

APPENDIX T

BOARD AWARENESS OF VIOXX'S CARDIOVASCULAR SAFETY PROFILE  
AND INVOLVEMENT IN VIOXX DEVELOPMENT AND MARKETING.

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## APPENDIX T

### BOARD AWARENESS OF VIOXX'S CARDIOVASCULAR SAFETY PROFILE AND INVOLVEMENT IN VIOXX DEVELOPMENT AND MARKETING.

#### A. Introduction.

From November 1998, when Merck submitted the New Drug Application for Vioxx, through September 2004, when Merck voluntarily withdrew Vioxx from the worldwide market, Merck's Board of Directors met approximately fifty times. At these meetings, the directors discussed many drugs and vaccines that Merck was marketing or developing, including Vioxx.

During this period, with respect to Vioxx, MRL scientists and Merck Marketing, Public Affairs and Business professionals gave presentations to the Board covering such topics as:

- The market for non-selective NSAIDs and the market potential for selective Cox-2 inhibitors, including Vioxx;
- The profile of Searle/Pfizer's Celebrex as compared to Vioxx and the competition for market share;
- Sales forecasts for Vioxx;
- Milestone events with the FDA, including Advisory Committee Meetings;
- The results of the VIGOR Trial and MRL's view that the naproxen cardioprotection hypothesis best explained the cardiovascular data, although other possibilities, including the FitzGerald prostacyclin hypothesis, had been raised;
- The September 2001 Warning Letter Merck received from the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC); and
- The decision to withdraw Vioxx from the market worldwide.

Merck's Board of Directors also regularly received copies of press releases that the Company issued as well as important news or scientific articles about Vioxx.

This Appendix: (i) describes in general terms the Board composition and the Board's interaction with Merck executives; (ii) reviews the Board's awareness of the science regarding the development and cardiovascular safety of Vioxx; and (iii) discusses the Board's knowledge of and involvement in the marketing of Vioxx.

B. Board Composition and Summary of Meetings.

During the time that Vioxx was marketed, Merck's Board of Directors included ten outside directors and two members of Merck management, Mr. Raymond Gilmartin, Chairman of the Board, Chief Executive Officer and President of Merck, and Dr. Edward Scolnick, President, Merck Research Laboratories. When Dr. Scolnick retired in 2002, he was not replaced on the Board by another member of management. The outside Board members from the time period when Vioxx was on the market are listed in Table 1, at the rear of this Appendix. Three of the outside Board members during this time were physicians: Dr. Lloyd C. Elam, Professor of Psychiatry at Meharry Medical College; Dr. William N. Kelley, Professor of Medicine, Biochemistry and Biophysics at the University of Pennsylvania School of Medicine; and Dr. Samuel O. Thier, Professor of Medicine and Professor of Health Care Policy at Harvard Medical School. In addition, outside Board member Dr. Thomas E. Shenk is Chairman of the Department of Molecular Biology at Princeton University. All Board members were briefed about the science behind the various drugs that Merck was developing or marketing.

Also present at most Board meetings were Mr. Kenneth C. Frazier, Senior Vice President and General Counsel, Mr. David W. Anstice, President of Merck's United States Human Health Division, and Ms. Judy C. Lewent, Executive Vice President and Chief Financial Officer.

In general, before each meeting, Board members received a pre-meeting package with materials relevant to the upcoming meeting. The distribution typically included an agenda, prepared by Mr. Gilmartin, that identified topics to be addressed at the meeting. All meetings began with a "Chairman's report" by Mr. Gilmartin, in which Mr. Gilmartin gave an overview of important developmental or marketing issues concerning a number of Merck's drugs.

After that report, senior members of Merck's Marketing, Public Affairs, Regulatory or Business Departments, or senior scientists from MRL, made presentations to the Board about the particular topics on that month's agenda. After the presentations, the outside directors frequently met privately. On occasion, the Board requested that specific individuals come before the Board to speak to a particular issue, or that a particular issue be addressed at a subsequent Board meeting.

Apart from their interaction with management at formal Board meetings, Board members also were in informal contact with members of senior management. For example, it was not unusual for a Board member to call or write to Mr. Gilmartin or Dr. Scolnick between meetings if the Board member had a specific question.

C. Board Awareness of Vioxx's Cardiovascular Profile.

After the VIGOR Trial cardiovascular data were unblinded, the Merck Board of Directors learned that Dr. Garret FitzGerald\* and his colleagues at the University of Pennsylvania had raised theoretical questions about the cardiovascular safety profile of Vioxx in 1997. Thereafter, the Board was kept abreast of important scientific developments and issues raised by the press, the scientific community, and the FDA with respect to the cardiovascular safety profile of Vioxx. This Section reviews chronologically the scientific presentations made to the Board regarding the cardiovascular profile of Vioxx.

1. The VIGOR Trial Data.

In late March 2000, a package similar to the packages sent to investigators in all ongoing Vioxx trials (discussed in Appendix E) was sent to all outside members of the Merck Board. The package, which informed Board members of the VIGOR Trial cardiovascular results and provided a primer on potentially relevant science, included Merck's March 27, 2000 press release announcing the VIGOR Trial results, the letter sent to investigators announcing the results of the VIGOR Trial and an amendment to all Vioxx trial protocols to allow low-dose aspirin use, and four scientific articles pertaining to the FitzGerald prostacyclin hypothesis and naproxen cardioprotection (the study that demonstrated cardioprotective effect of flurbiprofen, the FitzGerald study, the

McAdam study, and an abstract of a case report of thrombosis in lupus patients who took Celebrex).<sup>1</sup>

On April 25, 2000, at the first Board meeting after the VIGOR Trial data had been unblinded, Dr. Scolnick presented to the Board of Directors a detailed analysis of the VIGOR Trial gastrointestinal and cardiovascular data, including a comparison of the Vioxx VIGOR and Celebrex CLASS Trials.<sup>2</sup> Dr. Scolnick also provided background information on the known effects of Cox-1 and Cox-2 on platelet aggregation and described to the Board both the NSAID cardioprotection hypothesis and the FitzGerald prostacyclin hypothesis.<sup>3</sup>

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<sup>1</sup> 3/28/00 memorandum from L. Distlerath to Merck Board of Directors, MRK-MIAA0004551.

<sup>2</sup> 4/25/00 slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000733, at 33-38.

<sup>3</sup> 4/25/00 slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000733, at 39. The text of the slide that was presented to the Board is illegible. An exact duplicate of that slide, from another presentation, is reproduced here. Undated slide presentation, "VIGOR Preliminary Results," MRK-NJ0368356, at 76

## **COX-1/COX-2 Effects on Platelet Aggregation**

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- COX-1/COX-2 derived prostacyclin causes blood vessels to dilate and prevents platelet aggregation
  - NSAIDs, rofecoxib and celebrex result in ~50% reduction in prostacyclin levels
- Potential Implications
  - NSAIDs that **completely inhibit thromboxane and platelet aggregation** could theoretically decrease the incidence of cardiovascular adverse events such as heart attacks and strokes compared to COX-2 selective inhibitors through its antiplatelet effects
  - COX-2 specific inhibitors could theoretically cause an imbalance in the platelet aggregation through inhibition of prostacyclin without inhibition of thromboxane. This imbalance could potentiate thrombotic events

Dr. Scolnick also highlighted the possibilities that (i) the cardiovascular data observed in the VIGOR Trial were related to a unique characteristic of the rheumatoid arthritis population studied, and (ii) given that the 50 mg dose used in the VIGOR Trial was much higher than the approved daily dose for chronic use, the data could reflect an effect that was not a problem at the lower, approved dosages.

Dr. Scolnick then explained the data supporting his and other MRL scientists' beliefs that the between-arm difference in the incidence of cardiovascular events in the VIGOR Trial was best explained by naproxen's cardioprotective effects.

First, Dr. Scolnick presented data from the Phase III osteoarthritis trials showing that the incidence of serious thromboembolic cardiovascular adverse events was similar

among patients on the Vioxx, placebo, and traditional NSAID comparators (ibuprofen and diclofenac).<sup>4</sup>

Second, Dr. Scolnick reviewed for Board members the partially unblinded cardiovascular data from the three placebo-controlled Alzheimer's disease trials, which did not reflect an increased incidence of cardiovascular events in patients taking Vioxx.<sup>5</sup>

Third, Dr. Scolnick described the aspirin-indicated subgroup analysis to the Board of Directors.<sup>6</sup> He pointed out that, based on preliminary data, the difference in the number of myocardial infarctions between the Vioxx and naproxen groups was 8 versus 0 in patients needing aspirin and only 6 versus 4 in those who did not. He also noted that the aspirin-indicated patients experienced 30%-40% of the total cardiovascular events in the study and that there was "no statistical difference in the occurrence of [cardiovascular] events" between Vioxx and naproxen in the non-aspirin-indicated patients.<sup>7</sup> The slides presenting that analysis are included below:<sup>8</sup>

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<sup>4</sup> 4/25/00 slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000733, at 43-44.

<sup>5</sup> 4/25/00 slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000733, at 44.

<sup>6</sup> 4/25/00 slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000733, at 45. The data Dr. Scolnick presented were from the April 14, 2000 analysis. The progression of the aspirin-indicated subgroup analysis is discussed in Appendix F.

<sup>7</sup> 4/25/00 slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000733, at 45-46.

<sup>8</sup> 4/25/00 slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000733, at 45-46. As discussed in Appendix F, it does not appear that Dr. Scolnick included deaths due to myocardial infarction in the aspirin-indicated data that he presented.

## Incidence of MI Stratified by Indication for Aspirin Use

A total of 4% (320) of VIGOR patients due to their history of stroke, MI, or CABG met FDA-approved indications for cardioprotective aspirin use (Patients who needed ASA).

	MI Events/Patients at Risk	
	<u>Rofecoxib</u>	<u>Naproxen</u>
Patients Who Needed ASA	8/169	0/151
All Other Patients	6/3877	4/3878

Only adjudicated cases

## Cardiovascular Subgroup Analyses (Preliminary Results)

- 3% of the patients in the study had a prior history of an MI, CVA, angina, CABG, angioplasty, carotid artery surgery
  - High risk patient population for CV events
  - Aspirin is strongly indicated in these patients for secondary prevention
  - 30-40% of the CV events occurred in this patient population
- There was no statistical difference in the occurrence of CV events in the other 97% of the patient population

After the April 25, 2000 Board meeting where Dr. Scolnick presented the various explanations of the VIGOR Trial data, members of the Board of Directors were satisfied that the naproxen cardioprotection hypothesis was a reasonable explanation for the cardiovascular results of the VIGOR Trial.

### 2. Post-VIGOR Board Discussions Concerning Cardiovascular Issues.

In late August 2000, Mr. Lawrence A. Bossidy, one of the members of Merck's Board of Directors, asked Mr. Gilmartin for further assurances about Vioxx's

cardiovascular safety based on concerns raised by friends of Mr. Bossidy. As reflected in the email below, Mr. Gilmartin had advised Mr. Bossidy about the results of Protocols 120 and 121, two recent Merck-sponsored studies that Mr. Gilmartin said had “confirmed safety,” and then wrote Mr. Anstice to ask if there was further information to report:<sup>9</sup>

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From: Gilmartin, Raymond  
Sent: Thursday, August 31, 2000 5:39 PM  
To: Anstice, David W.  
Subject: Bossidy

David, Bossidy is on Nantucket; his friends are all on Vioxx; and they are all concerned after hearing about a report given at Vail by an orthopedist named Stedman(?) that there are increasing cases of stroke with Vioxx. I told him that we have had no issues like that with the drug and that, in fact, Ed passed along to me the results of a just completed study on lower back pain that confirmed safety, particularly with regard to CV events. I said that I would ask about it and would call him if there was any new information.

Ed is away, but I suspect that this is part of Pfizer marketing and you probably have more current information and may even know of this orthopedist.

At the next Board Meeting, held on September 25, 2000, Dr. Scolnick made a presentation regarding Vioxx’s cardiovascular safety profile in further response to Mr. Bossidy’s question.<sup>10</sup> Dr. Scolnick’s presentation (i) included data regarding the cardiovascular safety of Vioxx and (ii) discussed Merck’s worldwide public presentations of the VIGOR Trial data.

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<sup>9</sup> 8/31/00 email from R. Gilmartin to D. Anstice, MRK-ABI0005751. The studies to which Mr. Gilmartin referred in the email involved 200 total patients with lower back pain. 8/28/00 email from J. Wu to E. Scolnick et al., MRK-ABH0018405-06. Dr. Scolnick’s reaction to those studies had been that they showed Vioxx being “effective and reamrkly [sic] safe again. NOTE TO THE TEAM; NICE JOB AND NO CARDIOVASCULAR EVENTS with another 200 patients ina [sic] controlled trial.” 8/28/00 email from E. Scolnick to J. Wu, MRK-ABH0018405. On August 31, 2000, after Dr. Scolnick had communicated the results of the back study to Mr. Gilmartin, Dr. Wu alerted him that there had been one myocardial infarction in a patient taking Vioxx 50 mg. 8/31/00 email from J. Wu to E. Scolnick et al., MRK-ABH0018405.

<sup>10</sup> Minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966, at 67.

With respect to the cardiovascular safety of Vioxx, Dr. Scolnick reviewed with the Board the final mortality and cardiovascular event data from the VIGOR Trial:<sup>11</sup>

**VIGOR**  
***Mortality and Cardiovascular Events***

<u>Outcome</u>	<u>VIOXX</u> <u>(N=4047)</u>	<u>Naproxen</u> <u>(N=4029)</u>	<u>Difference</u> <u>(95% CI)</u>
Death	0.50%	0.40%	0.1 (-0.15 to 0.49)
CV Death	0.20%	0.20%	0 (-0.21 to 0.21)
MI	<b>0.40%</b>	<b>0.10%</b>	0.3 (0.07 to 0.57)
Ischemic CVA	0.20%	0.20%	0 (-0.17 to 0.27)

He noted that there had been no detectable increase in stroke in the Vioxx arm of the VIGOR Trial or in other clinical studies involving Vioxx, and no increase in myocardial infarction on Vioxx versus comparators in trials other than the VIGOR Trial.<sup>12</sup>

Dr. Scolnick also reviewed data from the ongoing placebo-controlled Alzheimer's disease trials and the Phase III osteoarthritis trials, which showed similar thrombotic event rates between Vioxx and placebo.<sup>13</sup>

<sup>11</sup> Undated slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000972, at 72 (attached to minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966). The mortality and cardiovascular event data that Dr. Scolnick presented were not updated with the events adjudicated after the February 10, 2000 cut-off date. See Appendix F. The inclusion of that data would have increased the percentage of myocardial infarctions seen in the VIGOR Trial to 0.50%, as opposed to the 0.40% reported by Dr. Scolnick in his presentation.

<sup>12</sup> Undated slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000972, at 73-74 (attached to minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966).

<sup>13</sup> Undated slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000972, at 75-76 (attached to minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966).

Dr. Scolnick also advised the Board members that four patients with lupus had experienced thromboembolic events very soon after initiating therapy with Celebrex,<sup>14</sup> which caused some “[a]cademic scientists [to] raise[] theoretical question[s] of safety of [the] COX-2 class in selected patient populations like the ones who might be at a high risk of thromboembolic events.”<sup>15</sup> His presentation indicated, however, that MRL’s review of the Vioxx post-marketing database had demonstrated that no cardiovascular safety signal had been seen in the 31,000 lupus patients who had received a prescription for Vioxx.<sup>16</sup>

Finally, Dr. Scolnick described to the Board the various public presentations that had been made or were planned regarding the VIGOR Trial data, including the publication of VIGOR Trial data in the New England Journal of Medicine.<sup>17</sup> He included a “Vioxx Collage” of numerous newspaper and magazine articles describing the favorable gastrointestinal safety profile of Vioxx.<sup>18</sup>

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<sup>14</sup> Undated slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000972, at 77 (attached to minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966). Appendices F and J include a more in-depth discussion of Dr. Oates’s\* observations and recommendations to Merck regarding the lupus patients.

<sup>15</sup> Undated slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000972, at 77 (attached to minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966).

<sup>16</sup> Undated slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000972, at 78 (attached to minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966).

<sup>17</sup> Undated slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000972, at 79 (attached to minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966).

<sup>18</sup> Undated slide presentation of E. Scolnick to Merck Board of Directors, MRK-MIAA0000972, at 82-85 (attached to minutes of 9/25/00 Merck Board of Directors meeting, MRK-MIAA0000966).

Another presentation given at the September 25, 2000 Board of Directors meeting described two objectives for Merck's Public Affairs activities regarding the VIGOR Trial: (i) "Create media interest in the benefits of VIOXX based on the significant GI results seen in VIGOR"; and (ii) "Place CV findings into proper perspective to alleviate potential safety concerns."<sup>19</sup>

3. Discussions Regarding 2001 FDA Advisory Committee Meeting.

At the February 27, 2001 Board meeting, Dr. Greene updated the Board members about the FDA Advisory Committee meetings that had taken place on February 8 and 9 to review the supplemental New Drug Applications that Merck had submitted for Vioxx post-VIGOR Trial and that Pfizer had submitted for Celebrex post-CLASS Trial.<sup>20</sup>

Dr. Greene noted that the FDA had determined that "CLASS did not establish superior GI safety of Celebrex to non-selective NSAIDs,"<sup>21</sup> and that "VIGOR study results conclusively established that Vioxx is superior to NSAID comparator naproxen on GI safety."<sup>22</sup>

Dr. Greene then briefed the Board about the discussions at the FDA Advisory Committee Meeting regarding the cardiovascular safety of Vioxx, including the fact that

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<sup>19</sup> Undated slide presentation to Merck Board of Directors, "Public Affairs Activities for VIGOR," MRK-MIAA0005737, at 37 (attached to 9/00 board overheads folder).

<sup>20</sup> 2/27/01 slide presentation of D. Greene to Merck Board of Directors, "VIGOR & CLASS GI Outcome Studies," MRK-MIAA0001281-319.

<sup>21</sup> 2/27/01 slide presentation of D. Greene to Merck Board of Directors, "VIGOR & CLASS GI Outcome Studies," MRK-MIAA0001281, at 300.

<sup>22</sup> 2/27/01 slide presentation of D. Greene to Merck Board of Directors, "VIGOR & CLASS GI Outcome Studies," MRK-MIAA0001281, at 314.

the Advisory Committee members had questioned whether the FitzGerald prostacyclin hypothesis was a possible explanation for the observed cardiovascular data.<sup>23</sup> Dr. Greene explained that at the meeting, MRL scientists and regulatory personnel had reviewed the universe of clinical data that MRL scientists believed confirmed Vioxx's cardiovascular safety profile and had presented Kaplan-Meier time-to-event plots (which Dr. Greene also presented to the Board) from the VIGOR Trial, the osteoarthritis studies, and the Alzheimer's disease trials.<sup>24</sup> The Kaplan-Meier plot from the Phase III osteoarthritis trials showed that there was no increased incidence of cardiovascular events on Vioxx as compared to two non-selective comparator NSAIDs (diclofenac and ibuprofen), and the plot from the Alzheimer's disease trials reflected that Vioxx had a lower cumulative incidence of cardiovascular events on Vioxx over time as compared to placebo.<sup>25</sup>

Dr. Greene also noted that “[n]aproxen is a long-acting NSAID with reported anti-platelet activity,”<sup>26</sup> and he presented additional supportive data for naproxen's possible cardioprotective effect. He indicated, however, that despite these data, standing alone, the VIGOR Trial could not answer the question: “Was the imbalance of

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<sup>23</sup> 2/27/01 slide presentation of D. Greene to Merck Board of Directors, “VIGOR & CLASS GI Outcome Studies,” MRK-MIAA0001281, at 307

<sup>24</sup> 2/27/01 slide presentation of D. Greene to Merck Board of Directors, “VIGOR & CLASS GI Outcome Studies,” MRK-MIAA0001281, at 309, 311-12.

<sup>25</sup> 2/27/01 slide presentation of D. Greene to Merck Board of Directors, “VIGOR & CLASS GI Outcome Studies,” MRK-MIAA0001281, at 311-12.

<sup>26</sup> 2/27/01 slide presentation of D. Greene to Merck Board of Directors, “VIGOR & CLASS GI Outcome Studies,” MRK-MIAA0001281, at 308.

cardiovascular events in VIGOR due to an anti-thrombotic effect of naproxen or a pro-thrombotic effect of Vioxx?”<sup>27</sup>

4. Discussions About Renewed Public Cardiovascular Safety Concerns.

As discussed in Appendices H and K, the cardiovascular safety of selective Cox-2 inhibitors gained more public attention beginning in the spring and summer of 2001, and the Board was kept apprised about the negative publicity as well as data regarding cardiovascular safety.

The Board members were notified when the first products liability lawsuits were filed in May 2001. The Audit Committee, which meets two or three times a year, discussed setting aside reserves for the lawsuits and including a liability footnote in the Company’s financial reports.

Before the September 2001 Board meeting, the Board received the August 21 and August 23, 2001 press releases entitled “Merck Stands Behind Cardiovascular Safety Profile of Vioxx” that Merck had issued in response to the JAMA article by Dr. Eric Topol\* and his colleagues from the Cleveland Clinic Foundation (the “Topol article”).<sup>28</sup> As discussed in Appendix J, the Topol article had suggested that selective Cox-2

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<sup>27</sup> 2/27/01 slide presentation of D. Greene to Merck Board of Directors, “VIGOR & CLASS GI Outcome Studies,” MRK-MIAA0001281, at 310.

<sup>28</sup> 8/21/01 Merck press release, “Merck Stands Behind the Cardiovascular Safety Profile of Vioxx®,” MRK-AGN00002027-30; 8/23/01 Merck press release, “Merck Stands Behind the Cardiovascular safety Profile of Vioxx®,” MRK-MIAA0001699.

inhibitors might increase patients' risk of cardiovascular adverse events and called for further study.<sup>29</sup>

At the September 25, 2001 meeting, Dr. Scolnick presented data comparing the cardiovascular risk of Vioxx, naproxen, non-naproxen NSAIDs, and placebo.<sup>30</sup>

**Relative to Rofecoxib: Risk of a Thrombotic Endpoint**

Comparator	Related Risk	95% CI
Naproxen <sup>1</sup>	0.59	(0.37, 0.94)
Non-naproxen NSAIDs <sup>2</sup>	1.27	(0.64, 2.50)
Placebo <sup>3</sup>	1.19	(0.73, 1.96)

<sup>1</sup>n = 7870 (naproxen) vs. n = 9083 (rofecoxib)  
- largely based on VIGOR

<sup>2</sup>n = 2755 (non-naproxen NSAIDs) vs. n=4549 (rofecoxib)  
- Phase IIb/III OA Program

<sup>3</sup>n = 3482 (placebo) vs. n=6290 (rofecoxib)  
- largely based on Alzheimers/mild cognitive impairment studies

Following the September Board meeting, Mr. Gilmartin forwarded to the members of the Board of Directors an article that recently had been published in The New York Times entitled “For Pain Reliever, Questions of Risk Remain Unresolved.”<sup>31</sup> The article quoted Dr. Topol’s\* concerns about the cardiovascular risk of Celebrex and Vioxx and also mentioned the Warning Letter regarding aspects of Vioxx marketing that

<sup>29</sup> Mukherjee\* D, Nissen\* SE, Topol\* EJ. Risk of cardiovascular events associated with selective COX-2 inhibitors. JAMA. 2001;286:954-59. MRK-ABK0154081.

<sup>30</sup> Undated slide presentation, “Relative to Rofecoxib: Risk of a Thrombotic Endpoint,” MRK-MIAA0001711 (attached to minutes of 9/25/01 Merck Board of Directors meeting, MRK-0001705-10).

<sup>31</sup> 10/17/01 memorandum from N. Van Allen to Merck Board of Directors, attaching Gina Kolata\* For Pain Reliever, Questions of Risk Remain Unresolved, N.Y. Times, Oct. 9, 2001, at 5. MRK-MIAA0001758.

Merck recently had received from the FDA's Division of Drug Marketing, Advertising and Communications.<sup>32</sup> The article quoted Dr. Scolnick's statement that "There are two possible interpretations [for the cardiovascular data from the VIGOR Trial] . . . .

Naproxen lowers the heart attack rate, or Vioxx raises it" and his acknowledgment that, "now that the clotting question has been raised, none of the findings to date are enough to prove that the issue is fully resolved."<sup>33</sup> With respect to the uncertainty of existing cardiovascular safety data for selective Cox-2 inhibitors, Dr. Topol\* echoed in the article a proposal he and his colleagues had made in the JAMA article: "someone – Merck or Pharmacia or the federal government – should conduct a study in patients with heart disease to find out conclusively if the cox-2 inhibitors increase heart disease risk."<sup>34</sup>

At the October 23, 2001 meeting of the Board of Directors, Drs. Scolnick, Anthony Ford-Hutchinson, and Greene presented a "Merck Research Laboratories: 2001 Update."<sup>35</sup> Dr. Peter Kim outlined the "2001 Franchise Accomplishments" for Vioxx and

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<sup>32</sup> Gina Kolata\* For Pain Reliever, Questions of Risk Remain Unresolved, N.Y. Times, Oct. 9, 2001, at 5. MRK-MIAA0001758.

<sup>33</sup> Gina Kolata\* For Pain Reliever, Questions of Risk Remain Unresolved, N.Y. Times, Oct. 9, 2001, at 5. MRK-MIAA0001758.

<sup>34</sup> Gina Kolata\* For Pain Reliever, Questions of Risk Remain Unresolved, N.Y. Times, Oct. 9, 2001, at 5. MRK-MIAA0001758.

<sup>35</sup> 10/23/01 slide presentation of E. Scolnick, P. Kim, A. Ford-Hutchinson, and D. Greene to Merck Board of Directors, "Merck Research Laboratories: 2001 Update," MRK-MIAA0005020-99.

other product lines.<sup>36</sup> With respect to Vioxx, Dr. Kim described the chief accomplishment as “Cardiovascular Safety Confirmed,” depicted in the slide below:<sup>37</sup>

### **VIOXX: Cardiovascular Safety Confirmed**

- Placebo controlled Alzheimer’s Study
- Meta-analysis of all VIOXX trials
  
- Presented to the FDA (Feb-2001)
- Oct-2001 *CIRCULATION* publication
  
- VIGOR labeling -- under negotiation

Dr. Kim further supported the cardiovascular safety by presenting the Kaplan-Meier time-to-event curve for the Alzheimer’s disease trials which, as discussed above, reflected that Vioxx had a lower cumulative incidence of cardiovascular events over time as compared to placebo.<sup>38</sup> He then presented a chart depicting the relative risk of Vioxx versus placebo, versus non-naproxen NSAIDs, and versus naproxen, which showed a decreased cardiovascular risk of Vioxx as compared to placebo or non-naproxen NSAIDs.<sup>39</sup>

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<sup>36</sup> 10/23/01 slide presentation of E. Scolnick, P. Kim, A. Ford-Hutchinson, and D. Greene to Merck Board of Directors, “Merck Research Laboratories: 2001 Update,” MRK-MIAA0005020, at 30-39.

<sup>37</sup> 10/23/01 slide presentation of E. Scolnick, P. Kim, A. Ford-Hutchinson, and D. Greene to Merck Board of Directors, “Merck Research Laboratories: 2001 Update,” MRK-MIAA0005020, at 32.

<sup>38</sup> 10/23/01 slide presentation of E. Scolnick, P. Kim, A. Ford-Hutchinson, and D. Greene to Merck Board of Directors, “Merck Research Laboratories: 2001 Update,” MRK-MIAA0005020, at 33.

<sup>39</sup> 10/23/01 slide presentation of E. Scolnick, P. Kim, A. Ford-Hutchinson, and D. Greene to Merck Board of Directors, “Merck Research Laboratories: 2001 Update,” MRK-MIAA0005020, at 34.

5. Discussions About a Cardiovascular Outcomes Trial.

The October 23, 2001 MRL update to the Board also informed the Board of MRL's plans to conduct a Vioxx cardiovascular outcomes trial.<sup>40</sup> As discussed in Appendix M, in October 2001, MRL scientists had decided to conduct such a study but had not yet determined its design. As such, the MRL representatives did not present design details to the Board of Directors.

6. Discussions About Epidemiological Studies.

As discussed in Appendix P, during the period that Vioxx was marketed, many epidemiological studies were conducted by scientists inside and outside of Merck to investigate the cardiovascular safety of Vioxx. Although epidemiological studies are accorded less weight in the scientific community than prospectively designed clinical trials, nevertheless, from time to time the Board was made aware of particular published articles on studies, favorable or unfavorable, concerning cardiovascular safety of Vioxx.<sup>41</sup>

In 2003, a number of epidemiological studies publicly raised the issue of Vioxx's cardiovascular safety, and the studies were discussed at the Board level.<sup>42</sup> One such

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<sup>40</sup> 10/23/01 slide presentation of E. Scolnick, P. Kim, A. Ford-Hutchinson, and D. Greene to Merck Board of Directors, "Merck Research Laboratories: 2001 Update," MRK-MIAA0005020, at 25, 78.

<sup>41</sup> See 10/30/03 memorandum from K. Frazier to Merck's Board of Directors attaching newspaper clippings regarding epidemiological studies, MRK-MIAA0003210.

<sup>42</sup> Minutes of 4/22/03 Merck Board of Directors meeting, MRK-MIAA0002827, at 28; Minutes of 5/27/03 Merck Board of Directors meeting, MRK-MIAA0002904, at 05 ("Dr. Kim alerted the Board to possible adverse publicity regarding observational, retrospective studies of cardiovascular events in patients on VIOXX (25 mg or greater) compared to those who took NSAIDs or placebo."); see also 8/25/04 facsimile from J. Wainwright to Merck Board of Directors attaching press reports and standby statement related to Graham Study (discussed in Appendix P), MRK-MIAA00003919.

study, a Merck-sponsored study conducted by Dr. Daniel Solomon\* of Brigham & Women's Hospital in Boston (the "Solomon Coxib Study") (discussed more fully in Appendix P), made the following conclusions:

- Compared to current use of Celebrex, current use of Vioxx was associated with a significantly increased risk of acute myocardial infarction (odds ratio 1.24; 95% confidence interval, 1.05 to 1.46);
- Compared to current use of naproxen, the risk of acute myocardial infarction associated with Vioxx was "elevated but did not reach statistical significance" (odds ratio 1.17; 95% confidence interval, 0.90 to 1.52);
- Compared to current use of ibuprofen, the risk of acute myocardial infarction associated with Vioxx was "elevated but did not reach statistical significance" (odds ratio 1.21; 95% confidence interval, 0.92 to 1.58);
- Compared to no current use of any NSAID, the risk of acute myocardial infarction associated with Vioxx was "elevated but did not reach statistical significance" (odds ratio 1.14; 95% confidence interval, 1.00 to 1.31).<sup>43</sup>

According to the Solomon Coxib Study, Vioxx was associated with a statistically significant increased risk of heart attack versus Celebrex, but that compared to naproxen and other NSAIDs, the risk of heart attack with Vioxx was elevated but did not reach statistical significance.<sup>44</sup>

On October 30, 2003, The Wall Street Journal published an article reporting on the findings of the Solomon Coxib Study which Dr. Kim mailed to the Board of Directors

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<sup>43</sup> Solomon\* DH, Schneeweiss\* S, Glynn\* RJ, et al. Relationship between selective cyclooxygenase-2 inhibitors and acute myocardial infarction in older adults. Circulation. 2004;109:2068-2073, at 2071 and Table 2, MRK-ADY0006986.

<sup>44</sup> Solomon\* DH, Schneeweiss\* S, Glynn\* RJ, et al. The relationship between selective cyclooxygenase-2 inhibitors and acute myocardial infarction in older adults. Circulation. 2004;109:2068-2073. MRK-ADY0006986.

that day.<sup>45</sup> The article reported only the statistically significant results, which showed an increased heart attack risk with Vioxx relative to Celebrex. According to Dr. Topol\* whom the article quoted extensively, the new study was “the best study to date” and “greatly substantiates our concern about the cardiac side effects.”<sup>46</sup>

On November 5, 2003, members of Merck’s Board of Directors received a copy of a letter from Dr. Kim to the editor of The Wall Street Journal responding to the October 30 article regarding Solomon’s Coxib Study.<sup>47</sup> Dr. Kim criticized the article for failing to report (i) the other findings from the Solomon Coxib Study, which showed no statistically significant difference between Vioxx and naproxen or other NSAIDs and (ii) that the American College of Rheumatology meeting had also included a presentation of another observational analysis, the Rahme Coxib Study (discussed in Appendix P) which showed no statistically significant difference between the rate of hospitalization for acute myocardial infarction between Vioxx and either diclofenac or ibuprofen.<sup>48</sup>

Dr. Kim also argued:

[O]bservational methods lack the rigor of randomized,  
controlled clinical trials, and have led the scientific

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<sup>45</sup> Thomas M. Burton\* and Patricia Callahan\*, Vioxx Study Sees Heart-Attack Risk, Wall St. J., Oct. 30, 2003, at B2. MRK-MIAA0003211 (attached to 10/30/03 fax from P. Kim to Merck Board of Directors, MRK-MIAA0003210).

<sup>46</sup> Thomas M. Burton\* and Patricia Callahan\*, Vioxx Study Sees Heart-Attack Risk, Wall St. J., Oct. 30, 2003, at B2. MRK-MIAA0003211.

<sup>47</sup> 11/5/03 facsimile from K. Frazier to Merck Board of Directors, MRK-MIAA0003329.

<sup>48</sup> Peter Kim, Letter to the Editor, Merck Stands Behind the Safety of Vioxx, Wall. St. J., Nov. 5, 2003, at A21, MRK-MIAA0003330 (attached to 11/5/03 facsimile from K. Frazier to Merck Board of Directors, MRK-MIAA0003329).

community astray before. . . . That is why observational studies must be interpreted with caution. Merck stands behind the safety of Vioxx based on the results of numerous randomized, controlled clinical trials.<sup>49</sup>

Dr. Kim concluded by noting that, as previously announced, Merck was “conducting large prospective, randomized placebo-controlled clinical trials that, when added to the extensive data from clinical trials already available, will provide an even more comprehensive picture of the cardiovascular safety profile of Vioxx.”<sup>50</sup>

On May 18, 2004, two weeks after the Solomon Coxib Study was published in Circulation, The Wall Street Journal published an article highly critical of Merck’s decision to remove Dr. Cannuscio’s name, accusing the Company of “[s]tepping into thorny ethical territory.”<sup>51</sup> Members of Merck’s Board of Directors received a copy of the article and memorandum from Ms. Celia A. Colbert, Vice President, Secretary and Assistant General Counsel for the Company, explaining the decision to remove Dr. Cannuscio’s name.<sup>52</sup>

Merck does not agree with the Journal’s characterization of the reasons behind Merck’s actions, which were guided by two important tenets of medical research: first, discussion

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<sup>49</sup> Peter Kim, Letter to the Editor, Merck Stands Behind the Safety of Vioxx, Wall. St. J., Nov. 5, 2003, at A21, MRK-MIAA0003330) (attached to 11/5/03 facsimile from K. Frazier to Merck Board of Directors, MRK-MIAA0003329).

<sup>50</sup> Peter Kim, Letter to the Editor, Merck Stands Behind the Safety of Vioxx, Wall. St. J., Nov. 5, 2003, at A21, MRK-MIAA0003330) (attached to 11/5/03 facsimile from K. Frazier to Merck Board of Directors, MRK-MIAA0003329).

<sup>51</sup> Thomas M. Burton\*, Merck Takes Author’s Name Off Vioxx Study, Wall St. J., May 18, 2004, at B1. MRK-MIAA0003610. The removal of Dr. Cannuscio from the article is discussed in Appendix P.

<sup>52</sup> 5/18/04 facsimile from C. Colbert to Merck Board of Directors, MRK-MIAA0003609.

and debate are an essential part of the scientific process; and second, that observational analyses must always be considered in light of their limitations and within the context of randomized, controlled clinical trials. . . . When Merck reviewed the final paper, there were still some points with which Merck disagreed. . . . Because having a Merck author's name appear on this observational study could imply that Merck agreed with the entire paper, which we do not, Merck asked that the employee's name be removed.

Dr. Thier, who was also a member of the Science Committee of the Board, advised management that in the future, an author's name should not be removed in such circumstances.

7. Board Discussions About Combination Therapy.

Appendix L details the efforts made by MRL scientists beginning in 1998 to develop a combination therapy with Vioxx. The Board was first apprised about a possible combination therapy in November 2002, when a combination with nitric oxide was proposed as a potential means through which MRL might capture more of the arthritis and analgesia market. MRL scientists theorized that a nitric-oxide/Vioxx combination product could be administered with aspirin, for patients indicated for aspirin prophylaxis, without harmful gastrointestinal safety consequences. In November 2002, Dr. Kim wrote a memorandum to the Board of Directors describing the collaboration, including the scientific rationale behind the combination, and the commercial terms of the proposed licensing agreement with NitroMed.<sup>53</sup> Dr. Kim wrote:

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<sup>53</sup> 11/20/02 memorandum from P. Kim to Merck Board of Directors, MRK-MIAA0005759-60.

MRL is interested in exploring NitroMed's proprietary approach of linking NO to Cox-2 inhibitors in an effort to produce a second generation Cox-2 product that retains the excellent anti-inflammatory and GI effects of Cox-2 inhibitors while at the same time further improving the safety profile, especially in the presence of aspirin. . . .

NitroMed has developed a platform for delivering therapeutically active NO in three core areas: cardiology, inflammation, and sexual dysfunction, and is interested in developing second generation NSAIDs and Cox-2 inhibitors. . . .

Of particular interest to Merck is the ability to preserve the excellent GI properties of a compound such as VIOXX, and to extend those properties into settings where it can be co-dosed with aspirin without causing GI lesions. Such characteristics would make coxibs the agents of choice by eliminating concerns that GI protection is lost if patients are also taking low-dose aspirin. It is also conceivable, though unproven, that compounds containing NO may have beneficial effects on kidney function, and hence blood pressure, which would further differentiate the coxibs.<sup>54</sup>

Dr. Kim concluded by noting that MRL planned to request approval from the Board of Directors to enter an agreement with NitroMed at its next meeting, scheduled for November 26, 2002.<sup>55</sup> At that meeting, the Board members unanimously voted to approve the resolution to allow the Company to enter the agreement with NitroMed.<sup>56</sup> Board members understood that the purpose of a combination therapy was to create a "super Vioxx" – a drug that was superior to Vioxx and aspirin. Board members were

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<sup>54</sup> 11/20/02 memorandum from P. Kim to Merck Board of Directors, MRK-MIAA0005759-60.

<sup>55</sup> 11/20/02 memorandum from P. Kim to Merck Board of Directors, MRK-MIAA0005759, at 61.

<sup>56</sup> Minutes of 11/26/02 Merck Board of Directors meeting, MRK-MIAA0002482, at 85-86.

clear that a combination therapy was not being developed to address any prothrombotic effect of Vioxx.

8. The APPROVe Trial and Withdrawal.

As discussed in Appendix Q, on September 27, 2004 Dr. Kim recommended to Mr. Gilmartin that Merck voluntarily withdraw Vioxx from the market, based upon the cardiovascular safety data from the APPROVe Trial. The following day, September 28, 2004, the Board of Directors convened for a regularly scheduled meeting.<sup>57</sup> At that meeting, Mr. Gilmartin and Dr. Kim reviewed the APPROVe Trial cardiovascular data and explained management's decision to withdraw Vioxx from the worldwide market.<sup>58</sup>

According to the minutes from that meeting:

Mr. Gilmartin explained that the decision had been made because it best serves the interests of patients. He noted that management believed it would have been possible to continue to market VIOXX with labeling that would incorporate the new data from the APPROVe study. However, given the availability of alternative therapies, and the questions raised by the data, Mr. Gilmartin advised that management had determined that a voluntary withdrawal was the appropriate course to take.<sup>59</sup>

After Mr. Gilmartin informed the Board of the basic background for the decision, Dr. Kim: (i) discussed the internal and external analyses that had been conducted with respect to the APPROVe Trial data; (ii) noted that the clinical significance of the

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<sup>57</sup> See 8/24/04 memorandum from C. Colbert to Merck's Board of Directors, MRK-MIAA0003918 (noting dates and times for September 2004 Board and committee meetings).

<sup>58</sup> Minutes of 9/28/04 Merck Board of Directors meeting, MRK-MIAA0004036, at 37.

<sup>59</sup> Minutes of 9/28/04 Merck Board of Directors meeting, MRK-MIAA0004036, at 37.

APPROVe Trial data for other selective Cox-2 inhibitors remained uncertain; and (iii) described the ongoing process of informing worldwide regulatory agencies of the voluntary withdrawal of Vioxx.<sup>60</sup> Following Dr. Kim's presentation, and full discussion, the Board unanimously endorsed the decision of Merck's management to withdraw Vioxx from the worldwide market.<sup>61</sup>

9. Post-withdrawal Analysis of APPROVe Trial Cardiovascular Data.

Shortly after Vioxx was withdrawn from the market, the Board of Directors was informed of the follow-up investigations Merck was conducting to understand the implications of the APPROVe Trial cardiovascular data and whether the increased risk that became apparent after 18 months in the APPROVe Trial continued after Vioxx use was discontinued.

As described in Appendix R, in May 2006, Merck (i) announced preliminary results of the off-drug follow-up investigations it had conducted, and (ii) issued a press release to correct a statistical error Merck scientists discovered they had made in the article published about the APPROVe Trial cardiovascular data in the New England Journal of Medicine in February 2005.

With respect to the former, Board members received the press release that Merck issued on May 11, 2006. With respect to the statistical error, Board members were informed about the error by Mr. Kenneth Frazier and Dr. Peter Kim at a regularly

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<sup>60</sup> Minutes of 9/28/04 Merck Board of Directors meeting, MRK-MIAA0004036, at 37-38.

<sup>61</sup> Minutes of 9/28/04 Merck Board of Directors meeting, MRK-MIAA0004036, at 38.

scheduled Board meeting held on May 23, 2006 – one day after the error had been discovered. As discussed in the Report, the Board then directed the Special Committee to continue its investigation of the conduct of senior management to examine the source and implications of the error, and specifically whether the error evidenced any bad faith on the part of Merck scientists, as well as related issues concerning post-withdrawal analysis of APPROVe Trial cardiovascular data.

D. Board Review of Marketing and Sales Practices.

As noted above, Dr. Thier and Dr. Kelley were the two physicians on the Board, and each had strong ties to the medical academic community. Their respective backgrounds made them particularly sensitive that the lines between pharmaceutical promotion and physician education not be inappropriately blurred. According to Dr. Thier, he and Dr. Kelley engaged the Board in discussions about this issue, and also discussed the issue with Merck management.

As the result of a confluence of factors, including the Board's keen interest in this area; Merck's longstanding commitment to ethical business practices; complaints about isolated sales practices from two Merck competitors; and commentary in the media criticizing the manner in which the pharmaceutical industry in general promoted products to physicians, in the fall of 2001 Merck introduced an initiative called the Culture of Compliance. As discussed in Appendix K, this broad-based initiative, which was not specifically targeted at addressing Vioxx sales practices, underscored the importance of complying not only with federal regulations (which Merck management believed was a given), but also with Merck's more aspirational policies, that went above and beyond

federal regulation. Senior management made presentations about Merck's compliance program to the Audit Committee of the Board in July 2002,<sup>62</sup> and to the Public Policy and Social Responsibility Committee of the Board in December 2004.<sup>63</sup>

With respect to Vioxx sales practices specifically, the Board of Directors was informed at its September 25, 2001 meeting about the Warning Letter that Merck had received on September 17, 2001 from DDMAC.<sup>64</sup> As discussed in Appendix G, the letter alleged, among other things, that Merck had "engaged in a promotional campaign for Vioxx that minimized the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresent[ed] the safety profile for Vioxx."<sup>65</sup> The Board also received a copy of the Company's October 1, 2001 response to the FDA Warning Letter, and was updated on the discussions and resolution of the issue at their October and November meetings.<sup>66</sup>

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<sup>62</sup> U.S. Marketing & Sales Compliance, July 23, 2002, MRK-AGNPRS00000010-27.

<sup>63</sup> USHH Marketing, Selling, and Medical Scientific Interactions with Academicians, Physicians, and Other Customers, December 20, 2004, MRK-AGNPRS-00000001-09.

<sup>64</sup> Minutes of 9/25/01 Merck Board of Directors meeting, MRK-MIAA0001705, at 07.

<sup>65</sup> 9/17/01 FDA warning letter from T. Abrams\* to R. Gilmartin, MRK-AAF0007777-85.

<sup>66</sup> 10/2/01 letter from K. Frazier to Merck Board of Directors, MRK-AGN00006944; Minutes of 10/23/01 Merck Board of Directors meeting, MRK-MIAA0001714, at 15; Minutes of 11/27/01 Merck Board of Directors meeting, MRK-MIAA0001799, at 99.

**Table 1**  
**Independent Members of Merck Board of Directors: 1999-present**

<b>Director</b>	<b>Dates of Service</b>	<b>Title at Time of Last Date of Service</b>
Mr. H. Brewster Atwater, Jr.	1988 – 2001	Retired Chairman of the Board and CEO General Mills, Inc.
Sir Derek Birkin	1992 – 2000	Retired Chairman of the Board The RTZ Corporation PLC
Mr. Lawrence A. Bossidy	1992 – present	Retired Chairman of the Board and CEO Honeywell International, Inc.
Dr. William G. Bowen	1986 – present	President The Andrew W. Mellon Foundation
Mr. Erskine B. Bowles	2001	General Partner Forstmann Little & Co. and Carousel Capital Company, LLC
Dr. Johnetta B. Cole	1994 – present	President Bennett College for Women
Mr. William M. Daley	2002 – 2004	President SBC Communications, Inc.
Dr. Carolyn K. Davis	1989 – 2000	International Health Care Consultant
Dr. Lloyd C. Elam	1973 – 2001	Professor of Psychiatry Meharry Medical College
Mr. Charles E. Exley, Jr.	1988 – 2000	Retired Chairman of the Board and CEO NCR Corporation
Ms. Carleton S. Fiorina	1999 – 2000	President and CEO Hewlett Packard Company
Mr. Niall FitzGerald	2000 – 2002	Chairman, Unilever PLC Vice Chairman, Unilever NV
Mr. William B. Harrison	1999 – present	Chairman of the Board J.P. Morgan Chase & Co.
Dr. William N. Kelley	1992 – present	Professor of Medicine, Biochemistry and Biophysics University of Pennsylvania School of Medicine
Rochelle B. Lazarus	2004 – present	Chairman and CEO Ogilvy & Mather Worldwide
Ms. Heidi G. Miller	2000 – 2004	Executive Vice President and CFO Bank One Corporation
Dr. Thomas E. Shenk	2001 – present	Elkins Professor and Chairman, Department of Molecular Biology Princeton University

Ms. Anne M. Tatlock	2000 – present	Chairman and CEO Fiduciary Trust Company, International
Dr. Samuel O. Thier	1994 – present	Professor of Medicine and Professor of Health Care Policy Harvard Medical School
Sir Dennis Weatherstone	1988 – 2001	Retired Chairman of the Board J.P. Morgan & Co. Incorporated and Morgan Guaranty Trust Company of New York
Mr. Wendell P. Weeks	2004 – present	President and CEO Corning Incorporated
Mr. Peter C. Wendell	2003 – present	Managing Director Sierra Ventures