

APPENDIX K

ADVOCATE DEVELOPMENT

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APPENDIX K

ADVOCATE DEVELOPMENT.

A. Introduction.

Beginning in the pre-launch phase and continuing throughout the period that Vioxx was marketed, Merck's Marketing Department assisted MRL scientists in understanding the NSAID and coxib markets, in part by convening consultants' and advisory board meetings. In addition to providing the Company with market research, these programs helped to develop doctors into "advocates" for Vioxx and/or to manage the Company's relationships with doctors who were critical of Vioxx. Programs run by the Marketing Department also helped to promote awareness of Vioxx with key physicians, particularly pre-launch through 2001. Merck called these relationship-building activities "advocate development," which the Company defined as "the process by which a Thought Leader is identified and converted to an Advocate [or] through which the degree of advocacy is strengthened/ increased/maintained."¹ Advocates were individuals whom members of the Marketing Department believed could "support Merck's position with prescribing physicians and in formulary decisions."²

¹ 7/7/02 Draft Year 2000 Advocate Plan for Merck Coxibs, MRK-AFI0014850, at 59.

² 5/8/00 memorandum from W. Dixon to E. Scolnick, MRK-ABI0002126, at 28. A formulary is a list of medications that physicians may prescribe under a specific managed care plan or at a hospital in order for the patient to be reimbursed. An "open formulary" allows physicians to prescribe as they wish, and all medicines will be covered. A "closed formulary" prevents patients from being reimbursed for a non-formulary drug without special approval from the healthcare plan. Inclusion on, or exclusion from, a formulary has significant sales implications for a given market. Merck training audiotape, "Understanding Managed Care," MRK-AAR0030843; Merck training audiotape,

Merck's advocate development activities included convening consultants' and advisory board meetings, sponsoring or facilitating discussions of Vioxx at promotional speaker programs and at non-promotional Continuing Medical Education programs, and involving doctors and scientists in the study of Vioxx by enlisting them as investigators in Merck trials or by supporting their own research through Merck's Medical School Grants Program. In the main, Merck directed advocate development activities at educating physicians about the benefits of Vioxx based on the premise that those who were critical or agnostic about Vioxx would be most likely to change their views if presented with data, which Merck personnel believed to be persuasive as to both the safety and the efficacy of the drug.

This Appendix reviews Merck's advocate development programs, including: (i) advisory boards; (ii) consultants' meetings; (iii) Merck's Health Education Liaison Speaker program; (iv) Merck's Medical School Grant program; and (v) Continuing Medical Education programs. It also reviews the manner in which Merck responded to physicians who were critical of Vioxx, as well as the "Culture of Compliance" initiative in late 2001 that clarified Merck's policies with regard to interactions with physicians by members of U.S. Human Health and underscored Merck's commitment to compliance with Company policies that went beyond the letter of the law.

"Managed Care Educators," MRK-AAR0073241 (both reviewing how formularies work, their importance, and how representatives should account for formularies as part of their sales jobs).

B. Advisory Boards.

Through advisory boards, the Marketing Department began a dialogue with doctors prior to launch that afforded Merck the opportunity to understand the NSAID market and what benefits doctors were looking for in the new selective Cox-2 inhibitors. Since Merck had little recent experience marketing NSAIDs, this market research was especially important to the Company. Ms. Susan Baumgartner, a Marketing Manager for Vioxx and a member of the Arthritis & Analgesia Therapeutic Business Group, was responsible for convening many of the advisory boards. She has testified:

It was important for us to get feedback from all of the individuals out there. We didn't just want individuals who were supportive of our views. We wanted to hear from those who were not supportive as well. So, we invited physicians who had a range of levels of support for the product and the company.³

The Marketing Department created a series of high-level advisory boards for Vioxx before and after launch that convened periodically throughout the time Vioxx was on the market.⁴ Prior to launch, the Marketing Department created an advisory board composed of rheumatologists and gastroenterologists. This advisory board, which included Drs. Loren Laine* and Michael Weinblatt*,⁵ later expanded into a

³ 9/30/05 deposition of S. Baumgartner at 512 (In re Vioxx Litig., MDL No. 1657, E.D. La.).

⁴ These advisory boards were distinct from the Board of Scientific Advisors discussed in Appendix A.

⁵ Proposal for Second Quarter 2000 Vioxx® Multidisciplinary Medical Advisory Board Meeting by John A. Romankiewicz* to Caroline Yarbrough, MRK-AFI0195488, 498-500. Dr. Loren Laine*, Professor of Medicine at the University of Southern California School of Medicine, was later a member of the VIGOR Trial Steering Committee and co-author of the New England Journal of Medicine article on the study. Dr. Michael Weinblatt*, Professor of Medicine at Harvard Medical School, was later a member of the Data Safety and Monitoring Board for the VIGOR Trial.

multi-disciplinary board as experts from other clinical specialties, such as nephrology, primary care, and nutrition, were added. After the launch of Vioxx, the Marketing Department formed three separate, more targeted advisory boards with specialists in orthopedic surgery, pain management, and cardio-renal issues.⁶ Advisory boards typically comprised twelve to fifteen members.⁷ The multi-disciplinary advisory board met approximately once per quarter, while the others met less frequently.⁸

Advisory boards provided an opportunity for the Marketing Department to gain feedback on data from Merck's clinical program from senior experts in specified fields.⁹ They covered a broad range of subjects of interest to the Company and board members, such as the VIGOR Trial cardiovascular data, effects of possible label changes on physician prescribing habits, and the naproxen cardioprotection hypothesis.¹⁰ Advisory

⁶ 1/5/01 slide presentation, "2001 Advocate Plan for Merck Coxibs," MRK-ADF0018569, at 580 (listing advisory boards).

⁷ 1/5/01 slide presentation, "2001 Advocate Plan for Merck Coxibs," MRK-ADF0018569, at 96 ("Target Audience: 12-15 national advocates on each AB"); 9/30/05 deposition of S. Baumgartner at 510-11 (In re Vioxx Litig., MDL No. 1657, E.D. La.) (multidisciplinary advisory board had approximately 15 members).

⁸ 5/8/00 memorandum from W. Dixon to E. Scolnick, MRK-ACR0010601, at 03; Multidisciplinary Strategic Advisory Board for Cox-2 Inhibitors Consulting Agreement, MRK-ADF0016270, at 70.

⁹ 9/30/05 deposition of S. Baumgartner at 508-09 (In re Vioxx Litig., MDL No. 1657, E.D. La.).

¹⁰ The Marketing Department used advisory boards for market research, which was considered non-promotional in nature. As a result, advisory board meetings were not limited to discussions of data consistent with the label. See Appendix G for an overview of regulatory requirements. For examples of topics covered at meetings, see, e.g., 9/30/05 deposition of S. Baumgartner at 117-18 (In re Vioxx Litig., MDL No. 1657, E.D. La.) (recounting experts' reactions to naproxen cardioprotection hypothesis); 11/2/00 Third Quarter Vioxx Multidisciplinary Medical Advisory Board Meeting Report, MRK-ADF0008134, at 43-44 (meeting agenda included updates on the VIGOR Trial, Merck's perspective on the renal effects of Coxibs, and the Clinical Development Program for Vioxx).

Board members were paid honoraria for their participation, and their pre-approved travel, meals, and lodging costs were covered.¹¹

C. Consultants' Meetings.

Consultants' meetings sponsored by the Marketing Department¹² were led by a moderator and often featured 5-6 speakers. Such meetings provided a forum in which to conduct market research on Vioxx from larger groups of approximately 30-80 regional consultants or 150-250 national consultants in relevant fields and to cultivate relationships with those physicians.¹³ In the meetings, which were often run like focus groups and were attended by MRL scientists, speakers presented data to physicians and sought detailed feedback on their reactions to the data, additional data they would like to see, and/or other issues relevant to the purpose for which the particular meeting had been

¹¹ See, e.g., Multidisciplinary Strategic Advisory Board for Cox-2 Inhibitors Consulting Agreement, MRK-ADF0016270-73 (providing for \$5,000 per day honorarium for advisory board members in 2000-2001, and travel expenses, including transportation, lodging, and meals, to be incurred only with advance written approval); Proposal for Second Quarter 2000 Vioxx® Multidisciplinary Medical Advisory Board Meeting by John A. Romankiewicz* to Caroline Yarbrough, MRK-AFI0195488, at 506 (estimating costs of coach class travel, hotel rooms, and miscellaneous travel expenses for advisory board members).

¹² During the relevant period, according to Ms. Baumgartner, the Marketing Department convened approximately 20-30 consultants' meetings per year concerning Vioxx. These consultants' meetings were distinct from the consultants' meetings convened by MRL, discussed in Appendix F.

¹³ Merck Health Education Field Training Initiative Participant Workbook at MRK-AAR0016583, at 627. All content and arrangements, including agendas and presentation materials, were reviewed and approved by the Health Education Liaison Department and by counsel prior to the meetings. Id.

convened.¹⁴ Marketing Department personnel debriefed with one another after such meetings, and the consultants' comments were summarized formally and informally.¹⁵

The Marketing Department considered such consultants' meetings non-promotional in nature and thus exempt from FDA regulation of promotional activity.¹⁶ Nevertheless, Marketing Department personnel stated that they provided balanced presentations at consultants' meetings to maintain Company credibility, and Merck policy required "[a]ll content and arrangements, including agendas and presentation materials [to] be reviewed and approved by HEL and Legal counsel prior to the meeting."¹⁷

Consultants generally included a range of specialists from the same clinical areas represented on the advisory boards (e.g., rheumatology, pain management, orthopedic surgery, etc.), each able to offer feedback on issues pertaining to his or her own areas of expertise. Merck paid consultants honoraria commensurate with "the fair market value of their services."¹⁸ With respect to expenses, Merck policy, which followed the relevant

¹⁴ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 91.

¹⁵ See, e.g., Summary of 4/01 National Pain Consultants Meeting prepared by Ziment Associates, MRK-AFI0160044-54; Minutes of 5/6/00 National Consultants Meeting on Pain Management, MRK-AFI0159087-92.

¹⁶ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 91 ("[F]or legitimate market research purposes, Merck may provide information to physicians that is not consistent with the labeling so long as there is a reasonable expectation that Merck may (within a reasonable time) be able to use such data in promotion.").

¹⁷ Merck Health Education Field Training Initiative Participant Workbook, MRK-AAR0016583, at 627.

¹⁸ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 91, 93. Susan Baumgartner estimated that the honoraria ranged from approximately \$500 to \$1,000 per day.

American Medical Association guidelines, was to pay consultants “who provide genuine services (e.g., market research) . . . reasonable compensation and reimbursement for reasonable travel, lodging and meal expenses,” but not to create “[t]oken consulting or advisory arrangements.”¹⁹

In the wake of the Culture of Compliance described in Section I of this Appendix, Merck policy required that consultants’ meetings and advisory boards be convened only as necessary when information was not available through alternate sources. The number of meetings was therefore reduced, the number of participants restricted, and uniform criteria put in place for participant selection. Senior-level personnel became responsible for ensuring that each program was conducted properly and for a proper purpose.²⁰

D. Health Education Liaison Speaker Program.²¹

Merck’s early advocate development activities for Vioxx included an extensive speaker program known within the Company as Health Education Liaison (“HEL”) in which speakers – either from within or outside the Company – delivered presentations to

¹⁹ 12/1/00 Policy Letter No. 140, MRK-AAR0016829, at 30 (summarizing the American Medical Association guidelines).

²⁰ 7/23/02 presentation of K. Steinbugler and L. Beauchard to Audit Committee of the Merck Board of Directors, “U.S. Marketing & Sales Compliance,” MRK-AGNPRS 00000010, at 20; 12/20/04 presentation of B. Sheares and K. Steinbugler to Public Policy and Social Responsibility Committee of the Merck Board of Directors, “USHH Marketing, Selling and Medical Scientific Interactions with Academicians, Physicians, and Other Customers,” MRK-AGNPRS 00000001, at 03.

²¹ In late 2001, the Health Education Liaison program was discontinued in connection with the Culture of Compliance. As discussed in Section I of this Appendix, the number of promotional education programs offered was reduced, as was the number of speakers. These new promotional education programs were run out the Educational Program Integration (EPI) Department. Slide, “Major Changes in EPI,” MRK-AFI0063030 (attached to 11/14/01 email from M. Redden to J. Keating et al., MRK-AFI0063029).

educate doctors about selective Cox-2 inhibitors in general and Vioxx in particular.²²

Health Education Liaison speaker programs in which a physician from outside Merck lectured other physicians were known as “Speaker Facilitated Programs.”²³ These speaker programs provided medical education to physicians in a promotional setting and furthered specific marketing goals, including: “advocate development, PCP [primary care physician] education, convey new messages to physicians, handle obstacles with particular group of physicians, increase rapport, gain access to particular physicians.”²⁴

Such talks were given both in person and remotely.²⁵

1. Governing Law.

Merck’s Health Education Liaison programs were governed by the Food, Drug, and Cosmetic Act and FDA regulations and the Company’s Policy Letters.²⁶ As promotional programs, Health Education Liaison talks were required to provide fair

²² Merck Health Education Field Training Initiative Participant Workbook at MRK-AAR0016583, at 600.

²³ Speaker Facilitated Programs took various forms, including roundtables, Remote Speaker Programs (“RSPs”), and symposia. The Health Education Liaison program also included Field-Managed Meetings, such as National Consultant Meetings and Speaker Training Seminars, the provision of research grants, and Merck Facilitated Programs in which Merck field personnel gave presentations to outside medical professionals. 6/01 slide presentation, “HEL Workshop,” MRK-AAR0012030, at 37.

²⁴ Merck Health Education Field Training Initiative Participant Workbook at MRK-AAR0016583, at 600.

²⁵ Telephonic presentations were made as part of the Remote Speaker Program. Remote Speaker Program talks were lectures by physicians to healthcare professionals staged remotely. Those attending might receive hardcopies of lecture overheads, and any distributed materials received Medical/Legal Review Board approval. As with live programs, a written speaker contract was required, and the lecture had to be consistent with the labeling for any and pharmaceuticals discussed. Merck Health Education Field Training Initiative Participant Workbook, MRK-AAR0016583, at 625.

²⁶ Our inquiry focused on these statutes and regulations.

balance and to conform to product labeling,²⁷ and Health Education Liaison speakers entered into written contracts with Merck agreeing to abide by these requirements.²⁸ The speaker contract instructed lecturers that they “should disclose to the audience that [their] prepared remarks must remain within labeling for all products because of Merck’s role in the design of the program and Merck’s financial support of [the] presentation.”²⁹

All materials distributed by Merck in connection with promotional talks were subject to Medical/Legal Review Board review and approval.³⁰ Although Merck did not dictate the precise content of a speaker’s presentation, speakers’ written contracts “specif[ied] that if they discuss products, they agree to keep their comments consistent with, and not contrary to, the labeling for Merck products and competing products and they must provide fair balance in their presentations.”³¹ Product circulars for all Merck drugs discussed were to be offered to all attendees, and on-site Merck representatives were required to contact Health Education Liaison program personnel if any

²⁷ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 485, 491, 505.

²⁸ Standard Consultant Agreement Letter, MRK-ABI0003256, at 57-58 (attached to 1/5/01 letter from E. Westrick to S. Salis*, MRK-ABI0003253-55).

²⁹ Standard Consultant Agreement Letter, MRK-ABI0003256, at 58 (attached to 1/5/01 letter from E. Westrick to S. Salis*, MRK-ABI0003253-55).

³⁰ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 491.

³¹ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 491; see also Standard Consultant Agreement Letter, MRK-ABI0003256, at 57 (attached to 1/5/01 letter from E. Westrick to S. Salis*, MRK-ABI0003253-55).

Merck-supported speaker failed to give a balanced presentation or to conform the talk to the product circular.³²

Health Education Liaison programs took place in private rooms in, for example, restaurants, hotel conference rooms, or medical facilities. Merck's Health Education Liaison regulations provided that "[t]he educational part of the [HEL program] is the cornerstone of the [program] and . . . should generally be twice as long as the social component."³³ One Health Education Liaison training workbook cautioned that "[a]ny event must pass a 'red-faced' test with external audiences."³⁴

2. Anticipated Benefits.

A 1999 document entitled "Rules of the Road for HEL Programs" that governed Health Education Liaison program offerings identified three advantages of such programs:

- "The ability to present credible clinical data to our customers;"
- "The ability to build and enhance relationships with our customers"; and

³² 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 491.

³³ 1/99 Rules of the Road for HEL Program, MRK-AAR0016467, at 474.

³⁴ Merck Medical Education Field Training Initiative Participant Workbook, MRK-AAR0016583, at 95; see also 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 479 (discussing permissible and impermissible social events). Following reforms to the HEL program in 2001-02 (discussed in Section I below), Merck's regulations expressly provided that "[t]he venue and any hospitality (i.e. modest meal) should not create an appearance of lavishness or extravagance as viewed through the eyes of the local community at large." 3/13/02 Bulletin: EPI Frequently Asked Questions (No. EPI 02-001), MRK-AAR0027760, at 70.

- “The ability to communicate important information about our products to thousands of our customers.”³⁵

The 2001 Profit Plan for Vioxx (developed prior to the Culture of Compliance) recommended targeting Health Education Liaison speakers for advocate development and using Health Education Liaison speaker programs as a resource with which to “influence the[] behavior” of thought leaders.³⁶

3. Administration.

The Health Education Liaison program was administered by personnel from various parts of Merck’s U.S. Human Health organization, including several groups within the Marketing and Sales Departments. Mr. Philip Reich (reporting to Mr. Bruce West) and Mr. James Dunn, in turn, led the Health Education Liaison group within U.S. Human Health during the relevant period.³⁷ The budget for the Health Education Liaison program was controlled by the Marketing Department.³⁸ Health Science Associates (“HSAs”) and Specialty Representatives identified, trained, and certified physicians for the Health Education Liaison program.³⁹

³⁵ 1/99 Rules of the Road for HEL Program, MRK-AAR0016467, at 470.

³⁶ 9/1/00 2001 Profit Plan for Vioxx, MRK-AAO0000073, at 92.

³⁷ 11/7/02 deposition of J. Dunn at 74-76 (Lehr v. Merck & Co., No. 01-516-MRJ, S.D. Ill.).

³⁸ 7/8/05 deposition of J. Dunn at 32 (Ernst v. Merck & Co., 19961*BH02, Tex. Dist. Ct.).

³⁹ 3/13/02 Bulletin: EPI Frequently Asked Questions (No. EPI 02-001), MRK-AAR0027760, at 65. Health Science Associates were a subset of the sales force with advanced medical or scientific training whose job was to discuss the science behind selective Cox-2 inhibitors with thought leaders rather than to promote and sell specific products. 4/16/03 deposition of J. Dunn at 101 (Barlow v. Merck & Co., No. CV-02-2842-MC, Ala. Cir. Ct.). Specialty Sales Representatives promoted products, although only in a single therapeutic area and usually to specialists, such as rheumatologists

Qualities considered in selecting Health Education Liaison speakers included “advocacy level; status in community; ability to speak; interest in product; understanding of message; experience, HSA Specialty Representative or HEL recommendation.”⁴⁰ Multiple Merck employees stated that prescription practices were irrelevant to selection as a speaker.⁴¹ Talks were often scheduled at the initiative of field sales representatives, who were then considered the program owners and who also handled certain program logistics.⁴² Health Education Liaison speakers received honoraria, and their travel expenses were reimbursed.⁴³ Speakers were not “guarantee[d] a minimum number of programs or a minimum amount of honoraria.”⁴⁴

or orthopedic surgeons, unlike regular sales representatives who might visit doctors to discuss an array of Merck pharmaceuticals. 4/16/03 deposition of J. Dunn at 29-30 (Barlow v. Merck & Co., No. CV-02-2842-MC, Ala. Cir. Ct.).

⁴⁰ 6/01 Basic Training HEL Workshop workbook, MRK-AAR0011883, at 98.

⁴¹ An April 2002 Bulletin, however, suggested under “Speaker criteria” “prescribed VIOXX as a treatment option for osteoarthritis, rheumatoid arthritis in adults or acute pain in adults.” 4/12/02 Bulletin for VIOXX: Action Required: EPI Directions on Label Change for Vioxx GI Outcomes Research Study and RA Indication (No. COX 02-031), MRK-AAR0021722, at 23.

⁴² 10/12/01 slide presentation, “District Implementation Meeting,” MRK-AAR0030548, at 564.

⁴³ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 531-32, 544. A guide for new sales representatives included the following honoraria for various Health Education Liaison programs: \$750 for speakers who delivered a formal slide presentation, often over dinner, to physicians or other healthcare providers; \$250 for attendees; \$1,500 for consultants attending market research focus groups, including disease/product-focused clinical presentations; and \$500 for doctors participating in preceptorships in which Merck sales representatives would follow a doctor during his practice for a day. “Now What? A Guide for the New Merck Professional Representative,” MRK-AFC0003650, at 67.

⁴⁴ Standard Consultant Agreement Letter, MRK-ABI0003256, at 56 (attached to 1/5/01 letter from E. Westrick to S. Salis, MRK-ABI0003253-55).

While Merck generally made slides available to speakers for their use in Health Education Liaison programs, speakers could also create their own slides.⁴⁵ Health Education Liaison contracts, however, prohibited speakers from distributing slides that were not approved by the Medical/Legal Review Board.⁴⁶ In response to such inappropriate distribution, Merck issued a Bulletin in March 2000 reminding all sales representatives of the prohibition against distribution of non-approved materials and stating that disciplinary action, including termination, could result from such a violation.⁴⁷

4. Dine n' Dash.

On May 14, 2001, The Wall Street Journal published an article regarding a Merck-sponsored Health Education Liaison speaker event that took place in New Orleans. The article reported that a Merck representative had invited physicians to a local restaurant where they could order dinner to take home for themselves and their spouses while listening to a speaker presentation about arthritis drugs. According to the article, when Merck's designated speaker arrived late to the restaurant, many doctors

⁴⁵ 3/6/00 Bulletin: Distribution of Non-Approved Materials Not Permitted (No. GEN 00-0222), MRK-AAR0009027 (noting that speaker-created slides could not be distributed at HEL programs because they did not receive Medical/Legal Board approval).

⁴⁶ 3/6/00 Bulletin: Distribution of Non-Approved Materials Not Permitted (No. GEN 00-0222), MRK-AAR0009027; 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 505. Dr. Peter Holt*, whose non-Merck-approved presentations on Vioxx in June 2000 were called "false and misleading" by DDMAC in its September 17, 2001 warning letter (discussed in more detail in Appendix G), was a Health Education Liaison speaker. Dr. Holt's* position, however, was terminated based on an investigation by Merck of DDMAC's allegations. 10/1/01 letter from D. Anstice to T. Abrams*, MRK-AFT0007691, at 94.

⁴⁷ 3/6/00 Bulletin: Distribution of Non-Approved Materials Not Permitted (No. GEN 00-0222), MRK-AAR0009027.

already had departed with food in hand, and the speaker talked informally about Vioxx with those doctors who remained. The article reported further that Merck called this a “Dinner to Go Program,” but that physicians colloquially referred to this and similar programs as a “Dine n’ Dash.”⁴⁸

Prior to publishing the article, the reporter from The Wall Street Journal called Ms. Jan Weiner of Merck’s Public Affairs Department regarding the program. Ms. Weiner investigated the matter by speaking to Merck employees in New Orleans. She also consulted Mr. Ronald Henshall from Merck’s Legal Department and her colleagues in the Public Affairs Department regarding the investigation.⁴⁹ The investigation revealed that the program, organized by a “fairly new representative . . . under the guidance of his mentor,” was not conducted in accordance with Merck policies.⁵⁰ Mr. Philip Reich, then head of the Health Education Liaison program, identified two concerns in an email summarizing the situation:

a buffet was not offered (ordered off menu while MD waited and chatted with speaker) and the invite was not an approved invitation (title: “WHY COOK? Merck and Co., Inc, [sic] has asked me to invite you to a Dinner and Go Program. Come in and order dinner to go for you and your spouse.”⁵¹

⁴⁸ 5/14/01 email from B. Rowley to Gifts, MRK-ADI0009362-63 (circulating text of article).

⁴⁹ 4/30/01 email from P. Reich to R. Baranick et al., MRK-ADI0008693.

⁵⁰ 4/30/01 email from P. Reich to R. Baranick et al., MRK-ADI0008693.

⁵¹ 4/30/01 email from P. Reich to R. Baranick et al., MRK-ADI0008693.

Mr. Reich continued, “Clearly, this brings up the need to TRAIN, TRAIN, TRAIN from new hires to experienced reps. Reps cannot rely on their colleagues. In this case, it reinforced ‘bad’ behavior.”⁵²

Following the investigation, Mr. David Anstice, President, Human Health – The Americas, spoke to the journalist, who reported Mr. Anstice’s comments in the May 14, 2001 article as follows:⁵³

David Anstice, the Merck official who oversees drug sales in North and South America, says the event was against company policy because it didn't encourage a substantial exchange of information between doctors and Merck's experts. The company has a detailed list of dos and don'ts for structuring events, but occasionally some take place against company policy, he says. "I understand the competitive pressures out there, but as far as I'm concerned, we need to get information to physicians and do it in the right way," he says. Even the invitation was improper, he adds, prompting a nationwide Merck assessment of how such documents should be written.

Mr. Anstice has testified that the type of speaker program at issue was stopped “because when we considered the purpose of the program, which was to educate doctors [i]t was clear that the intention of the program was not being achieved, that is, to impart medical information to attending physicians.”⁵⁴

⁵² 4/30/01 email from P. Reich to R. Baranick et al., MRK-ADI0008693.

⁵³ 5/14/01 email from B. Rowley to Gifts, MRK-ADI0009362, at 65 (circulating article from The Wall Street Journal).

⁵⁴ 3/17/05 D. Anstice deposition at 483 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

E. Medical School Grant Program.

Merck also provided Marketing Department-funded grants of up to \$50,000 per year to independent researchers for use in the study of Vioxx.⁵⁵ In 2000, the Medical School Grant Program (“MSGP”) had a budget for Vioxx of \$1.4 million and awarded approximately \$1.3 million in grants.⁵⁶

The Medical School Grant Program was managed by a review committee comprising primarily clinical and basic scientists and U.S. and international marketers.⁵⁷ Grant proposals were submitted by physicians directly and/or through Merck personnel such as Health Science Associates. The review committee evaluated grant applications for a variety of factors, including whether the proposal addressed a “valid scientific question” and a “marketing need.”⁵⁸

It appears that one objective of the Medical School Grant Program was to develop and improve relationships with thought leaders.⁵⁹ In this vein, Health Science Associates

⁵⁵ 8/8/00 letter from B. Morrison to G. Dalbagni*, MRK-NJ0419107, at 107 (stating the \$50,000 cap on Medical School Grant Program grants); 5/2/00 letter from R. Young to R. Delgado*, MRK-EAI0002028 (same).

⁵⁶ 11/12/00 email from S. Baumgartner to A. Dixon, MRK-AFI0193242 (attaching a list of approximately 30 grants awarded in 2000 for a total of almost \$1.3MM); see also Minutes of 8/21/00 Vioxx Medical School Grant Program Review Committee, MRK-AEH0016471 (indicating that the total budget for year 2000 was \$1.4MM). Seventy-nine grants had been awarded as of January 1, 2001. Coxib Medical School Grants as of January 1, 2001, MRK-AFI0193583.

⁵⁷ See, e.g., Minutes of 6/16/00 Vioxx Medical School Grant Program Review Committee meeting, MRK-ADF0010826, at 26 (listing committee members).

⁵⁸ Vioxx Medical School Grant Program: Revised Procedures, MRK-AFI0192419, at 19 (attached to 5/12/00 email from H. Lange to A. Gelhorn, et al., MRK-AFI0192417).

⁵⁹ Ms. Baumgartner has testified to certain “business reasons” that have received consideration in the grant making process: “You have an institution who has a lot of patients in pain. You have

and members of the Medical School Grant Program Review Committee directed special attention to proposals submitted by thought leaders with whom Merck wanted to develop or maintain relationships.⁶⁰ In at least one instance, the Review Committee reviewed on an expedited basis a proposal submitted by a doctor whom Merck perceived as influential and who worked at a hospital that the Marketing Department considered a “Must Win Account.”⁶¹ In a memorandum sent to Ms. Susan Baumgartner, who sat on the Medical School Grant Program Review Committee, members of the Marketing Department expressed the view that approving the grant could “help us achieve our goal of getting Vioxx® on [the] formulary” at the hospital in question.⁶² The proposal was granted.

Marketing considerations also played a role in the Review Committee’s consideration of a June 2000 proposal by Dr. Garret FitzGerald* for funding to test the hypothesis that a biochemically selective dose of Vioxx would retard atherogenesis in

investigators, researchers who are looking to study a product and looking to work with Merck to understand information about our product, and those, in my opinion, are business reasons to work with them in that capacity.” 2/25/05 deposition of S. Baumgartner at 130 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

⁶⁰ See, e.g., 7/31/00 email from S. Welsh to H. Lange et al., MRK-AFI0193024 (“Due to strong relationships that both of these physicians have with Merck[,] I would ask that this proposal be reviewed with ‘special attention’ [sic.]”); 10/28/99 email from I. Rodger to VIOXX Medical School Grant Program Committee, MRK-AFI0193757 (“There is considerable pressure from a variety of sources to have this proposal reviewed ASAP since it has been around since July of this year Please bear in mind that Altman is an influential investigator and this area of investigation is one considered to be of potential importance to Vioxx.”).

⁶¹ 10/18/00 email from A. Calabro to S. Reiss et al., MRK-AFI0193165; see also 10/26/01 email from S. Baumgartner to D. Banerjee and P. Alberti, MRK-ACZ0069048-49; 2/12/01 email from S. Baumgartner to I. Rodger and H. Pearly, MRK-ACZ0069061.

⁶² Memorandum from R. Landenberger and A. Kassa to J. Glasmire, MRK-AFI0193166, at 67 (attached to 10/18/00 email from L. Coppola to S. Baumgartner, MRK-AFI0193165).

apolipoprotein E knockout (ApoE KO) mice.⁶³ The minutes of a June 16, 2000 Review Committee meeting recorded comments regarding the proposal and five issues to consider in evaluating the proposal.⁶⁴

*Proposal #270
FitzGerald/USA*

A biochemically selective dose of rofecoxib retards atherogenesis in the DKO mouse (Reviewer: GG)

Comments: There was a very extensive debate on this topic. Scientifically this is a sound prospective study in an animal model of atherogenesis that has a distinct relevance to the human disease. The investigator's group is very highly regarded and an international authority in eicosanoid research.

Issues:

- a) The science merits support.
- b) There is a commercial/marketing anxiety about a possible downside risk that enhanced mortality may occur in the rofecoxib-treated animals from cardiovascular complications that is mechanism based. This may attach to the cardiovascular events from VIGOR.
- c) Any anti-atherogenic activity of rofecoxib would be of very significant potential impact.
- d) How significant, and relevant, are observations in a double knock-out mouse model to those occurring in man? Is there any real risk?
- e) There is senior management impetus to try and support Garrett's research effort.

The Committee concluded that it "was not prepared to make a decision on supporting the proposed work without input from MRL and its senior Management."⁶⁵

Upon reviewing the proposal and consulting with colleagues, Dr. Nies wrote to Dr. Daniels and Dr. Ian Rodger, Chair of the Medical School Grant Program Review

⁶³ Minutes of 6/16/00 Vioxx Medical School Grant Program Review Committee meeting, MRK-ADF0010826, at 27.

⁶⁴ Minutes of 6/16/00 Vioxx Medical School Grant Program Review Committee meeting, MRK-ADF0010826, at 27.

⁶⁵ Minutes of 6/16/00 Vioxx Medical School Grant Program Review Committee meeting, MRK-ADF0010826, at 27.

Committee and suggested that the study be performed with a “selective COX-2 inhibitor that is not Vioxx or Celebrex.”⁶⁶ Dr. Rodger responded, “We have taken precisely this approach with many investigators in the past two years. We have usually supplied MF-tricyclic [an experimental Cox-2 inhibitor] . . . and will probably do so again here.”⁶⁷ The Medical School Grant Program gave Professor FitzGerald* \$75,000 over two years to conduct his proposed study using MF-tricyclic.⁶⁸

Two months later, Mr. E.B. Brakewood, a member of the Medical School Grant Program Review Committee and Director of Marketing for the Arthritis & Analgesia Therapeutic Business Group at the time, annotated the Medical School Grant Program Review Committee meeting minutes quoted above with handwritten notes directed to his supervisors.⁶⁹

One of my more significant contributions to the MSG program was to reduce the company’s risk with FitzGerald’s [study] by recommending substituting MF-tricyclic for either Vioxx or 663 [Arcoxia] and in general, raising awareness of the commercial consequences of this study.⁷⁰

⁶⁶ 6/23/00 email from A. Nies to B. Daniels and I. Rodger, MRK-ACR0010946.

⁶⁷ 6/24/00 email from I. Rodger to B. Daniels and A. Nies, MRK-ACR0010946. The “MF” MF-Tricyclic stands for “Merck Frosst,” Merck’s Canadian research lab.

⁶⁸ 7/16/01 email from G. Geba to B. Gertz, MRK-NJ0198527; Minutes of 8/21/00 Vioxx Medical School Grant Program Review Committee meeting, MRK-AEH0016471, at 71. The study was ultimately published. See Egan* KM, Wang* M, Lucitt* MB, et al. Cyclooxygenases, thromboxane, and atherosclerosis: plaque destabilization by cyclooxygenase-2 inhibition combined with thromboxane receptor antagonism. Circulation. 2005;111:334-342.

⁶⁹ Mr. Brakewood did not recall why he wrote the note when he did.

⁷⁰ Minutes of 6/16/00 Vioxx Medical School Grant Program Review Committee meeting, MRK-ADF0010826, at 26.

Next to the statement in the minutes of “possible downside risk that enhanced mortality may occur in the rofecoxib-treated animals,” Mr. Brakewood wrote, “pretty good thing to worry about!”⁷¹

As a result of the Culture of Compliance, reforms were made to the Medical School Grants Program.⁷² The process of soliciting and reviewing submissions has been standardized, and there is now a web-based system by which all applicants submit their proposals.⁷³ Grant payments are tied to performance, and final payment cannot be made until a presentation or manuscript is completed by the investigator. The Review Committee comprises solely scientists, and no member of the Marketing or Sales Departments sits on the Committee. Marketers are allowed to contribute their views on limited topics, such as areas of interest to the Marketing Department, but do not otherwise participate in selecting among applicants (although the budget for the program is ultimately allocated from the Marketing budget).

⁷¹ Minutes of 6/16/00 Vioxx Medical School Grant Program Review Committee meeting, MRK-ADF0010826.

⁷² The name of the group was also changed, so that the U.S. arm of the worldwide Medical School Grant Program became known as the Investigator-Initiated Studies Program (“IISP”). See 7/7/04 Bulletin: US-Investigator-Initiated Studies Program (Medical School Grants Program) and Customer Requests, MRK-AAR0070086.

⁷³ See 7/7/04 Bulletin: US-Investigator-Initiated Studies Program (Medical School Grants Program) and Customer Requests, MRK-AAR0070086 (describing web-based submission system and stating that “Merck Field Based Employees may NOT initiate discussions regarding the IISP or solicit proposals from potential investigators” and “[n]o Merck personnel outside of certain Headquarters groups may interact with investigators about their studies or funding”) (emphasis in original).

F. Continuing Medical Education.

In addition to Speaker Facilitated Programs organized by the Health Education Liaison Department, Merck also provided financial support for Continuing Medical Education (“CME”) presentations. Unlike promotional programs, Continuing Medical Education programs were not directly sponsored by Merck. Instead, Merck provided grants to accredited sponsors that took responsibility for program content and faculty recruitment.⁷⁴

Merck’s Policy Letter 128, dated December 1, 1998, stated that Continuing Medical Education programs differed from promotional presentations in that they had to (i) satisfy FDA guidance requiring the content to be sufficiently independent of Merck and (ii) comply with the Accreditation Council on Continuing Medical Education (“ACCME”) Standards for Commercial Support of Medical Education.⁷⁵ FDA standards required Continuing Medical Education lectures to be free of commercial bias, and discussion of commercial products had to present objective information based on scientific methods generally accepted in the medical community. ACCME standards likewise required that the information presented be objective and balanced, but proactive

⁷⁴ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 490 (restating Merck’s Policy Letter No. 128).

⁷⁵ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 490 (restating Merck’s Policy Letter No. 128).

discussion of off-label uses of pharmaceutical products was permissible as long as the fact that such uses were off-label was disclosed.⁷⁶

The Marketing Department viewed Continuing Medical Education programs as a forum in which to educate physicians about Vioxx.⁷⁷ In addition, while Merck could not control the sponsor's choice of speaker for the programs that Merck had funded, from time to time sponsors sought speaker recommendations from Merck, which provided the Company with an opportunity to recommend a physician whom it saw as an advocate for Vioxx.

G. Employing Physicians as Clinical Investigators.

Merck also worked to develop doctors as advocates by employing them as paid investigators in clinical trials.⁷⁸ This was done largely through Merck's Clinical Development Program ("CDP"), a subgroup of the Medical and Scientific Affairs Department.

The Clinical Development Program sponsored Marketing Department-funded studies "to support the marketing needs of an approved product (e.g. differentiation,

⁷⁶ 1/99 Rules of the Road for HEL Programs, MRK-AAR0016467, at 490 (restating Merck's Policy Letter No. 128).

⁷⁷ See, e.g., 1/5/01 slide presentation, "2001 Advocate Plan for Merck Coxibs," MRK-ADF0018569, at 610 (describing advocate development objectives of 2001 Continuing Medical Education initiatives); 5/8/00 memorandum from W. Dixon to E. Scolnick, MRK-ACR0010601, at 03 (listing Continuing Medical Education as among the measures employed by the Arthritis & Analgesia Therapeutic Business Group to counter negative messaging from Searle/Pfizer about cardiovascular and renal effects of Vioxx).

⁷⁸ 7/7/02 slide presentation, "Year 2000 Advocate Plan for Merck Coxibs – Draft," MRK-AFI0014850, at 93 (CDP "Objective #2: provide advocates with an opportunity to participate in Merck-sponsored research").

competitive issues, etc.).”⁷⁹ Clinical Development Program studies complemented those run by MRL, whose charter was to bring drugs to market or explore new indications.⁸⁰

Clinical Development Program studies also served to expose investigators to the Company’s products. Marketing and Sales personnel sometimes suggested investigators for Clinical Development Program trials, in part in response to a doctor’s influence, ability to place patients quickly, and relationship with Merck.⁸¹

The ADVANTAGE Trial, conducted in early 2000, shortly after Vioxx was approved for sale, is illustrative. The ADVANTAGE Trial tested the efficacy and tolerability of Vioxx 25 mg as compared to naproxen in osteoarthritis patients. The trial employed a large number of investigators, many of whom were primary care physicians, a group often charged with treating osteoarthritis patients. Clinical trials such as those sponsored by the Clinical Development Program that were designed, at least in part, to introduce investigators to a drug for marketing purposes were sometimes referred to by members of the Marketing and Public Affairs Departments as “seeding studies,” a term

⁷⁹ 7/7/02 slide presentation, “Year 2000 Advocate Plan for Merck Coxibs – Draft,” MRK-AFI0014850, at 93.

⁸⁰ 7/7/02 slide presentation, “Year 2000 Advocate Plan for Merck Coxibs – Draft,” MRK-AFI0014850, at 93.

⁸¹ See, e.g., Slide presentation, “ADVANTAGE,” MRK-ADI0017754, at 59 (attached to 3/16/99 email from C. Yarbrough to M. Dixon *et al.*, MRK-ADI0017753) (charging Regional Health Science Associates with identifying “physicians important to business for consideration as investigators”); 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044563 (“As you move forward with the clinical development program for [Vioxx], please consider including the following physicians as investigators for your clinical trials. These ‘physicians to neutralize’ are important from an A&A business perspective in terms of influence and/or prescribing and have not been as supportive of Merck and/or Vioxx as we would like.”)

that, for some, implied a lack of scientific rigor to the study.⁸² Multiple people have testified that the ADVANTAGE Trial was not a “seeding study” and that Merck did not permit them.⁸³ In addition, witnesses have reported that all Merck studies, including studies conducted out of the Marketing Department, are scientifically rigorous and that MRL is consulted before a study begins. As discussed in Appendix I, in an April 7, 2001 email to Dr. Douglas Greene discussing how the ADVANTAGE Trial results “compromised” the VIGOR Trial results, Dr. Scolnick called the ADVANTAGE Trial “intellectually redundant” and stated that, in general, studies run by the Clinical Development Program were designed with a “marketing emphasis.”⁸⁴

⁸² See e.g., Memorandum from J. Webb to B. Smith, MRK-AFB0001598 (list of suggested doctors for use as investigators in seeding studies); 3/22/99 email from R. Higbee to K. Lindemann *et al.*, MRK-ADI0024337, at 37 (discussing deleting references to the ADVANTAGE study as a “seeding study” in internal documents); 4/12/05 deposition of D. Anstice at 303, 310 (*In re Vioxx Litig.*, No. 619, N.J. Super. Ct. Law Div.) (“I think the terminology is used to indicate that a large number of physicians get experience and use of the product, and through that use and experience gain further insights into the drug. . . . I think that to the extent that somebody can define a seeding study as something which doesn’t have a primary purpose an appropriate clinical endpoint, the I am uncomfortable with that. . . .); 4/29/05 deposition of E. Scolnick at 190 (*In re Vioxx Litig.*, No. 619, N.J. Super. Ct. Law Div.) (“A seeding study is a trial designed with a medical purpose which also will give physicians experience with an approved drug.”).

⁸³ See, e.g., 8/16/05 deposition of B. Gertz at 349-50 (*In re Vioxx Litig.*, No. 619, N.J. Super. Ct. Law Div.); 8/19/05 deposition of A. Reicin at 840 (*In re Vioxx Litig.*, No. 619, N.J. Super. Ct. Law Div.). Ms. Lucine Beauchard, Vice President, Business Practices and Compliance Department, has stated that while some studies were proposed or performed for the purpose of introducing doctors to Vioxx that would not otherwise have lived up to Merck’s standards for collecting and using the resulting data, no such studies could be performed today post-Culture of Compliance. Additionally, while Marketing and Sales personnel can still suggest physicians to serve as investigators, Medical and Scientific Affairs makes the ultimate determination on the issue and Ms. Beauchard did not believe that doctors were supposed to be told that their name had been suggested.

⁸⁴ 4/7/01 email from E. Scolnick to D. Greene, MRK-ACR0009150.

H. Neutralizing Physicians.

As discussed above, the Marketing and Sales Departments worked to turn doctors into advocates through various contacts intended to impress them with Merck's data and otherwise familiarize them with Merck and Vioxx. This Section discusses activities directed at physicians and academics thought to be critical of Vioxx by the Marketing Department as well as by Dr. Louis Sherwood, head of the Medical & Scientific Affairs Department within the U.S. Human Health Division.

1. Marketing Department Neutralizing Efforts.

During the market development phase, Health Science Associates identified certain doctors as having negative perceptions about Merck or Vioxx that the representatives believed would prevent the doctors from becoming advocates. Members of the U.S. Human Health Division directed their efforts at mitigating any negative effect those physicians might have on future sales of Vioxx by "neutralizing the physicians," *i.e.*, bringing them to a more neutral position with respect to Vioxx by providing more exposure, education and information about Vioxx.

In April 1999, prior to the launch of Vioxx, Ms. Susan Baumgartner, then a Marketing Manager for Vioxx, compiled "a list of 'problem' physicians that we must, at a minimum neutralize" and suggested possible ways to get the doctors involved with Merck, including enrolling them as investigators in Clinical Development Program trials,

offering them speaker positions or other consulting activities, or providing them with research grants.⁸⁵

The list compiled by Ms. Baumgartner was a precursor to a chart of thirty-six “Physicians to Neutralize” that she circulated on July 1, 1999 to Dr. Wendy Dixon, Senior Vice President, Marketing, and Ms. Charlotte McKines, Executive Director of the Arthritis & Analgesia Therapeutic Business Group.⁸⁶ In her cover memorandum, Ms. Baumgartner identified three criteria for inclusion on the list: (i) the doctors were “important from a business perspective in terms of influence and/or prescribing”; (ii) the doctors either “do not support or are negative toward Merck and/or VIOXX®”; and (iii) the doctors “[p]rovide extensive support and a strong voice for our competitors.”⁸⁷

Ms. Baumgartner described the project as follows:

Part of my responsibility was to develop advocates for the product, and in doing so, we identified a number of individuals who had misinformation, had incomplete information or a lack of information and were not supportive of Merck or Vioxx and may have been supporters of Celebrex at the time. And my responsibility was to provide those individuals with accurate information and bring them to a more neutral or a balanced position.⁸⁸

⁸⁵ 4/29/99 email from S. Baumgartner to L. Mendez, MRK-AFI0174637.

⁸⁶ 7/1/99 memorandum from S. Baumgartner and C. Yarbrough to C. McKines and W. Dixon, MRK-AFI0182292-93; see also List of Physicians to Neutralize, MRK-AFI0044570-96 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569).

⁸⁷ 7/1/99 memorandum from S. Baumgartner and C. Yarbrough to C. McKines and W. Dixon, MRK-AFI0182292, at 92.

⁸⁸ 2/25/05 deposition of S. Baumgartner at 24 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

It is not clear who instructed Ms. Baumgartner to assemble the list. Health Science Associates and Specialty Representatives submitted the names of the physicians, background descriptions, and suggested neutralization tactics to Ms. Baumgartner, who compiled them into the chart.⁸⁹ According to Ms. Baumgartner and Mr. Leonardo Mendez, who formerly supervised the Specialty Representatives and forwarded their suggestions to Ms. Baumgartner, they did not edit the comments they received from the field. An illustrative page from the chart containing recommendations is excerpted below.⁹⁰

NAME (Highlighted = National)	RECOMMENDATIONS (in addition to continued focus by the Specialists and HSAs)
Dietz, Frederick NEUTRALIZED	Now an Advocate; clinical trials
Dillin, William	Weekend Consultants' Meeting in an elegant location (New York, Hawaii) or a 5-day International Meeting with the top thought leaders on pain management - Visit from L. Mendez or M. Thomas to open door. Would prefer to stay with Specialty Senior Management
Ettlinger, Robert NEUTRALIZED	Currently a speaker, doing 2 launch symposia - He is participating in a number of clinical trials - Invite him to NY or NE meeting in the future - Keep him busy - Advantage

⁸⁹ 3/11/05 deposition of S. Baumgartner at 467 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

⁹⁰ List of Physicians to Neutralize, MRK-AFI0044570, at 78 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569).

Much of the background provided on the doctors reflected a perception that they were aligned with Searle/Pfizer. For example, the chart included the following descriptions of three of the physicians:

- “[P]resentations are biased and sometimes contain inaccurate information; shown extreme indifference to correcting his information; definitely anti-Merck; has national impact as Pfizer and Searle are scheduling him all over the country; works very closely with Searle and will deliver biased message in Searle-sponsored events but is balanced in [grand rounds], etc.”⁹¹
- “National impact; speaking extensively for Searle/Pfizer (200 days this year); numerous reports of biased and inaccurate presentations.”⁹²
- “National and international reputation; well-respected; excellent speaker; currently speaking for Celebrex.”⁹³

The doctors listed were generally identified either as high NSAID prescribers or as physicians who were well respected and influential in their fields. The chart noted that ten of the doctors on the list already had been “neutralized” or converted into advocates for Merck.

The chart recommended actions that Company personnel might take to help “neutralize” each physician at issue, including, in many instances, getting the physicians

⁹¹ List of Physicians to Neutralize, MRK-AFI0044570, at 77 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569).

⁹² List of Physicians to Neutralize, MRK-AFI0044570, at 89 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569).

⁹³ List of Physicians to Neutralize, MRK-AFI0044570, at 92 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569).

involved with Merck by means of one or more of the advocate development programs described above. Personal visits by Merck physicians and scientists to certain physicians on the list to explain or review data in detail were also suggested.⁹⁴ The recommended actions included, for example:

- “[U]tilization as speaker in small, controlled settings to repair relationship with Merck (tutorials, precepts, roundtables), continue to monitor talks given for Searle/Pfizer”;⁹⁵
- “Invitation to Merck Consultant Meetings; product experience; research (significant trials, not ADVANTAGE)”;⁹⁶
- “Use in many speaking engagements; investigational research; provide clinical data; at least \$20,000 for speaking engagements for the remainder of the year; personal visit from MRL/CDP/RMD [Regional Medical Director]”;⁹⁷
- “Would prefer a \$10,000 grant – we are currently waiting for [her] proposal to conduct a study”;⁹⁸ and

⁹⁴ Ms. Baumgartner’s chart regarding physicians to “neutralize” suggested with respect to several physicians a personal visit by Dr. Louis Sherwood, Senior Vice President for Medical and Scientific Affairs and Chief Medical Officer for the U.S. Dr. Sherwood met often with doctors at various medical meetings and in other forums. Dr. Sherwood’s activities are discussed below.

⁹⁵ List of Physicians to Neutralize, MRK-AFI0044570, at 96 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569) (recommendations for Dr. Thomas Stillman^{*}).

⁹⁶ List of Physicians to Neutralize, MRK-AFI0044570, at 84 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569) (recommendations for Dr. Kent Huston^{*}).

⁹⁷ List of Physicians to Neutralize, MRK-AFI0044570, at 93 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569) (recommendations for Dr. Nicholas Scarpa^{*}).

⁹⁸ List of Physicians to Neutralize, MRK-AFI0044570, at 93 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569) (recommendations for Dr. Michelle Petri^{*}).

- “Weekend Consultants’ Meeting in an elegant location (New York, Hawaii) or a 5-day International Meeting with the top thought leaders on pain management.”⁹⁹

For one physician, Professor James McMillen^{*},¹⁰⁰ the sole proposed course of action identified on the chart was a “[s]trong recommendation to discredit him.”¹⁰¹

Ms. Baumgartner has testified that she was not familiar with any effort to do so.¹⁰²

Witnesses agreed that discrediting a doctor would not be appropriate and denied knowing of any effort to discredit Professor McMillen^{*} or any other physician.¹⁰³

⁹⁹ List of Physicians to Neutralize, MRK-AFI0044570, at 78 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569) (recommendations for Dr. William Dillin^{*}).

¹⁰⁰ Professor McMillen^{*}’s name was misspelled as “MacMillan” on the chart. Professor McMillen^{*}, along with Professors Thomas Stillman^{*}, Michelle Petri^{*}, and Lee Simon^{*}, who were also on the list of physicians to “neutralize,” were later identified by Professor James Fries^{*} in his 1/9/01 letter to Mr. Gilmartin regarding the activities of Dr. Louis Sherwood, discussed below.

¹⁰¹ List of Physicians to Neutralize, MRK-AFI0044570, at 90 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569).

¹⁰² 2/25/05 deposition of S. Baumgartner at 226 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

¹⁰³ As noted in footnote 100, Dr. McMillen^{*} was, however, listed in Dr. James Fries^{*}’s January 9, 2001 letter to Mr. Raymond Gilmartin as a doctor who had been intimidated allegedly by Merck’s Dr. Louis Sherwood. Moreover, Dr. McMillen^{*} alleged that unspecified Merck personnel repeatedly stated publicly that Dr. McMillen^{*} was fired from his position at the Division of Rheumatology and Department of Medicine at The Pennsylvania State University College of Medicine. 11/15/00 facsimile from J. McMillen^{*} to J. Fries^{*}, MRKFRI0000021, at 30. It appears that Dr. Sherwood did, in fact, attempt to confirm Dr. McMillen^{*}’s faculty appointment with Dr. Stanley J. Naides^{*}, chief of the department, and was told that Dr. McMillen^{*} had been a Clinical Assistant Professor of Medicine at the Milton S. Hershey Medical Center of The University of Pennsylvania State University College of Medicine, but no longer held that position for reasons that “should not be interpreted as a commentary on the quality of his work and contribution.” 2/1/00 letter from S. Naides to L. Sherwood, MRKFRI0000023-24. Dr. McMillen also believed that Merck personnel cancelled or otherwise interfered with a number of his professional engagements. See, e.g., 11/15/00 facsimile from J. McMillen^{*} to J. Fries^{*}, MRKFRI0000021, at 30-31 (handwritten list from Dr. McMillen^{*} to Dr. Fries^{*} of examples of, among other things, his speaking engagements on behalf of competitors for which he believed Merck had scheduled competing speaker programs).

In February 2001, DDMAC sent Searle/Pfizer a Warning Letter complaining, in relevant part, about a

Another physician on the list, Dr. Max Hamburger^{*}, was labeled as an “advocate,” and the comment next to his name read:

[S]eeking support from the pharmaceutical industry for IPA [Independent Practice Association]; companies that provide funding will receive preferred status with its members and those that do not will have trouble accessing the IPA members; first endeavor to put together a ‘Standards of Care’ retreat meeting to develop a document that will serve as their manifesto (to include a drug formulary and how the members will treat certain diseases, preferred medications); price tag is \$25,000 to support this meeting and to have access during it. . . Pfizer/Searle are signed on to the ‘Standards of Care’ retreat. . . .¹⁰⁴

The next entry on the chart for Dr. Hamburger^{*} stated: “Financial support of private practice rheumatology IPA – (has taken place)” and “Has been turned around.”¹⁰⁵

When asked about the entries, Dr. Nancy Santanello, Executive Director of the Epidemiology Department within MRL, has testified that “[t]his is a very common practice, where physicians who are going to set up a meeting actually come to a number of different industries and ask for support, and the various companies will provide

series of promotional audio conferences presented by Professor McMillen^{*} on Searle/Pfizer’s behalf. DDMAC alleged that the audio conferences included unsubstantiated claims favorably comparing Celebrex to Vioxx, among other things. See 2/1/01 letter from T. Abrams^{*} to F. Hassan^{*}, MRK-ABI0003233, at 34. DDMAC sent a similar untitled letter directly to Professor McMillen^{*} alleging that he was giving presentations that were false and misleading. 2/2/01 letter from T. Abrams^{*} to J. McMillen^{*}, MRK-ABI0003249-52. Professor McMillen^{*} told the press that he thought the letter had likely been sent because of complaints by Merck. 2/9/01 email from K. Stauffer to L. Beauchard *et al.*, MRK-ABW0005619-20 (circulating news article). We have found no evidence of such a complaint.

¹⁰⁴ List of Physicians to Neutralize, MRK-AFI0044570, at 80 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569).

¹⁰⁵ List of Physicians to Neutralize, MRK-AFI0044570, at 81 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569).

support without any kind of involvement.”¹⁰⁶ Dr. Santanello stated that the purpose of such a meeting would have been for doctors to come together to “put together guidances on treatment,” and that the access gained by the Company would have meant that “somebody from Merck could attend or see the document that came out the meeting.”¹⁰⁷

Mr. David Anstice has testified that “[p]ayments made to a doctor from the point of view of getting their business or changing their viewpoints would be inappropriate, against the Merck policy. Payments made for legitimate purposes, contracted services, would be appropriate.”¹⁰⁸ With respect to the fee allegedly paid to Dr. Hamburger*, Mr. Anstice has testified that although he did not know the precise circumstances of that arrangement, he “would condone grants that were consistent with our policies and within our budget and within our grants of authority.”¹⁰⁹

2. Activities of Dr. Louis Sherwood.

Ms. Baumgartner’s chart regarding physicians to “neutralize” suggested with respect to several physicians a personal visit by Dr. Louis Sherwood, Senior Vice President for Medical and Scientific Affairs and Chief Medical Officer for the U.S. Dr. Sherwood who was previously the Chairman of Medicine at Michael Reese Medical Center and the Albert Einstein College of Medicine, and who was one of U.S. Human

¹⁰⁶ 7/19/05 transcript of Ernst v. Merck & Co., No. 19961*BH02, Tex. Dist. Ct., at 27.

¹⁰⁷ 7/19/05 transcript of Ernst v. Merck & Co., No. 19961*BH02, Tex. Dist. Ct., at 30.

¹⁰⁸ 3/17/06 deposition of D. Anstice at 395-96 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

¹⁰⁹ 3/17/06 deposition of D. Anstice at 343 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

Health's chief liaisons between the Company and the academic medical community. In this role, Dr. Sherwood met often with doctors at various medical meetings and in other forums.

In addition, Dr. Sherwood from time to time took steps to correct what he and/or other Merck personnel perceived as anti-Vioxx bias in presentations or other public statements by physicians outside the Company. These steps ranged from contacting physicians to lodging complaints against them. The following discussion describes representative incidents in more detail.

a. Dr. Peter Lipsky*

In December 1998, Dr. Sherwood filed a complaint with the Accreditation Council for Continuing Medical Education ("ACCME") pertaining to a Continuing Medical Education program sponsored by the University of Texas, Southwestern Medical Center ("UT Southwestern") and chaired by Professor Peter Lipsky*.¹¹⁰ Merck scientists who attended the program felt that it was "very unbalanced and highly selective in emphasizing Searle data as opposed to Merck data."¹¹¹ In a letter to the ACCME responding to Dr. Sherwood's complaint, a representative of UT Southwestern wrote, in part: "We see this complaint as commercial interference in the medical education process and an abuse of the ACCME monitoring procedures."¹¹² Following an

¹¹⁰ 4/16/99 letter from W. Maddrey* to L. Sherwood, MRK-ABO0003752; 1/23/01 memorandum from L. Sherwood to D. Anstice, MRK-ABW0002605, 606.

¹¹¹ 1/23/01 memorandum from L. Sherwood to D. Anstice, MRK-ABW0002605, 606.

¹¹² 2/2/99 letter from C. Stravato* to J. Mayham*, MRK-ABO0003756, at 56.

investigation, the Accreditation Council for Continuing Medical Education found the program to have been in compliance with all relevant guidelines.¹¹³

b. Dr. Thomas Stillman*

In 1999 and 2000, Dr. Thomas Stillman*, a Professor of Medicine at Hennepin County Medical Center in Minneapolis, Minnesota, gave a series of lectures in which he publicly questioned the renal safety of Vioxx and compared Vioxx's renal safety unfavorably to that of Celebrex. Although at least one person at Merck felt that "Tom is not too far off base with his concern [about Vioxx's increasing edema rates],"¹¹⁴ others believed Dr. Stillman's remarks to constitute unfair attacks on the drug.¹¹⁵ In June 2000, Dr. Sherwood complained to Dr. Stillman* about a Continuing Medical Education lecture that Dr. Stillman* had given that Dr. Sherwood called "an unbalanced and unscientific presentation of the issue of peripheral edema."¹¹⁶

In correspondence with Dr. Sherwood, Dr. Stillman* agreed that one slide in his deck could have been misinterpreted as representing a non-existent head-to-head

¹¹³ 4/16/99 letter from W. Maddrey* to L. Sherwood, MRK-ABO0003752.

¹¹⁴ 5/30/00 email from A. Gelhorn to G. Bell, B. Daniels, W. Dixon, J. Lahner et al., MRK-ABO0001417.

¹¹⁵ 5/3/00 email from K. Moore to J. Torrelli et al., MRK-ABO0001384, at 85 (complaining that a talk given by Dr. Stillman* was "a celebrex infomercial."); List of Physicians to Neutralize, MRK-AFI0044570, at 95 (attached to 7/23/99 email from S. Baumgartner to S. Johnson, MRK-AFI0044569) (stating that Dr. Stillman* "believes greater selectivity of Vioxx = higher propensity for renal side effects" and "tends to point out what he believes are negative effects of Vioxx"); 3/28/00 memorandum from S. Kubo to L. Sherwood et al., MRK-ABO0000463-64; 6/2/00 letter from L. Sherwood to T. Stillman*, MRK-ABO0000455-57.

¹¹⁶ 6/2/00 letter from L. Sherwood to T. Stillman*, MRK-ABO0000455, at 56.

comparison of data on edema rates associated with Vioxx and Celebrex.¹¹⁷ Dr. Stillman* did not, however, agree that the presentation was biased. “Until data regarding incidence of hypertension and edema is shared with me, information I have requested several times,” he wrote to Dr. Sherwood, “my opinion [that the renal effects of Vioxx are worse than those of Celebrex] is no more ‘highly speculative and inappropriate’ than [sic] the explanation give that Naprosyn [naproxen] may be cardioprotective in [the VIGOR Trial].”¹¹⁸

Dr. Stillman* also reminded Dr. Sherwood of an incident that Dr. Stillman* had previously complained to him about: the inappropriate cancellation by Merck of a series of Merck-sponsored Continuing Medical Education lectures that Dr. Stillman* had been scheduled to give the preceding year. “I am concerned,” Dr. Stillman* wrote, “that the canceling of such a CME [Continuing Medical Education] program by a sponsoring pharmaceutical company represents inappropriate censorship of medical information to be presented”¹¹⁹ Dr. Stillman* wrote that despite his previous conversation with Dr. Sherwood about the issue, nothing had been done.¹²⁰

Mr. Anstice, who was copied on Dr. Stillman’s* June 9, 2000 letter to Dr. Sherwood, did not recall the exchange. Mr. Anstice indicated, however, that once

¹¹⁷ 6/9/00 letter from T. Stillman* to L. Sherwood, MRK-ABO0000448, at 48.

¹¹⁸ 6/9/00 letter from T. Stillman* to L. Sherwood, MRK-ABO0000448, at 49.

¹¹⁹ 6/9/00 letter from T. Stillman* to L. Sherwood, MRK-ABO0000448, at 50.

¹²⁰ 6/9/00 letter from T. Stillman* to L. Sherwood, MRK-ABO0000448, at 50.

Merck commits to funding a Continuing Medical Education presentation, that funding should not be revoked if Merck does not like the resulting program. If this was done, he believed it was wrong.

c. Allegations of Professor James Fries*

On January 9, 2001, Dr. James Fries*, Professor of Medicine at Stanford University School of Medicine, wrote a letter to Mr. Gilmartin about what he characterized as “the suppression of data by Merck and a consistent pattern of intimidation of investigators by Merck staff, principally Dr. Sherwood but also others on his staff.”¹²¹ Dr. Fries* copied Mr. Anstice and Dr. Scolnick on the letter.

Dr. Fries* wrote that his complaint was prompted by a call he received from Dr. Sherwood on October 28, 2000 during which Dr. Sherwood complained that Dr. Gurkirpal Singh*, a member of the Stanford faculty, was giving presentations that were biased against Merck and against Vioxx. According to Dr. Fries*, Dr. Sherwood had previously called two other senior Stanford faculty members to discuss the issue.

Dr. Fries* wrote that Dr. Sherwood had detailed several allegedly biased presentations by Dr. Singh*, including the use of a slide showing a man hiding under bed covers (an allusion to Merck’s allegedly hiding data) and a purported statement that Merck was the “Firestone of the drug industry.”¹²² According to Dr. Fries*,

¹²¹ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 51.

¹²² 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 50.

Dr. Sherwood told him that if the behavior continued, “Dr. Singh would ‘flame out’ and there would be consequences for [Dr. Fries] and for Stanford.”¹²³

The letter explained that Dr. Fries* had spoken with Dr. Singh* and with others present at the purportedly biased presentations. From a review of the slides that Dr. Singh* used, Dr. Fries* concluded that equal attention was given to Vioxx and Celebrex, although data from an as-yet-unpublished study – the Whelton Study discussed in Appendix H – favored Celebrex on renal and cardiovascular toxicity.¹²⁴ Dr. Singh* had since removed the slide showing the man under the covers because Merck had provided him with the requested data.¹²⁵ Ultimately, on the basis of his review of the slides and his conversations with Dr. Singh* and members of Dr. Singh’s* audience, Dr. Fries* found no evidence of bias.

In the course of his review of the facts involving Dr. Singh*, Dr. Fries* learned of a series of what he characterized as “allegations of Merck damage control by intimidation, often with a pattern of going to the Dean or Department Head with complaints of anti-Merck bias and always alleging unbalanced anti-Vioxx presentations.”¹²⁶ He reported that at least eight other physicians to whom he had spoken personally claimed to have suffered various wrongs ranging from having academic

¹²³ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 50.

¹²⁴ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 51.

¹²⁵ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 51.

¹²⁶ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 51.

appointments jeopardized or revoked to speaking engagements cancelled.¹²⁷ Four of the eight physicians identified by Dr. Fries* had appeared on Ms. Baumgartner's 1999 chart of "Physicians to Neutralize."¹²⁸ In addition, Dr. Fries* stated that he had "confirmed" with several former Merck employees who asked to remain anonymous "the existence of a pattern of intimidation through the Department Chairs or the equivalent, often with the hint of loss of Merck funding to the institution."¹²⁹

Based on his own investigation, Dr. Fries* made two broad allegations regarding Merck's conduct. First, Dr. Fries* alleged that Dr. Sherwood and others on his staff had "systematically attacked those investigators or speakers who expressed what Merck staff felt were critical opinions in a manner which seriously impinges on academic freedom."¹³⁰ Second, Dr. Fries* reported that he and a number of other physicians had tried without success to obtain data from Merck, apparently concerning the VIGOR Trial, responsive to their concerns about possible cardiovascular and renal side effects of Vioxx. "Merck," Dr. Fries* wrote, "has been attempting to systematically downplay

¹²⁷ These were doctors Gurkirpal Singh* of Stanford University, Peter Lipsky* of the University of Texas, Southwestern, Andrew Whelton* of the Johns Hopkins University, Michelle Petri* of the Johns Hopkins University, David Yocum* of the University of Tucson, Lee Simon* of Harvard University, James McMillen* formerly of Pennsylvania State University, and Thomas Stillman* of the University of Minnesota. See 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 51-52.

¹²⁸ These were Drs. Petri*, Stillman*, McMillen*, and Simon*, as described above.

¹²⁹ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 52. Notes from what appear to be a conversation with between Dr. Fries* and former Merck Regional Medical Director Gregory Bell*, which include either a notation requesting or promising confidentiality, include the following statements: "company holding back on interpretation," "concern about intimidation," "Lou feels a duty to make the hard phone calls to dept chairs, etc." Undated handwritten notes of J. Fries*, at FRI0000042.

¹³⁰ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 53.

some unusual side effect patterns of Vioxx. I would hesitate to use the term ‘hiding data’ but Merck has certainly not been forthcoming with data and has made access to data difficult.”¹³¹ Dr. Fries* noted that, from the data he had seen, and subject to future study based on complete data, “the cover-up is a worse problem than the side effects of fluid retention and hypertension and CHF [congestive heart failure], which could be handled by stronger labeling for at risk patients, or by other means.”¹³²

In his letter, Dr. Fries* stated that he had written to Mr. Gilmartin after speaking to the persons described in the correspondence and after having had a second conversation with Dr. Sherwood in which he had expressed his concerns and had not been satisfied with Dr. Sherwood’s response.¹³³

d. Merck’s response to Dr. Fries* letter.

Upon receipt of Dr. Fries* letter, Mr. Gilmartin asked Mr. Anstice, Dr. Sherwood’s supervisor, to investigate the issues raised in the letter.¹³⁴ With regard to the alleged suppression of data, Mr. Anstice asked MRL’s Dr. Douglas Greene to contact Dr. Fries* and to provide him with all appropriate information. Dr. Greene called Dr. Fries* and discussed the allegations in his letter.¹³⁵ Shortly thereafter, Mr. Anstice

¹³¹ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 53.

¹³² 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 52.

¹³³ 1/9/01 letter from J. Fries* to R. Gilmartin, MRK-ABO0000250, at 52-53.

¹³⁴ 4/12/05 deposition of D. Anstice at 112 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

¹³⁵ 3/17/05 deposition of D. Anstice at 487-88 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.) (Mr. Anstice asked Dr. Greene to call Dr. Fries*, which he did).

sent Dr. Fries* copies of briefing documents prepared for the FDA Advisory Committee on February 8, 2001, and a background packet that Merck had sent to Veterans' Affairs consultants during formulary discussions relating to Vioxx and selective Cox-2 inhibitors.¹³⁶ Mr. Anstice subsequently spoke to Dr. Fries* and understood that the issue of alleged data suppression had been resolved.

Mr. Anstice took responsibility personally for investigating Dr. Fries's* accusations of physician intimidation and spoke with Dr. Fries* on multiple occasions.¹³⁷ Dr. Fries'* contemporaneous notes recorded four relevant statements by Mr. Anstice: (i) "probably not an ecology problem @ Merck," (ii) "needs to find loose cannons and act appropriately," (iii) "needs code of conduct to prevent reoccurrence," and (iv) "personal approach and apologies to individuals and to those contacted over the individuals."¹³⁸ Mr. Anstice believed that he would have expressed to Dr. Fries* that he did not believe the issues raised in Dr. Fries's* letter to constitute a systemic problem at Merck but did

¹³⁶ 2/16/01 letter from D. Anstice to J. Fries*, MRK-ABI0007169.

¹³⁷ 3/16/05 deposition of D. Anstice at 297, 298-99 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.) (Mr. Anstice called Dr. Fries* almost immediately upon receiving his letter and spoke with him perhaps three times).

¹³⁸ 2/1/01 handwritten notes of J. Fries* of call with D. Anstice, MRK-FRI0000020. Mr. Anstice has testified that he told Dr. Fries* "that I thought the best way to resolve the matter was that I was going to request Dr. Sherwood to stand down from further communication with physicians, that I would speak to sales and marketing people in my organization and that I would tell them this is not the way Merck wants to handle itself." 3/17/05 deposition of D. Anstice at 488 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

not recall making statements to the effect of the second through fourth points above or believe that he would have done so based on his view of the matter.¹³⁹

Mr. Anstice's investigation included meeting with Dr. Singh* personally. Mr. Anstice has testified of the conversation, "we agreed that this had been an unfortunate matter, it did reflect poorly on Merck, and that we wanted to move forward, and that I certainly was committed that behaviors that could even be perceived as intimidation would stop going forward."¹⁴⁰ Upon hearing from Dr. Singh* that certain of his speaking engagements had been cancelled in apparent retaliation for remarks critical of Vioxx, an accusation that also had been levied by Dr. Stillman* six months earlier, Mr. Anstice informed senior members of the Sales Department (whose names he could not recall) that such cancellations were not appropriate.

Mr. Anstice also asked Dr. Sherwood to prepare a report responding to Dr. Fries'* accusations and detailing his contacts with each of the physicians named in the letter.¹⁴¹

Dr. Sherwood responded in a four-page memorandum dated January 23, 2001.

Dr. Sherwood stated that he "found the letter from Fries disappointing, with many

¹³⁹ Mr. Anstice has testified that, "What I acknowledge is that there was certainly the perception by those who Dr. Fries referenced in his letter that they thought that they had been not treated appropriately by Merck." 3/17/05 deposition of D. Anstice at 505 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.) He has also testified that he asked Dr. Fries* to report back to the doctors named in the letter on their conversations and that Dr. Fries* did not request that he contact them. 3/18/05 deposition of D. Anstice at 851 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.) (Mr. Anstice asked Dr. Fries* to report back on their conversations); 4/12/05 deposition of D. Anstice at 111 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.) (Mr. Anstice was not asked to contact any of the physicians).

¹⁴⁰ 3/17/05 deposition of D. Anstice at 496 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

¹⁴¹ 4/12/05 deposition of D. Anstice at 113 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

inaccuracies and misquotes”¹⁴² and addressed Dr. Fries’* allegations with respect to each of the eight physicians either by defending Merck’s actions as appropriate under the circumstances or by stating that he had no personal knowledge of the incident alleged.¹⁴³ Dr. Fries’* letter and Dr. Sherwood’s responsive memorandum are reproduced in their entirety at the end of this Appendix.

Except for Dr. Singh*, Mr. Anstice did not speak with the doctors identified by Dr. Fries* as having been subjected to intimidation and did not try to identify the former Merck employees whom Dr. Fries* claimed had corroborated the pattern of intimidation. Mr. Anstice did not investigate Dr. Fries’* allegation that others besides Dr. Sherwood had been involved in intimidating physicians.¹⁴⁴ Mr. Anstice stated that he was probably overly focused on the allegations against Dr. Sherwood and did not pick up on the fact that the letter alleged broader involvement by other Merck employees.

Mr. Anstice concluded that no official reprimand was called for, and none was issued.¹⁴⁵ Mr. Anstice stated that he told Dr. Sherwood to refrain from further contact with the doctors named in the letter, which Mr. Anstice characterized as a significant

¹⁴² 1/23/01 memorandum from L. Sherwood to D. Anstice, MRK-ABO0002801, at 801.

¹⁴³ 1/23/01 memorandum from L. Sherwood to D. Anstice, MRK-ABO0002801-804.

¹⁴⁴ 3/18/05 deposition of D. Anstice at 862-63 (*In re Vioxx Litig.*, No. 619, N.J. Super. Ct. Law Div.) (Mr. Anstice did not speak with others on Dr. Sherwood’s staff about the allegations).

¹⁴⁵ 9/23/05 transcript of *Humeston v. Merck & Co.*, ATL-L-2272-03 MT, N.J. Super. Ct. Law Div., at 1863-64 (Mr. Anstice did not make any note in Sherwood’s personnel file stating that Sherwood did anything wrong); 3/16/05 deposition of D. Anstice at 299-300 (*In re Vioxx Litig.*, No. 619, N.J. Super. Ct. Law Div.) (Mr. Anstice believed no such note necessary).

rebuke for someone in Dr. Sherwood's position.¹⁴⁶ Mr. Anstice reported that he told Dr. Sherwood that Merck should never intimidate doctors or be perceived as doing so. According to Dr. Sherwood, however, Mr. Anstice never criticized or reprimanded him for any conduct that may have led to Dr. Fries'* complaints. Dr. Sherwood stated that the only thing the two discussed was that it would be better for Mr. Anstice to handle the situation from that point forward.¹⁴⁷

On March 22, 2001, Mr. Gilmartin sent Dr. Fries* a brief, confidential letter closing the matter.¹⁴⁸ In prepared remarks to the Senate Finance Committee on November 18, 2004, Dr. Singh* testified of the incident, "Mr. Gilmartin and Mr. Anstice took immediate action, and the threats stopped immediately. From then onwards till today, Merck scientists and officials have treated me and my colleagues with appropriate respect and have always shared scientific data promptly."¹⁴⁹ Drs. Stillman* and Simon* reportedly told the Philadelphia Inquirer that Merck personnel, including Dr. Sherwood's successor, Dr. John Yates, later called them to apologize.¹⁵⁰ Dr. Yates believed that he

¹⁴⁶ 4/12/05 deposition of D. Anstice at 137, 279-80 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.); 9/23/05 transcript of Humeston v. Merck & Co., ATL-L-2272-03 MT, N.J. Super. Ct. Law Div., at 1863 ("I was the person that asked him to step down from further contact with doctors in this area, yes.").

¹⁴⁷ 12/20/04 deposition of L. Sherwood at 520 ("I know that Mr. Anstice dealt with whatever the allegations were. I communicated to David Anstice my side of the information. He and I did not discuss the issue further, but he did not express further concerns to me.").

¹⁴⁸ 3/22/01 letter from R. Gilmartin to J. Fries*, MRK-ABI0007187.

¹⁴⁹ Prepared Remarks of Professor Gurkirpal Singh* for the Senate Finance Committee, <http://www.senate.gov/~finance/hearings/testimony/2004test/111804GStest.pdf>.

¹⁵⁰ Thomas Ginsberg*, "Threats to Critics of Vioxx Alleged," Philadelphia Inquirer, June 5, 2005, at A01.

eventually spoke with all of the doctors named in Dr. Fries’* letter and that the essence of his message to each, in part, was that to the extent that the doctors had concerns about how they had been treated, such treatment would not reoccur.

I. “Culture of Compliance” Initiative.

In the fall of 2001, Merck implemented a series of enhanced policies and procedures known as the “Culture of Compliance” that addressed Company sales practices across products. The impetus for the broad-based initiative was not specifically Vioxx-related, but rather was due to a confluence of factors. First, in the pharmaceutical industry, companies often bring an alleged problem with respect to a competitors’ sales practices to the attention of their competitor before complaining to the FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC). In the first half of 2001, Merck received two such complaints, from two different competitors. Each took issue with the actions of the local sales representatives in different parts of the country.

Although these complaints did not indicate that there was any Company-wide breach of policy, they did raise concern in the mind of Mr. Kenneth C. Frazier, Senior Vice President and General Counsel, that at least some local sales representative were not adhering to Merck’s policies.

Second, as discussed in Appendix T, based on their strong ties to the academic medical community, two members of the Merck Board of Directors – Dr. Samuel O. Thier and Dr. William N. Kelley – wanted assurances that all interactions between representatives of Merck and physicians were appropriately delineated as promotional or scientific, and they raised this concern with senior management.

Third, Mr. David Anstice, President U.S. Human Health, concluded that while Merck's policies regarding interactions with physicians were clearly delineated and sales representatives were trained on appropriate – and inappropriate – conduct, more could be done in terms of clarifying existing policies, training of sales representatives, and accountability.

In addition, although not a precipitating factor for the Culture of Compliance, it should be noted that also in the fall of 2001, Merck received a warning letter from the DDMAC on September 17, 2001 (discussed in Appendix G) that alleged that certain of Merck's sales practices with respect to Vioxx were contrary to FDA regulations.

1. Office of Compliance.

Mr. Anstice, who spearheaded the initiative with the support of Mr. Gilmartin, established an Office of Compliance in late 2001, led by Ms. Lucine Beauchard. Mr. Anstice also suspended certain existing programs, including the HEL speaker program, field-based grants, and other programs in which physicians were paid for their assistance in training representatives, pending a review of all Merck promotional and educational activities.

As head of the Office of Compliance, Ms. Beauchard reported to Mr. Anstice and to Ms. Kathryn Steinbugler, a senior attorney in U.S. Human Health. Beginning in October 2001, Ms. Beauchard undertook a comprehensive review of all existing Merck Sales and Marketing programs with an eye toward winnowing down the number of programs so that compliance would be easier to monitor. As part of this review, Merck evaluated its compliance history and the organization's understanding of existing policies

and procedures. In addition, Ms. Beauchard and her team implemented certain structural changes to clarify further the distinction between promotional activities and educational programs. Ms. Beauchard, Merck's Compliance Officer, echoed Mr. Anstice in emphasizing the importance of involving "line management" in ensuring compliance rather than delegating responsibility solely to a separate department. Some of these major changes are reviewed below.

Two members of senior Sales management, the Executive Vice President Primary Care Sales and Managed Care and the individual with responsibility for the Health Education Liaison ("HEL") program, left the Company in connection with this effort. In addition, approximately six other members of Sales management received formal reprimands, which included losing their annual bonus. According to Mr. Anstice, because Merck had always had a strong commitment to ethics and compliance, management was responsible for ensuring that that commitment was engrained in the Merck culture and carried out by the sales force. To the extent that sales representatives were not adhering to policy, according to Mr. Anstice, line management within the Merck Sales organization was responsible.

2. Programs.

The comprehensive Culture of Compliance codified many already existing policies and changed or clarified others to ensure greater accountability and compliance. An overarching objective was to enhance policies concerning the separation of marketing and selling from medical scientific activities. The Office of Compliance articulated focused, well-defined objectives for the programs reviewed, provided and published

detailed standards for the activities, reduced overall the number of educational programs and centralized management and oversight.¹⁵¹

As part of the Culture of Compliance, Merck eliminated certain field-based programs, such as local grants and preceptorships in which physicians were paid to allow representatives to shadow them for a day. Changes to specific program are discussed below.

a. Educational Program Integration.

The Health Education Liaison program (discussed above), which was suspended by Mr. Anstice in late 2001, was not reinstated after the Office of Compliance review. This program had included many different types of speaker programs and engaged approximately 15,000 speakers across products.¹⁵² In its stead, Merck founded the Educational Program Integration (“EPI”) Department, which consisted of far fewer programs and reduced the number of physicians speaking for Merck. Formalized policies for this program (some new and some merely reinforcing preexisting policies) included:¹⁵³

- All Representative Facilitated Meetings must be conducted in an office or hospital setting;

¹⁵¹ See generally 7/23/02 presentation of K. Steinbugler and L. Beauchard to Audit Committee of the Merck Board of Directors, “U.S. Marketing & Sales Compliance,” MRK-AGNPRS 00000010-27.

¹⁵² 7/23/02 presentation of K. Steinbugler and L. Beauchard to Audit Committee of the Merck Board of Directors, “U.S. Marketing & Sales Compliance,” MRK-AGNPRS 00000010, at 18.

¹⁵³ See 3/13/02 Bulletin: EPI Frequently Asked Questions (No. EPI 02-001), MRK-AAR0027760-82.

- The EPI Department (not the representative) is responsible for selecting and scheduling all speakers;
- As before, speakers must present balanced information about each drug discussed covering both the risks and benefits; all prepared remarks must conform to the product label, as before, and speakers may go off label only if necessary to answer unsolicited questions; should a speaker provide off-label information but fail to make clear that the information is in fact not on the label, the Merck representative must disclose this fact to the audience;
- Speakers not allowed to distribute handouts;
- Venues for speaker facilitated programs must be modest in nature and conducive to the exchange of medical information;
- Established spending limits for meals;
- All speaker fees handled by the EPI Department;
- The number of programs that could be presented by a speaker in a single year was capped at 20 to 30; and
- No tutorials or preceptorships allowed.

b. Medical School Grant Program.

According to Ms. Beauchard, another structural change was made with respect to the Medical School Grant Program. Marketing personnel, who previously had been allowed to participate in a voting capacity on grant decisions, were removed from the process. Indeed, as of the drafting of this Report, Marketing professionals are not even permitted in the room when grant proposals are discussed. Ms. Beauchard explained that

often, Marketing may bring to bear a valuable perspective – such as the type of research that physicians have been asking for – and it may be that in the future marketers may participate in discussions about grants but in a non-voting capacity. In addition, in exchange for all medical school grants, the researcher must agree to publish or otherwise present his or her findings in order to receive full payment.

c. Consultants' Meetings / Advisory Boards.

The use of customers as consultants was another area addressed by the Culture of Compliance. The initiative clarified that such interactions could only be of one of two types: a forum for market research, or a means to obtain scientific advice. To ensure that the consulting arrangement was not a “promotional program in disguise,” Merck’s policy was to permit consultancies only when “information is not reasonably accessible through other means.”¹⁵⁴ Market research professionals are required to moderate all market research programs, and interactions occur only in modest business venues with no entertainment provided.

d. Continuing Medical Education.

To oversee the selection and funding of continuing medical education program requests, Merck also centralized the processes into a headquarters-based continuing medical education function. To ensure that Merck funding goes only to quality programs, and that payments are not made to customers or others in a position to

¹⁵⁴ See 7/23/02 presentation of K. Steinbugler and L. Beauchard to Audit Committee of the Merck Board of Directors, “U.S. Marketing & Sales Compliance,” MRK-AGNPRS 00000010, at 20 (describing changes to Merck’s use of customers as marketing consultants).

influence the use of Merck products, Merck funds only programs that provide continuing medical education credits to participants through an accredited provider. Merck only funds the educational (as opposed to any social) component of the accredited program.¹⁵⁵ Merck will not suggest speakers to the continuing medical education provider unless it receives a written request to do so, in which case Merck will provide a list of recommended speakers and cannot provide merely one or two names.

3. Implementation.

The Culture of Compliance was presented to Sales and Marketing management at two mandatory meetings in the fall of 2001.¹⁵⁶ In addition to informing attendees about the discontinued programs, introducing the new programs and highlighting the importance of compliance and accountability, the role of training was featured. As part of the Culture of Compliance, all Marketing and Sales personnel (not just those who interact with physicians) must be trained about appropriate sales and marketing practices and pass tests on relevant subjects. In addition, all representatives undergo annual training on Merck policies and procedures (which support and generally exceed the requirements of federal regulations).

* * *

¹⁵⁵ See 7/23/02 presentation of K. Steinbugler and L. Beauchard to Audit Committee of the Merck Board of Directors, "U.S. Marketing & Sales Compliance," MRK-AGNPRS 00000010, at 19 (describing changes to Merck's Continuing Medical Education programs).

¹⁵⁶ See generally 10/12/01 slide presentation, "District Implementation Meeting," MRK-AAR0030548-94.



FEB-02-2001 13:37 FROM

TO

JUSTICE P.001/204

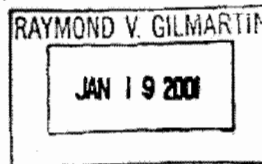


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1/2/01
K.O. BRAZIER

January 9, 2001

Mr. Raymond Gilmartin
Chief Executive Officer
Merck and Co.
One Merck Drive
Whitehouse Station, New Jersey 08889

Dear Dr. Gilmartin,

A series of serious events involving certain employees of, and possibly a policy of, Merck & Co. has come to my attention rather accidentally and I wanted to relay these events which might have substantial implications and complications. The result is harmful to the traditionally very fine Merck public image and is counter-productive to the Vioxx sales effort. My perspective is that of the Principal Investigator of ARAMIS (Arthritis, Rheumatism, and Aging Medical Information System). This NIH-funded national data bank first identified and quantitated the stealth epidemic of NSAID gastropathy, quantitated differences in toxicity among NSAIDs, and ARAMIS investigators have worked hard for a long time to find and implement ways of reducing the frequency of serious GI adverse events with NSAIDs. I believe that the Cox-1 sparing agents are our best approach toward better drug safety in this area.

My accidental involvement: On Saturday October 28th I received a call at home from Dr. Louis Sherwood of Merck Pharmaceuticals. Dr. Sherwood complained that Dr. Gurkirpal Singh of our group had an anti-Merck bias and was giving lectures that were irresponsibly anti-Merck and specifically anti-Vioxx. Dr. Singh was held to have used a slide which depicted a person hiding data under the covers, had called Merck the "Firestone of the drug industry", and had requested data from Merck which was not appropriate for him to have. Dr. Sherwood suggested that if this continued Dr. Singh would "flame out" and there would be consequences for myself and for Stanford. Dr. Sherwood had previously called Dr. Judith Swain, Chair of our Department, and subsequently called Dr. Edward Harris, Chair of our Division, with similar complaints. I agreed to look into the matter and to take appropriate action and indicated that it is not our policy to bias any presentation in any direction. I asked him to provide me with full details of any such transgression that occurred after this date.

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I spoke with Dr. Singh and reviewed the slides of his presentation. The talk was mainly about the frequency and severity of NSAID Gastropathy and secondly about the advantages of the new Cox-1 sparing agents, of which Vioxx is one. Equal numbers of slides were devoted to Celebrex and to Vioxx. The talk was strongly in favor of broad use of the new Cox-1 sparing agents. Data were mainly from the standard studies, although three slides were from a presented but not yet published randomized renal toxicity study of Celebrex and Vioxx by Andrew Whelton comparing side-by-side renal and cardiovascular toxicity which was not in favor of Vioxx. The little man under the covers was not in the sequence, having been removed when Dr. Singh succeeded in getting the requested data (again not favorable to Vioxx), from Merck. Dr. Singh clearly did not understand the "Firestone" reference and indicated that he had not made the statement. I asked Dr. Singh to be certain to be rigorously balanced in future presentations and he agreed, although stressing that he had also been balanced in the past. I talked with three people who had been in Dr. Singh's audience; one thought the presentation contained humor directed at Merck but that the data were balanced and the other two found the presentations completely unremarkable.

The much broader issues, which surfaced at the American College of Rheumatology meetings, were most disturbing and involve suppression of data by Merck and a consistent pattern of intimidation of investigators by Merck staff, principally Dr. Sherwood but also others on his staff.

A number of physicians have concerns that Vioxx may have some serious and under-emphasized drug toxicity problems, particularly at the 50 mg dose approved for pain control—these concerns are shared by the FDA renal reviewer. Vioxx has been reported to have more frequent peripheral edema problems, more aggravated hypertension, more congestive heart failure, and more heart attacks than other NSAIDs, especially Celebrex. Some 0.4 % of Vioxx subjects had heart attacks compared with 0.1 % in the naproxen arm in the Merck-sponsored VIGOR study and this was statistically significant. Some of these data have been described in the Wall Street Journal and may have affected stock prices but there has been little information presented to date in the medical literature. Merck presented two posters on the VIGOR trial at the recent ACR meetings which did not contain data on the side effects of interest; the posters were very well attended, with everyone wanting to know about the data on these points, but it was not available. I tried unsuccessfully to get the data myself; it is hard to judge these areas without the numerical details. Yet, one could not avoid the conclusion that because of the interest in these issues the data would have been presented had they been favorable. There was a lot of muttering and a lot of people with concerns. The publication of the VIGOR trial recently in the NEJM did not contain the data on edema and fluid retention at all, and dismissed the heart attack data with weak arguments.

Even worse were the allegations of Merck damage control by intimidation, often with a pattern of going to the Dean or Department Head with complaints of anti-Merck bias and always alleging unbalanced anti-Vioxx presentations. This has happened to at least eight investigators: Dr. Singh; Dr. Peter Lipsky, now research chief at the Arthritis Institute;

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Dr. Andrew Whelton of Hopkins; Dr. Michelle Petri of Hopkins; Dr. David Yocum of Tucson, currently head of the FDA advisory panel; Dr. Lee Simon of Harvard; Dr. James McMillen; and Dr. Thomas Stillman. I suppose I was mildly threatened myself, although I have never spoken or written on these issues.

I documented the intimidation of the individuals listed above by personally speaking with each of them. Dr. Simon believes that one of his two academic appointments has been jeopardized. Dr. McMillen believes that his VCF appointment at Hershey was revoked because of these accusations. Dr. Petri had a speaking engagement unprofessionally cancelled by Merck and an unrenowned speaker substituted; he was also bothered by phone calls from Merck persons alleging unbalanced presentations. Dr. Singh had a speaking engagement cancelled and the audience was told that he had been fired. Dr. David Yocum had similar experiences. Dr. Lipsky, while at Southwestern, was forced to do a slide by slide justification of a CME program felt to be critical of Vioxx. These are respected investigators with long experience and high integrity. I also spoke with several past Merck employees who asked to remain anonymous but who confirmed the existence of a pattern of intimidation through the Department Chairs or the equivalent, often with the hint of loss of Merck funding to the institution.

An ironic result of all this is that Vioxx is getting more scrutiny of its salt and water toxicity than if the data had been clearly presented, and Merck is taking a big public relations hit among rheumatologists. The investigators whose balance was criticized are prominent and several advise the FDA—a role not often given to unbalanced presenters. In the view of most rheumatologists including myself, Vioxx (and Celebrex) represent a major medical advance in terms of improving GI safety, which is the dominant toxicity of NSAIDs and is the most common serious adverse event of NSAIDs. These drugs should on balance, save a substantial number of lives. The fluid retention and related problem data are actually not all that bad, and the cover-up is a worse problem than the side effects of fluid retention and hypertension and CHF, which could be handled by stronger labeling for at risk patients, or by other means. Else, there is a risk of case reports of seriously complicated congestive heart failure or other serious adverse reactions, which could threaten the drug approval. The heart attack data, of course, need to be confirmed or refuted by further study, as do the data on comparative renal toxicity between Cox-1 sparing agents.

I spoke with Dr. Sherwood at length on November 22 and aired the above concerns directly. He defended by saying that Merck was a great company and, therefore, could not be doing anything inappropriate. He said that he had been with Merck for 13 years and had never noticed anything that was not appropriate. He noted that he had previously been a Department Chair and that he knew what was appropriate and what was not, and that he knew how to get things done through the network. He said that if he heard about something that was alleged to be anti-Vioxx that it was his right to call anyone he wanted to about it. When told that each of the investigators maintained that presentations had been balanced he said he didn't want to get into "he said, she said" kinds of discussions. He said that there weren't any problems with the drug and that anyway they only occurred at high dose. When told that an ex-Merck employee had quoted him as saying

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"we only have three problems, Whelton, Simon, and McMillen, and Simon has been taken care of" there was a long pause and then he said that he "did not remember" saying that. When told that while both I and the people I had talked with had often had differences in viewpoint with one or another drug firm, none of us had ever heard of harassment of investigators through their institutions he did not have a response but said that he "heard me."

From the discussions above I make three conclusions. First, some investigators at some times probably do make statements that may seem seriously unbalanced to those vested or instructed in opposite opinions and that close attention to strict impartiality is essential for any person making presentations on any such subject. Second, Merck has been attempting to systematically downplay some unusual side effect patterns of Vioxx. I would hesitate to use the term "hiding data" but Merck has certainly not been forthcoming with data and has made access to the data difficult. Finally, and most importantly, Merck employees have systematically attacked those investigators or speakers who expressed what Merck staff felt were critical opinions in a manner which seriously impinges on academic freedom.

I believe that these are serious matters and that Merck should take care of them internally, in its own interest, and in the interest of patients. I will appreciate your response to the issues raised here and to learning about actions which have been taken.

Sincerely,



James F. Fries, M. D.
Professor of Medicine

cc: Mr. David Anstice, President Merck U. S. Human Health
Dr. Ed Skolnick, President Merck Research Labs

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MEMO

January 23, 2001

TO: MR. D. W. ANSTICE

FROM: L. M. Sherwood

SUBJECT: Academic Interactions

As you know well, I have spent more than 21 years in academia and now more than 13 at Merck. As an academic chairman, I always felt responsibility for the actions (good and bad) of faculty members in my department. I believe this is generally the view held by academic department chairmen and division heads. Even though faculty members operate as independent entrepreneurs, they also represent the university or medical school when they are out doing things or speaking in the world at large. As such, they are expected to be credible, honest and fair representatives of their institutions. In this light, I have felt it appropriate in highly selected instances (fortunately, not often) to intervene with individuals and/or their division head, chair or dean, depending on the circumstance. Without trying to appear immodest, I believe I am the most respected physician in the pharmaceutical industry among academic chairs and deans. Therefore, when I call them on a matter of urgent concern, they generally take it seriously. This has been a source of strength for USHH, as I have been able to exert balanced leverage in some difficult situations.

I am obviously a strong supporter of Merck and passionate about its science, credibility and stature in the pharmaceutical world. We make our mistakes, as does everybody, but, in general, taking the high road the way Merck does, leads us to be more often right than wrong.

During the past three years, as the COX-2 wars have been waged, there have been several instances in which I have heard repeated messages from the field and headquarters about problem individuals. There is certainly no orchestrated campaign or specific program for dealing with these kinds of issues. They come up purely on an ad hoc basis. I will only get involved when our representatives, HSAs, Regional Medical Directors, MRL physicians, Senior Business Director or key individuals in the TBG have felt frustrated by their inability to reach out to or "balance" selected individuals. At such points, I have been willing to intervene either with the individual or with their superior. It is in this context that I have tried to help resolve challenges for Merck. I found the letter from Fries disappointing, with many inaccuracies and misquotes. As we discussed, it is much better for me not to get into the issues with him and let you and others deal with the situation. I did want, however, to indicate to you what my involvement has or has not been with the individuals mentioned in his letter, as follows:

1. Dr. Peter Lipsky – Dr. Lipsky was the former Chief of Rheumatology at the University of Texas Southwestern in Dallas and is currently at the National Institute of Arthritis and Musculoskeletal Diseases as Research Director. I have known Dr. Lipsky for 20 years; I once tried to recruit him to Einstein as Chief of Rheumatology. Dr. Lipsky has a checkered record with Merck. He was previously a member of the Board of Scientific Advisors for MRL. His contract was not renewed, because MRL felt that he had leaked confidential information to competitors. I was not involved in any of those discussions, and heard about it second hand, enough to know that Dr. Lipsky was not trusted by MRL.

My primary interaction with Dr. Lipsky occurred around a CME symposium that he chaired for Searle at the American College of Rheumatology 2+ years ago. The concern had to do with a symposium that was attended by a number of Merck physicians including Greg Bell, Beth Seidenberg, Ben Shapiro, etc. It was felt to be very unbalanced and highly selective in emphasizing Searle data as opposed to Merck data. We discussed the matter extensively with the TBG, MRL and the lawyers. It was decided that I would write a letter expressing our concern to the American College of Continuing Medical Education, which I did. The matter was reviewed extensively by the ACCME with the University of Texas. In the final analysis, they determined that the program was not unbalanced, although all of the Merck personnel felt differently. The matter was closed and resolved, and we have excellent relationships with the rheumatologists at the University of Texas Southwestern and with the medical school in general. Dr. Lipsky left more than a year ago for NIH, and the matter is closed. I have seen him on occasion at scientific meetings and exchanged pleasantries.

2. Dr. Andrew Whelton at John Hopkins – Dr. Whelton was a former full-time nephrologist at Johns Hopkins Medical School. He has now left the full-time faculty and works as a private consultant. He spends the major portion of his time involved with Pharmacia/Pfizer speaking about the renal and hypertensive adverse experiences of COX-2 inhibitors and emphasizing the unique safety aspects of Celebrex as opposed to VIOXX. He has published several articles on the subject. Experts in the field like Craig Brater, Dean at the University of Indiana, are in strong disagreement with Dr. Whelton on the issues and have a different view. A number of Merck personnel, including HSAs, Regional Medical Directors and members of MRL (Beth Seidenberg and Brian Daniels before they left) have talked with Dr. Whelton, tried to provide him with balancing data, etc. Dr. Whelton continues to speak regularly at symposia and talks sponsored by our competitors and to highlight differences between VIOXX and Celebrex in terms of safety. I have never met Dr. Whelton, talked with him or discussed with anyone at Johns Hopkins his activities. I have heard lots about him, but have felt others at Merck have talked extensively to him. Furthermore, since he is no longer on the full-time faculty at Johns Hopkins, there is little leverage available.
3. Dr. Michele Petri – Dr. Michele Petri is a faculty member at Johns Hopkins in Rheumatology. I have never met Dr. Petri or spoken to her. She has been known to say some “outrageous” things about Merck and VIOXX, such as Merck stealing VIOXX from Searle, etc. Others such as HSAs and Regional Medical Directors have met with Dr. Petri and had little success in helping her achieve balance. On one occasion, when Dr. Edward Benz (then Chairman of Medicine at Johns Hopkins) was visiting Merck as part of the Hopkins proposal, I mentioned to Dr. Benz confidentially that we had some concerns about some of Dr. Petri’s comments in her talks. Dr. Benz threw up his hands and indicated a certain level of frustration himself with Dr. Petri. That is where the matter ended, and I have had no further information. As far as a speaking engagement being canceled, that would have been done in the field.
4. Dr. David Yocum – Dr. David Yocum is a rheumatologist at the University of Tucson whom I do not know. Whether he is currently head of the FDA Advisory Panel or not, I do not know. Dr. Pamela Davis, our Regional Medical Director in Arizona, knows Dr. David Yocum as they are both members of faculty at the University of Arizona. She has interacted with him in a very positive and friendly way. He has done a great number of clinical studies and an observational study for Searle, but he has also been involved to a limited degree in studies for Merck. According to Dr. Davis, about one year ago, some of the representatives expressed concern to the HSA in Tucson about Dr. Yocum’s talks. As far as I know, nothing further happened, and my knowledge of this is strictly third hand. Dr. Yocum may have been involved with Dr. Fries’ ARAMIS database (speculation from me).

5. Dr. Lee Simon – Dr. Lee Simon is an Associate Professor of Medicine at Harvard at the Beth Israel-Deaconess Hospital. He is fairly well known to me and to Merck. Dr. Simon has been extensively involved with Searle and Pfizer for many years, is widely viewed not only at Merck, but also in the academic world as an individual in the competitors camp. He is said to receive very large amounts of consulting and other grant monies from our competitors. Dr. Simon is not respected (according to our Boston team) in the Harvard community. For example, Dr. Michael Weinblatt at Brigham & Women's, current President of the ACR, has no respect for Dr. Simon. In the past, Dr. Simon has been described as giving a number of unbalanced presentations on Celebrex versus VIOXX, despite our giving him data. I have talked to Dr. Simon on a couple of occasions myself about these issues, and his talks at times have been balanced (particularly if they are in an academic institution), and at other times not. At the time of the CLASS presentation and the press release on VIGOR, Dr. Simon made the following statements to our HSA in Boston with whom I spoke: "These data will allow us to bury Merck and put the nails in Merck's coffin. VIOXX is a dangerous drug. Beth Seidenberg left Merck because she would have been fired and Charlotte McKines and Lou Sherwood will also be fired because of the VIGOR study." Dr. Simon was apparently quite vociferous, enthusiastic about the prospects of burying Merck. I thought his statements were pretty unusual for an academic. On a subsequent occasion when I had opportunity to speak to Dr. Michael Rosenblatt, President of the Beth Israel Deaconess Hospital and a former Merck employee, I mentioned to him my concern about Dr. Simon making unbalanced presentations and being so anti-Merck and aggressive in pursuing that agenda. I indicated to Dr. Rosenblatt that I felt academics should be more balanced and data-driven. On a subsequent occasion, Dr. Rosenblatt had the Chairman or Vice Chairman of the Department of Medicine talk with Dr. Simon. That is the only interaction of which I am aware. I have had subsequent casual interactions with Dr. Simon and exchanged pleasantries.
6. Dr. James McMillen – Dr. McMillen is a "rheumatologist" in Harrisburg, PA. Dr. McMillen was never trained in rheumatology, but somehow was grandfathered. Although he is in the practice of medicine in Harrisburg, he spends a major portion of his time traveling the country for Pharmacia/Pfizer, boosting Celebrex and blasting VIOXX. For example, Dr. McMillen presents a list of top 10 reasons why VIOXX should not be prescribed, a presentation that was the basis for a complaint filed by Ellen Westrick at FDA. Numerous Merck personnel, HSAs, RMDs, Business personnel have met with Dr. McMillen without success. For at least a year after he was terminated from the Penn State Medical School faculty (not because of Merck, but because he no longer did anything there) our competitors continued to list his faculty title on flyers. I heard numerous concerns for the field (Senior Business Directors, etc.) and Headquarters. I contacted the Chair of Medicine at Penn State to indicate that he was still using the title even though he was no longer on the faculty. I have never met Dr. McMillen or spoken with him on the telephone.
7. Dr. Thomas Stillman is a well-known senior rheumatologist on the faculty of the Hennepin County Hospital at the University of Minnesota. Dr. Stillman has been used by Merck in the past as a speaker, but has not been used for the last couple of years. He is passionate in his view that Celebrex is a much safer drug, and despite regular visits from the HSA (who doesn't trust him), Greg Bell, other Regional Medical Directors, Spencer Kubo, etc., Dr. Stillman continues to be a passionate advocate for our competitors. Unfortunately, a number of talks that Stillman was supposed to give were canceled abruptly by individuals in the field. This led to hard feelings, and finally at my urging, Paul Fonteyne actually met with Stillman and smoothed over the situation.

My principal interaction with Dr. Stillman had to do with a video that he prepared for the Veterans Administration which was widely distributed. He was on the videotape, presenting

data that were misleading and false about renal safety issues concerning VIOXX. As a result of these inaccuracies, I wrote Dr. Stillman a letter pointing out our concerns. Dr. Stillman acknowledged the error in a return letter, and indicated that he would change his slides. On one occasion, I also spoke to Dr. William Keane, Chief of Medicine at Hennepin County, about my concerns about Dr. Stillman. Basically, the situation is that we have agreed to disagree with Dr. Stillman, and there have been no recent interactions.

8. Finally, the letter from Dr. Fries was stimulated by my discussions with him about Dr. Gurkirpal Singh. Dr. Singh is a senior scientist who works for Dr. Fries as part of the ARAMIS database and has a clinical but not full-time faculty appointment at Stanford. He speaks widely for our competitors, but has also spoken for Merck in the past. Again, some of his talks were canceled in the field and led to some local issues that had to be smoothed over by Marilyn Krahe. The principal concern about Dr. Singh was his speaking widely in a very anti-Merck tone about Merck hiding data (showing a slide which he acknowledged which had Merck hiding under the covers and not being willing to show the public its data), and therefore questioning Merck's research integrity. He went after some of our advocates to try to express the same message. As a consultant to Kaiser, the Veterans Administration, etc., he has also tried to undermine Merck in its dealings in Managed Care. There were repeated meetings with Dr. Singh through Marilyn Krahe, David Abrahamson (our Senior Medical Director in the West) and Dr. Gregory Bell before he left. Even after meetings in which Dr. Singh agreed to be better balanced, on a speaking tour of Ohio in September, he went after Merck vigorously. We had a number of reports from the field of physicians who wondered why Dr. Singh was so anti-Merck in his tone and rhetoric. It was very clear that he was unprofessional and biased in his speaking. On this basis, I called Dr. Fries and expressed my concerns about Dr. Singh in terms of what he was doing to his own image. I also expressed concern to Dr. Fries (not in a threatening way) that he could be an embarrassment to Dr. Fries and to the university because of the mode of his speaking. Dr. Fries agreed to meet with Dr. Singh and review the situation. Dr. Fries and I also agreed that if there were any further instances around Dr. Singh, I would contact him. I am not aware of any subsequent instances of unbalanced talks, and I have had no reason to communicate with Dr. Fries on that account. I did also call the Chief of Rheumatology and former Chairman of Medicine, Dr. Edward Harris, and the current Chair of Medicine, Dr. Judith Swain, to find out about Dr. Singh and express some concerns. Both indicated spontaneously little or no respect for Dr. Singh, indicating that he was not qualified or appropriate to be a full-time faculty member at Stanford.

I hope this clarifies for you the degree of my involvement with various individuals who were mentioned by Dr. Fries. There has certainly been no concerted or organized campaign to deal with these issues. They are strictly ad hoc, and I have only responded after individuals in the field and in headquarters have felt high levels of frustration in dealing with these physicians. I am passionate about scientific credibility, the truth, and fair balance. Merck preaches and practices those values. Not everyone in academia does. Just because one is a faculty member at a university, does not mean one can go out and say anything and do anything one pleases. That is not the definition of academic freedom. I firmly believe that academic physicians should be balanced and credible and be good representatives of their universities. In that regard, I found the letter from Dr. Fries disappointing, unbalanced and full of errors. I will be happy to discuss with you further. Thank you very much.

L.M.S. - 652-3730

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