Organized in 1926, the Company currently markets and sells various pharmaceutical products around the world, reporting net income in 2007 of more than \$4.6 billion. Wyeth's stock trades on the New York Stock Exchange under the symbol WYE. Throughout the Class Period, Wyeth traded in an efficient market on the New York Stock Exchange.

52. Defendant Robert Essner was, at all relevant times, the Chairman of the Board and Chief Executive Officer of Wyeth. In addition to serving as the Chairman of the Board and Chief Executive Officer, Essner was Chairman of the Executive Committee of the Board and Chairman of Wyeth's Law/Regulatory Review Committee along with defendants Bernard Poussot, Kenneth Martin, Joseph Mahady and Robert Ruffolo. The Law/Regulatory Review Committee met regularly during the Class Period and was tasked with monitoring legal and regulatory issues pertinent to Wyeth, including the FDA submissions for Pristiq. According to Wyeth's corporate governance

policies, the Law/Regulatory Review Committee was responsible for environmental, health and safety compliance, and the members of the committee “continually evaluate and assess [Wyeth’s] products and processes in order to reduce adverse environmental, health, and safety impacts.” Essner was also a member of the Wyeth Board’s Operations Committee.

(a) As part of his duties as Chairman of the Board and Chief Executive Officer, Essner was responsible for monitoring and reporting to investors and the market on the status of Wyeth’s pharmaceutical pipeline and new drug applications. In particular, throughout the Class Period, Essner presented himself as knowledgeable about the status and results of Wyeth’s clinical trials and the NDA for the use of Pritiq for VMS.

(b) During the Class Period, Essner participated in the issuance of false and misleading statements and failed to disclose the known SAEs uncovered in Wyeth’s clinical trials for the use of Pristiq for VMS. As detailed in ¶¶62-106, Essner publicly communicated with investors and the market regarding Wyeth’s clinical trials, the Pristiq NDAs and the use of Pristiq for VMS, was responsible for Wyeth’s press releases and SEC filings and represented himself as one of the primary persons with knowledge about Pristiq. In addition to issuing statements throughout the Class Period, defendant Essner repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Wyeth.

(c) In conjunction with each of Wyeth’s public financial statements filed with the SEC during the Class Period, Essner signed a certification pursuant to §302 of the Sarbanes-Oxley Act, attesting that he reviewed the contents of the filing to confirm the “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.” To assure that the certification was not simply a hollow gesture, Essner was required to and did further

confirm that he, along with defendant Martin was responsible for establishing and maintaining Wyeth's disclosure controls and procedures, had designed such controls to assure that material information relating to Wyeth's business was promptly made known to Essner and the Company's senior executives and had routinely evaluated the effectiveness of the Company's policies with regard to assuring that he and other executives were made aware of material information. At no time during the Class Period did Essner or any other defendant assert that they were not aware of material aspects of the status and results of Wyeth's clinical trials and the NDA for the use of Pristiq for VMS.

(d) During the Class Period, while in possession of material, undisclosed information about the SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS, Essner sold 177,610 shares of his personal Wyeth stock for insider trading proceeds of \$9,231,648. Essner's stock sales were not part of any pre-established trading plan and were dramatically out of line with his pre- and post-Class Period trading practices.

53. Defendant Joseph Mahady was, at all relevant times, Senior Vice President of Wyeth and President of Global Business at Wyeth Pharmaceuticals. In addition to serving as Senior Vice President of Wyeth and President of Global Business at Wyeth Pharmaceuticals, Mahady was a member of the Management Committee and was a member of Wyeth's Law/Regulatory Review Committee along with defendants Essner, Poussot, Martin and Ruffolo. The Law/Regulatory Review Committee met regularly during the Class Period and was tasked with monitoring legal and regulatory issues pertinent to Wyeth, including the FDA submissions for Pristiq. According to Wyeth's corporate governance policies, the Law/Regulatory Review Committee was responsible for environmental, health and safety compliance, and the members of the committee "continually

evaluate and assess [Wyeth's] products and processes in order to reduce adverse environmental, health, and safety impacts.”

(a) As part of his duties as Senior Vice President of Wyeth and President of Global Business at Wyeth Pharmaceuticals, Mahady was responsible for monitoring and reporting to investors and the market on the status of Wyeth's pharmaceutical pipeline and new drug applications. In particular, throughout the Class Period, Mahady presented himself as knowledgeable about the status and results of Wyeth's clinical trials and the NDA for the use of Pristiq for VMS.

(b) During the Class Period, Mahady participated in the issuance of false and misleading statements and failed to disclose the known SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS. As detailed in ¶¶62-106, Mahady publicly communicated with investors and the market regarding Wyeth's clinical trials, the Pristiq NDAs and the use of Pristiq for VMS, was responsible for Wyeth's press releases and SEC filings and represented himself as one of the primary persons with knowledge about Pristiq. In addition to issuing statements throughout the Class Period, defendant Mahady repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Wyeth.

(c) During the Class Period, while in possession of material, undisclosed information about the SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS, Mahady sold 202,000 shares of his personal Wyeth stock for insider trading proceeds of \$10,344,420. Mahady's stock sales were not part of any pre-established trading plan and were dramatically out of line with his pre- and post-Class Period trading practices.

54. Defendant Kenneth Martin was, at all relevant times, Chief Financial Officer and Vice Chairman of Wyeth. In addition to serving as Chief Financial Officer and Vice Chairman,

Martin was a member of the Management Committee and Operations Committee and was a member of Wyeth's Law/Regulatory Review Committee along with defendants Essner, Poussot, Mahady and Ruffolo. The Law/Regulatory Review Committee met regularly during the Class Period and was tasked with monitoring legal and regulatory issues pertinent to Wyeth, including the FDA submissions for Pristiq. According to Wyeth's corporate governance policies, the Law/Regulatory Review Committee was responsible for environmental, health and safety compliance, and the members of the committee "continually evaluate and assess [Wyeth's] products and processes in order to reduce adverse environmental, health, and safety impacts."

(a) As part of his duties as Chief Financial Officer and Vice Chairman, Martin was responsible for reporting to investors and the market on the status of Wyeth's pharmaceutical pipeline and new drug applications. In particular, throughout the Class Period, Martin presented himself as knowledgeable about the status and results of Wyeth's clinical trials and the NDA for the use of Pristiq for VMS.

(b) During the Class Period, Martin participated in the issuance of false and misleading statements and failed to disclose the known SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS. As detailed in ¶¶62-106, Martin publicly communicated with investors and the market regarding Wyeth's clinical trials, the Pristiq NDAs and the use of Pristiq for VMS, was responsible for Wyeth's press releases and SEC filings and represented himself as one of the primary persons with knowledge about Pristiq. In addition to issuing statements throughout the Class Period, defendant Martin repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Wyeth.

(c) In conjunction with each of Wyeth's public financial statements filed with the SEC during the Class Period, Martin signed a certification pursuant to §302 of the Sarbanes-Oxley

Act, attesting that he reviewed the contents of the filing to confirm the “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.” To assure that the certification was not simply a hollow gesture, Martin was required to and did further confirm that he, along with defendant Essner was responsible for establishing and maintaining Wyeth’s disclosure controls and procedures, had designed such controls to assure that material information relating to Wyeth’s business was promptly made known to Martin and the Company’s senior executives and had routinely evaluated the effectiveness of the Company’s policies with regard to assuring that he and other executives were made aware of material information. At no time during the Class Period did Martin or any other defendant assert that they were not aware of material aspects of the status and results of Wyeth’s clinical trials and the NDA for the use of Pristiq for VMS.

(d) During the Class Period, while in possession of material, undisclosed information about the SAEs uncovered in Wyeth’s clinical trials for the use of Pristiq for VMS, Martin sold 637,641 shares of his personal Wyeth stock for insider trading proceeds of \$35,608,037. Martin’s stock sales were not part of any pre-established trading plan and were dramatically out of line with his pre- and post-Class Period trading practices.

55. Defendant Bernard Poussot was, at all relevant times, President, Chief Operating Officer and Vice Chairman of the Board of Directors. In addition to serving as President, Chief Operating Officer and Vice Chairman of the Board of Directors, Poussot was a member of the Management Committee and Operations Committee and was a member of Wyeth’s Law/Regulatory Review Committee along with defendants Essner, Martin, Mahady and Ruffolo. The Law/Regulatory Review Committee met regularly during the Class Period and was tasked with

monitoring legal and regulatory issues pertinent to Wyeth, including the FDA submissions for Pristiq. According to Wyeth's corporate governance policies, the Law/Regulatory Review Committee was responsible for environmental, health and safety compliance, and the members of the committee "continually evaluate and assess [Wyeth's] products and processes in order to reduce adverse environmental, health, and safety impacts."

(a) As part of his duties as President, Chief Operating Officer and Vice Chairman of the Board of Directors, Poussot was responsible for monitoring and reporting to investors and the market on the status of Wyeth's pharmaceutical pipeline and new drug applications. In particular, throughout the Class Period, Poussot presented himself as knowledgeable about the status and results of Wyeth's clinical trials and the NDA for the use of Pristiq for VMS.

(b) During the Class Period, Poussot participated in the issuance of false and misleading statements and failed to disclose the known SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS. As detailed in ¶¶62-106, Poussot publicly communicated with investors and the market regarding Wyeth's clinical trials, the Pristiq NDAs and the use of Pristiq for VMS, was responsible for Wyeth's press releases and SEC filings and represented himself as one of the primary persons with knowledge about Pristiq. In addition to issuing statements throughout the Class Period, defendant Poussot repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Wyeth.

(c) During the Class Period, while in possession of material, undisclosed information about the SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS, Poussot sold 267,266 shares of his personal Wyeth stock for insider trading proceeds of \$13,883,880. Poussot's stock sales were not part of any pre-established trading plan and were dramatically out of line with his pre- and post-Class Period trading practices.

56. Defendant Robert Ruffolo, Jr. was, at all relevant times, Senior Vice President and President of Wyeth Research. In addition to serving as Senior Vice President and President of Wyeth Research, Ruffolo was a member of the Management Committee and Operations Committee and was a member of Wyeth's Law/Regulatory Review Committee along with defendants Essner, Poussot, Martin and Mahady. The Law/Regulatory Review Committee met regularly during the Class Period and was tasked with monitoring legal and regulatory issues pertinent to Wyeth, including the FDA submissions for Pristiq. According to Wyeth's corporate governance policies, the Law/Regulatory Review Committee was responsible for environmental, health and safety compliance, and the members of the committee "continually evaluate and assess [Wyeth's] products and processes in order to reduce adverse environmental, health, and safety impacts."

(a) As part of his duties as Senior Vice President and President of Wyeth Research, Ruffolo was responsible for monitoring and reporting to investors and the market on the status of Wyeth's pharmaceutical pipeline and new drug applications. In particular, throughout the Class Period, Ruffolo presented himself as knowledgeable about the status and results of Wyeth's clinical trials and the NDA for the use of Pristiq for VMS.

(b) During the Class Period, Ruffolo participated in the issuance of false and misleading statements and failed to disclose the known SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS. As detailed in ¶¶62-106, Ruffolo publicly communicated with investors and the market regarding Wyeth's clinical trials, the Pristiq NDAs and the use of Pristiq for VMS, was responsible for Wyeth's press releases and SEC filings and represented himself as one of the primary persons with knowledge about Pristiq. In addition to issuing statements throughout the Class Period, defendant Ruffolo repeatedly had the opportunity to correct any misstatement or omission by or on behalf of Wyeth.

(c) During the Class Period, while in possession of material, undisclosed information about the SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS, Ruffolo sold 270,000 shares of his personal Wyeth stock for insider trading proceeds of \$14,756,800. Ruffolo's stock sales were not part of any pre-established trading plan and were dramatically out of line with his pre- and post-Class Period trading practices.

57. Defendant Ginger Constantine was, at all relevant times, Vice President of Women's Health. Constantine was one of the top two clinicians in the Women's Health division and, as part of her duties as Vice President of Women's Health, Constantine was responsible for monitoring studies related to women's health issues, including Wyeth's Pristiq clinical trials. Constantine personally sat in on Study Team meetings evaluating the data on Pristiq and, during the Class Period, Constantine presented herself as knowledgeable about the status and results of Wyeth's clinical trials and the NDA for the use of Pristiq for VMS.

(a) During the Class Period, Constantine also participated in the issuance of false and misleading statements and failed to disclose the known SAEs uncovered in Wyeth's clinical trials for the use of Pristiq for VMS. As detailed in ¶¶62-106, Constantine publicly communicated with investors and the market regarding Wyeth's clinical trials, NDA and the use of Pristiq for VMS and represented herself as one of the primary persons with knowledge about the use of Pristiq for VMS.

### **JURISDICTION AND VENUE**

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

59. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and §27 of the Exchange Act.

60. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Many of the acts and transactions giving rise to the violations of law complained of herein occurred in substantial part in this District. Wyeth's securities trade on the New York Stock Exchange, which is located in this District, and the Company maintains corporate offices in this District in Pearl River, New York

61. 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 U.S. mails, interstate telephone communications and the facilities of the national securities markets.

#### **FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD**

62. The Class Period begins on June 26, 2006, when defendants issued a press release and announced that Wyeth had submitted a NDA for Pristiq for the VMS indication. The press release stated in part: "The simultaneous submission of these . . . NDAs emphasizes Wyeth's position as a leader and innovator in women's health." Previously, on May 25, 2006, defendants had reported that the Pristiq Phase 3 clinical trials had been successful, that the adverse events in the trials were "mild or moderate in severity" and that Pristiq "did not affect the QT interval . . . , one of many important measures of cardiovascular safety."

63. On July 12, 2006, defendants Essner and Martin participated in the Wyeth Mid-Year Business Update conference call with investors and analysts. During the call, defendant Essner reiterated that Wyeth had filed the Pristiq NDA for VMS and extensively discussed Pristiq, stating that "the first half of 2006 has seen many significant accomplishments at Wyeth. . . . We made two NDA filings, for bazedoxifene for osteoporosis prevention and [Pristiq] *as a nonhormonal treatment for menopausal symptoms.*" Commenting on additional clinical trials for Pristiq, Essner

said: “I don’t think this is being done at all for the FDA. This is being done to expand the profile of the product.”

64. During the July 12, 2006 conference call, defendants Essner and Martin also responded to numerous questions from analysts regarding Pristiq and Wyeth’s clinical trials associated with Pristiq. During the call, Essner responded to analyst questions and stated that “*these [Pristiq] studies have been underway for some time, and were part of the long-term development plan for the product*” and “*we feel very comfortable launching with the current package and current doses. . . . [W]e’re very comfortable launching this product with its current regimen.*”

65. On July 20, 2006, Wyeth held a second quarter 2006 earnings conference call with investors and analysts. During the conference call, defendants Poussot and Martin discussed and responded to questions about Pristiq. Addressing a question about the pending Pristiq NDAs, defendant Poussot stated that “*we think we have a package that could warrant approvability by FDA, so that is why we filed.*”

66. On August 7, 2006, defendants filed Wyeth’s Form 10-Q for the quarter ended June 30, 2006 with the SEC. The August 7, 2006 Form 10-Q discussed Pristiq and the Pristiq NDAs filed with the FDA. Filed together with Wyeth’s Form 10-Q were certifications from defendants Essner and Martin in compliance with §§302 and 906 of the Sarbanes-Oxley Act of 2002. Included in the certifications were statements by Essner and Martin asserting that they had reviewed Wyeth’s Form 10-Q and that the public 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.”

67. Defendants' statements made between June 26 and August 7, 2006, were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that usage of Pristiq for treatment of VMS was associated with hepatic and cardiovascular side effects, including heart attacks, partial or complete obstruction of the coronary artery and hypertension;

(b) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that 27 women on a treatment regimen of Pristiq for VMS suffered SAEs either during the therapy or post-therapy periods. In comparison, no women in the placebo-treated group suffered an SAE during the therapy or post-therapy periods. Moreover, the significance of all adverse events was increased because significantly more women on a treatment regimen of Pristiq discontinued their participation in the study in comparison to those women who received placebo;

(c) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that as the dose of Pristiq was increased, the incidence of hypertension increased in women treated with the drug. For instance, hypertension was reported in only 1.3% of the placebo-treated group, while an average of 5.9% of all women in the Pristiq-treated group reported hypertension and 7.9% of women receiving a 200-mg dose of Pristiq reported suffering from hypertension. Given that the target market for Pristiq for VMS – post-menopausal women – would have heightened sensitivity to hypertension, these results were particularly material to any evaluation of Pristiq; and

(d) After receiving the results of Study 315 and prior to filing the VMS NDA for Pristiq, defendants initiated two additional studies of Pristiq and VMS – Study 319 and Study 321. In the aftermath of the Study 315 SAEs, however, defendants excluded from the later studies any woman with a history of heart attack, chest pains, elevated blood pressure and blood clots, changing the exclusion criteria to reduce the likelihood of additional SAEs. As a result, the safety data for Study 319 and Study 321 were manipulated and were not comparable to Study 315.

68. As a result of defendants’ false statements and omissions between June 26 and August 7, 2006, Wyeth stock traded at artificially inflated levels. Indeed, during the period July 13 through July 24, 2006, defendants’ misleading statements and omission of material information about Pristiq had a direct effect on Wyeth’s stock price, which increased \$4.46 per share.

69. On October 5, 2006, defendants Essner, Poussot, Mahady, Ruffolo and Constantine hosted Wyeth’s annual conference for analysts and investors, which focused on the major clinical programs in Wyeth’s pipeline, including Pristiq. During the conference, defendants re-introduced Pristiq as “a single product for two indications” rather than the two distinct product approaches – one for MDD and one for VMS – Wyeth had initially planned. During a slide presentation at the conference, defendants presented Pristiq as the “*first and only SNRI proven to effectively address the distinctive symptoms and therapeutic needs of women with depression associated with menopause, vasomotor symptoms and fibromyalgia*” and “*the first non-hormonal treatment of moderate-to-severe vasomotor symptoms (VMS) associated with menopause.*” During the slide presentation, defendants also declared Pristiq “*[s]imilar to Effexor XR in terms of efficacy, safety and tolerability*” and that Pristiq had a “*[w]ell-established QTc safety profile . . . [p]roviding [s]pecific [b]enefits for [o]ver 35 [m]illion [w]omen.*” The slide presentation also reiterated the purportedly positive Phase 3 clinical trial results for Pristiq both in terms of efficacy and safety.

70. During Wyeth's October 5, 2006 conference, defendant Essner reiterated the re-positioning of Pristiq to a "single product for two indications" and, comparing the product to Effexor XR, Essner stated:

You'll hear how we are creating a natural position for Pristiq, which is our brand name for DVS-233, which we believes [sic] ***gives the drug multi-billion dollar potential*** and which will allow it to coexist successfully with Effexor XR, in the minds of our customers and in the hands of our sales representatives.

71. During Wyeth's October 5, 2006 conference, defendant Mahady discussed the differentiation between Pristiq and Effexor and the market potential for Pristiq stating:

***What's been demonstrated to date is that Pristiq possesses much of the proven SNRI clinical profile with respect to efficacy, safety, tolerability.***

\* \* \*

With Pristiq, the molecule begins to really differentiate itself with its ability to reduce the frequency and severity of moderate to severe [sic] vasomotor symptoms associated with the menopause.

Subject to approval, it will be the first and only approved non-hormonal product for this indication. Now, while the WHI trial may have reduced the number of prescriptions that were written for hormone products by almost 50%. Those findings did nothing to reduce the number of women suffering from menopausal symptoms or the severity of those symptoms.

There are nearly 23 million women in just the United States who are menopausal and experiencing hot flashes. Of those with natural menopause, only 10% use hormone therapy. And while those with hysterectomies, even that group, only about 30% of those in therapy today.

***Pristiq is the only approved non-hormonal product. It will fill a significant unmet medical need in women's health, and I've got to tell you, we at Wyeth are really pleased to expand the options for women in this important population.***

***Clearly, the two pending NDAs, depression and VMS, yield critical points of entry into two large and exciting markets, where Wyeth was already well established from a commercial perspective. The resulting combined label will be unique among all other SSRIs and SNRIs.***

But as we continued to move Pristiq through development, our scientists became more excited by data suggesting that the transition of women into menopause can be associated with new onsets or a recurrence of major depressive episodes.

\* \* \*

So as we look to the emerging profile of Pristiq and the patient needs, we saw an overlap of opportunities, really, that existed in this population of females and in particular the population who are at a point in their lives where symptoms of the menopause and depression are so frequently encountered.

So what we initially envisioned as two products, one indicated for depression, the other indicated for VMS, has really evolved into a single product for two indications, each of which can present first-line therapy for a broad population of women. . . .

Now, when you consider just the two filed indications, depression and vasomotor symptoms, as well as the indication for fibromyalgia, which is still in development, *we see a female patient population, corrected for overlap, of over 35 million patients, and again, that's just using the US market.*

And let me address something very quickly. Pristiq works equally well in men, equally well in younger women with depression. But its intrinsic pharmacologic properties, the manner in which it's been developed and the way we introduce it to the market may enable it to be uniquely valuable to women and the physicians who treat them.

72. Defendant Constantine also spoke at Wyeth's October 5, 2006 conference and discussed the market for Pristiq and the Phase 3 trials. During the conference, Constantine stated:

Interestingly, we have evidence to support particular benefits of this SNRI, or Pristiq, versus other SSRIs in major depression, vasomotor symptoms and fibromyalgia.

\* \* \*

*It's important to keep in mind that we use the most conservative analysis approach to analyze these [clinical trial] data.*

\* \* \*

So now let's review Pristiq's beneficial effects on the treatment of vasomotor symptoms. Vasomotor symptoms are also referred to as hot flashes, hot flushes or VMS. You'll hear all of them. No matter what you call them, they are the number-one reason that women go to their doctors for menopause.

Vasomotor symptoms usually begin several years before the menopause. They peak at around age 54. Their main duration is about two to three years, although some women may experience as much as 15 years – that's about 15% of women. *We have seen that Pristiq is effective in treating vasomotor symptoms, and this was demonstrated at both 100 and 150 milligrams in our two pivotal trials.*

\* \* \*

Pristiq also achieved statistically significant positive results across all of the domains that were looked at.

\* \* \*

So, Pristiq is our first non-hormonal agent, specifically designed to meet the needs of a woman, that allows physicians to provide a non-hormonal option to women who may have multiple symptoms. This includes depression and vasomotor system, especially during the peri- and postmenopausal period.

73. Discussing the safety and tolerability profile for Pristiq during Wyeth's October 5, 2006 conference, Constantine failed to disclose the known cardiovascular and hepatic side effects, but stated:

*Now I'm going to talk about the safety and tolerability profile for Pristiq. The safety and tolerability profile of Pristiq in both programs, vasomotor symptoms and MDD is consistent with the SNRI class.*

\* \* \*

In the MDD program, nausea was the most frequent adverse event reported in Pristiq subjects. . . .

. . . A very similar pattern can be described for the vasomotor program.

\* \* \*

*Additional safety features include no prolongation of QT interval in a specific QT study. Blood pressure and pulse were comparable with other SNRIs. Importantly, Pristiq has very low drug-drug interactions, and this is important in this population, because agents that a postmenopausal woman may take will not be affected by Pristiq, whereas others, SSRIs, SNRIs, may affect cytochrome pathways which are spared by Pristiq.*

74. During the October 5, 2006 conference, defendant Mahady also discussed Pristiq's NDA and prospects for FDA approval, stating:

So where are we in our planning for Pristiq? As you heard, two NDAs filed and a significant amount of ongoing development around Pristiq. Now, we've already said, we've got a solid Effexor XR franchise in place, *we've got a period of Pristiq exclusivity for 2022, and we see a real opportunity for Pristiq to actually broaden our SNRI franchise and not only serve – and it's an important role, as a replacement for Effexor.*

The NDA for Effexor is well advanced in the review process. And from my perspective, I'm moving on presuming that we resolve this Puerto Rico warning letter issue in time to not interfere with any launch plans. I think Bernard is going to address that a little bit later in his talk.

*So, at the current time, we are not aware of any issues that would prevent approval* by the action date of January 22nd.

\* \* \*

Now, remember, the NDA for VMS was filed in June. Our regulatory group has already received the notice of acceptance of the filing by FDA and the potential review issue. And Ginger [Constantine] has highlighted that one issue on one primary time point. *I think it's fair to say that our regulatory and clinical teams, however, remain pretty optimistic that the current filing can result in favorable action by April 23rd. And it's with that potential of an April action date that you can see why we want to plan our launch options for both indications, to take advantage of potential synergies and the excitement that can come from bringing these two products with a focus on women's health at or about the same time.*

Now, we have more than 15 years of Pristiq exclusivity and an opportunity to actually build a new franchise with specific value focused on women. Should these efforts prove successful, we predict that Pristiq has the potential to exceed \$2 billion in peak sales, and that's the cost of the two indications that we've spoken about, MDD and VMS. This does not include any numbers for neuropathic pain or fibromyalgia.

75. During the conference, defendant Mahady also responded to a securities analyst's question as follows:

[ANALYST]: Can you qualify your greater than \$2 billion estimate that you put up for Pristiq.

\* \* \*

MAHADY: . . . *The 2 billion estimate is for vasomotor and depression combined.* It does not include the other indication. It is global in perspective, so it accommodates all of our global launch plans there.

76. During the October 5, 2006 Wyeth conference, defendant Poussot also spoke about the importance of Pristiq to Wyeth's pharmaceutical pipeline:

And Pristiq is emerging differently from what we initially envisaged, a replacement for Effexor. We started with two development programs, one in vasomotor symptoms, and *in the course of this dual-development effort we realized that Pristiq could be the answer to several conditions that develop frequently in the female*

*population around menopause. And that's depression, vasomotor symptoms or both.*

Such a therapeutic solution does not exist today in one single agent, and the needs are important. We introduced this product under one single brand, Pristiq, and in particular for the first time a non-hormonal treatment can be proposed to women experiencing vasomotor symptoms. In the US alone, 6 million women stopped taking hormones since the WHI study's initial publication, *so we are confident that the profile we have identified will make Pristiq a welcome solution in its indications with specific utility in the female population.*

\* \* \*

And, by the way, we think that this is going to make Pristiq more friendly and easier to use and prescribe compared even to Effexor on where we had been or more. Those variations, I think that's going to make it easier also to use, including in general practice.

77. On the same day as Wyeth's annual conference, October 5, 2006, defendants issued a press release entitled "Wyeth Presents R&D Highlights at Investor Conference," covering "Near-Term Pipeline Highlights." The press release quoted defendants Essner and Ruffolo and provided:

*Clinical studies confirm that Pristiq is effective in both men and women.*

\* \* \*

*FDA action for the second application for Pristiq for vasomotor symptoms (VMS) associated with menopause is anticipated in April 2007. Pristiq is expected to provide significant relief of hot flashes (decrease in number and severity) associated with menopause.*

If approved, Pristiq will be the first non-hormonal treatment indicated for relief of VMS.

*The dual indications represent the beginning of Wyeth's optimization of this promising compound.* The Company also plans to pursue indications for Pristiq that would include fibromyalgia syndrome and diabetic neuropathic pain.

78. Defendants' October 5, 2006 statements were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that usage of Pristiq for treatment of VMS was associated with

hepatic and cardiovascular side effects, including heart attacks, partial or complete obstruction of the coronary artery and hypertension;

(b) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that 27 women on a treatment regimen of Pristiq for VMS suffered SAEs either during the therapy or post-therapy periods. In comparison, no women in the placebo-treated group suffered an SAE during the therapy or post-therapy periods. Moreover, the significance of all adverse events was increased because significantly more women on a treatment regimen of Pristiq discontinued their participation in the study in comparison to those women who received placebo;

(c) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that as the dose of Pristiq was increased, the incidence of hypertension increased in women treated with the drug. For instance, hypertension was reported in only 1.3% of the placebo-treated group, while an average of 5.9% of all women in the Pristiq-treated group reported hypertension and 7.9% of women receiving a 200-mg dose of Pristiq reported suffering from hypertension. Given that the target market for Pristiq for VMS – post-menopausal women – would have heightened sensitivity to hypertension, these results were particularly material to any evaluation of Pristiq; and

(d) After receiving the results of Study 315 and prior to filing the VMS NDA for Pristiq, defendants initiated two additional studies of Pristiq and VMS – Study 319 and Study 321. In the aftermath of the Study 315 SAEs, however, defendants excluded from the later studies any woman with a history of heart attack, chest pains, elevated blood pressure and blood clots, changing the exclusion criteria to reduce the likelihood of additional SAEs. As a result, the safety data for Study 319 and Study 321 were manipulated and were not comparable to Study 315.

79. As a result of defendants' false and misleading statements on October 5, 2006, Wyeth stock continued to trade at artificially inflated prices above \$51 per share.

80. On October 19, 2006, defendants Poussot and Martin participated in a conference call with Wyeth investors and securities analysts. In addition to discussing Wyeth's earnings and drug pipeline, defendants responded to analyst questions about Pristiq and announced that the Pristiq dossier for vasomotor symptoms was submitted in Europe on October 4, 2006.

81. Between October 24 and 30, 2006, promptly following defendants' false and misleading statements about Pristiq at Wyeth's October 5, 2006 annual conference, defendants Essner, Mahady, Martin, Poussot and Ruffolo took advantage of the artificial inflation in Wyeth's stock price and collectively sold 895,994 shares of their personal stock. Defendants' coordinated insider trading resulted in insider trading proceeds of \$46.34 million.

82. On November 6, 2006, defendants filed Wyeth's Form 10-Q for the quarter ended September 30, 2006 with the SEC, in which defendants stated in part:

Our Product Pipeline

Our New Drug Application (NDA) filings with the U.S. Food and Drug Administration (FDA) for PRISTIQ (desvenlafaxine succinate), a serotonin norepinephrine reuptake inhibitor (SNRI), for the treatment of major depressive disorder in 2005 and vasomotor symptoms associated with menopause in 2006 remain under regulatory review. With respect to PRISTIQ for the treatment of major depressive disorder (MDD), we expect to receive an FDA action letter in January 2007. With respect to PRISTIQ as a non-hormonal treatment for vasomotor symptoms (VMS) associated with menopause, we expect to receive an FDA action letter in April 2007.

83. Filed together with Wyeth's Form 10-Q were certifications from defendants Essner and Martin in compliance with §§302 and 906 of the Sarbanes-Oxley Act of 2002. Included in the certifications were statements by Essner and Martin asserting that they had reviewed Wyeth's Form 10-Q and that the public 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.”

84. Defendants’ statements made between October 19 and November 6, 2006, were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that usage of Pristiq for treatment of VMS was associated with hepatic and cardiovascular side effects, including heart attacks, partial or complete obstruction of the coronary artery and hypertension;

(b) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that 27 women on a treatment regimen of Pristiq for VMS suffered SAEs either during the therapy or post-therapy periods. In comparison, no women in the placebo-treated group suffered an SAE during the therapy or post-therapy periods. Moreover, the significance of all adverse events was increased because significantly more women on a treatment regimen of Pristiq discontinued their participation in the study in comparison to those women who received placebo;

(c) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that as the dose of Pristiq was increased, the incidence of hypertension increased in women treated with the drug. For instance, hypertension was reported in only 1.3% of the placebo-treated group, while an average of 5.9% of all women in the Pristiq-treated group reported hypertension and 7.9% of women receiving a 200-mg dose of Pristiq reported suffering from hypertension. Given that the target market for Pristiq for VMS – post-menopausal

women – would have heightened sensitivity to hypertension, these results were particularly material to any evaluation of Pristiq; and

(d) After receiving the results of Study 315 and prior to filing the VMS NDA for Pristiq, defendants initiated two additional studies of Pristiq and VMS – Study 319 and Study 321. In the aftermath of the Study 315 SAEs, however, defendants excluded from the later studies any woman with a history of heart attack, chest pains, elevated blood pressure and blood clots, changing the exclusion criteria to reduce the likelihood of additional SAEs. As a result, the safety data for Study 319 and Study 321 were manipulated and were not comparable to Study 315.

85. On November 15, 2006, defendant Ruffolo attended the Credit Suisse Annual Health Care Conference as Wyeth’s representative and discussed and answered questions from analysts about the status of Pristiq. During the conference call, Ruffolo stated:

But let’s talk about some of the activity ongoing now. It is true that the action date is January for the depression, April for vasomotor symptoms. And those are two major indications – very important for us.

\* \* \*

*We think that will also be important for the vasomotor indication where – it would obviously be our intent for this drug to be used as another option for women who are suffering from vasomotor symptoms, which is the number one reason women will go to the doctor to seek treatment. So we think actually from that standpoint, it would be a first-line drug in potentially both indications.*

\* \* \*

*In fact, the way Pristiq looks like it’s positioning itself right now, it’s a drug primarily for women’s health.* And we spoke about this at the analyst meeting.

\* \* \*

So while Effexor was positioned as for psychiatric disorders, we’re looking to anchor Pristiq with the depression indication, but expand it toward indications that are also more prevalent in women, such as vasomotor symptoms and fibromyalgia.

*And there are data that suggest that this is the right agent to use. . . .*

In addition, that is the same population that will [sic] vasomotor symptoms, ***where we have now the two pivotal trials that have been submitted as part of the vasomotor NDA.*** And so that is really why it is all coming together now as a new therapy for women. And so that seems to be a difference in the position between the two right now.

86. On January 3, 2007, defendant Essner gave an oral presentation at the Morgan Stanley Pharmaceutical CEOs Unplugged Conference. Essner discussed the importance of Pristiq to Wyeth and confirmed that the Pristiq NDAs for both the MDD and VMS indications were complete, approvable packages. Essner stated:

We have the vasomotor symptoms indication where we have an action date I believe in April. . . .

***We think the package that we filed is an approvable one. We think the package that we filed is a marketable one. If we can launch it with something significantly stronger in women's health, then that is what we will do.***

87. On January 9, 2007, during the J.P. Morgan 25th Annual Healthcare Conference, Wyeth representative Joseph Camardo, the Company's Director of Medical Affairs, discussed Pristiq with investors, analysts and media representatives and stated:

Pristiq has another benefit in addition to antidepressant. It supports its position as a drug for women. It reduces vasomotor symptoms that occur with menopause. So it's positioned also to be the first non-hormonal treatment approved for vasomotor symptoms.

\* \* \*

***Talk a little bit about the side effects. We know a lot about the side effects of serotonin-norepinephrine reuptake inhibitors.*** This slide shows a list of adverse reactions that occurred in about 5% of patients. It's very close to what we see with the other drugs in the class, including XR, which has been very successful, and duloxetine. ***Dry mouth, nausea, vomiting in some, you have some sexual side effects. They're well known to occur with these drugs. There's really nothing new here.***

88. On January 23, 2007, defendants issued a press release entitled "Wyeth Receives Approvable Letter from FDA for Pristiq (Desvenlafaxine Succinate) for the Treatment of Major Depressive Disorder." The press release stated in part:

***“The approvable letter is in line with Wyeth’s expectations and we remain on track with our plans for Pristiq,”*** says Joseph Mahady, President, Wyeth Pharmaceuticals – North America and Global Businesses.

\* \* \*

“Given the importance of Pristiq, we are committed to ensuring the most complete profile and product information is available to physicians and patients at the time of this product’s launch,” Mahady says.

89. On January 30, 2007, during Wyeth’s fourth quarter 2006 earnings conference call with investors, analysts and media representatives, defendants Essner, Poussot and Martin discussed Pristiq. Addressing Pristiq, Poussot stated:

On the subject of the two indications, nothing has changed either on the way we intend to introduce Pristiq. ***It’s going to be a product very adapted for women at the time of menopause and beyond. If we introduce VMS indications first, this will just serve as a better way even to show the unique position of Pristiq into the marketplace before the MDD indication is added to that.*** So I think it would be very logical and really solidifies the position we have in mind for Pristiq.

\* \* \*

***[O]n Pristiq, I think VMS is just going well.***

90. Defendants’ statements made between November 15, 2006 and January 30, 2007, were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that usage of Pristiq for treatment of VMS was associated with hepatic and cardiovascular side effects, including heart attacks, partial or complete obstruction of the coronary artery and hypertension;

(b) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that 27 women on a treatment regimen of Pristiq for VMS suffered SAEs either during the therapy or post-therapy periods. In comparison, no women in the

placebo-treated group suffered an SAE during the therapy or post-therapy periods. Moreover, the significance of all adverse events was increased because significantly more women on a treatment regimen of Pristiq discontinued their participation in the study in comparison to those women who received placebo;

(c) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that as the dose of Pristiq was increased, the incidence of hypertension increased in women treated with the drug. For instance, hypertension was reported in only 1.3% of the placebo-treated group, while an average of 5.9% of all women in the Pristiq-treated group reported hypertension and 7.9% of women receiving a 200-mg dose of Pristiq reported suffering from hypertension. Given that the target market for Pristiq for VMS – post-menopausal women – would have heightened sensitivity to hypertension, these results were particularly material to any evaluation of Pristiq; and

(d) After receiving the results of Study 315 and prior to filing the VMS NDA for Pristiq, defendants initiated two additional studies of Pristiq and VMS – Study 319 and Study 321. In the aftermath of the Study 315 SAEs, however, defendants excluded from the later studies any woman with a history of heart attack, chest pains, elevated blood pressure and blood clots, changing the exclusion criteria to reduce the likelihood of additional SAEs. As a result, the safety data for Study 319 and Study 321 were manipulated and were not comparable to Study 315.

91. As a result of defendants' false and misleading statements between November 2006 and January 2007, Wyeth stock continued to trade at artificially inflated prices.

92. On February 7, 2007, during the Merrill Lynch Global Pharmaceutical, Biotechnology and Medical Device Conference, defendant Essner discussed Pristiq's market niche with investors, analysts and media representatives, and dispelled analyst concerns that Pristiq

showed no additional benefit over already approved drugs on the market. During the conference call, Essner stated:

Again, I think these products have clear differentiations in the marketplace. With Pristiq as the first drug really designed for the complex of symptoms that women have from depression or menopausal systems, which are frequently from the perspective of a prescribing physician a constellation of symptoms that occur in the same woman. I think we do have a unique, and we believe powerful position in the market that would allow physicians to understand Pristiq and understand when to use it vis-a-vis the competition.

93. In response to a securities analyst's question about safety issues during the February 7, 2007 conference, Essner replied that "[i]f you take the Pristiq, for example, we received an approvable letter, which was very satisfactory to us, and *I just think that is a nonissue.*"

94. On March 13, 2007, during the Cowen and Company Annual Health Care Conference, Wyeth representatives Gino Giamano, the President of Wyeth affiliate, GM Pharma Strategy, and Wyeth's Vice President of Investor Relations, Justin Victoria, discussed Pristiq with investors, analysts and media representatives and stated:

And we saw in the clinical trials with [Pristiq] a profile that was similar, in terms of its efficacy and safety and tolerability [to Effexor]. So to have something that could perform as well as the top-selling antidepressant in the world was not a bad start.

It had maybe an improved drug-drug interaction profile, *and maybe an even well established cardiac safety profile, based on some of the trials that we did.* So we felt that we had something to work with, here – and a product that we could build into a successor to Effexor that could be very successful.

But as a result of the work that we were also doing in the vasomotor symptom side of the equation, and understanding better the interplay between vasomotor symptoms and estrogen status and neurotransmission, we came up with some additional thoughts on how we might be able to not have a successor to Effexor, but maybe build an entirely new brand – and entirely new product for the Company.

\* \* \*

So looking at these 2 together, we're looking to position [Pristiq] as the product that's the first and only SNRI that will effectively address the distinctive symptoms and therapeutic needs of women for both depression and vasomotor symptoms. So we think this has very, very significant upside potential.

95. Defendants' statements made between February 7 and March 13, 2007, were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that usage of Pristiq for treatment of VMS was associated with hepatic and cardiovascular side effects, including heart attacks, partial or complete obstruction of the coronary artery and hypertension;

(b) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that 27 women on a treatment regimen of Pristiq for VMS suffered SAEs either during the therapy or post-therapy periods. In comparison, no women in the placebo-treated group suffered an SAE during the therapy or post-therapy periods. Moreover, the significance of all adverse events was increased because significantly more women on a treatment regimen of Pristiq discontinued their participation in the study in comparison to those women who received placebo;

(c) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that as the dose of Pristiq was increased, the incidence of hypertension increased in women treated with the drug. For instance, hypertension was reported in only 1.3% of the placebo-treated group, while an average of 5.9% of all women in the Pristiq-treated group reported hypertension and 7.9% of women receiving a 200-mg dose of Pristiq reported suffering from hypertension. Given that the target market for Pristiq for VMS – post-menopausal women – would have heightened sensitivity to hypertension, these results were particularly material to any evaluation of Pristiq; and

(d) After receiving the results of Study 315 and prior to filing the VMS NDA for Pristiq, defendants initiated two additional studies of Pristiq and VMS – Study 319 and Study 321. In the aftermath of the Study 315 SAEs, however, defendants excluded from the later studies any woman with a history of heart attack, chest pains, elevated blood pressure and blood clots, changing the exclusion criteria to reduce the likelihood of additional SAEs. As a result, the safety data for Study 319 and Study 321 were manipulated and were not comparable to Study 315.

96. As a result of defendants' false and misleading statements about Pristiq, Wyeth's stock continued to trade at artificially inflated prices during the first quarter of 2007.

97. On April 19, 2007, defendants Essner, Martin, Mahady and Poussot participated in Wyeth first quarter 2007 earnings conference call for investors, analysts and media representatives. During the conference call, defendants specifically discussed Pristiq and stated:

[MAHADY:] For vasomotor symptoms, we have just submitted to the FDA a recently completed study of 100 milligram and 150 milligram doses of Pristiq that included a three day, 50 milligram starting dose. This dosing approach markedly reduced nausea and adverse event related discontinuations that had been seen upon initiating therapy in the earlier trials, thereby delivering a substantially improved tolerability profile. This additional pivotal study also confirmed the efficacy of the 100 and the 150 milligram doses.

Based on these newly submitted data, FDA has advised us that they will expand the review cycle three months to July. *We're optimistic about approval at that time. Following FDA approval we'll be prepared to launch Pristiq in the U.S. as the first FDA approved non-hormonal therapy for the treatment of moderate to severe vasomotor symptoms in menopause.* We also plan to submit these new data to the European regulatory authorities to support the ongoing review of our marketing authorization application for Pristiq for VMS in Europe.

\* \* \*

[POUSSOT:] We believe that the studies completed over the past few months for Pristiq, Viviant, and Aprela will significantly contribute to the certainty of the regulatory approval, improved labeling, and the initial profiling of these new products in the market and their potential for long term success. *We expect these products will contribute to the growth of Wyeth for years to come . . . .*

\* \* \*

MAHADY: *We've always been excited about the profile of Pristiq for vasomotor. It really is the only non-hormonal choice that looks like it's going to be available for any length of time, so it's important to advance.* What we saw in this study though was a remarkably better profile with respect to the initiation of therapy. If you looked at the previous data, nausea and vomiting had been something associated with the SNRI pharmacology and this particular utilization of a 50 milligram starting dose, we see that we virtually almost eliminate any dropout for adverse events. *Nausea and vomiting was certainly the one we were most excited about but quite frankly, it's the overall total tolerability profile that really kind of stands out as a significant advance with this approach, so we see it as a big help to the launch and the long term utility of this product.*

\* \* \*

[ANALYST:] I just had two questions one about Pristiq in vasomotor. I want to be clear, the fact that you guys are comfortable with the July PDUFA date is because you are resubmitting all of this data before an approvable letter and hence that's a three-month extension and you don't expect any additional time past that point . . .

MARTIN: *I think you've got it, that's very good.*

98. On May 9, 2007, defendants filed Wyeth's Form 10-Q for the first quarter of 2007 with the SEC, in which defendants stated:

Our Product Pipeline

Our continued success depends, in large part, on the discovery and development of new and innovative pharmaceutical products and additional indications for existing products.

Our New Drug Application (NDA) filings with the FDA for PRISTIQ (desvenlafaxine succinate), a serotonin/norepinephrine reuptake inhibitor, for the treatment of major depressive disorder in 2005 and vasomotor symptoms associated with menopause in 2006 remain under regulatory review.

\* \* \*

With respect to PRISTIQ as a non-hormonal treatment for vasomotor symptoms associated with menopause, in April 2007, we submitted to the FDA data from a recently completed study of 100 mg and 150 mg doses that included a 50 mg titration step. We have been advised that the FDA will extend its review cycle for this indication by three months, to late July 2007, to include these data in its review of the NDA. We also plan to submit these data to the European regulatory authorities to support the ongoing review of our October 2006 marketing authorization application for PRISTIQ for the treatment of vasomotor symptoms in Europe.

99. Filed together with Wyeth's Form 10-Q were certifications from defendants Essner and Martin in compliance with §§302 and 906 of the Sarbanes-Oxley Act of 2002. Included in the certifications were statements by Essner and Martin asserting that they had reviewed Wyeth's Form 10-Q and that the public 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."

100. On May 9, 2007, defendants also issued a press release entitled "Wyeth Presents Phase 3 Data for Pristiq, an Investigational Non-Hormonal Therapy for Menopausal Hot Flashes and Night Sweats; First Scientific Presentation for Pristiq Occurs at the 55th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists," stating in part:

Wyeth Pharmaceuticals, a division of Wyeth . . . , presented results from the first Phase 3 studies evaluating Pristiq™ (desvenlafaxine) for the treatment of moderate-to-severe vasomotor symptoms (hot flashes and night sweats) associated with menopause. ***These studies showed that women who took Pristiq experienced a reduction in both the number and severity of hot flashes.*** Additional analyses presented demonstrated that Pristiq reduced the number of nighttime awakenings and mood disturbances in postmenopausal women with hot flashes and night sweats and did not have a negative effect on sexual function.

The data were presented at the 55th Annual Meeting of the American College of Obstetricians and Gynecologists (ACOG) in San Diego. Pristiq is currently under review by the U.S. Food and Drug Administration (FDA) and could be the first non-hormonal treatment for menopausal hot flashes and night sweats.

"Millions of women experience hot flashes and night sweats during menopause, but there are currently no effective non-hormonal treatment options approved by the FDA," says Joseph Camardo, M.D., Senior Vice President, Global Medical Affairs, Wyeth Pharmaceuticals. "***The data indicate Pristiq has the potential to expand the range of effective treatment options by providing a non-hormonal choice for menopausal women with moderate to-severe vasomotor symptoms.***"

#### ***Evaluation of Safety and Efficacy***

Three studies presented examine the efficacy of Pristiq at various doses while also evaluating its safety and tolerability profile. The most common side effect in all

three studies was nausea, which was generally mild to moderate, was dose-dependent, and resolved quickly, on average within three days.

***Efficacy and Safety of Desvenlafaxine Succinate for Treatment of Menopausal Vasomotor Symptoms***

This one-year, multicenter, randomized, double-blind, placebo-controlled trial evaluated the safety and efficacy of Pristiq at multiple doses. The study included 689 postmenopausal women with 50 or more moderate-to-severe hot flashes per week. Primary endpoints were assessed at weeks four and 12 and included the daily number and severity of hot flashes and night sweats.

Results from this study showed a reduction in the number and severity of hot flashes and night sweats at weeks four and 12 for several of the doses investigated. There was a rapid onset of action – within one week of starting therapy.

***Efficacy of Desvenlafaxine Succinate in the Treatment of Menopausal Vasomotor Symptoms***

This six month multicenter, randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of Pristiq. The study included 541 postmenopausal women with 50 or more moderate-to-severe hot flashes per week. Primary endpoints were assessed at weeks four and 12, and included the daily number and severity of hot flashes and night sweats.

Pristiq demonstrated significant improvements compared with placebo for all primary endpoints. A statistically significant reduction in the number of hot flashes (60 to 66 percent) was maintained throughout the 26-week study period.

***A Placebo-Controlled Trial of Desvenlafaxine Succinate and Tibolone for Menopausal Vasomotor Symptoms***

This 12-week, multicenter, randomized, double-blind, placebo- and active-controlled trial evaluated the safety and efficacy of Pristiq. The study included 451 postmenopausal women with 50 or more moderate-to-severe hot flashes per week, in multiple countries outside of the United States.

Results showed that at weeks four and 12, all groups experienced a decrease in the number and severity of hot flashes from baseline. There was no statistically significant difference between Pristiq and placebo; whereas, the difference between active comparator and placebo was significant.

101. On May 22, 2007, defendant Ruffolo represented Wyeth at a healthcare conference with investors and analysts hosted by Citigroup. Ruffolo discussed Pristiq and the Pristiq clinical

trials, stating that “on the vasomotor symptoms, that is undergoing a review right now and we have submitted there.”

102. On May 31, 2007, Wyeth representatives participated in a health care conference call with investors and analysts hosted by Bank of America during which Wyeth representative Mary Kate Wold, Senior Vice President of Tax & Treasury, discussed the status of the Pristiq NDA for VMS and the drug’s importance to Wyeth. During the conference Wold stated:

Close on the heels of these two new approvals we have other products queued up at the FDA being reviewed and with near-term action. The first is Pristiq for vasomotor symptoms. With Pristiq, this will be the first nonhormonal therapy indicated for VMS symptoms of menopause which we think is very important.

103. On June 12, 2007, Wyeth representatives participated in a health care conference with investors and analysts hosted by Goldman Sachs during which Wyeth’s President of U.S. & General Manager Geno Germano discussed the status of the Pristiq NDA for VMS and the drug’s importance to Wyeth. During the conference Germano stated:

Looking ahead, we’re expecting FDA actions in the next six to eight or nine months here for five important new products – Pristiq for vasomotor symptoms . . . .

I’m going to talk a little bit about Pristiq, because I get lots of questions about Pristiq. And this is a product that we have a lot of excitement about at Wyeth. We think this can be a very big product. It enables us to draw upon our experience and success in both the neuroscience area as well as women’s health to create an entirely new product and build a new product and a new brand in the marketplace that we think can be very, very successful.

\* \* \*

So we’re going to start with vasomotor symptoms. We expect the indication for vasomotor to come out later this year. We’ll be launching this product as the first FDA-approved non-hormonal treatment for moderate to severe vasomotor symptoms. So this offers physicians and patients an alternative to hormone therapy and enables them to reach for another solution to this kind of complex decision on how to manage vasomotor symptoms in the perimenopausal and postmenopausal time frame.

\* \* \*

And with the combination of the vasomotor indication and the experience that we have in the perimenopausal and postmenopausal patient population, and the fact that we know that fluctuating estrogen levels impact both norepinephrine and serotonin, both neurotransmitters that are also impacted by Pristiq, we think we'll have the ultimate product for all genders, but particularly useful for women in the 40-year-plus time of their life in depression. And if we're able to achieve this, we think there'll be a great opportunity for Pristiq that goes beyond the opportunity even for Effexor.

\* \* \*

Pristiq will be an alternative to hormone therapy for patients, frankly, with just vasomotor symptoms. . . . So it will have a – I think it'll have a big place initially when we launch the product later this year.

104. On July 19, 2007, defendants Essner and Poussot participated in Wyeth's second quarter 2007 earnings conference call with investors and analysts and discussed Pristiq, stating:

[ESSNER:] Looking to the second half of the year we expect FDA action on Pristiq, for vasomotor symptoms associated with menopause . . . .

\* \* \*

[POUSSOT:] For Pristiq the user fee date for the vasomotor symptoms NDA is July 23. FDA is evaluating the efficacy and safety data with 100 milligram dose using a three-day 50 milligram starting dose. The user fee date is only a few days away, and we will advise you further as soon as we receive FDA's letter next week.

\* \* \*

[ANALYST:] First on Pristiq in VMS, can you confirm that you are expecting a full approval on July 23, based on your discussions to date with the FDA, and can you also summarize for us the cardiovascular risk profile of the drug based on all the clinical studies that Wyeth has completed so far, and how does it compare to the other SNRIs and how do you expect it will be reflected on the label . . . .

\* \* \*

POUSSOT: On Pristiq first I can confirm that we are a few days away from getting action letter from the FDA, so we would like to wait for that response from FDA to further comment. *On the cardiovascular profile, we stand by the safety of the product. We've analyzed our database on the cardiovascular field, and believe that what we see in the product is no different than what you would observe in a population, a general population of that age and condition, so overall, we believe we have a very safe product and stand by that.*

105. Defendants' statements made between April 19 and July 19, 2007, were materially false and misleading when made. Defendants knew or recklessly disregarded, but failed to disclose, the following:

(a) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that usage of Pristiq for treatment of VMS was associated with hepatic and cardiovascular side effects, including heart attacks, partial or complete obstruction of the coronary artery and hypertension;

(b) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that 27 women on a treatment regimen of Pristiq for VMS suffered SAEs either during the therapy or post-therapy periods. In comparison, no women in the placebo-treated group suffered an SAE during the therapy or post-therapy periods. Moreover, the significance of all adverse events was increased because significantly more women on a treatment regimen of Pristiq discontinued their participation in the study in comparison to those women who received placebo;

(c) Prior to and during the Class Period, defendants were in possession of the results of Study 315, which showed that as the dose of Pristiq was increased, the incidence of hypertension increased in women treated with the drug. For instance, hypertension was reported in only 1.3% of the placebo-treated group, while an average of 5.9% of all women in the Pristiq-treated group reported hypertension and 7.9% of women receiving a 200-mg dose of Pristiq reported suffering from hypertension. Given that the target market for Pristiq for VMS – post-menopausal women – would have heightened sensitivity to hypertension, these results were particularly material to any evaluation of Pristiq; and

(d) After receiving the results of Study 315 and prior to filing the VMS NDA for Pristiq, defendants initiated two additional studies of Pristiq and VMS – Study 319 and Study 321. In the aftermath of the Study 315 SAEs, however, defendants excluded from the later studies any woman with a history of heart attack, chest pains, elevated blood pressure and blood clots, changing the exclusion criteria to reduce the likelihood of additional SAEs. As a result, the safety data for Study 319 and Study 321 were manipulated and were not comparable to Study 315.

106. As a result of defendants' false and misleading statements about Pristiq, Wyeth's common stock continued to trade at artificially inflated prices during the second quarter of 2007, reaching a Class Period high of over \$58.42 per share on May 22, 2007.

#### **DISCLOSURE OF THE FRAUD**

107. On July 24, 2007, defendants issued a press release disclosing that the Company had failed to gain FDA approval for Pristiq as a treatment for VMS. The press release reported:

Wyeth Pharmaceuticals, a division of Wyeth . . . , announced today that it received an approvable letter from the U.S. Food and Drug Administration (FDA) for PRISTIQ™ (desvenlafaxine), a serotonin-norepinephrine reuptake inhibitor (SNRI), currently under review as a treatment for moderate-to-severe vasomotor symptoms (hot flashes and night sweats) associated with menopause.

In its letter, *the FDA said that before the application could be approved, it would be necessary for Wyeth to provide additional data regarding the potential for serious adverse cardiovascular and hepatic effects associated with the use of PRISTIQ in this indication.* The Agency requested that these data come from a randomized, placebo-controlled clinical trial of a duration of one year or more conducted in postmenopausal women.

108. On July 24, 2007, *The Associated Press* reported:

*The Food and Drug Administration wants more data from Wyeth on how its proposed drug to treat hot flashes and other symptoms of menopause affects the heart and liver, the company said Tuesday.*

The FDA is seeking a one-year study of how the drug Pristiq affects those organs, said Wyeth's chief medical officer, Dr. Gary Stiles.

The FDA on Monday stopped short of approving Pristiq for menopause symptoms, sending Wyeth a so-called approvable letter, according to agency spokeswoman Rita Chappelle. That indicates the company's application is acceptable in many respects, but that staff scientists want more information about the treatment before approving it.

*The decision was a blow to Madison-based Wyeth*, which hopes to market the drug as the first non-hormonal treatment for menopausal symptoms.

109. On July 24, 2007, *The Wall Street Journal* reported:

***The Food and Drug Administration declined to approve an experimental Wyeth drug to treat hot flashes and other symptoms of menopause.***

The agency issued an "approvable letter" for the drug, which Wyeth has proposed selling under the brand name Pristiq, an agency spokeswoman said. The FDA can't comment on the contents of such letters other than to confirm they have been issued.

\* \* \*

***Pristiq, which is derived from Wyeth's blockbuster antidepressant Effexor XR, has been expected to help compensate for an anticipated decline in sales of that drug, which is set to face generic competition by 2010.***

110. On July 24, 2007, *TheStreet.com* reported:

Wyeth . . . watched its shares drop sharply after U.S. regulators said they want another clinical trial for the menopause-symptoms treatment Pristiq.

\* \* \*

The company didn't provide an exact timetable for the new clinical trial. The FDA also asked Wyeth to answer questions about "certain chemistry, manufacturing and controls deficiencies" before it approves the drug. Wyeth didn't provide details.

\* \* \*

Merrill Lynch analyst David Risinger cut his rating to hold from buy, telling clients that Pristiq probably wouldn't be available for treating menopause symptoms until the first quarter of 2010. He doesn't own shares, but his firm has had a noninvestment banking relationship.

111. On July 24, 2007, several analysts discussed the importance of the FDA's action with regard to their outlook on Wyeth. For instance, Barbara Ryan, an equity analyst for Deutsche Bank Securities, noted:

In our view, the fact that Pristiq would be a “non-hormonal” treatment for [hot flushes] was the only visible commercial hook for the “me too” SNRI. ***For all intents and purposes, this indication is dead . . . [and] will intensify the company’s exposure to Effexor [XR] generics in 2010 . . . .***

Jon LeCroy, M.D., of Natixis Bleichroeder Inc., also reported:

[The FDA] stated that Wyeth would need an additional study . . . to clarify cardiovascular and hepatic issues with Pristiq in vasomotor symptoms. . . .

***. . . Pristiq will have extreme difficulty replacing Effexor XR lost sales, implying that Wyeth will face an extremely large earnings cliff in 2011.***

112. As a result of the disclosures regarding the FDA’s decision on July 24, 2007, Wyeth’s stock price dropped from a July 23, 2007 close of \$56.00 per share, to a close of \$50.30 per share on July 24, 2007. This decrease in Wyeth’s stock price was a result of the artificial inflation caused by defendants’ false and misleading Class Period statements coming out of the stock price.

113. On July 25, 2007, *The Associated Press* reported:

Leerink Swann analyst Seamus Fernandez downgraded the Madison, N.J., company to “Market Perform” from “Out-perform,” questioning sales of Pristiq and Wyeth’s ability to get regulators to approve its drugs.

114. On July 25, 2007, *The Star-Ledger* reported:

Wyeth said a new clinical trial for Pristiq, one of the company’s most important experimental medicines, could take a year or longer to complete.

***Industry analysts said the safety concerns could doom the drug – which is also awaiting approval as a treatment for depression – and its potential to ensure earnings growth when Wyeth’s Effexor antidepressant and Protonix ulcer drug face generic competition in coming years.***

Credit Suisse analyst Catherine Arnold said she is no longer counting on any sales from Pristiq, given the FDA’s cautionary stance.

“The effect is negative in the longer term and we see a \$2.6 billion revenue shortfall and a 31 cent (per share) hit” to Wyeth’s 2011 results, Arnold said in a research note.

\* \* \*

[Wyeth] has been counting on Pristiq, a derivative of Wyeth's \$3.5-billion-a-year Effexor, to ease the sting when Effexor's U.S. patent lapses in 2010 and cheaper generics hit the market.

Revenue from Pristiq, which analysts have said could top \$2 billion a year, would also help prevent a sharp earnings decline in 2011, when Protonix loses patent protection.

\* \* \*

"It's a big setback for Wyeth," said Bannister, who noted Pristiq was unlikely to be approved until 2009 or 2010 – too late to sufficiently ramp up its sales before Effexor's patent lapses.

115. The disclosures made by Wyeth on July 24, 2007, and subsequent analyst and press coverage addressing the Company's failure to gain FDA approval for Pristiq, continued to remove the artificial inflation from Wyeth's stock price caused by defendants' false and misleading Class Period statements. Between July 25, 2007 and July 27, 2007, the Company's stock price continued to decrease in value, on heavy trading volume, closing at \$49.61 and \$48.82 per share, respectively.

116. On August 1, 2007, Barbara Ryan of Deutsche Bank Securities reported her continued pessimism about Wyeth's outlook, including the fact that Wyeth had discontinued its Pristiq fibromyalgia Phase 2 study program:

WYE's Pristiq Update for VMS and MDD – *Nothing's changed . . . . The opportunity for Pristiq was VMS (dead) . . . .*

\* \* \*

*With the recent Pristiq setback, WYE's EPS growth outlook through 2010 is now below that of the DB Pharma group and the market, and a relatively severe multiple contraction has ensued. . . . [A] decline in 2010 EPS could be substantial due to disappointing prospects for Pristiq.*

\* \* \*

*Even if WYE were to succeed in VMS, an approval is not likely until 2010+, by which time, it is too late, as Effexor will be generic by then.*

\* \* \*

*Outside of VMS, we don't think Pristiq has a hook or a competitive leg to stand on* – the flat efficacy does response above 100 mg in MDD, poor tolerability at the higher doses, and the recent setback for the fibromyalgia program – all suggest that Pristiq is no better than, and perhaps even a less effective option than current SNRIs.

117. On August 13, 2007, *The Wall Street Journal* reported:

The Food and Drug Administration's rejection of Wyeth's schizophrenia drug bifeprunox is the latest in a string of disappointments that is sapping the confidence of investors in the big drug company's long-term growth prospects.

\* \* \*

The setbacks come after a bigger disappointment in late July, when the FDA issued what is known as an approvable letter – which typically indicates the agency needs more information before it will approve a drug – for Wyeth's experimental drug Pristiq for menopause symptoms.

\* \* \*

While Wyeth's profits have been strong lately, *the string of bad news raises concerns over how the company will compensate for a future drop in sales of two of its blockbuster drugs, antidepressant Effexor XR and acid-reflux drug Protonix. The pills accounted for combined world-wide sales of \$5.5 billion last year*, about 27% of the company's revenue, and both are expected to face generic competition for the first time in the U.S. in 2010 or early 2011.

\* \* \*

Wyeth's shares were down \$2.99, or 6%, to \$46.59 at 4 p.m. Friday in trading on the New York Stock Exchange. That is about 21% below the stock's 52-week high of \$59 reached in May.

118. Also in August 2007, defendants discontinued "Study 407," which was designed to test the effectiveness and safety of Pristiq as a treatment to be used by breast cancer survivors. Wyeth discontinued Study 407 as a result of the FDA's concerns about the severe liver damage and cardiovascular side effects associated with Pristiq.

119. On March 12, 2008, Wyeth revealed that it was withdrawing its application for Pristiq as a treatment for VMS in Europe. The EMEA expressed to Wyeth the exact same concerns as the FDA had on July 24, 2007. In response to the EMEA's concerns, Wyeth stated that "planned"

clinical trials, including a 12-month study to be initiated in early 2008, would address the EMEA's questions about the drug's safety.

120. As of March 12, 2008, however, Wyeth had not enrolled any patients in a follow-up study that would address the FDA and EMEA's concerns with Pristiq's association with serious hepatic and cardiovascular side effects.

#### **ADDITIONAL INDICIA OF SCIENTER**

121. As detailed herein, defendants acted with scienter during the Class Period in that they had actual knowledge, through Wyeth's own clinical trial completed by May 2005 – one year *before* the start of the Class Period – of the undisclosed and significant cardiovascular and hepatic side effects associated with using Pristiq for the treatment of VMS, and defendants acted with reckless disregard for the truth by failing to ascertain and disclose the true facts, even though such facts were readily available to them. In addition to their orchestration of the fraudulent scheme, defendants' scienter is evidenced by their unprecedented and coordinated sale of over 1.55 million shares of Wyeth stock for insider trading proceeds of \$83.82 million.

122. While issuing the false and misleading statements identified herein about Pristiq, defendants Essner, Mahady, Martin, Poussot and Ruffolo (the "Insider Defendants") sold their shares of Wyeth stock at prices as high as \$58.33 per share. Moreover, the Insider Defendants sales were highly coordinated, with nearly 60% of the sales occurring in October 2006, quickly following Wyeth's October 5, 2006 annual investor conference and October 19, 2006 press release. *See* ¶¶69-78. The Insider Defendants were remarkably successful in timing their trades, capturing peak prices when selling. The average trading price for Wyeth stock in the 90 days after defendants' fraud was revealed was only \$46.77 per share. In sharp contrast, the Insider Defendants unloaded their stock during the Class Period at an average of over \$54 per share. Both the timing and volume of their trades were suspicious.

123. The Insider Defendants' stock sales also violated Wyeth's internal Code of Conduct. Wyeth's Securities Transactions Policy specifically prohibited defendants "from buying or selling Wyeth securities while aware of material information about Wyeth that is not publicly known." The Policy mandates that "[b]oth positive and negative information may be material, and *information that is likely to affect the market price of a security almost always is material.*"

124. Notwithstanding the Insider Defendants' knowledge about the SAEs associated with Pristiq and their duties under Wyeth's Code of Conduct and as officers and directors of the Company to disclose adverse material facts before trading in Wyeth stock, the Insider Defendants personally profited from the artificial inflation in Wyeth's stock price which their fraudulent scheme created.

125. Defendant Essner personally sold 177,600 shares of Wyeth stock on October 27, 2006 for insider trading proceeds of \$9.23 million, thereby profiting from the artificially inflated price of Wyeth's stock caused by defendants' false statements and omissions. Essner's insider trading was not part of any general or specific pre-planned pattern of stock sales, but was timed to profit from the artificial inflation in Wyeth's stock price. In the 12 months prior to the Class Period, Essner sold only 60,000 shares of Wyeth stock for proceeds of \$2.95 million, less than one-third of his Class Period sales, and in the eight months since the end of the Class Period Essner has not sold any Wyeth stock. Based on defendant Essner's Form 4s filed with the SEC, as of Essner's October 27, 2006 stock sales, he had sold 70% of his Wyeth common stock holdings and only beneficially held 75,535 shares of common stock individually or jointly with his spouse.

126. Defendant Mahady personally sold 202,000 shares of Wyeth stock on October 24, 2006 for insider trading proceeds of \$10.34 million, thereby profiting from the artificially inflated price of Wyeth's stock caused by defendants' false statements and omissions. Mahady's insider trading was not part of any general or specific pre-planned pattern of stock sales, but was timed to

profit from the artificial inflation in Wyeth's stock price. In the 12 months prior to the Class Period and the eight months after the Class Period, Mahady did not sell any Wyeth stock. Based on defendant Mahady's Form 4s filed with the SEC, as of Mahady's October 24, 2006 stock sales, he had sold 97% of his Wyeth common stock holdings and only beneficially held 6,414 shares of common stock.

127. Defendant Martin personally sold 637,641 shares of Wyeth stock between October 25, 2006 and June 13, 2007 for insider trading proceeds of \$35.61 million, thereby profiting from the artificially inflated price of Wyeth's stock caused by defendants' false statements and omissions. Martin's reported insider trading during the Class Period is detailed below:

<b>Date</b>	<b>Shares Sold</b>	<b>Price</b>	<b>Proceeds</b>
10/25/06	109,564	\$52.35	\$5,735,675
04/25/07	101,514	\$55.97	\$5,681,739
04/25/07	66,600	\$55.97	\$3,727,602
04/27/07	92,000	\$55.29	\$5,086,680
04/27/07	50,000	\$55.29	\$2,764,500
04/27/07	2,486	\$55.29	\$137,451
04/27/07	2,436	\$55.29	\$134,686
05/22/07	112,500	\$57.97	\$6,521,625
05/22/07	88,000	\$57.97	\$5,101,360
06/13/07	12,541	\$57.15	\$716,718
<b>Total:</b>	<b>637,641</b>		<b>\$35,608,037</b>

Martin's insider trading was not part of any general or specific pre-planned pattern of stock sales, but was timed to profit from the artificial inflation in Wyeth's stock price. In the 12 months prior to the Class Period, Martin sold only 100,000 shares of Wyeth stock for proceeds of \$4.96 million, only 14% of his Class Period sales, and in the eight months since the end of the Class Period Martin has not sold any Wyeth stock. Based on defendant Martin's Form 4s filed with the SEC, as of Martin's final stock sale, he had sold 99% of his Wyeth common stock holdings and only beneficially held 4,805 shares of common stock.

128. Defendant Poussot personally sold 267,266 shares of Wyeth stock on October 27 and October 30, 2006 for insider trading proceeds of \$13.88 million, thereby profiting from the artificially inflated price of Wyeth's stock caused by defendants' false statements and omissions. Poussot's reported insider trading during the Class Period is detailed below:

<b>Date</b>	<b>Shares Sold</b>	<b>Price</b>	<b>Proceeds</b>
10/27/06	115,493	\$52.00	\$6,005,636
10/27/06	102,666	\$52.00	\$5,338,632
10/27/06	2,600	\$52.00	\$135,200
10/30/06	46,507	\$51.70	\$2,404,412
<b>Total:</b>	<b>84,2000</b>		<b>\$13,883,880</b>

Poussot's insider trading was not part of any general or specific pre-planned pattern of stock sales, but was timed to profit from the artificial inflation in Wyeth's stock price. In the 12 months prior and eight months following the Class Period, Poussot did not sell any Wyeth stock. Based on defendant Poussot's Form 4s filed with the SEC, as of Poussot's final stock sale, he had sold 89% of his Wyeth common stock holdings and only beneficially held 32,264 shares of common stock.

129. Defendant Ruffolo personally sold 270,000 shares of Wyeth stock between October 24, 2006 and May 22, 2007 for insider trading proceeds of \$14.76 million, thereby profiting from the artificially inflated price of Wyeth's stock caused by defendants' false statements and omissions. Ruffolo's reported insider trading during the Class Period is detailed below:

<b>Date</b>	<b>Shares Sold</b>	<b>Price</b>	<b>Proceeds</b>
10/24/06	77,064	\$51.22	\$3,947,218
10/24/06	62,500	\$51.22	\$3,201,250
05/22/07	128,000	\$58.33	\$7,466,240
05/22/07	2,436	\$58.33	\$142,092
<b>Total:</b>	<b>270,000</b>		<b>\$14,756,800</b>

Ruffolo's insider trading was not part of any general or specific pre-planned pattern of stock sales, but was timed to profit from the artificial inflation in Wyeth's stock price. In the 12 months prior to the Class Period, Ruffolo sold only 15,580 shares of Wyeth stock for proceeds of \$719,329, less than

6% of his Class Period sales, and in the eight months since the end of the Class Period Ruffolo has not sold any Wyeth stock. Based on defendant Ruffolo's Form 4s filed with the SEC, as of Ruffolo's final stock sale, he had sold 90% of his Wyeth common stock holdings and only beneficially held 30,000 shares of common stock.

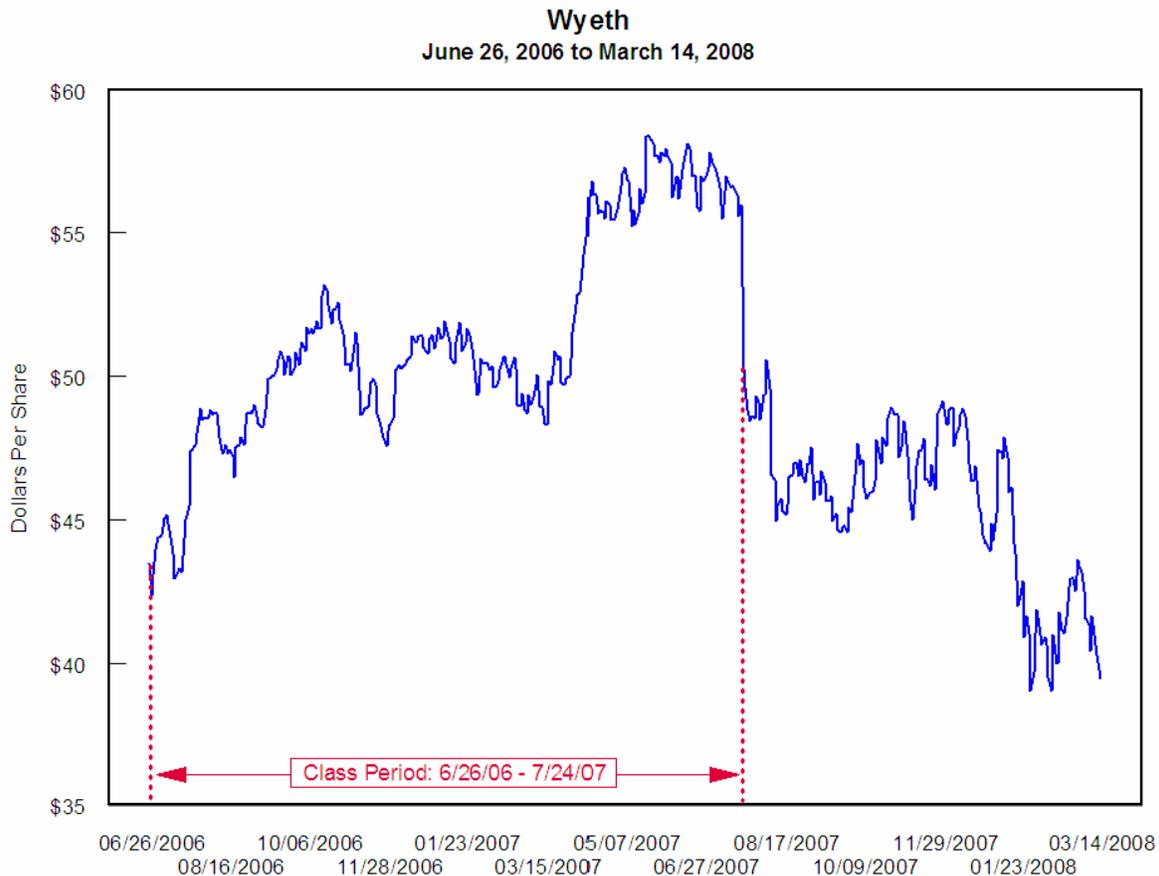
130. In addition to the Insider Defendants, numerous other Wyeth officers dumped the Company's stock during the Class Period and before the truth about the SAEs associated with Pristiq were disclosed. Class Period stock sales for just those senior Wyeth officers, other than defendants, required to report their stock transactions to the SEC totaled more than 815,000 shares sold for proceeds of \$43.78 million. Among those selling during the Class Period were Law/Regulatory Review Committee members Paul Jones (\$12.05 million in Wyeth stock sales), Rene Lewin (\$6.06 million in Wyeth stock sales), Charles Portwood (\$2.64 million in Wyeth stock sales), Douglas Rogers (\$3.97 million in Wyeth stock sales) and Lawrence Stein (\$4.49 million in Wyeth stock sales), and Senior Vice President for Public Affairs Marily Rhudy (\$4.45 million in Wyeth stock sales).

#### **PROXIMATE LOSS CAUSATION/ECONOMIC LOSS**

131. During the Class Period, as detailed herein, defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated and maintained Wyeth's stock price and operated as a fraud or deceit on Class Period purchasers of Wyeth's publicly traded securities by misrepresenting and omitting material information about serious adverse side effects associated with Pristiq. When defendants' prior misrepresentations and omissions were disclosed and it became apparent to the market that Wyeth was unlikely to be able to market Pristiq for VMS, Wyeth's stock price fell precipitously as the prior artificial inflation came out of the price. As a result of their purchases of Wyeth stock during the Class Period, plaintiffs and

other members of the Class, as defined in ¶139, suffered economic loss, *i.e.*, damages, under the federal securities laws.

132. Defendants' false statements and omissions, identified herein at ¶¶62-106, had the intended effect and caused Wyeth stock to trade at artificially inflated levels up to and above \$58 per share during the Class Period. See stock chart below:



133. As a direct result of the July 24, 2007 disclosure that the FDA was requiring significant additional study of the cardiovascular and hepatic side effects associated with Pristiq, Wyeth's stock price immediately dropped \$5.70 per share on unusually high volume. Wyeth's stock price continued to lose value as the impact of the negative information was digested by the market. In the three trading days following the July 24, 2007 disclosure, Wyeth shares were trading for less

than \$49 per share, closing at \$48.41 on July 27, 2007. These drops removed the inflation from Wyeth's stock price, causing real economic loss to investors who had purchased the stock during the Class Period.

134. The decline in Wyeth's stock price at the end of the Class Period was a direct result of the nature and extent of defendants' prior false statements and omissions being revealed to investors and the market. The timing and magnitude of Wyeth's stock price declines negate any inference that the loss suffered by plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the defendants' fraudulent conduct. Indeed, on July 24, 2007, the same day Wyeth's stock price fell more than 10% as a result of defendants' fraud being revealed, Standard & Poor's 500 securities index remained essentially flat. The economic loss, *i.e.*, damages, suffered by plaintiffs and other members of the Class, was a direct result of defendants' fraudulent scheme to artificially inflate Wyeth's stock price and maintain the price at artificially inflated levels and the subsequent significant decline in the value of Wyeth's stock when defendants' prior misrepresentations and omissions were revealed.

#### **NO SAFE HARBOR EXISTS FOR DEFENDANTS' STATEMENTS**

135. 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 was 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 Wyeth who knew that those statements were false when made.

**APPLICABILITY OF PRESUMPTION OF  
RELIANCE: FRAUD ON THE MARKET**

136. Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's stock traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and

(e) Plaintiffs and other members of the Class purchased Wyeth securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

137. At all relevant times, the market for Wyeth securities was efficient for the following reasons, among others:

(a) Wyeth common stock met the requirements for listing, and was listed and actively traded, on the New York Stock Exchange;

(b) As a regulated issuer, Wyeth filed periodic public reports with the SEC, including Forms S-3; and

(c) Wyeth stock was regularly followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and customers of their respective brokerage firms;

(d) Wyeth regularly communicated with the public and investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

138. As a result, the market for Wyeth securities digested current information with respect to Wyeth from publicly available sources and reflected such information in Wyeth's securities prices. Under these circumstances, all purchasers of Wyeth securities during the Class Period suffered similar injury through their purchase of securities at artificially inflated prices and a presumption of reliance applies.

#### **PLAINTIFFS' CLASS ACTION ALLEGATIONS**

139. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of purchasers and/or acquirers of Wyeth's publicly traded securities during the Class Period who were damaged thereby (the "Class"). Excluded from the Class are defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

140. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Wyeth's common stock was actively traded on the New York Stock Exchange. While the exact number of Class members is unknown to plaintiffs at this time and can only be ascertained through appropriate discovery, plaintiffs believe that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Wyeth or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

141. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class were similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

142. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

143. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by defendants' acts and omissions as alleged herein;

(b) Whether statements made by defendants to the investing public during the Class Period misrepresented and omitted material facts about the business, operations and financial results of Wyeth; and

(c) To what extent the members of the Class have sustained damages and the proper measure of damages.

144. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

**COUNT I**

**Violation of Section 10(b) of the Exchange Act and Rule 10b-5  
Promulgated Thereunder Against All Defendants**

145. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

146. During the Class Period, Wyeth and the individual defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public, including plaintiffs and other members of the Class, regarding Pristiq and Wyeth's business, operations, financial prospects and the intrinsic value of Wyeth's publicly traded securities; (b) artificially inflate and maintain the market price of Wyeth's securities; and (c) cause plaintiffs and other members of the Class to purchase Wyeth's securities at artificially inflated prices and, as a result, suffer economic losses when the truth and impact about defendants' fraud was revealed. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

147. 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 made 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 publicly traded securities in an effort to maintain artificially high market prices for Wyeth's publicly traded securities in violation of §10(b) of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

148. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a

continuous course of conduct to conceal adverse material information about Pristiq as specified herein.

149. These defendants employed devices, schemes and artifices to defraud, while in possession of material, adverse, non-public information and engaged in acts, practices and a course of conduct as alleged herein in an effort to assure investors of Wyeth's value and performance and continued growth, which included the making of, or the participation in the making of, untrue statements of material fact and omitting to state material facts necessary in order to make the statements made about Wyeth and Pristiq, in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Wyeth's publicly traded securities during the Class Period.

150. Each of the individual defendants' primary liability, and controlling person liability, arises from the following facts: (a) the individual defendants were high-level executives and in certain circumstances, directors at the Company during the Class Period and members of the Company's senior management team; (b) each of these defendants, by virtue of his or her responsibilities and activities as a senior officer and director of the Company was privy to and participated in the clinical trials, regulatory filings and reporting regarding Pristiq; (c) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the serious adverse effects associated with Pristiq, at all relevant times; and (d) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading and omitted material information.

151. In addition to the duties of full disclosure imposed on defendants as a result of their making of affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X, 17 C.F.R. §§210.01, *et seq.*, and Regulation S-K, 17 C.F.R. §§229.10, *et seq.*, and other SEC regulations, including accurate and truthful information with respect to Pristiq so that the market price of the Company's securities would be based on truthful, complete and accurate information.

152. The defendants 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 to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were made knowingly or with a reckless disregard for the truth and for the purpose and effect of inflating Wyeth's operating results, concealing the serious adverse effects associated with Pristiq and supporting the artificially inflated prices of the Company's publicly traded securities.

153. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Wyeth's publicly traded securities were artificially inflated during the Class Period. In ignorance of the fact that the market price of Wyeth's publicly traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the markets in which the securities trade and/or on the absence of material adverse information that was known to or recklessly disregarded by defendants, but not disclosed in public statements by defendants during the Class Period, plaintiffs and the other members of the Class acquired Wyeth publicly traded

securities during the Class Period at artificially inflated prices and were damaged when the artificial inflation came out of the securities.

154. At the time of said misrepresentations and omissions, plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had plaintiffs, the other members of the Class and the marketplace known the truth regarding the serious adverse effects associated with Pristiq which were not disclosed by defendants, plaintiffs and other members of the Class would not have purchased or otherwise acquired their Wyeth publicly traded securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

155. By virtue of the foregoing, defendants have violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

156. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's publicly traded securities during the Class Period.

## COUNT II

### **Violation of Section 20(a) of the Exchange Act Against All Defendants**

157. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

158. The individual defendants acted as controlling persons of Wyeth within the meaning of §20(a) of the Exchange Act as alleged herein. Wyeth controlled all of its employees and each of the individual defendants. By virtue of their high-level positions, and their ownership and contractual rights, participation in and awareness of the Company's operations and intimate knowledge of the false statements and omissions made by the Company and disseminated to the

investing public, the individual defendants had the power to influence and control and did influence and control, directly or indirectly, the decision making of the Company, including the content and dissemination of the various statements which plaintiffs contend are false and misleading. The individual defendants participated in conference calls with investors and were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements, alleged by plaintiffs to be misleading, prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

159. In particular, each of these defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

160. As set forth above, Wyeth and the individual defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this complaint. By virtue of their positions as controlling persons, defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's publicly traded securities during the Class Period.

#### **PRAYER FOR RELIEF**

WHEREFORE, plaintiffs respectfully pray for relief and judgment, as follows:

A. Determining that this action is a proper class action, and certifying plaintiffs as class representatives under Federal Rule of Civil Procedure 23;

B. Awarding compensatory damages in favor of plaintiffs and the other members of the Class 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 plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

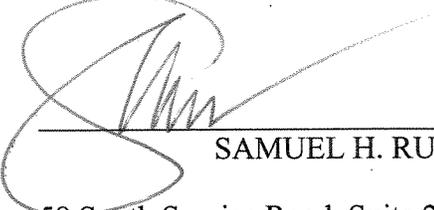
D. Such equitable, injunctive or other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiffs demand a trial by jury.

DATED: April 11, 2008

COUGHLIN STOIA GELLER  
RUDMAN & ROBBINS LLP  
SAMUEL H. RUDMAN  
DAVID A. ROSENFELD



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SAMUEL H. RUDMAN

58 South Service Road, Suite 200  
Melville, NY 11747  
Telephone: 631/367-7100  
631/367-1173 (fax)

COUGHLIN STOIA GELLER  
RUDMAN & ROBBINS LLP  
TOR GRONBORG  
TRIG R. SMITH  
LAURIE L. LARGENT  
655 West Broadway, Suite 1900  
San Diego, CA 92101  
Telephone: 619/231-1058  
619/231-7423 (fax)

Lead Counsel for Plaintiffs

**CERTIFICATE OF SERVICE**

I, Kelly Stadelmann, hereby certify that on April 11, 2008, I caused a true and correct copy of the attached: CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS to be served via United States mail on:

Michael J. Chepiga, Esq.  
Lynn K. Neuner, Esq.  
Simpson Thacher & Bartlett LLP  
425 Lexington Avenue  
New York, NY 10017-3954

  
Kelly Stadelmann