Matthew Herper, Forbes Staff
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Merck To Pay $688 Million To Shareholders For Delaying Vytorin Results

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Merck announced this morning that it will pay a total of $688 million to settle lawsuits brought by pension funds and other shareholders who say they lost money because of Merck's handling of a clinical trial that caused prescriptions of its blockbuster Vytorin pill to plummet. A trial had been expected to begin on March 4.

The settlement, according to plaintiffs attorneys, is one of the top 25 securities class action settlements of all time.

As I was first to report in 2007, Merck and then-partner Schering-Plough delayed analyzing the study, called ENHANCE, for months over what they believed were data quality problems. John Kastelein, the outside scientist in charge of the trial, believed that the data were ready to be analyzed.

Under mounting public pressure, the companies released the ENHANCE data in early 2008. They showed that Vytorin, a combination of the generic cholesterol drug Zocor and the newer medicine Zetia, did not reduce ultrasound readings of thickness in the neck artery any more than Zocor alone. When the data were presented at the annual meeting of the American College of Cardiology, Yale cardiologist Harlan Krumholz (now a Forbes contributor) told thousands of heart doctors that Zetia might be just an expensive placebo. Adding Zetia to Zocor, he said, might lower cholesterol levels without reducing heart attacks and strokes.

The stock prices of both Merck and Schering-Plough fell, and so did prescriptions of Zetia and Vytorin. Vytorin was hardest hit, as doctors switched

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patients with high cholesterol to other drugs that were similar to Zocor but more potent, including Pfizer's Lipitor and AstraZeneca's Crestor. Eventually, Merck bought Schering-Plough partly to get full control of the shrinking franchise. Zetia usage has increased since, because doctors still use it when Lipitor or Crestor is not enough.

Merck admitted no liability or wrongdoing in the decision, and continues to believe its handling of the study was proper. But the settlement could make investors nervous anyway. One of the reasons Vytorin has never recovered (sales of the pill are $1.5 billion, $1 billion less than before the results were released, but that partly reflects a price increase) is that Merck's other clinical trials, so far, have never again compared Vytorin to Zocor to look for differences in real cardiovascular problems like heart attack and stroke. Instead, the other big trial of Vytorin compared it to placebo in patients who had a heart valve that did not close fully.

But Merck is doing that big Vytorin versus Zocor study, a giant clinical trial called IMPROVE-IT. Results have been delayed several times, and probably won't come until next year. But the company has said that the independent board that is monitoring the results of the trial will meet in March. They could decide to stop the trial if it has already proved more effective, if Vytorin appears more dangerous than Zocor, or if there is no hope that Vytorin will prove more effective.

Most experts expect the committee to simply allow the trial to continue until its conclusion. But Wall Street analyst are skittish about what will happen, especially after the unrelated delay of a key experimental bone drug. David Risinger, the pharmaceuticals analyst at Morgan Stanley, made worries about the IMPROVE-IT result one of his key reasons for downgrading Merck shares.

Add: Merck strongly believes that ezetimibe's ability to cut bad cholesterol does translate into lowered risk of heart attack and stroke, and sent this statement:

> "We are confident in ezetimibe and in the established relationship between lowering LDL (bad) cholesterol and reducing cardiovascular events. Numerous clinical trials conducted over the years have demonstrated a strong relationship between lowering LDL cholesterol and reduced risk of cardiovascular morbidity and mortality. We continue to look forward to learning the results of the ongoing IMPROVE-IT study. IMPROVE-IT is addressing the important scientific question of whether additional lowering of LDL cholesterol to very low levels with ezetimibe on top of simvastatin reduces CV events more than simvastatin alone.

Merck will pay $215 million to resolve the class action by Merck defendents, and $473 million to settle the action brought by shareholders in Schering-Plough.

The settlement will result in Merck taking a $473 million charge in the fourth quarter of 2012, lowering its already announced earnings per share for that quarter to $0.30 from $0.46. That lowers EPS for the full year to $2.00 from $2.16. This doesn't affect the non-GAAP results used by the company in communicating with Wall Street analysts, as it is a one time item.

"This agreement avoids the uncertainties of a jury trial and will resolve all of the remaining litigation in connection with the ENHANCE study," said Bruce N. Kuhlik, executive vice president and general counsel of Merck, in a prepared statement. "We believe it is in the best interests of the company and

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its shareholders to put this matter behind us, and to continue our focus on scientific innovations that improve health worldwide."

In a separate press release, lawyers at Bernstein Litowitz Berger & Grossmann LLP, who co-led the five year battle over the results, struck a triumphant tone, stating: "The combined $688 million in settlements is the second largest securities class action settlement in the Third Circuit, among the top 25 securities class action settlements of all time, and among the ten largest recoveries in a securities class action not involving a restatement."

The plaintiffs bringing the cases were largely pension funds and other institutional investors. BLB&G represented BLB&G Arkansas Teacher Retirement System, Public Employees' Retirement System of Mississippi, and Louisiana Municipal Police Employees' Retirement System on behalf of the Class in the Schering-Plough action, and Jacksonville Police and Fire Pension Fund and General Retirement System of the City of Detroit on behalf of the Class in the Merck case.

The Massachusetts Pension Reserves Investment Management Board was a co-lead plaintiff in the Schering action represented by Labaton Sucharow LLP. Stichting Pensioenfonds ABP and International Fund Management, S.A. Luxemburg served as co-lead plaintiff in the Merck action represented by the law firm of Grant & Eisenhofer P.A. Pilgrim Mediation Group served as mediators.

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underwriters of a 2007 Schering stock offering today announced that they have reached settlements on behalf of investors totaling $688 million subject to Court approval. The actions relate to a clinical trial called "ENHANCE" involving the anti-cholesterol drugs Zetia and Vytorin.

The actions, currently pending in the U.S. District Court for the District of New Jersey before Judge Dennis M. Cavanaugh, are *In re Schering-Plough Corporation/ENHANCE Securities Litigation*, Master File No. 08-397, which settled for $473 million; and *In re Merck & Co., Inc. Vytorin/Zetia Securities Litigation*, Master File No. 08-2177, which settled for $215 million. The combined $688 million in settlements is the second largest securities class action settlement in the Third Circuit, among the top 25 securities class action settlements of all time, and among the ten largest recoveries in a securities class action not involving a restatement.

The settlements were reached after almost five years of protracted litigation led by Bernstein Litowitz Berger & Grossmann LLP ("BLB&G") and co-counsel, and only after the District Court granted Plaintiffs' motions for class certification and denied Defendants' motions for summary judgment and the Third Circuit denied Defendants' Rule 23(f) appeals of the District Court's decisions granting class certification. Trial was scheduled to begin on March 4, 2013.

BLB&G is Court-appointed Co-Lead Counsel representing Arkansas Teacher Retirement System, Public Employees' Retirement System of Mississippi, and Louisiana Municipal Police Employees' Retirement System on behalf of the Class in the *Schering-Plough* action, and Co-Lead Counsel representing Jacksonville Police and Fire Pension Fund and General Retirement System of the City of Detroit on behalf of the Class in the *Merck* case.

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Background

These two actions stem from claims that Merck and Schering (which merged in November 2009) artificially inflated their securities by concealing material information and making false and misleading statements regarding the blockbuster anti-cholesterol drugs Zetia and Vytorin. Namely, Lead Plaintiffs alleged that even though the Defendants knew that a clinical trial of Vytorin, called "ENHANCE," demonstrated that Vytorin (a combination of Zetia and a generic statin medication) was no more effective than the cheaper, generic statin drug at reducing artery thickness, the Companies nonetheless championed the "benefits" of the drugs, attracting billions of dollars of capital in the process. Yielding to public pressure to release the results of the ENHANCE trial, Lead Plaintiffs allege that the companies reluctantly announced that the cholesterol drugs showed "no statistically significant difference" in plaque buildup, and that news of these negative results and their related consequences caused sharp declines in the value of the companies' securities, resulting in significant losses to investors.

For more information on these actions, please visit www.blbglaw.com.

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