# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF LOUISIANA

In Re: VIOXX

:

MDL Docket NO. 1657

PRODUCTS LIABILITY LITIGATION:

SECTION L

This document relates to ALL ACTIONS:

JUDGE FALLON

MAG. JUDGE KNOWLES

# PLAINTIFFS' LIAISON COUNSEL'S MEMORANDUM IN SUPPORT OF MOTION FOR AWARD OF PLAINTIFFS' COMMON BENEFIT COUNSEL FEES AND REIMBURSEMENT OF EXPENSES

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#### I. <u>INTRODUCTION</u>

The Vioxx MDL Settlement is a monumental achievement. Within three years of the largest pharmaceutical recall of its kind, this Court, along with the assistance of Judges Carol E. Higbee, Victoria G. Chaney and Randy Wilson, resolved consolidated and coordinated litigation of enormous magnitude. The judicial oversight of extensive discovery, substantive and procedural motions practice, 6 bell-whether trials within the MDL and coordination with other state jurisdictions wherein 13 trials also transpired within this constrained time period, compelled the parties to reconcile their differences and resolve tens of thousands of outstanding claims.

The work of the Plaintiff's Steering Committee (PSC), the PSC's affiliated "common benefit" attorneys working at their direction, and the coordinated state litigations in New Jersey, California and Texas, were clearly instrumental in achieving this crowning success. The collective work of these counsel was essential to establish the liability of Merck & Co., Inc. ("Merck"). Whereas Merck defended Vioxx alternatively on the grounds that Vioxx did not increase the risk of cardiovascular injuries or that the increase in risk of injury that did exist did not occur for persons using the drug less than 18 months, the PSC and common benefit counsel, gathered and developed the crucial evidence that debunked Merck's arguments and supported plaintiffs' liability case. As a consequence of the evidence employed by the PSC, and the relentless coordinated efforts by all counsel (both federal and state), Merck was driven to resolve its liability exposure.

Thanks to the efforts of the dedicated common benefit counsel and with the courts' guidance, the litigation was well situated for resolution. All of the common benefit efforts by

these counsel culminated in the fruit of the labors of the Negotiating Plaintiffs Counsel (NPC), consisting of federal and state litigators, who were able to hammer out a settlement with Merck, after approximately one year of intensive negotiations. The Settlement Agreement quickly and amply met the needs of all the Vioxx patients that suffered a heart attack, ischemic stroke or sudden cardiac death by offering them entree into the largest private, individual settlement program of any mass tort claim. The novel \$4.85 billion settlement is indeed unparalleled in size, scope and speed of recovery for the claimants. As a medical-record driven settlement, enrolled claimants are having their claims determined at a record pace. Already, 4,585 persons have received interim payments on their claims and final payments of all MI claims are expected by Summer of 2009. See Status Conf. Hearing Transcript at 19 (E.D.La, Dec. 19, 2008).

With the advent of the Vioxx MDL Settlement, Merck agreed to provide \$4.85 billion to pay the claims of those claimants enrolled in the program. Whereas payment of the claimants is assured, payment to the counsel that bestowed this benefit upon them remains contingent. The attorneys have yet to receive compensation for their services because their fees are properly subject to Court approval. Under the terms of Article 9 of the Settlement Agreement an assessment of common benefit fees is to be imposed upon the gross recoveries of any person participating in the settlement and deducted from the total amount of counsel fees payable under individual plaintiffs' counsel's retainer agreements. Given the enormous benefits conferred upon these persons, the affiliated Common Benefit Counsel request an award of 8% of the \$4.85

<sup>&</sup>lt;sup>1</sup>See Settlement Agreement §9.2.1. Reimbursement of litigation expenses will be separately funded out of the clients' recoveries pursuant to the Settlement Agreement §9.2.2 ("Reimbursement of these expenses shall be deducted from the clients' net recovery").

billion fund or \$388 million for attorneys fees.<sup>2</sup> These funds would be obtained by approving the 8% assessment that was agreed upon by Merck and the NPC when they endorsed the Settlement Agreement on November 9, 2007, and, which assessment, was also agreed upon by each Vioxx claimant that registered in the Settlement. This 8% assessment for attorneys fees would supercede the assessment provided to MDL common benefit attorneys pursuant to Pretrial Order No. 19.

The amount requested here reflects a relatively modest percentage of recovery compared to the benchmark range in other class actions and global settlements and to percentage awards in these other large settlements that compare to this settlement only in terms of dollar value.

Further, in contrast to what Merck paid to its counsel, the fees requested by the Joint Petitioners are modest. Based upon Merck's public filings, it appears that Merck expended in excess of \$1.6 billion in aggregate Vioxx legal defense costs and, unlike the petitioners, Merck's counsel operated with no contingent risk.<sup>3</sup>

Nonetheless, we are mindful that our request is for a substantial amount of money. But apart from the quantum, the 8% award has been fairly earned. The common benefit attorneys devoted 503,185 hours to this litigation having a collective lodestar valued between \$217,128,800.40 and \$321,897,534.95. For many counsel involved, they dedicated their entire

<sup>&</sup>lt;sup>2</sup>One member of the PSC and his affiliated counsel does not subscribe to the relief requested in this motion.

<sup>&</sup>lt;sup>3</sup>Merck's defense costs were calculated only for the period between 2005 - 2008. See Form 10-K of Merck & Co., Inc. for the year ended December 31, 2005, at 3 (\$285 million); Form 10-K of Merck & Co., Inc. for the year ended December 31, 2006, at 3 (\$500 million); Form 10-K of Merck & Co., Inc. for the year ended December 31, 2007, at 17 (\$616 million); Form 10-Q of Merck & Co., Inc. for the quarterly period ended September 30, 2008, at 19 (\$222 million for the first 3 quarters of 2008).

practice to this litigation alone. For counsel undertaking such risks, ample reward is justified. Here, the reward requested is well within any judicially established benchmark. And given the superlative efforts by counsel, the single-digit percentage award requested, which was agreed to by the parties, is not only eminently fair and reasonable, but well deserved.

We will leave to the Court for another day the allocation of whatever award is permitted.<sup>4</sup> The present determination of the percentage award merely sets the bounds by which all counsel will be compensated. But the time for this petition has now arrived, bringing to mind the sage's adage:

If I am not for myself, who will be for me?
But if I am only for myself, who am I?
If not now, when?

Hillel, Ethics of the Fathers, 1:14

As will be demonstrated, the percentage award requested herein falls well within the Fifth Circuit's jurisprudence of *Johnson v. Georgia Highway Express, Inc.*, 488 F.2d 714, 717-19 (5th Cir.1974) and *High Sulfur Content*, 517 F.3d at 227-28.

#### II. <u>FACTUAL BACKGROUND</u>

#### A. THE HISTORY OF VIOXX

Vioxx was a medication sold for the treatment of acute pain and relief of osteoarthritis

<sup>&</sup>lt;sup>4</sup>Pursuant to PTO No. 6D, the Allocation Committee is actively engaged in efforts that will result in a recommendation to the Court for allocations of any award amongst counsel participating in this petition at the completion of its analysis. In that connection, the committee has reviewed affidavits submitted by counsel and met with counsel in Atlantic City, New Orleans, Houston and Los Angeles, to create a record for this Court's review. In due course, the Allocation Committee's recommendation will be presented that will address the relative input and value of services provided by fellow common benefit attorneys as dictated by existing jurisprudence. See, e.g., High Sulpher Content Gasoline Products Liability Litigation, 517 F.3d 220 (5th Cir. 2008); Turner v. Murphy Oil USA, Inc., 2008 WL 4661806 (E.D.La. Oct. 6, 2008).

and other conditions. It was designed to avoid the adverse gastrointestinal problems experienced by patients using the class of pain relievers known as non-steroidal anti-inflammatory drugs ("NSAIDs"). The adverse reaction most frequently associated with NSAIDs is the risk of gastrointestinal perforations, ulcers, and bleeds (PUBs). *In re Vioxx Products Liability Litigation*, 448 F.Supp.2d 741, 743 (E.D.La. 2006).

The mechanism by which NSAIDs relieve pain is through the inhibition of cyclooxygenase ("COX"), an enzyme that stimulates synthesis of prostaglandins. *Id.* When it was discovered that prostaglandin synthesis in humans was catalyzed by two forms of COX, *i.e.*, cyclooxygenase-1 ("COX-1") and cyclooxygenase-2 ("COX-2"), scientists began investigating the potentials for developing drugs that mediated only COX-2, but not COX-1. It was understood that COX-1 functioned to protect the gastric mucosa and promoted normal platelet functions while COX-2 mediated inflammation and pain. The hypothesis was formed that by selectively inhibiting COX-2 without effecting COX-1, the benefits of pain relief without the associated PUB adverse reactions could be accomplished. In the early 1990's, Merck and other pharmaceutical companies rushed into researching what promised to be an extremely profitable and growing market for such pain relievers.

Merck developed a selective COX-2 inhibitor, Rofecoxib or Vioxx, that received approval for marketing from the Food and Drug Administration ("FDA") on May 20, 1999. At that time, Vioxx was approved for the treatment of osteoarthritis, acute pain in adults, and the treatment of severe menstrual pain. Through Merck's efforts, Vioxx was widely promoted and achieved "blockbuster" success. Merck averaged over \$2 billion in sales per year with total sales from 1999 through 2004 exceeding \$10 billion. See Chris Mondics, Two Vioxx Critics

Allege Pressure, PHILADELPHIA INQUIRER, Nov. 19, 2004, at A1, A22 ("Vioxx generated sales of \$2.5 billion a year, making it a blockbuster product for a company that in recent years has had difficulty developing new medications, a problem faced by much of the pharmaceutical industry."). Despite this financial success, on September 30, 2004, Merck withdrew Vioxx from marketing after the data safety monitoring board overseeing Merck's long term study of Vioxx in patients at increased risk of colon polyps, Adenomatous Polyp Prevention on Vioxx ("APPROVe"), revealed a significantly increased risk of serious cardiovascular events, including heart attacks and strokes.

Prior to the alarming results of the APPROVe study, Merck had insisted that Vioxx was safe based upon the findings of its pivotal clinical study known as VIGOR (Vioxx Gastrointestinal Outcomes Research). See Bombardier, C., Laine L., Reicin A, et al., Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis, New England Journal of Medicine, 11/23/00: 343 (21); 1520-1528. This pivotal trial study for Vioxx involved 8,076 patients with rheumatoid arthritis that demonstrated that Rofecoxib had lower gastrointestinal toxicity than Naproxen. VIGOR was not designed to evaluate cardiovascular events, however, it did reveal that Vioxx was highly associated with cardiovascular events. Despite private, internal emails acknowledging that "the CV events are clearly there," Merck publicly interpreted the VIGOR study to maintain that "significantly fewer thromboembolic events [in other words heart attacks and strokes] were observed in

<sup>&</sup>lt;sup>5</sup> See McDarby v. Merck & Co., Inc., 949 A.2d 223 (N.J.App.Div. 2008), quoting March 9, 2000 Email of Edward M. Scolnick, then President of Merck Research Laboratories, and further quoting Dr. Scolnik's comments: "it is a shame but it is a low incidence and it is mechanism based as we worried it was." See also In re Merck & Co., Inc. Securities Derivative & "ERISA" Litig., 543 F.3d 150, 154 (3d Cir. 2008)

patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation." *In re Merck*, 543 F.3d at 154. In other words, Merck inverted the study's findings to suggest that Naproxen was cardio-protective, not that Vioxx caused cardiovascular problems.

Chinks in Merck's armor disputing the absence of CV risk caused by Vioxx quickly began to develop and pile up. In August 2001, in an article published in the Journal of the American Medical Association co-authored by noted cardiologists at the Cleveland Clinic, the authors challenged VIGOR's study design which had excluded all patients requiring aspirin for cardiac reasons. In addition, they noted that if all serious cardiovascular events were compared between the patients in the Vioxx group and the Naproxen group, "the risk of of serious cardiovascular events in the rofecoxib group was 2.2 times higher than in the naproxen group." Mukherjee D., Nissen S., Topol E., Risk of Cardiovascular Events Associated with Selective COX-2 Inhibitors, JAMA 2001; 286:954-9. On September 21, 2001, the FDA issued a warning letter to Merck stating that its promotional efforts were "false, lacking in fair balance or otherwise misleading" due to misrepresentations of the safety profile of Vioxx. In re Merck, 543 F.3d at 156. Later in the fall of 2001, the FDA had begun the process to require Merck to strengthen the warning in the Vioxx label to address the CV safety profile of the drug. Those efforts were rebuffed, refused and diluted by Merck over a period of months, until April 11, 2002, at which time, a revised label issued. No cardiovascular warning appeared in this revised label as desired by FDA. It was replaced with a much more narrowly worded precaution to use Vioxx with caution in patients with a "history of ischemic heart disease." See McDarby, 949 A.2d at 246; In re Merck, 543 F.3d at 159.

As time progressed more and more studies exposed the dangers of Vioxx. In August 2004, an FDA researcher, Dr. David Graham, presented the results of his analysis of Kaiser Permanente's database which revealed that Vioxx users were more likely to suffer a heart attack or sudden cardiac death than those taking another COX-2 Inhibitor, Celebrex. See Graham D., Risk of Acute Myocardial Infarction and Sudden Cardiac in Patients Treated with Cyclo-Oxygenase 2 selective and Non-selective Non-Stearoidal Anti Inflammatory Drugs: Nested Case Control Study, Lancet, Vol. 365, 475 (Feb. 2, 2005)(the publication of the study occurred months after its initial presentation). Merck immediately challenged Dr. Graham's report. Shortly thereafter, however, Graham's findings were corroborated by Merck's study results in the then on-going APPROVe study. This clinical study demonstrated a more than two-fold risk of heart attack and other cardiovascular events in patients taking Vioxx as compared to placebo, which necessitated its immediate cessation. See Topol E., Failing the Public Health – Rofecoxib. Merck, and the FDA, N.Engl.J.Med. 351;17, 1707-08 (Oct. 21, 2004). Without any comparator drug upon which to pass the blame (as was done with Naproxen), Merck was ignominiously forced to withdraw Vioxx from marketing. With an estimated 105 million prescriptions. involving approximately 20 million patients taking Vioxx in the United States alone, it was the largest withdrawal of any pharmaceutical drug in history.<sup>6</sup> See In re Vioxx Products Liability

<sup>&</sup>lt;sup>6</sup> The scale and impropriety of virtually every facet of Merck's marketing of Vioxx was phenomenal. Perhaps most emblematic of the insults which the public and medical community suffered was the rare publication of the Expression of Concern in the New England Journal of Medicine. See Curfman G, et al., Expression of Concern: Bombardier, et al., "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis," N Engl J Med, 2000; 343:1520-1528, N Engl J Med 2005; 353:2813-2814. After being presented with evidence disclosed in his MDL deposition, the editor-in-chief of the journal voiced his shock and incredulity regarding Merck's improper treatment of the data reported in its (continued...)

Litigation, 2008 WL 4681368, \*1 (E.D.La. Oct. 21, 2008).

Nevertheless, Merck employed the APPROVe study in an effort to demonstrate the there was no cardiovascular risk posed by Vioxx before 18 months of continuous use of the drug. Even this so-called "18-month Hypothesis" was discredited and the immediate dangers presented by Vioxx use were revealed as the study results became final. Indeed, in 2006, a *Correction* to the APPROVe study was published that eliminated Merck's basis for asserting an increase in risk after 18 months use. *See* Bresalier, *Cardiovascular Events Associate with Rofecoxib in a Colorectal Adenoma Chemoprevention Trial*, N Engl J Med 2005; 352:1092-1102 as amended by Correction, N Engl J Med 2006; 355(2): 221. As a result of Merck's malfeasance, it has been estimated that as many as 139,000 Americans experienced unnecessary Vioxx-induced cardiovascular events and that as many as 55,000 of these people died. *See* Graham, M.D., M.P.H., Testimony before the United States Senate Committee on Finance, Nov. 18, 2004 available at http://finance.senate.gov/hearings/testimony/2004test/111804dgtest.pdf. This conduct led to the extraordinary litigation now before the Court.

#### B. THE LITIGATIONS INSTITUTED AGAINST MERCK

#### 1. An Overview of Vioxx Litigation in State Courts

In certain venues, litigation against Merck began prior to the company's withdrawal of

<sup>&</sup>lt;sup>6</sup>(...continued) pivotal VIGOR study that was heavily relied upon by Merck to merchandise Vioxx. Recounting the knowing omission of three myocardial infarctions from the data presented to the Journal, Dr. Curfman lamented that, "these inaccuracies and deletions call into question the integrity of the data on adverse cardiovascular events in this article." Bias and misrepresentation in scientific findings has come under increasing scrutiny by the courts. The judiciary must now exercise caution when relying upon industry sponsored studies. See Exxon Shipping Co. v. Baker, 128 S.Ct. 2605, 2626 n. 17 (U.S. 2008)("Because this research was funded in part by Exxon, we decline to rely on it.").

Vioxx. In Texas, for example, some litigants represented by certain common benefit attorneys put Merck on notice of dangerous cardiovascular events by filing lawsuits beginning as early as 2000. See Affidavit of Russ M. Herman in Support of The Plaintiffs' Liaison Counsel's Motion for Award of Plaintiffs' Common Benefit Counsel Fees and Reimbursement of Expenses, ¶7 [hereafter "Herman Affid., ¶\_\_"]. These prescient claimants asserted that the label originally associated with Vioxx was deficient and failed to warn of the dangers of cardiovascular events associated with the drug. Individual cases were filed shortly thereafter in multiple venues in Texas. California, however, was the first state jurisdiction to aggregate Vioxx litigation. There, the Judicial Council of California agreed to coordinate all of the California Vioxx proceedings in one Superior Court, In re Vioxx Coordinated Cases, No. JCCP 4247 (Los Angeles Co., Calif., Super. Ct. Oct. 30, 2002). See Herman Affid., ¶11. The California litigation was centralized before the Honorable Victoria G. Chaney.

Likewise, in New Jersey, where Merck is headquartered, the New Jersey Supreme Court centralized for management purposes all Vioxx cases filed in the state court system on May 20, 2003. *Id.*, ¶6. Designated as a "Mass Tort," the litigation was coordinated before one Superior Court judge, the Honorable Carol E. Higbee. Under Judge Higbee's watchful eyes, the litigation was capably managed with discovery taking place and cases being prepared for trial. *Id.* 

In Texas, the Honorable Randy Wilson was appointed on September 6, 2005, to preside over that state's multi-district litigation, *In re Texas State Vioxx Litigation*, No. 2005-59499 (District Ct., Harris County, Tx, 157th Judicial District). *See* Herman Affid., ¶9.

Vioxx litigation was developed in these state jurisdictions prior to the JPML's initial transfer order. In Texas, Carlene Lewis and Shelly Sanford first began representing clients

against Merck in the summer of 2000 and by September of 2001 they were representing several hundred individuals. Throughout 2001 and 2002, they retained and prepared experts, took depositions of Merck executives, and had produced to them 10.5 million pages of documents. *Id.*, ¶7-8. These counsel associated themselves with trial counsel on certain cases. They also took a number of the original depositions of Merck witnesses, including Alice Reicin, Deborah Shapiro and Adam Schechter. Moreover, they helped develop experts such as Benedict Lucchesi, Wayne Ray, Cheryl Blume, Joye Carter and David Egilman. In preparation for the trial of *Ernst v. Merck*, the firm also examined thousands of documents, hired, and deposed experts and conducted several mock trials. The case was significant as it was the first Vioxx trial against Merck. The case was tried for 8 weeks in the Summer of 2005. The jury returned with a verdict for the plaintiff in the amount of \$253 million. *Id.*, ¶14.

Ultimately, the Texas MDL involved approximately 900 cases that were filed for pretrial. Judge Wilson appointed his own PSC comprized of 11 counsel. Under Judge Wilson's guidance, these counsel were actively preparing 5 waves of cases for trial to begin in the Spring of 2007. *Id.*, ¶9. On April 19, 2007, however, after extensive briefing and argument, Judge Wilson granted Merck's Motion for Summary Judgment on the Texas "Presumption" Statute and all discovery and trials in Texas courts were stayed pending appeal of the Order. The matter was in the Texas Appellate Courts when the Vioxx Settlement Agreement was announced in November of 2007. *Id.* 

In New Jersey, Seeger Weiss was appointed as Liaison Counsel of the coordinated proceedings in 2003. Through the efforts of a working group of excellent trial lawyers, these common benefit lawyers litigated the case aggressively long before Vioxx was withdrawn from

the US market in September 2004. *Id.*, ¶6. They engaged in extensive motions practice, coordinated discovery of corporate documents and multiple corporate depositions. These early New Jersey efforts included, but are not limited to, the following efforts:

The establishment of a large, multi-user electronic document depository maintained at Seeger Weiss in New York. This depository made available to Vioxx litigants the millions of pages of then-produced documents in searchable format, as well as multiple databases and raw clinical trial data produced by Merck, as well as deposition transcripts and exhibits. Through this depository, the Common befit applicants created document and reviewing protocol.

Reviewed countless pages of Merck documents which ultimately became the basis of the "Theme Grid" that became an integral part of the MDL 1657 "Trial Package."

·Conducted numerous pivotal depositions, including, but not limited to Beth Seidenberg, Brian Daniels, Thomas Bold, Louis Sherwood, Douglas Watson, Adam Schecter, Jennifer Ng, David Anstice, Briggs Morrison, Alise Reisin, Alan Neis, Ray Gilmartin, and Peter Honig.

Developed numerous experts who ultimately became MDL experts, including Wane Ray, PhD, Benedict Lucchesi, MD and Richard Kronmal, Ph.D.

In California, Judge Chaney actively presided over intense litigation that resulted in three Vioxx trials that reached a jury verdict. All were defense verdicts or hung jurys. But the court's efforts in the Summer of 2007 to accelerate 80 trial settings for California residents subject to preferential trial settings under California Code of Civil Procedure §36 created tremendous incentives for the parties to conclude the litigation. *Id.*, ¶11. *See also Individual Vioxx Cases*, Case No. JCCP No. 4247, Order re: June 1, 2007 General Status Conf. (Los Angeles Co., Calif., Super. Ct. June 28, 2007)[Attached hereto as Exhibit "A"].

#### 2. An Overview of Vioxx Litigation in the MDL

After September 30, 2004, upon the withdrawal of Vioxx from marketing, a tidal wave of litigation against Merck ensued. Thousands of cases began to compile in the federal district

courts across the country and in state venues, as well. On behalf of the federal litigation, a petition for consolidation was filed before the Judicial Panel on Multi-district Litigation (the "JPML"). The JPML issued its initial Transfer Order to this Court on February 16, 2005. See In re Vioxx Products Liability Litigation, 360 F.Supp.2d 1352 (J.P.M.L. 2005).

Upon transfer, this Court immediately charted a course to organize the litigation. The Court reached out to its state counterparts and the litigation became successfully coordinated. On February 28, 2005, through Pretrial Order No. 2, this Court appointed Russ Herman to act as Plaintiffs' Liaison Counsel. Thereafter, in PTO No. 6, the Court appointed its Plaintiffs' Executive Committee ("PEC") comprised of Russ Herman, Andy D. Birchfield, Jr. (Co-Lead), and Christopher A. Seeger (Co-Lead). PTO No. 6 also identified the Plaintiffs' Steering Committee ("PSC"), comprised of the aforementioned counsel and Arnold Levin, Thomas R. Kline, Richard J. Arsenault, Carlene Rhodes Lewis, Elizabeth J. Cabraser, Gerald E. Meunier, Troy A. Rafferty, Mark P. Robinson, Jr., Drew Ranier and Christopher V. Tisi. Leonard Davis was subsequently approved by the Court to assist the PLC. The role of the PSC was to be responsible for efficiently coordinating with all of the plaintiffs in the MDL, to represent their interests before the Court, to complete all generic discovery, litigate pretrial issues and conduct settlement negotiations on behalf of plaintiffs. The PSC immediately set about to complete the

<sup>&</sup>lt;sup>7</sup> Upon Ms. Lewis's untimely death, the court appointed her partner, Shelly Sanford, to replace Ms. Lewis on the PSC. See In re Vioxx Products Liability Litigation, MDL No. 1657, Order (E.D.La. June 8, 2006).

<sup>&</sup>lt;sup>8</sup> In Pretrial Order No. 7, the Court also appointed Defendants' Steering Committee comprised of Douglas R. Marvin (lead counsel), Theodore V. H. Mayer, John H. Beisner, Richard C. Stanley, Anthony M. DiLeo and Phil Whittmann (liaison counsel). Subsequently, Dorothy H. Wimberly was also appointed to the Defendants' Steering Committee. *See In re Vioxx Products Liability Litigation*, MDL No. 1657, Order (E.D.La. Dec. 16, 2005).

duties bestowed upon it.

Shortly after PTO No. 6 was entered and consistent with the mandate of that order, the PSC presented a series of administrative orders to the Court, usually in advance of the regularly held monthly Status Conferences, that addressed the various anticipated procedural matters in the litigation. These orders were introduced to effectively and efficiently streamline practices so as to avoid burdening the Court. The orders presented resulted in their adoption or issuance of several pretrial orders covering numerous topics, including: Electronic Service (PTO No. 8); Deposition Guidelines (PTO No. 9); Confidentiality of documents (PTO No. 13); and Plaintiff and Merck Profile Forms (PTO No. 18 as amended).

#### 3. Significant Discovery Took Place

With the initial practice guidelines in place, the MDL was situated to function efficiently and effectively, so as to avoid any criticism of being labeled a "black hole." Under this regime,

<sup>&</sup>lt;sup>9</sup> Multidistrict litigation involving dangerous drugs and medical devices has been criticized for inefficiency, with individual cases becoming stranded in the transferee court without prompt resolution. See Fallon, Bellwether Trials in Multidistrict Litigation, 82 Tulane L.Rev. 2323, 2330 n. 21 (June 2008); Gary Wilson, et al., "The Future Product Liability In America," 27 WILLIAM MITCHELL L.REV. 85, 112-113 (2000) ("Generally, MDL transfer has been a black hole [where] remand and trial come only after years of slow-moving pretrial activity....); Judith Resnick, "Aggregation, Settlement and Dismay," 80 CORNELL L.REV. 918, 920 (1995) ("functionally, MDL transfers often translate into stays that decrease the value of cases by the delay produced"). One need only cite the litigation experience involving Asbestos, Three Mile Island, Bendectin, Dalkon Shield, Breast Implants, Agent Orange, and HIV Contaminated Blood to make the point that in a mass tort case, victims typically go without relief or, if they are lucky, receive meager amounts of compensation decades after they suffered their injuries. See Bellwether Trials, 82 Tulane L.Rev. at 2330 n. 21; Deborah R. Hensler, "Fashioning a National Resolution of Asbestos Personal Injury Litigation," 13 CARDOZO L.REV. 1967 (Apr.1992); In re TMI Litig., 193 F.3d 613 (3rd Cir.1999)(sustaining summary judgment against those exposed to radiation because of the difficulty of proving injury causation); Wilson v. Merrell Dow Pharm., Inc., 160 F.3d 625 (10th Cir.1998)(sustaining summary judgment in a prescription drug product liability action because of the difficulty of establishing causation); (continued...)

the PSC set about to conduct discovery. Three comprehensive sets each of Interrogatories and Requests for Production of Documents were prepared and served upon Merck. See Herman Affid., ¶20. Seventy-eight (78) subpoenaes were prepared and served upon third parties. Id. From this discovery, review of approximately 50 million pages of documents produced by Merck and third parties took place. Id. Depositions of 170 key witnesses were noticed, prepared for and taken within the MDL and another 1757 relevant depositions were collected and reviewed by the PSC. Id. Overall, more than 2000 depositions were conducted. See In re Vioxx Products Liability Litigation, 2008 WL 4681368 at \*2 n.6. The PSC prepared over 45 substantive motions, monitored well over 100 substantive motions prepared by other plaintiffs in the MDL, and similarly monitored or responded to the almost 200 substantive motions filed by Merck. See Herman Affid, ¶25, Exhibits B, C, & D. In addition, the PSC monitored as appropriate the hundreds of non-substantive and procedural motions routinely filed within the

<sup>&</sup>lt;sup>9</sup>(...continued)

Raynor v. Merrell Pharm., Inc., 104 F.3d 1371 (D.C.Cir.1997)(same); Georgene M. Vairo, "Georgine, The Dalkon Shield Claimants Trust, and the Rhetoric of Mass Tort Claims Resolution," 31 LOYOLA OF LOS ANGELES L.REV. 79, 125 (Nov.1997); Deborah R. Hensler & Mark A. Peterson, "Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis," 59 BROOKLYN L.REV. 961 (Fall 1993); Jack W. Snyder, "Silicone Breast Implants: Can Emerging Medical, Legal and Scientific Concepts be Reconciled?," 18 J. LEGAL MED. 133 (June 1997); Joseph M. Guzzardo & Jennifer L. Monachino, "Gulf War Syndrome-Is Litigation the Answer?: Learning Lessons from In Re Agent Orange," 10 St. John's J. Legal Comment 673 (Summer 1995); Joseph Kelly, "The Liability of Blood Banks and Manufacturers of Clotting Products to Recipients of HIV-Infected Blood: A Comparison of Law and Reaction in the United States, Canada, Great Britain, Ireland, and Australia," 27 J. MARSHALL L.REV. 465 (Winter 1994). This is because of the vast financial resources available to the pharmaceutical giants to conduct a "scorched earth" defense, the legal obstacles to securing class relief, the delays engendered by the complexity of the litigation, and the risk of a bankruptcy as the inevitable and ultimate defense against the financial press of such cases. Id. Obviously, this MDL has transcended the difficulties experienced by past MDLs to prove itself to be the model for other cases that follow.

MDL. See generally Hearing Transcript at 39-40 (E.D.La. Nov. 9, 2007). 10

The PSC also retained experts in the fields of cardiology, pharmacology, and neurology, among others, to assist all of the plaintiffs in the prosecution of the MDL. See Herman Affid., ¶22. These experts presented reports and each was defended at their deposition by PSC attorneys consistent with this Court's scheduling orders. The PSC also reviewed the Defendants' expert reports and deposed each of the Defendants' experts. *Id.*, ¶24.

To support the PSC, a document depository that was coordinated with the New Jersey, Alabama and California depositories was established in New Orleans to house the substantial forest of documents produced. *Id.*, ¶20. The MDL depository acted as the nerve and communication center for all litigation nationally. The depository inhabited separately rented office space nearby the offices of Herman, Herman Katz & Coltar, LLP. It was equipped with modern office equipment including photocopiers, computers, faxes and telephones. Rent and equipment costs were borne by the PSC and have not yet been reimbursed. The depository was administered by Penny Grisamore and staffed by attorneys and capable paralegals. Salaries of these professionals and para-professionals were borne by members of the PSC. *Id.* 

#### 4. The Bellwether Trials

From the outset of the MDL, this Court contemplated a series of bellwether trials to advance the litigation. *See Bellwether Trials*, 82 Tulane L.Rev. at 2325. Given Merck's

<sup>&</sup>lt;sup>10</sup> During the course of the MDL proceedings before this court, thousands of orders and opinions were issued by the Court. *See* Herman Affid., ¶28, Exhibit E. Fifty-one of the Court's opinions are available on Westlaw. *Id.* Two reported opinions of appeals to the Fifth Circuit are also available on Westlaw. *Id.*, ¶29.

repeated insistence that it intended to try every case,<sup>11</sup> the necessity for representative trials to mature the claims and provide a range of values from which the parties could evaluate the litigation for settlement purposes was necessary. In the MDL, a series of six bellwether trials were contemplated. The premier trial for the MDL of Plunkett took place in Houston, Texas due to the devastating disruptions caused by Hurricane Katrina. *See* Herman Affid., ¶42. That trial resulted in a hung jury. Thereafter, the Plunkett retrial and the remaining bellwether trials took place in the recovering New Orleans.<sup>12</sup> One of the MDL trials, Barnett, resulted in a \$51 million plaintiff's verdict that was subject to remititur. All the others resulted in defense verdicts won by Merck.

The MDL trials and the other 13 trials are captured in the following chart:

CAPTION	RESULT	
MDL	CASES ?	
Evelyn Irvin Plunkett, Individually, and as the Personal Representative of the Estate of Richard Irvin, Jr. v. Merck & Co., Inc., Case No. 05-4046	(S.D.Tex., Houston Div., Dec. 13, 2005) (hung jury), retried (E.D.La., Feb. 13, 2006) (judgment for defendant), vacated (E.D.La., May 29, 2007)	
Barnett et al v. Merck & Co., Inc., Case no. 06-485	(E.D.La., June 28, 2007) (\$51 million verdict for plaintiff, \$1 million as punitive damages, with \$1.6 million remittitur award accepted by plaintiff), appeal dismissed, Case No. 07-30897 (5th Cir., Apr. 18, 2008)	

<sup>&</sup>lt;sup>11</sup>See, e.g., Press Release: Merck Wins Federal VIOXX Product Liability Case (Feb. 17, 2006) available at http://www.merck.com/newsroom/press\_releases/corporate/2006\_0217.html.

<sup>&</sup>lt;sup>12</sup>The first in-depth demographic analysis of the Hurricane strike zone revealed the disproportionate impact the storm had on particular communities of New Orleans. See Logan, The Impact of Katrina: Race and Class in Storm-Damaged Neighborhoods (Brown Univ. Jan. 25, 2006) available at <a href="www.s4.brown.edu/Katrina/report.pdf">www.s4.brown.edu/Katrina/report.pdf</a>. As a consequence, the jury pools in the New Orleans vicinage were noticeably different following Katrina.

Smith v. Merck & Co., Inc., Case No. 05- 04379	(E.D.La., Oct. 4, 2006) (defense verdict)		
Mason v. Merck & Co., Inc., Case No. 06- 00810	(E.D.La., Nov. 20, 2006) (defense verdict)		
Dedrick v. Merck & Co., Inc., Case No. 05- 02524	(E.D.La., Dec. 15, 2006) (defense verdict)		
TE	XAS		
Ernst et al v. Merck & Co., Inc., Trial Court Cause No. 19961*BH02	(Dist. Ct., Brazoria County, Tx. Aug. 15, 2005) (awarding Ernst's estate \$26 million after a verdict of \$253 million), reversed, 2008 WL 2201769 (Tex. App. May 29, 2008)		
Garza v. Merck & Co., Inc., Trial Court No. DC-03-84	(Dist. Ct., Starr County, Tx. Apr. 21, 2006) (awarding Garza's estate \$7.75 million following a verdict of \$32 million), reversed, 2008 WL 5169577 (Tex. App. Dec. 10, 2008)		
NEW JERSEY			
Humeston v. Merck & Co., Inc., No. ATL-L-2272-03	(N.J. Sup. Ct., Atlantic County, Nov. 3, 2005) (defense verdict), vacated, No. ATL-L-2272- 03 (N.J. Sup. Ct., Atlantic County, Aug. 17, 2006), retried (N.J. Sup. Ct., Atlantic County, Mar. 12, 2007) (\$47.5 million verdict)		

McDarby (and Cona) v. Merck & Co., Inc., No. ATL-L-1296-05	(N.J. Sup. Ct., Atlantic County, April 5, 2006) (\$15.7 judgment for McDarby, awarding compensatory and punitive damages, as well as attorneys' fees and costs; \$2.27 million judgment for Cona, awarding damages of \$135 and the remainder as attorneys' fees and costs), affirmed in part, reversed in part, 949 A.2d 223 (N.J. Sup. Ct., Appellate Division, May 29, 2008) (affirming award of compensatory damages to McDarby pursuant to the New Jersey Products Liability Act ("PLA"); reversing the award of punitive damages pursuant to the PLA as preempted by the Federal Food and Cosmetic Act; reversing the awards of damages to McDarby and Cona and the awards of attorneys' fees pursuant to the New Jersey Consumer Fraud Act ("CFA"), determining that plaintiffs' CFA claims are subsumed within the PLA)
Doherty v. Merck & Co., Inc., No. ATL-L-638-05	(N.J. Sup. Ct., Atlantic County, July 13, 2006) (defense verdict)
Hermans v. Merck & Co., Inc., No. ATL-L-5520-05	(N.J. Sup. Ct., Atlantic County, Mar. 12, 2007) (defense verdict)
ALAI	BAMA
Albright v. Merck & Co., Inc., Case No. CV05-2316	(Alabama Circuit Ct., Jefferson County, Dec. 15, 2006) (defense verdict)
CALIF	ORNIA
Grossberg v. Merck & Co., Inc., Docket No. BC 327729	(Superior Ct. of California, County of Los Angeles, Aug. 2, 2006) (defense verdict)
Arrigale v. Merck & Co., Inc., No. 05CC03136	(Superior Ct. of California, County of Los Angeles, Jan. 18, 2007) (hung jury)
Appell v. Merck & Co., Inc., No. BC328858	(Superior Ct. of California, County of Los Angeles, Jan. 18, 2007) (hung jury)

ILLINOIS	
Schwaller v. Merck & Co., Inc., Case No. 05- L-687	(Illinois Circuit Court, 3 <sup>rd</sup> Judicial Circuit, Madison County, March 27, 2007) (defense verdict)
FLORIDA	
Kozic v. Merck & Co., Inc., Case No. 03- 9248	(Circuit Court for the 13 <sup>th</sup> Judicial Circuit, Hillsborough City, Florida, October 5, 2007) (defense verdict)

#### 5. The Settlement Agreement with Merck

During the Bellwether trials, this Court along with coordinate Judges from New Jersey, Texas, and California, directed certain plaintiffs' counsel from each respective litigation center to focus their efforts on a negotiated resolution with Merck. *See* Hearing Transcript at 5 (E.D.La. Nov. 9, 2007). The NPC, Russ Herman, Andy Birchfield, Christopher Seeger, Arnold Levin, Edward Blizzard and Thomas Girardi, were selected based upon recognition of their core responsibility for strategic and tactical decisions in their relevant jurisdictions. The NPC began negotiating in earnest on behalf of the plaintiffs' interests with counsel for Merck beginning in December 2007. *See* Herman Affid., ¶43. After a year of hard fought, "robust" and very armslength negotiations, Hearing Transcript at 16 (E.D.La. Nov. 9, 2007), the Settlement Agreement was reached. It was presented to the Court, sitting along with its brother and sister Judges, on November 9, 2007.

The Settlement Agreement was a uniquely tailored instrument. "Unlike a class settlement, the MSA is a private, opt-in settlement that was not secured through a settlement class vehicle and therefore pose[d] no risk of binding any unwilling plaintiff to its terms." *In re Vioxx Products Liability Litigation*, MDL No. 1657, Order & Reasons at 7 (E.D.La. Dec. 12.

2008). The settlement provides compensation for Vioxx claimants whose objective medical records establish their use of Vioxx in proximity to certain defined injuries (myocardial infarctions, ischemic strokes and sudden cardiac death). The details of the Settlement Agreement are contained within a 65 page document with 14 highly specialized exhibits exceeding 100 pages.

To be activated, the Settlement Program required a minimum participation, favorable response rate of 85% of all eligible claimants. The Settlement Program, however, was so well received that the minimum participation levels were far exceeded. In total, 99.79% of all Vioxx Claimants that registered in the program enrolled into the Settlement Program. *See* Status Conf. Hearing Transcript at 9 (E.D.La. Dec. 19, 2008). This overwhelming response reflects the extraordinary benefits conferred upon the Vioxx plaintiffs who otherwise confronted litigation risks, including proof of causation at trial.

The administration of the Settlement Program is based upon objective data. Eligible Claimants were therefore required to submit to the Claims Administrator certain medical records documenting their injury ("Event Records") and records documenting their Vioxx usage. This so-called "Claims Package" was to be submitted along with a Release and Dismissal Stipulation in order for the Eligible Claimant to participate in the Settlement Program. Based upon the Claims Package, BrownGreer, LLC, the Claims Administrator determines whether an Eligible Claimant qualifies for compensation based upon certain threshold criteria being met. These threshold criteria are referred to as "Gates" which evaluate the (1) event, (2) duration of Vioxx use, and (3) proximity of Vioxx use to the injury. To meet the "Event Gate", medical records must confirm that the Eligible Claimant suffered a heart attack, ischemic stroke or sudden

cardiac death. The "Duration Gate" requires that medical or pharmacy records establish that the Eligible Claimant receive at least 30 Vioxx pills within sixty days prior to the injury. Finally, the "Proximity Gate" requires that medical or pharmacy records confirm that Vioxx was being used by the Eligible Claimant within fourteen days of the Vioxx-related heart attack, ischemic stroke or sudden cardiac death.

The Settlement permits Eligible Claimants review opportunities of the Claims

Administrator's determination of whether Eligible Claimant's qualify for compensation. All determinations by the Claims Administrator that a claim is ineligible are reviewed by a "Gates Committee." The Gates Committee has been and remains actively involved in reviewing thousands of such determinations since the initiation of the Settlement Program. A Gates Committee determination is also appealable to the Special Master who is to review *de novo* any determination that an Eligible Claimant did not qualify for compensation.

Based upon any determination of not qualifying for compensation, each Eligible

Claimant has the right to return to the tort system and receive back their Release and Dismissal

Stipulation contingent upon the submission of a future evidence stipulation, or do nothing and
have their case dismissed, or, as previously discussed, appeal the negative determination to the

Special Master. In the event the Special Master rules in favor of the Eligible Claimants

qualifying for compensation then, like all eligible claimants, the claim gets submitted to the

Claims Administrator to participate in the valuation process.

The valuation process for qualifying claims uses a point system to ensure that the valuation is consistent across similarly situated Qualifying Claimants and reflects the likely relative value of each claim within the tort system. Under the points system, the Claims

Administrator individually evaluates the medical records in support of each Qualifying Claimant along several dimensions. Claims are first assigned a base point total, which reflects the qualifying claimants injury type, level of injury within the injury type, age at the time of the MI or IS, and duration of Vioxx use. Claims involving longer Vioxx use, a younger Vioxx Claimant, and a more severe injury will be assigned more points than claims involving briefer Vioxx use, and older Vioxx Claimant, and less severe injury.

Adjustments to the base point total are then adjusted by the Claims Administrator based on various standardized liability adjustments and risk factor adjustments. The adjustments reflect aspects of the Qualifying Claimant's Vioxx use and medical history that would be expected to affect the value of the Qualifying Claimant's claim within the tort system and are based upon a Qualifying Claimant's event records, follow up records, and any Profile Form, submitted to Merck or the Court. The liability adjustments involve the consistency of the Qualifying Claimant's Vioxx usage in the twelve months preceding the event and whether the Qualifying Claimant's Vioxx use and the MI or IS occurred prior to March 9, 2000, between March 9, 2000 and April 11, 2002, or after the April 11, 2002 label change. The risk factor adjustments include consideration such as smoking history, high cholesterol, hypertension, diabetes, etc. Again, the Claims Administrator's determination of each Qualifying Claimant's total point award is appealable to the Special Master.

Once the total number of points of all qualifying MI and IS claims is known, the Claims Administrator will then be able to make final payments from the settlement funds. The total gross payments to be made to Qualifying Claimants under the agreement is \$4.85 billion, with approximately \$4 billion to be allocated among MI Qualifying Claimants and approximately

\$850 million to be allocated among IS Qualifying Claimants.

The Settlement Agreement also provides for interim settlement payments to certain claimants. The Claims Administrator regularly reports to the Court at its monthly status conferences, the status of interim settlement payments amongst its reports on the progress of claims administration. In addition, the program also provides for extraordinary injury payments for certain Qualifying Claimants with documented economic damages of at least \$250,000.00. The Settlement also provides for a Lien Resolution Administrator, Matthew L. Garretson and the Garretson Law Firm. Mr. Garretson has already favorably resolved the governmental liens on behalf of all Vioxx Claimants, which in and of itself affords claimants an extraordinary benefit. Herman Affid., ¶46.

In addition, the Settlement Agreement contemplated the use of a bank to provide financial services attendant to funding the Settlement Program. The MDL common benefit counsel conferred with and interviewed several prospective institutions before selecting and retaining U.S. Bank as the escrow agent to provide these financial services. Significant negotiations and collaboration have taken place between MDL common benefit counsel and U.S. Bank in connection with its role as escrow agent. U.S. Bank has been and remains a financially sound financial institution despite the current financial crisis within the banking industry. Herman Affid., ¶48.

The Settlement Agreement received widespread notice. It was published on the MDL Court's website, a website entitled <a href="www.officialvioxxsettlement.com">www.officialvioxxsettlement.com</a> and other locations. In addition, the members of the NPC traveled to various forums to promote the Settlement Agreement and to inform interested claimants and their counsel of the benefits of the Settlement