

VIOXX Claims Administrator

Toll-Free Telephone: (866) 866-1729

Facsimile: (804)521-7299

claimsadmin@browngreer.com

Mailing Address:

P.O. Box 85031
Richmond, Virginia 23285-5031

Delivery Address:

115 South 15th Street, Suite 400
Richmond, Virginia 23219-4209

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Dear Claimant:

After 18 trials involving 20 plaintiffs who allegedly incurred injuries from the use of Vioxx, representatives of plaintiffs in the Vioxx litigation and representatives from Merck, the manufacturer of Vioxx, negotiated an agreement to establish a program for the resolution of approximately 50,000 claims pending at the time of the settlement. This letter seeks to provide background on the Settlement Agreement, its requirements, the levels of review each claim received and the due process protections built into the program to ensure that claims were treated consistently and fairly by all who were involved in the process. It is fair to say that each claim was reviewed at least four times by different teams of individuals to ensure that all relevant facts associated with the claim had been carefully considered.

1. Settlement Agreement Background. The settlement was negotiated and the Settlement Program was designed to provide a fair and efficient means to compensate claimants who could present objective evidence of Vioxx usage and an associated heart attack, ischemic stroke or sudden cardiac death. This settlement is one of the largest settlements of litigation involving the use of a drug. Judges who were presiding over Vioxx litigation in courts around the country, including The Honorable Eldon E. Fallon of the United States District Court of the Eastern District of Louisiana, Judge Carol E. Higbee of the Superior Court in New Jersey, Judge Victoria G. Chaney of the Superior Court in California, and Judge Randy Wilson in Texas, encouraged the parties to adopt a settlement program as a way to provide compensation to those who suffered heart attacks or strokes while using Vioxx without waiting years and years for cases to be brought to trial, and on November 9, 2007, the Settlement Agreement was signed.

Once announced, the Settlement Agreement received almost unanimous support from lawyers and claimants who had filed lawsuits against Merck. In fact, more than 99.5% of those who were eligible to participate in the Settlement Program joined. To be eligible to participate, a claimant was required to have had a filed lawsuit or a tolled claim before the date the Settlement was announced. In addition, the claimant must have sustained a heart attack or an ischemic stroke in proximity to Vioxx use. In all, 51,036 claimants elected to join the Settlement Program.

Parties enrolling in the Settlement Program were required to sign a Release that released Merck from any and all liability associated with Vioxx use. These releases, under the terms of

the Settlement Agreement, would be delivered to Merck once the claim was paid or the claimant had elected to pursue other avenues for consideration of their claims under the terms of the Settlement Agreement. The Release required a claimant's original signature, in part to ensure that the claimant had read and understood its terms.

2. Submission of a Claim to the Settlement Program. After the submission of an Enrollment Form, including a Release and a Stipulation of Dismissal, enrolling claimants were given the opportunity to gather and send necessary Medical Records and proof of Vioxx use to the Claims Administrator for processing and review.

Guided by the objectives of fairness, efficiency and minimizing costs to the claimant, the Settlement Program limited the types and volume of records required for the evaluation of the claim. Unlike many claims processes where claimants are required to submit years of records from all health care providers, the Settlement Program limited the records to those surrounding the injury alleged, as well as proof of Vioxx use. The medical records were called Event Records, and they were usually the records from the hospitalization or care immediately surrounding the alleged heart attack or the stroke. To ensure that only those who actually used Vioxx would be compensated, the Settlement Program also required pharmacy records of Vioxx use or medical records from a doctor showing that he or she prescribed Vioxx or gave samples. In claims alleging death as a result of Vioxx use, more records were required. In addition, each claimant was required to submit a Claims Form, which contained only basic demographic information and required the claimant to specify which type of injury he or she was asserting.

By the terms of the Settlement Agreement, Claims Forms and all other records were required to be submitted by July 1, 2008. For many, this was a difficult deadline because of the time required to contact and wait on records from health care providers or pharmacies. Recognizing this, there were automatic extensions built into this deadline, ultimately giving claimants until November 30, 2008 -- more than one year from the announcement of the settlement -- to provide the records, as well as a Claims Form giving basic information about the injury being alleged. Out of an abundance of fairness, the Claims Administrator even went beyond the November 30, 2008 deadline by allowing records received by December 30, 2008, which the Settlement Agreement mandated be the absolute last date the basic records such as the Claims Form and Proof of Vioxx Use and Event records could be submitted.

Subsequently, claimants were given even more opportunities to submit records in support of their claim. Any claimant failing to qualify was given at least one opportunity to provide records if the ones they had previously submitted were not enough to pass the claim. The Claims Administrator gave reasonable extensions if the 21 days otherwise allowed was not enough time to gather the missing records. The Court and the Parties eventually directed the Claims Administrator on April 1, 2009, to stop granting extensions because years had passed since lawsuits had been originally filed against Merck, records had been collected during those years, and at the very least, the Settlement Agreement had been announced on November 9, 2007, giving people 17 months from that date until April 1, 2009, to get all the records necessary to support the claim. The cessation of extensions did not preclude those found to fail Gates the 21 days to provide any missing records, but it did set the stage for claimants to be paid without undue delay.

3. The Three Gates. To be eligible for payment in the Settlement Program, the Program required that each claim had to pass three Gates: Injury, Duration, and Proximity.

a. Injury. The Settlement Agreement was very specific about the proof necessary to prove a heart attack, sudden cardiac death, or an ischemic stroke. The easiest way to satisfy the Injury Gate was to have a clear diagnosis of the injury documented in the medical records upon discharge from the hospital. When a patient experiences a heart attack or an ischemic stroke, it is almost always documented in the hospital's discharge summary. However, knowing that some physicians record things differently in medical records, the Settlement Agreement allowed other types of objective medical proof that the injury had occurred. The key ingredient of this proof was a record from a cardiologist for heart attack claims, or a neurologist for ischemic stroke claims, reaching the conclusion *at that time that the claimant had sustained an eligible injury*, or that the claimant's signs and symptoms, coupled with other objective medical findings in the records, meant that the claimant had suffered the injury. The process was driven by actual medical records relating to the injury and not documents prepared years later or affidavits from physicians or others years later. This requirement was necessary to treat everyone consistently based on objective proof created at the time and not in contemplation of a lawsuit or submission of a claim in the Settlement Program.

b. Duration. To meet the Duration Gate, a claimant had to prove that he or she had received 30 Vioxx pills within a 60 day period at any time prior to the Event. In short, evidence that the claimant actually had used Vioxx was a necessary element for any claim.

c. Proximity. Finally, a claimant had to prove that he or she had received Vioxx in certain quantities at a time close to, or proximate to the Event. Again, the Settlement Agreement was very specific about the number of pills and the period of time prior to the Event that would satisfy the Proximity Gate. The basic purpose of this requirement was to link the timing of the use of Vioxx to the timing of the injury.

A claim failing one or more of these Gates, was not eligible for Payment. But, before this determination was finally made, the claim was reviewed multiple times by various teams and claimants were given multiple opportunities to produce evidence to show that the claim met the Gate requirements.

4. Layers of Review. Each claim went through the following processes before any *Gate Committee Notice of Ineligibility* was issued informing a claimant that his or her claim was not eligible.

a. Claims Administrator Review. Each claim was first reviewed by the Claims Administrator. BrownGreer, the Claims Administrator, is an entirely neutral party whose only allegiance is to fairness and whose only report is ultimately to the Court. We understand that the Parties chose us, and that the Court approved us to be the Claims Administrator because of our past experience in administering settlements. Before any claim

was reviewed, we conducted extensive training of our staff to ensure claims were carefully evaluated.

We reviewed the Claims Form and all records submitted for each claim and applied the very specific criteria in the Settlement Agreement to determine whether a claim passed all three Gates. We had no discretion to deviate from the objective terms of the Settlement Agreement. At the Claims Administrator level, each claim received an initial Gate review by a trained reviewer, and then at least one more review by another trained reviewer to ensure all relevant facts were considered accurately.

Following review and denial of at least one of the Gates, a claimant was sent a *Claims Administrator Notice of Ineligibility*. This Notice informed a claimant of which Gates were failing and offered the claimant the opportunity to submit additional records to satisfy the Gate.

If additional records were submitted, the Claims Administrator reviewed the claim again. If the records still did not support a passing claim, the claimant was sent a *Claims Administrator Notice of Ineligibility Following Submission of Additional Materials* and notified the claimant that his or her claim would be forwarded to the Gate Committee for further review.

b. *The Gate Committee.* The Gate Committee is comprised of representatives from counsel representing the interests of claimants and counsel from Merck. When the Gate Committee received a claim that the Claims Administrator had found did not meet the specific, objective criteria set forth in the Settlement Agreement, it reviewed it *anew* to see whether the Claims Administrator had made a mistake in denying the claim, or whether, although the claim did not technically meet the terms of the Settlement Agreement as found by the Claims Administrator, it should nevertheless come into the Settlement Program. The Gate Committee had much broader discretion than the Claims Administrator to allow a claim into the Settlement Program. In fact, Judge Fallon has referred to the Gate Committee as the “human touch” in this process, meaning that its members had the ability to look at the totality of the claim and, despite technical noncompliance with one or more of the Gates, put it into the Settlement Program because it met the spirit of the types of claims intended to be compensated.

Members of the Gate Committee personally reviewed each claim that failed Gates at the Claims Administrator level, and they voted whether to put the claim into the Settlement Program or fail it because it did not pass even their more liberal review. To date, the Gate Committee has placed more than 8,100 claims into the Settlement Program using the discretion it is afforded under the Settlement Agreement.

c. *Merck’s Unilateral Push Decision.* If the Gate Committee did not pass the claim, the claim was then sent for yet another review, this time to Merck for consideration of whether it should be included in the Settlement Program. Under the terms of the Settlement Agreement, Merck had the right to review a claim the Gate Committee had failed and decide to put it into the Settlement Program if there was evidence of Vioxx use and evidence of a heart attack,

ischemic stroke, or sudden cardiac death. The Settlement Agreement imposed limits on the number of claimants that it could push into the Settlement Program. Although Merck had even greater discretion than the Gate Committee, it was still bound by the Settlement Agreement's directive that there be a minimal showing of Vioxx use and injury as a result of that use. If Merck did not find any evidence warranting inclusion of the claim in the Settlement Program, the Claims Administrator would then issue the *Gate Committee Notice of Ineligibility*.

d. Options Available to Claimants Failing Gates. In an effort to provide continued due process to those who were not found eligible for the Settlement Program, the Settlement Agreement provided two options to those receiving the *Gate Committee Notice of Ineligibility*.

1) Appeal to the Special Master. First, the claimant could appeal any *Notice of Ineligibility* to a Special Master, an officer of the Court. Judge Fallon appointed a Special Master and two Deputy Special Masters to review and decide any appeal from a *Gate Committee Notice of Ineligibility*. The Special Master is Patrick A. Juneau, a lawyer who has served as Special Master in numerous other matters and enjoys a well-deserved reputation for fairness and objectivity. The Deputy Special Masters were The Honorable John K. Trotter, a former justice on the California Court of Appeals, and Judge Marina Corodemus, a former state court judge in New Jersey, both of whom have extensive experience in mediation, arbitration, and dispute resolution and who enjoy equally well-deserved reputations for fairness and objectivity. Any appeal filed with the Claims Administrator was assigned randomly to the Special Master and Deputies to ensure fairness. Upon receipt of the appeal, the Special Master reviewed the claim *anew* to see if it met the terms of the Settlement Agreement and should come into the Settlement Program. The Special Master's decision was final and binding. So, if the Special Master decided that the claim was not eligible for the Settlement Program, that was the final layer of review.

2) File a Future Evidence Stipulation. For claimants who did not want to appeal to the Special Master but wanted to resume a lawsuit against Merck, they were able to do so, if they submitted a Future Evidence Stipulation within 30 days of the *Gate Committee Notice of Ineligibility*. The purpose of the Future Evidence Stipulation was to ensure that claimants were not able to present at trial evidence that the Claims Administrator, the Gate Committee or Merck had not been able to consider in the Claims Process.

Built into the Future Evidence Stipulation Process was one final opportunity for those who failed to produce records to support eligibility. If a claimant or Firm produced records that would have changed the Gate result and showed due diligence in trying to obtain those records earlier, the Claims Administrator could permit those records and reverse the decision of ineligibility. The standard of due diligence was important to ensure that claimants submitted records timely and not wait until the claim had already been reviewed multiple times. If someone had used best efforts to get records and had been unable to because a health care provider was uncooperative, there was

one last safety valve to make sure a claimant was not unfairly excluded from the Settlement Program.

Those who filed a Future Evidence Stipulation that was signed and otherwise completed properly within 30 days of the *Gate Committee Notice of Ineligibility* were free to pursue their lawsuit in Court. However, there are time limits on proceeding with that lawsuit. For example, for claims pending in the MDL or with Tolling Agreements, Judge Fallon entered PTO 43, specifying that plaintiffs submit an Expert Report and other discovery within 30 days of submitting the Future Evidence Stipulation to the Claims Administrator.

5. Conclusion. More than 51,000 claimants registered and enrolled in the Settlement Program and claimed use of Vioxx and an injury as a result of that use. The Settlement Program was designed to compensate claimants who, based on objective medical evidence could show they had taken Vioxx and as a result suffered a heart attack, ischemic stroke or sudden cardiac death.

In any trial or in any Settlement Program, not everyone will succeed. Claims that do not present evidence meeting the settlement criteria will not receive compensation. While a claimant may be disappointed that his or her claim may not be compensated, each claimant should be assured that his or her claim was given very careful consideration, was reviewed multiple times by different levels of individuals, and was evaluated according to the same criteria that were applied to all claims.

We hope that this letter has helped explain the process by which all claims were considered. Thank you.

Sincerely,

Vioxx Claims Administrator