where Trasylol was being used only in a small percentage of CABG procedures being performed. Bayer internally referred to such as hospitals as “Grow Accounts.”

224. These messages were purposely designed by Bayer to be dismissive of existing important information about serious risks, such as MI, graft patency and renal toxicity that were shown to exist in earlier clinical trials. These generalized and inaccurate statements also suppressed the fact that these risks were higher for certain procedures which Bayer knew, through its own off-label marketing and usage data, were known intended uses of Trasylol. Furthermore, these statements suppressed the fact that the risks associated with Trasylol were significantly higher for certain patient populations such as women, diabetics and persons taking certain other medications. These marketing messages were also directly contrary to the information contained in the “Adverse Reactions” sections in earlier labels that warned of a statistically significant increased risk of renal dysfunction, as well as an increased risk of renal failure.

225. In response to physicians’ perceptions that Trasylol was causing adverse events, Bayer actively communicated the false and misleading message that those adverse events were solely due to a patients’ other risk factors, rather than due to Trasylol use.

226. Bayer was also aware that physician practice patterns had changed since the majority of Trasylol clinical trials were conducted in the late 1980’s and early 1990’s, and that a variety of surgical blood conservation techniques were now common use. Thus, older Trasylol trials tended to show more benefit in terms of blood-sparing than could be expected in current practice. Bayer did not communicate this fact to decisionmakers which served to further mislead prescribers about the risk/benefit of using Trasylol.
2. **Conflict of Interest and Biased Research.**

227. Bayer was aware that, in this market in particular, decisionmakers were strongly influenced by the opinions of their peers, and thus Bayer embarked on an extensive program under the guise of “scientific communication and advocacy.” That strategy included compensating physicians in various fashions to endorse Trasylol use to other physicians and to hospital administrators; paying for educational programs where the intended objective was to increase Trasylol use and encourage off-label prescribing; setting up a program called “Ask the Professor” which provided an avenue for off-label promotion; and offering grants for off-label research.

228. Further leveraging the value of peer influence, Bayer also cultivated and supported biased and/or misleading messages through professional publications and CME programs by physicians with extensive ties to Bayer. Bayer also utilized those studies and programs to bolster particular marketing tactics, such as promoting administration of the full dose rather than the half dose, promoting various off-label uses, or presenting unsubstantiated and misleading information about outcomes and/or safety risks.

229. Based upon Relator’s experience at Bayer, as part of Bayer’s marketing strategy it was typically Bayer’s custom and practice to ghostwrite and/or review and influence published studies and programs it sponsored. Bayer and the authors, however, purposefully minimized or hid their relationship in order to create the false appearance that the studies were independent and free from conflict-of-interest or bias, and therefore reliable. Bayer often purchased reprints of the articles by the thousands and distributed them to their target audience of marketplace decisionmakers with the intention of creating the false impression that the studies were independent and reliable.
230. Bayer also controlled and/or influenced published studies by limiting access to the wealth of data in its clinical trials safety database to selected Bayer KOLs, the influential physicians recruited by Bayer to help promote a particular drug, and for which Bayer usually provided remuneration in various forms. Thus, the only published studies based on Bayer’s clinical trials safety database were by Bayer KOLs, who were presumptively biased in favor of Bayer, although frequently the author’s status as a Bayer KOL was not revealed.

231. In one particular instance concerning an analysis evaluating the impact of Trasylol on atrial fibrillation, Relator knows that Stanley Horton, Director of Marketing for Trasylol, specifically directed Bayer colleagues to look only at clinical trials with results favorable for aprotinin.

232. In or about 2004, Bayer became increasingly dissatisfied with the fact that the American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for Coronary Artery Bypass Graft Surgery, although recently updated, still did not recommend routine use of Trasylol for all patients. In response, Bayer employees brainstormed other methods to gain professional endorsement and conceived a method to develop a new set of practice guidelines for blood conservation. To this end, Bayer encouraged the Society of Thoracic Surgeons ("STS") to request a grant for the development of these guidelines, intended by Bayer to provide a recommendation for routine Trasylol use. Bayer KOLs were stacked onto the drafting committee, whose initial draft was toned down before publication in 2007 as a result of the Mangano and Karkouti trials. Bayer later paraded these guidelines to the FDA as proof of widespread acceptance and support of Trasylol usage during both the 2006 and 2007 FDA Advisory Committee meetings, without mentioning the fact that these efforts were conceived, paid for and influenced by Bayer.
By and through the foregoing conduct, Bayer suppressed, omitted and/or distorted
safety information material to decisionmakers and thereby caused the submission of false or
fraudulent claims for payment to State and/or Federal governments.

3. **Off-Label Marketing for other Cardiac Procedures.**

Bayer’s off-label promotion of Trasylol initially focused on expanding Trasylol to
other uses in the heart surgery context, such as valve patients, CABG/valve patients, heart
transplant patients, and pediatric patients.

In some cases, Bayer’s marketing of Trasylol for off-label cardiac procedures was
sophisticated and subtle, so as not to appear to be off-label marketing at all. Specifically, Bayer
was familiar with decisionmakers’ use of terminology and exploited colloquialisms in order to
promote Trasylol for off-label cardiac procedures without the overt appearance of doing so.

For example, Bayer used written marketing materials stating that Trasylol was
approved for “CABG” procedures, knowing from its market research that decisionmakers
colloquially understood and used the term “CABG,” when used in reference to procedures with a
high risk for bleeding, as somewhat interchangeable with most open heart surgeries, including
off-label valve replacement and CABG/valve procedures.

In oral representations to marketplace decisionmakers Bayer went even further,
knowing there would be no paper trail of its actions. Through its own sales representatives and
through anecdotal stories by paid Bayer KOLs, Bayer orally communicated to prescribers and
hospital administrators, among others, that Trasylol was appropriate for “cardiac surgery
patients,” “open heart patients” and/or patients at “high risk for bleeding.” Bayer knew from its
market research and understanding of the market that those terms were colloquially understood
and used by decisionmakers as implicating off-label valve replacement and CABG/valve
procedures, and that physicians reported Trasylol usage in over 50% of each of those procedures.
Bayer rarely clarified that Trasylol was not approved for those procedures, and even when it was presented, it was treated as a mere technicality.

238. Bayer promoted and encouraged Trasylol use in off-pump CABG surgery despite an acknowledged lack of data and questions about its safety and efficacy. Furthermore, Bayer avoided sponsoring clinical trials in off-pump CABG surgery because of concerns that the potential results could restrict growth in this off-label market.

239. Bayer also sponsored multiple programs such as biased CME programs, Cardiac Team Meetings, and other programs that routinely suggested Trasylol was safe and effective for all cardiac surgeries, including off-pump surgery, cardiac surgery using Deep Hypothermic Circulatory Arrest, valve surgeries and pediatrics.

240. These statements were also coupled with Bayer’s misleading marketing slogans that Trasylol had a “clean safety profile” with “no evidence of increased risk of renal dysfunction” and that “graft patency, MI, renal or hepatic dysfunction, and mortality were comparable to placebo.” Importantly, Bayer made no known efforts to communicate that these claims might not be applicable to all Trasylol patients.

241. By and through these actions, Bayer knowingly and/or with reckless disregard for the truth concealed and/or distorted risks it knew of concerning Trasylol, which created a false and misleading presentation of the drug’s safety and efficacy, thereby misbranding Trasylol.


242. After the 1998 labeling revisions, Bayer promoted off-label use of Trasylol for non-indicated procedures, such as liver transplants.

243. Starting around 2004 (with some additional efforts prior to this), Bayer specifically promoted Trasylol for use in orthopedic procedures such as hip replacement procedures. This focus was driven by Bayer’s need to generate additional revenue from Trasylol
and the identification of a large potential non-cardiac market in which there were several times more potential prescribing surgeons than the cardiac arena.

244. Leveraging approval under FDAMA to distribute qualifying journal reprints on Trasylol use in orthopedic surgery, Bayer undertook an extensive off-label promotional program to expand orthopedic use of Trasylol prior to FDA-approval for such an indication. These efforts included plans for an expanded number of investigators for pivotal trials (trials conducted to support FDA applications) selected on the basis of their perceived ability to drive prescribing and use; use of investigator meetings and associated kickbacks as promotional vehicles; encouraging use outside of the pivotal trial, and publication of case studies; funding and assisting with off-label publications; funding and influencing biased off-label CME programs featuring Trasylol KOLs; plans to identify investigators to conduct supposed "investigator initiated" off-label trials; and orthopedic Advisory Boards consisting of potential prescribers whose real purpose was to increase prescribing.

245. Due to the fact that some patients undergo either multiple orthopedic procedures or both cardiac and orthopedic procedures within six to twelve months of each other, Bayer’s orthopedic strategy greatly increased the chances and actual incidences of patients being re-exposed to the drug within six months. Such re-exposure carries a heightened risk for potentially fatal hypersensitivity reactions and anaphylaxis. Furthermore, Bayer was aware of the probability for an increase in adverse events as a result of these promotional efforts. In fact, Bayer considered the development of an IgG test in 2004 to test for hypersensitivity, but did not pursue it at the time because of concerns that it might dampen the demand for Trasylol.

246. After Bayer began off-label promotion of Trasylol for orthopedic surgery in late 2004, serious adverse events due to anaphylaxis and hypersensitivity reactions reported to the
FDA more than doubled (from 21 in 2004 to 54 in 2005) as did the number of deaths attributed to Trasylol use (from 4 in 2004 to 10 in 2005). The majority of these cases were attributed to off-label use of Trasylol, and helped prompt the September 2006 FDA Advisory Committee meeting.

247. Bayer even flouted a new FDA black box warning added in December 2006 admonishing that “Trasylol should only be administered in an operative setting where cardiopulmonary bypass can be rapidly initiated.” Notwithstanding this FDA-imposed warning, as of late 2007 Bayer continued to promote Trasylol for off-label uses in orthopedic and oncology patients, where cardiopulmonary bypass would not be readily available, by continuing to visibly sponsor “educational programs” on these uses by Bayer KOL’s. For example, Bayer worked with Ken Taylor, MD, a paid Bayer KOL, to offer a number of Bayer-sponsored off-label Trasylol programs on MedSite, the website associated with a medical education company that also had the contract for Trasylol e-detailing (promotional) efforts. While the option for CME credit for these programs expired, these programs remained freely available and clearly sponsored, despite updated labeling, which provides a Black Box warning against use in these settings. Furthermore, no safety warnings were added to these programs.

248. By and through the foregoing conduct, Bayer suppressed, omitted and/or distorted safety information material to decisionmakers and thereby caused the submission of false or fraudulent claims for payment to State and/or Federal governments.

5. **Misbranding via Promotion of Unsubstantiated Outcomes.**

249. From and after August 1998, Bayer also misbranded and promoted Trasylol off-label by falsely promoting it as providing unproven and unsubstantiated benefits. 21 U.S.C. § 352(a). These suggestions were false and misleading, and designed to promote unnecessary use of Trasylol and increase utilization of the “full” dose. Furthermore, these unsubstantiated
benefits were the foundation of pharmacoeconomic programs designed to cost justify the high
cost of using Trasylol.

250. For example, Bayer claimed that high-dose Trasylol improved outcomes through
a reduction in Systemic Inflammatory Response Syndrome ("SIRS"). Bayer made this claim
even after the FDA had admonished it, during the S-004 approval process in 1998, that a
statement that reduction in inflammatory response by aprotinin translates into improved patient
(clinical) outcome was unsubstantiated, clarifying that "[t]he only claim is for decreased need for
donor blood transfusion." Bayer also asserted that these improved outcomes were only attainable
through the use of high-dose Trasylol despite the fact the FDA had admonished that it would be
false and misleading to suggest that a reduction in SIRS may only occur at the high dose. The
FDA stated that this claim was unsubstantiated and "could encourage the use of high- dose
aprotinin without any evidence of additional clinical benefit from the reduction of
inflammation." Bayer also falsely claimed Trasylol improved outcomes due to a reduction in
strokes, even though several small studies had suggested that fewer strokes was actually the
result of using fewer units of blood products rather than the administration of Trasylol.
Nonetheless, Bayer's promotional efforts frequently suggested that using Trasylol would provide
cardio- and neuroprotection resulting in improved outcomes, including reduced strokes and
myocardial infarctions. As far as Relator is aware, to date these claims are still considered
unsubstantiated and in any case, constituted off-label promotion. Furthermore, Bayer used these
claims of reducing stroke and MI in biased pharmacoeconomic analyses to help encourage and
justify the use of Trasylol.

251. Significantly, as part of its efforts to falsely assert improved outcomes due to a
reduction in strokes, Bayer caused such claims to be published in a 2004 meta-analysis by a
Bayer KOL, Dr. Sedrakyan. A 2002 consultant’s report had concluded Trasylol use in cardiac surgery was close to maximum expected penetration and, in order to drive additional Trasylol sales, it would be necessary to document that Trasylol improved patient outcomes.

252. Sedrakyan and Bayer failed, however, to disclose Sedrakyan’s ties to Bayer, even though he had such a close relationship with Bayer that at one point he even had a Bayer telephone number and email address. Sedrakyan and Bayer also failed to disclose Bayer’s direct assistance, despite acknowledging the assistance of Jennifer Mauer who was not properly identified as a Bayer employee. Bayer also appears to have presented the Sedrakyan meta-analysis to the FDA as an independent effort.

253. The Sedrakyan article’s promotional intent was evident from its abstract, which stated: “[d]espite proven blood transfusion benefits, aprotinin may be underused in coronary artery bypass grafting.” It was further evident from the Discussion section, which stated: “Concerns about MI (graft closure) and renal failure may contribute to the relative underuse of this medication in CABG.”

254. The Sedrakyan article then falsely and misleadingly dismissed potential Trasylol risks with statements such as “[a]lthough increased or decreased risks of MI and renal failure cannot be definitively excluded (because of wide confidence intervals), our findings should alleviate concerns that aprotinin causes increases in the occurrence of these adverse events.” This statement was unduly broad, since it did not qualify that the analysis eliminated sixteen CABG studies and only looked at a non-representative sub-population of Trasylol patients, typically consisting of relatively healthy males undergoing primary CABG procedures. That

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group tended to have lower overall adverse event rates, and was potentially the only group for which adverse event rates for Trasylol were close to placebo.

255. Finally, in order to support the desired conclusion that outcomes were improved via a reduction in strokes, Sedrakyan engaged in unverifiable data supplementation through personal correspondence with other investigators to obtain information concerning strokes and other “data” that were not published in the original studies. For example, the majority of the patients (2179 out of 2976 patients, representing 9 of 18 trials) had stroke data that were only investigator reported. Furthermore, those investigators were typically other Bayer consultants, a fact that was not revealed in the analysis. He also used the supplementation process as explicit grounds to eliminate one or more of the sixteen excluded CABG studies.

256. Sedrakyan’s conclusions were also questionable since he did not analyze differences in adverse events between half and full dose, and did not examine total dose per patient, despite the fact Bayer was aware that adverse events were dose-related. These significant omissions caused the article to be false and misleading about Trasylol’s risks, and thereby misbranded the drug when used by Bayer.

257. Underscoring the shortcomings of Sedrakyan’s biased 2004 meta-analysis, an independent meta-analysis published in 2007 by Brown\textsuperscript{17} did not find any impact on stroke outcomes. Unlike the Sedrakyan meta-analysis that was limited to a cherry-picked subset of CABG patients, the Brown meta-analysis examined a broader set of cardiac surgery trials and was therefore more representative of actual Trasylol usage--of which at least half is for off-label uses in cardiac surgeries for valve replacement, CABG/valve and off-pump CABG surgeries that Bayer promoted. The Brown meta-analysis also found that high dose aprotinin increased the risk

\textsuperscript{17} J.R. Brown, PhD et al., Meta-Analysis Comparing the Effectiveness and Adverse Outcomes of Antifibrinolytic Agents in Cardiac Surgery, Circulation, June 5, 2007; 115; 2801-2813.
of renal dysfunction, thus supporting the Mangano and Karkouti findings published in January 2006.

E. **Bayer’s Unlawful Kickback Scheme as to Trasylol.**

258. Bayer routinely paid kickbacks and other incentives to physicians to illegally influence them to prescribe Trasylol to increase utilization of the drug. These incentives included, but were not limited to, the creation of sham consultant/Advisory Board meetings in order to promote Trasylol, the use of unrestricted grants as quid pro quo for increased prescribing or use of Trasylol, and the provision of other illegal incentives to influence physicians to prescribe Trasylol.

1. **Cardiac Team Meetings/Advisory Board Meetings.**

259. In an attempt to increase sales, four or five times during the year, Bayer organized various Cardiac Team Meetings for “influencers” who play a pivotal role in prescribing or using Trasylol. (These “influencers” include primarily cardiac surgeons, anesthesiologists, and perfusionists and, occasionally, physician assistants and nurses.)

260. Each Cardiac Team Meeting targeted approximately 100 participants. The meetings generally lasted for two and one-half days with 5 hours of “educational” or promotional component. Bayer paid participants’ travel, hotel, meals, and meeting related expenses. Ten speakers each talked for thirty minutes and were paid $3,000 each in honorarium. All other participants were paid a $500 “consultant’s honorarium . . . for your feedback and participation” under a consulting agreement. The meetings also employed the use of an Audience Response System (“ARS”) to “collect data” and make it appear as though the meeting had a legitimate purpose beyond pure promotion of the product. The total cost for holding such a meeting in New York City in 2003 was approximately $367,320. Examples of such meetings included:
a. November 3-5, 2000 meeting at the Renaissance Mayflower Hotel in Washington, D.C., entitled *Innovative Strategies to Improve Open Heart Surgery Outcomes*, which was attended by over 56 medical professionals. This meeting was also the subject of a formal return on investment analysis demonstrating that Trasylol usage increased considerably at the institutions represented by the attending professionals. In fact, the analysis showed that the $149,000 cost of the meeting yielded increased Trasylol revenue that was six times the cost of the meeting, or about $894,000.

b. April 20-22, 2001 meeting in San Francisco, CA, entitled *Innovative Strategies to Improve Open Heart Surgery Outcomes*. This meeting was attended by over 60 participants, who were physicians and perfusionists at institutions targeted by Bayer as “Grow Accounts,” reflecting the meetings’ true purpose of increasing Trasylol sales. During the year 2001, over 270 medical professionals from 101 institutions attended such Cardiac Team Meetings.

c. January 25-26, 2002 meeting held at the Hyatt Regency Pier 66 in Ft. Lauderdale, FL, entitled *Innovative Strategies to Improve Open Heart Surgery Outcomes*. This meeting exclusively targeted cardiothoracic surgeons, since Bayer annually held one meeting within a few days of the Society of Thoracic Surgeons’ (“STS”) annual meeting each January. By timing this meeting in this manner, Bayer effectively covered the surgeons’ travel costs to their annual STS meeting, conferring a further benefit and inducement to the surgeons.

meeting was attended by “[m]ore than 130 medical professionals from hospitals across the country” with the “major objective of the three-day meeting” stated as “[b]uilding professional support for the use of the product [Trasylol].” The newsletter also noted that “[t]en key opinion leaders — cardiac thoracic surgeons and anesthesiologists — presented data.” During the year 2002, over 500 medical professionals from 120 institutions attended such Cardiac Team Meetings, at a total cost of $1,425,000.

e. November 7-9, 2003 meeting in San Francisco, entitled Innovative Strategies to Improve Open Heart Surgery Outcomes which was attended by over 110 professionals.

f. These meetings continued well into 2004, as evidenced by a meeting in June 2004, at the Mayflower Hotel in Washington, D.C., and at least two other meetings held in the Fall of 2004.

a. Disguise of the Promotional Nature of Meetings.

261. In theory, the Cardiac Team Meetings were designed to provide “valuable input” to Bayer and were held out as being run by Bayer’s Scientific Affairs group. However, these meetings were actually conducted with the primary objective of increasing Trasylol sales, and were, in fact, included in the budget for the marketing department. Direction for these meetings came from the Director of Marketing for Trasylol, Stanley Horton, as well as Val Pascale, Trasylol Product Manager, with the Scientific Affairs department responsible for some of the day-to-day activities.

262. In an attempt to disguise these meetings as advisory in nature, Bayer incorporated questions administered after each presentation and collected via individual respondent keypads. This data collection methodology was known as an ARS. The data collected through the ARS is of marginal benefit to Bayer. Questions were primarily designed to reinforce the value of
Trasylol rather than actually gather valuable information. While graphs of the responses for individual questions were provided to Bayer, no analysis was done of the results, and no conclusions or recommendations were developed. Results were typically not ever reviewed by Product Management.

263. When consulted by Bayer, an outside market research vendor estimated that it would have cost $92,000 to complete a similar survey by 300 physicians, along with a comprehensive analysis of the results. Instead, Bayer spent approximately $1 million dollars to conduct three Cardiac Team Meetings for approximately 300 physicians.

264. Over the years, Bayer’s marketing department adjusted the program to give the program the appearance of being a legitimate advisory board meeting. For instance, to help justify the honoraria, Bayer collected additional information through the use of open-ended questions. However, there was no real need for this information. As an example, during the November 16-17, 2002 Cardiac Team Meeting at the Westin St. Francis Hotel in San Francisco, California, the participants were asked open-ended questions, allegedly to benefit Bayer’s research and development of the drug. However, no tabulation, report or analysis of the open-ended responses was ever completed and distributed to the product team or Bayer management, nor was any summary ever requested. In addition, at the time, there were no plans for any further development of the drug.

265. Another adjustment proposed to help justify the honoraria paid to the participants in these meetings was a request to obtain additional feedback and advice from the participants after the meetings. Implementation was supposed to began in January 2003. However, as of May 2004, this follow-up activity had not been implemented, because there was no perceived need for additional data.
b. **Return on Investment Analysis.**

266. As further evidence of the promotional nature of these meetings, Bayer conducted a Return on Investment ("ROI") analyses to determine if Trasylol sales increased in the hospitals whose purchasing decisionmakers attended the meetings. Bayer also conducted ROI analyses on the institutions affiliated with the speakers for these programs. One such ROI analysis for 2000 showed a 50% increase in sales after the meetings; yielding Bayer a 3 to 1 return. Another ROI analysis in 2001 showed a 50% increase in sales; yielding Bayer a 6 to 1 return. Bayer’s Product Management knew that paying these physicians as “consultants” when the primary purpose of the meeting was to increase Trasylol sales was illegal conduct. The ROI analyses for these meetings were omitted from the “justification” document, instead stating “No financial return on investment is calculated.”

267. The physicians and institutions targeted for these Cardiac Team Meetings are from a list known as “Grow Accounts.” Bayer management had been so pleased with the impact of these Cardiac Team Meetings that it planned to increase the budget for the meetings from $1.2 million in 2004 to $1.7 million in 2005.

2. **Grants.**

268. Bayer also employed the use of unrestricted grants and other kickbacks to influence the prescribing behavior of physicians to increase its share of the prescription drug market.

a. **Dr. Peter Smith of Duke University Medical Center.**

269. Dr. Peter Smith of Duke University Medical Center, a key opinion leader (KOL), requested $500,000 to organize two meetings in 2005. The money was to sponsor attendees to attend the meetings and for overhead expenses, including payment for the meeting organizers. The proposed topics of the meetings are designed to increase the use of Trasylol. This request
contradicts Bayer's compliance guidelines. While the Relator is unaware whether this recent grant request was actually funded in its entirety, Bayer previously granted Dr. Smith $75,000 to organize a similar meeting. This request also specified that 8.5% of the budget was to be used to cover "institutional overhead."

b. **United Way of Forsyth County, North Carolina.**

270. Similarly, Bayer disguised illegal incentives as payments to non-profit organizations. For instance, Bayer approved a $13,000 charitable donation to the United Way of Forsyth County, North Carolina requested on behalf of Wake Forest Baptist Medical Center where Dr. David Stump, a speaker for Trasylol and Key Opinion Leader, is a professor of anesthesiology. The request for the grant did not specify what the grant (or contribution) would be used for, which clearly contradicts Bayer's compliance guidelines. This was not the first time that Bayer made such a payment.

c. **Cardiovascular Surgical Clinic of Northwest Arkansas.**

271. On information and belief, Bayer provided a $5,000 grant to the Cardiovascular Surgical Clinic of Northwest Arkansas to analyze data pertaining to practical and therapeutic changes to CABG surgery implemented in the clinic as a result of attending a Cardiac Team Meeting. Despite misgivings about the value of such information by Bayer personnel, the Product Marketing Team granted the money to the clinic.

3. **The Textbook Program.**

272. Bayer also provided financial incentives through a textbook program. Bayer purchased a large amount of textbooks written by Trasylol's KOLs. These textbooks, valued at $135 each, were then distributed to 1,800 cardiac surgeons including cardiac surgeons who were Federal Government employees. The surgeons were requested to review Trasylol marketing materials and to complete a very brief market survey. Sales representatives were to hand-deliver
the books with the expectation that they would be further able to influence prescribing. While the purported purpose of this program was to obtain market research data, more than six months after the program was implemented no data had been received (or sought by Product Management). At Relator’s inquiry, Product Management tracked down the data and forwarded the data file; however, no interest was shown in any analysis of the data. The program was a violation of Bayer’s stated compliance policy, wherein a textbook valued over $100 should never be provided to an individual physician. In addition, the textbook program was also a violation of Federal regulations which specify a $20 limit on the retail value of textbooks to individual Government employees. In addition, textbooks valued at over $100 were routinely used as premium items for physicians, outside of the textbook program described above.

F. Bayer’s Unlawful Off-Label Marketing Scheme as to Trasylol.

273. Bayer has actively engaged in a clandestine off-label marketing campaign for its drug Trasylol.

274. Repeated use of Trasylol significantly increases the danger of serious side-effects; promoting Trasylol for off-label uses endangers the patient because the physician prescribing the drug does not know to ask whether the patient has previously received the drug for an off-label use. In addition, use of the drug itself has been shown to be risky and increase adverse events.

275. Bayer was permitted to market Trasylol only for the reduction of blood transfusion during “On-Pump” CABG. Nevertheless, Bayer engaged in a policy of making, or causing to be made, false and/or misleading statements in order to market Trasylol for off-label, unapproved purposes, such as “Off-Pump” CABG surgery and orthopedic surgery, in order to increase market share. In fact, the Medical Director for Trasylol expressed concerns to Relator about patient safety in connection with such off-label promotion for orthopedic usage and felt that the marketing group was too aggressive in its promotion of Trasylol for off-label uses. The
response by Senior Management reportedly was “Keep quiet! Trasylol is funding your paycheck.” Other off-label uses included valve surgery and pediatric surgery.

276. The 2004 Strategic Marketing Review for Trasylol (dated June 3, 2003) identified 2004 Required Sales growth of $8 million for Off-Pump CABG. The 2004 Strategic Plan (dated July 2004) defined the #1 key Strategy as “Drive physician demand for ALL CABG patients through communication of Trasylol Benefits” (emphasis added). Although Bayer acknowledged a lack of data regarding the safety and efficacy of Trasylol for use in Off-Pump CABG patients, and expressed concerns over conducting clinical trials in off-pump patients due to uncertain outcomes, Bayer promoted this off-label use. Consistent with this strategy, Bayer exclusively sponsored a supplemental publication by The Heart Surgery Forum, “The Official Journal of the International Society for Minimally Invasive Cardiac Surgery” (i.e. Off-Pump cardiac surgery), which prominently featured at least four articles about Off-Pump cardiac surgery, of which at least three were co-authored by Trasylol Key Opinion Leaders. The supplement also prominently contained a four page color advertisement for Trasylol, as well as a CD-ROM featuring a Trasylol multimedia presentation. As noted earlier, Bayer was also aware that the FDA had not approved Trasylol for use in combined CABG/valve procedures, yet generally failed to mention this either internally or externally.

277. Bayer also promoted Trasylol for off-label use in valve replacement surgeries, despite the fact clinical trials demonstrated mixed efficacy results and higher rates of adverse events precluded approval for such usage. Bayer even continued to promote Trasylol for such usage after it received a letter on January 23, 1997 from the FDA’s Division of Drug Marketing, Advertising and Communication (“DDMAC”) disapproving of certain promotional materials.
Bayer had submitted for review to the FDA on the grounds it “discusses uses [specifically valve replacement] other than those for which aprotinin has demonstrated safety and efficacy.”

278. To promote Trasylol, Bayer used various illegal incentives:

1. **Grants.**

   a. **Dr. Robert J. Porter.**

   279. In November 2004, Bayer sponsored Dr. Robert J. Porter, an anesthesiologist, as a visiting professor at the University of Wisconsin-Madison Medical School to speak on the off-label uses of Trasylol for liver transplant surgeries. Bayer paid for his travel expenses, including airfare and lodging. In addition, Bayer paid Dr. Porter an honorarium of $2,500. This honorarium was disguised as an unrestricted educational grant to the University of Wisconsin-Madison Medical School.

   280. Bayer’s compliance policy stated that “a grant should never be made if one purpose is to provide a financial inducement for dispensing or ordering Bayer products or to encourage off-label use or reward referrals for Bayer products.”

   281. Bayer also paid Dr. Porter $10,000 to present five symposia on the use of Trasylol for off-label use in liver transplant surgery.

   b. **Orthopedic Research and Education Foundation.**

   282. Bayer granted the Orthopedic Research and Education Foundation $30,000 to award a research grant to an orthopedic resident, with the clear intent that the Foundation would support off-label use of Trasylol in orthopedic cases.

   283. In anticipation of increased focus on expanding off-label use in orthopedics, Bayer’s budget for educational grants for 2005 increased almost 100% from $490,000 to $890,000. Furthermore, in 2005 unrestricted educational grants increased from $136,000 to $300,000.
c. **CABG-consult.com.**

284. Bayer also fully sponsored, through an “unrestricted educational grant” to Thomson, a website entitled www.CABG-consult.com that prominently featured publications concerning off-label uses of Trasylol. The website was designed for the specific purpose of promoting Trasylol, and substantially all content was provided by Bayer, which also placed links to the website on its Trasylol product website. In addition, the CABG-consult.com website provided a link entitled “FreeCME,” which enabled access to Bayer-sponsored continuing medical education (“CME”) programs. These CME programs offered free textbooks and journals, free meals and free CME credits for attending Trasylol-related presentations. The CABG-consult.com website was discontinued when serious safety issues concerning Trasylol were brought to light.

2. **Continuing Medical Education.**

285. Bayer, through the use of biased CME seminars taught by its paid consultants, promoted the off-label use of Trasylol to “influencers” who play a pivotal role in prescribing or using Trasylol. These “influencers” include primarily cardiac surgeons, anesthesiologists, and perfusionists (operators of the heart/lung machine). Influencers also included hospital administrators, who Bayer actively targeted, and for whom Bayer crafted messages promoting Trasylol’s “cost-effectiveness.”

a. **Supplement to the Journal Orthopedics.**

286. In December 2003, Bayer contracted with Slack Incorporated, a CME provider to publish presentations from Trasylol Orthopedics Advisory Board members who are paid consultants and Bayer-sponsored faculty. These presentations contained false and/or misleading statements and were the basis for a supplement to the journal *Orthopedics* that promoted off-label Trasylol use for orthopedic surgery which is prohibited conduct.

287. In 2004, Bayer contracted with CME provider American Health Consultants ("AHC") (a subsidiary of Thomson) to promote the use of Trasytol for cardiothoracic surgery in a series of biased CMEs targeted to clinicians, as well as hospital administrators. The program was entitled *Coronary Artery Bypass Graft (CABG) Surgery: A Year 2004 Update.* These sessions used pharmacoeconomic data (developed by Duke in conjunction with Bayer) to cost-justify the use of Trasytol based on unsubstantiated clinical outcomes such as reduction of MI and stroke. In addition to off-label and misleading information and direct input from Bayer, the program also used kickbacks to encourage support and use of Trasytol. Each attendee received a complimentary subscription to a hospital administration or clinical journal of their choice, as well as a free textbook. The benefit conferred upon the administrator or physician is reflected by the retail prices, with the journals ranging up to $657 per year, plus the price of the textbook. Further demonstrating a biased approach, the original proposal from AHC stated that "we will establish and disseminate expert and evidence-based endorsement and support for Trasytol in the form of a cardiothoracic surgery Clinical Consensus Report which will be disseminated to about 25,000 key targets."

3. **Other Meetings and Projects.**

a. **KOL Programs/ Peer-to-Peer Selling.**

288. Bayer paid KOLs to present Trasytol information, including biased information and off-label uses, to physicians at high-end dinner meetings and other programs. Bayer also provided grants to hospitals and physician groups to fund Trasytol presentations by Bayer KOLs which featured off-label promotion.

289. For example, Bayer paid Dr. Peter Smith to speak at two programs in San Antonio in August 2000, including a dinner talk at a Ruth’s Chris steak house. Dr. Smith’s talks focused
on off-label uses of Trasylol, including claiming a “positive impact” on neurological outcomes, and a reduction in strokes and heart attacks. Smith recommended, “at the very least,” using a full dose for anyone over age 60, as well as for repeat CABG surgery and valve surgery. At least one attendee, from the Department of Defense, was reported to have used Trasylol for the first time in a valve case the day after Dr. Smith’s presentation.

b. **Cardiac Team Meetings.**

290. As previously detailed, during the years 1999 through at least 2004, Bayer held Cardiac Team Meetings for medical professionals across the United States. At these meetings Bayer actively made, or caused to be made, statements concerning the use of Trasylol which were false and/or misleading because they promoted off-label uses such as off-pump cardiac surgery, Deep Hypothermic Circulatory Arrest (“DHCA”) and pediatric procedures, as well as unsubstantiated outcomes.

c. **Orthopedic Surgery Promotion.**

291. In 2003-2004, Bayer announced its intention to seek FDA approval of Trasylol for use during orthopedic surgery, and subsequently initiated the required clinical trial program. At the same time, Bayer requested approval from the FDA, under FDAMA, to distribute journal articles describing the off-label use of Trasylol in orthopedic surgery. FDAMA only entitled Bayer to disseminate, without initiating any discussion, approved orthopedic journal articles to physicians under the strict guidelines of FDAMA.

292. Notwithstanding the effective gag order imposed by FDAMA precluding Bayer from initiating discussions on Trasylol use in orthopedic surgery, in 2004, Bayer was also working with Pharmatecture, LLC (“Pharmatecture”), a medical education company and with sister company American Health Consultants, to actively promote the off-label orthopedic surgery use of Trasylol to key orthopedic surgeons. The objectives of the project according to
the proposal from Pharmatecture were “to galvanize 40 orthopedic surgery thought leaders to
develop and publish guidelines focusing on adoption of Trasylol in orthopedic surgical practice.”
Included in the original proposal was the vendor task: “Development, writing, editorial design,
peer review and publication of an Orthopedic Surgery Clinical Consensus Report followed by
distribution to 20,000 targets,” representing the vast majority of orthopedic surgeons. In reality,
it was Pharmatecture and Bayer, not the orthopedic surgeons, who were to develop the
guidelines, while the surgeons would be paid a substantial honorarium to attend the meeting as
consultants and approve the guidelines. As part of this project funded by Bayer, Pharmatecture
was then to disseminate this report to 20,000 targets. The cost of this effort was approximately
$900,000. Although Bayer modified the initial proposal, the primary intent of gaining support
for off-label use of Trasylol in orthopedics (in part through paying honoraria to orthopedic
surgeons under the guise of an advisory board and/or through CME) remained the key objective
of these efforts.

293. In the context of the strict FDAMA regulations, such widespread promotion of
Trasylol for a use that was still off-label gave the false and/or misleading impression that the use
had effectively been approved, as well as violated the strict letter of the FDAMA regulations.

4. **Contract Discounts.**

294. Bayer entered into a two year contract with Premier, a group purchasing
organization on behalf of hospitals. The contract stated that full discounts of 20% are provided
for those Premier hospitals conducting more than 150 CABG procedures annually with 100%
“appropriate Trasylol utilization.” The contract terms were not available to all hospitals and
were labeled a “pilot program.” The implications were to promote off-label use of Trasylol in
combined CABG valve procedures and “Off-Pump” CABG surgery because the hospitals could
not attain the required amount of the drug to qualify for the full discounts if used only for “On-
Pump” FDA-approved CABG procedures. Trasylol discounts under the Premier contract totaled approximately $3 million annually.

5. **Bayer’s Concealment of Off-Label Marketing Has Avoided Cutoff of Government Reimbursement Funds.**

295. The Medicare and Medicaid programs of the Federal Government include detailed statutory and regulatory provisions concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for full Federal participation, price controls on prescription drugs, and drug manufacturer rebate agreements. These laws and regulations include, *inter alia*, as set forth in 42 U.S.C. § 1395Y(e), that no Federal payment shall be made in the case of a prescription drug for which the FDA has issued a notice of hearing regarding the effectiveness of the drug. Thus, the taking of regulatory action by the FDA against the sale and promotion of a drug will, in certain circumstances, immediately interrupt the flow of Federal funds for reimbursements of prescriptions written for the drug.

296. Promotion of off-label usage of a drug constitutes “mislabeling” as defined by the FDA.

297. Upon information and belief, Bayer was aware that if the FDA learned of its promotion of off-label uses of Trasylol, the FDA would have taken administrative action against Bayer, in the form of a notice of hearing regarding the effectiveness of the off-label uses promoted by Bayer. Such a notice would, by Federal statute, instantly interrupt the flow of Federal funds for reimbursement for off-label prescriptions.

298. Upon information and belief, Bayer has actively concealed its off-label marketing which has had the effect of preserving the flow of Federal funds to reimburse for off-label prescriptions.
VIII. SPECIFIC ALLEGATIONS AS TO AVELOX.

A. Generally.

299. Avelox is Bayer's trade name for moxifloxacin hydrochloride, a synthetic broad-spectrum antibacterial agent classified as a fluoroquinolone. Avelox is considered extremely powerful because the bactericidal action of the drug results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV required for bacterial DNA replication, transcription, repair, and recombination. For this reason, the drug is only approved for use in treating certain subsets of conditions caused by particular bacteria scientifically proven to be highly susceptible to such treatment. Moreover, FDA-approved labeling directs that it should only be administered after appropriate culture and susceptibility tests are performed to determine that the pathogen is one of those listed. Initiating therapy prior to test results is only permitted where local epidemiology and susceptibility patterns strongly indicate presence of one of the listed pathogens, and is to be discontinued if actual test results prove otherwise.

300. On about December 13, 1999 the FDA approved Avelox for limited upper respiratory infections, specifically:

i. Acute Bacterial Sinusitis ("ABS")
   (caused by Streptococcus pneumoniae, Haemophilus influenzae, or Moraxella catarrhalis);

ii. Acute Bacterial Exacerbation of Chronic Bronchitis ("ABECB")
    (caused by Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Staphylococcus aureus, or Moraxella catarrhalis); and

iii. Community Acquired Pneumonia ("CAP")
    (caused by Streptococcus pneumoniae (including multi-drug resistant strains), Haemophilus influenzae, Mycoplasma pneumoniae, Chlamydia pneumoniae, Klebsiella pneumoniae, Staphylococcus aureus, or Moraxella catarrhalis).
At that time, a fourth indication was deemed “approvable” pending post-marketing safety data, and received full FDA approval in 2001, specifically:

iv. *Uncomplicated Skin and Skin Structure Infections* ("uSSSI") (caused by *Staphylococcus aureus* or *Streptococcus pyogenes*).

A few years later, on about June 30, 2005 and November 22, 2005, respectively, Avelox was approved for additional types of skin infections and certain intra-abdominal infections, specifically:

v. *Complicated Skin and Skin Structure Infections* ("cSSSI") (caused by methicillin-susceptible *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, or *Enterobacter cloacae*); and

vi. *Complicated Intra-Abdominal Infections* ("cIAI") (approved 11-30-05)(including polymicrobial infections such as abscess caused by *Escherichia coli*, *Bacteroides fragilis*, *Streptococcus anginosus*, *Streptococcus constellatus*, *Enterococcus faecalis*, *Proteus mirabilis*, *Clostridium perfringens*, *Bacteroides thetaotaomicron*, or *Peptostreptococcus species*).

Also in June 2005, the *Staphylococcus aureus* indication for CAP was further limited to only methicillin-susceptible strains.

301. Dosage is 400 mg once every 24 hours over the course of 5-21 days depending on the condition diagnosed. It is available as tablets for oral administration and as a liquid dilution in 250 ml bags for intravenous administration.

302. Avelox competes in the marketplace against other antibacterial drugs, primarily Levaquin (levofloxacin) and Tequin (gatifloxacin), as well as Augmentin (amoxicillin), Biaxin (clarithromycin), Cipro (ciprofloxacin), Floxin (ofloxacin), Rocephin (ceftriaxone), Zithromax (azithromycin) and later against Factive (gemifloxacin mesylate) (launched April 2004) and Ketek (telithromycin) (launched July 2004).

303. Avelox drug labeling carries several warnings, including the fact it is known to cause fatal anaphylactic shock, sometimes even after the first dose, and also to cause a serious
cardiac condition known as prolongation of the QT interval of the electrocardiogram. The label also warns that Avelox is to be used with caution on anyone with known or suspected central nervous system disorders or other risk factors that may predispose them to seizures. In addition, on July 14 and 18, 2004, the FDA required additional label warnings concerning the risks of peripheral neuropathy (resulting in paresthesias, hypoesthesias, dysesthesias and weakness) and tendon effects (particularly spontaneous ruptures of shoulder, hand and Achilles tendons).

Generally, the label states that Avelox is contraindicated for any person with a hypersensitivity to moxifloxacin or any member of the quinolone class of antimicrobial agents, and has never been established as safe and effective for children under age 18 or for pregnant or lactating women. In addition, Avelox has been reported to cause fatal liver damage after just a few doses, and the class of quinoline drugs is associated with causing a range of central nervous system impairments including convulsions, increased pressure in the head, psychosis, tremors, restlessness, light-headedness, nervousness, confusion, depression, nightmares, insomnia, and hallucinations. Side-effects can be long-lasting and/or permanent.

304. The initial sales volume in 2000 was considered disappointing by Bayer and thereafter considerable effort was put into increasing sales volume. As a result of those efforts, Avelox became a very lucrative drug for Bayer. The reported Average Wholesale Price (AWP) per 400 mg tablet of Avelox was $7.51 in 2002, $7.79 in 2003 and $8.07 in 2004. Each prescription of Avelox averages 8.8 tablets. Total Avelox prescriptions were 2.6 million in 2002, 3.2 million in 2003 and an estimated 3.7 million in 2004. These figures do not include free samples which exceeded 13 million tablets/year — the equivalent of another 1.5 million prescriptions/year, or about 30% of the total tablet volume placed in the market.
305. Fully 12% of sales were to hospitals, with the remaining 88% of sales through retail channels. Upon information and belief, prescriptions for approved uses, however, only account for 44% of sales while 56% of sales are for off-label uses. Medicaid patients accounted for $25 million in 2003 and an estimated $33 million in 2004.

306. Initially, Bayer marketed Avelox to physicians who treat patients with upper respiratory infections. In order to change the prescribing behavior of these doctors, Bayer routinely paid kickbacks and other incentives, as it did for Trasylol, to physicians to illegally influence them to prescribe Avelox to increase utilization of the drug. These incentives included:

a. payments to physicians as “consultants” to attend meetings which did little more than promote Avelox;

b. the use of unrestricted grants as incentives for increased prescribing or use of Avelox;

c. fully funding accredited CME courses, thereby enabling physicians to obtain free CME credits, while also failing to disclose that the presenters were physicians trained by Bayer to advocate greater usage of Avelox, including off-label uses;

d. giving medical equipment, such as otoscopes, and textbooks as “prizes” or premiums for the purpose of influencing physicians to prescribe Avelox; and

e. the provision of other illegal gifts, entertainment and other incentives to influence physicians to prescribe Avelox.

These programs were primarily financed through Bayer’s marketing budget for Avelox.
307. As a result of Bayer’s aggressive schemes of kickbacks to prescribing physicians and marketing of off-label uses, gross sales grew from $194.9 million in 2002 to an estimated $273.1 million in 2004, and were projected to grow to $469.5 million by 2009. Moreover, as a result of Bayer’s aggressive campaign to promote Avelox for off-label uses, prescriptions for approved uses accounted for only 44% of sales, while prescriptions for off-label uses accounted for 56% of sales.

B. Defendants Bayer’s Unlawful Kickback Schemes as to Avelox.

308. Bayer’s marketing department routinely engaged in several programs that were designed to improperly convey a benefit to prescribing physicians in order to influence their prescribing behavior toward Avelox.

309. As further evidence of the promotional nature of these programs, Bayer routinely conducted ROI analyses to determine if Avelox sales increased as a result of these efforts and refined its tactics based on these analyses.

1. Cash Honoraria Paid to Doctors as Avelox Key Opinion Leaders.

310. In order to create credible sources for delivering its message to each target audience, Bayer actively recruited KOLs and other physicians from each area of medicine in which Avelox had potential application, i.e. infectious disease (“ID”) and ear, nose & throat (“ENT”) to be advocates for Avelox. Bayer trained each KOL concerning Avelox and paid them substantial honoraria ranging from $500 to $5,000 or more, and sometimes including travel, lodging and other expenses, to consult and/or speak favorably about Avelox at meetings, CME’s and telesymposia for prescribing physicians.

311. A lengthy document entitled Avelox Tactics Brainstorming Workshop, September 10, 2004, included a section describing Avelox promotional tactics. Part of that section was entitled “Opinion Leader Development” and listed several programs where Bayer trained and
deployed KOLs. The chart indicated time periods, investments of hundreds of thousands of dollars per program, return on investment analyses, and other assessments of the programs.

312. According to Bayer's 2003 financial records for Avelox, Bayer had budgeted $2.7 million for "Speakers Alliance costs" which included PAN and Speaker Development meetings. The 2004 Avelox budget included $1 million for Speakers Development Meetings. Moreover, a marketing department e-mail dated March 8, 2004 from Nancy Retzlaff to Paul Bedard indicates that the scientific affairs department is to get "more involved with national KOL initiative . . . to manage the minutia," a remark which underscores the fact that the "scientific" gloss on these meetings was nothing more than a facade to disguise their primary promotional purpose.

a. **PAN and Key Opinion Leader/Speaker Development.**

313. PAN was one program that was used to develop KOL into supporters for Avelox. Participants (10-20 KOL Physicians) were paid thousands of dollars to attend PAN meetings and assist with the development of marketing strategies for Avelox, and to subsequently promote Avelox to other physicians.

314. Despite the fact that Bayer Compliance Regulations prohibit payments to government employees, at least two of the key participants were affiliated with government healthcare facilities: Dr. Sanjay Sethi, a KOL and Avelox speaker, was affiliated with the Veteran's Hospital in Buffalo NY; and Dr. Antonio Anzunuto, another KOL and Avelox speaker, was affiliated with the South Texas Veterans Health Care System, Audie L. Murphy Veterans Hospital Division.

2. **Honoraria Paid to Doctors as Avelox "Consultants" to Bayer.**

315. In an effort to increase sales, Bayer product management routinely tried to hide promotional efforts under the guise of "market research" or "getting advice," including various
efforts where Bayer paid doctors a cash or gift honorarium "as a consultant to Bayer Corporation."

a. **Cash Honoraria.**

i. **Clinical Advisory Panels.**

316. During certain times, including 2000, Bayer conducted Clinical Advisory Panel ("CAP") meetings, such as "New Directions in Antibiotic Selection: AVELOX (moxifloxacin)." In the New Directions panels, for example, Bayer paid each physician $250 as a "consultant" to attend, ostensibly for providing Bayer with useful information pursuant to a "Consultant's Agreement" that was sent with the invitation to attend. These meetings were paid for with funds from the Avelox budget for the stated purpose of reviewing the latest information on Avelox and gaining personal and clinical feedback. The primary purpose of these meetings was as a vehicle to change the prescribing habits of doctors toward more usage of Avelox and/or as rewards for existing prescribers.

317. Bayer also held other Avelox Advisory Boards which typically involved dinner and paying high prescribing physicians a consulting honoraria for listening to the latest information on Avelox, and presumably providing input. In certain instances, Bayer also paid participants' travel, hotel, meals, and meeting related expenses, conveying further benefits upon those prescribing physicians.

ii. **Avelox Clinical Experience Study ("ACES 2000").**

318. During certain times, including in 2000, Bayer conducted the Avelox Clinical Experience Study ("ACES 2000"). Over 5,000 high-prescribing physicians were recruited and paid to prescribe Avelox for 3 to 6 patients, track patient experience and then attend dinner meetings as follow-up. Although the results were reported to FDA as part of the process for seeking approval for additional indications, the structure of the study indicates that the primary
purpose of the study was to reward Avelox prescribers and encourage additional Avelox
prescribing. This is evidenced by the fact that in order to gather reliable clinical information,
significantly fewer physicians were needed, there was no need to limit physicians to 3 — 6
patients each, and there was no reason to limit the study to high prescribers. These criteria
evidence a pure marketing strategy designed to alter the prescribing behavior of those physicians
who, by the nature of their practice, write the most prescriptions.

iii. Managed Care Advisory Board.

319. Bayer Product Management requested issuance of a $10,000 check to RJ Health
Systems for management fees in conjunction with a Managed Care Advisory Board held with
representatives from Harvard Pilgrim Healthcare, which presumably either had Avelox on
formulary or was considering it for inclusion. Along with a dinner component, Advisory Boards
typically involved paying members of the organization for listening to an Avelox presentation
designed to highlight the positive aspects of the product and in getting feedback on how to sell
more Avelox and other Bayer products into the organization. The dinner and cash payments to
these representatives constituted an illegal kickback for the purpose of obtaining favorable
treatment and/or the referral of business.


320. Beginning in the summer of 2001, Bayer introduced a Newsletter entitled The
Avelox Consultant Exchange which it described as a “quarterly newsletter for you as Bayer
consultants to provide a forum for the exchange of ideas around antibiotics, specifically Avelox”
and which implored its recipients “to share your ideas and perspectives as they relate to the
newsletter topics.” The format of the publication was as an informative questionnaire (i.e.,
information interspersed with short questions) designed to be folded and mailed back to Bayer.
A quick summary of some of the survey results were then published in the next quarterly issue.
The nature of the information and the questions were not scientific and clinical, but rather focused on whether certain studies and information correlated with the physicians experience and whether the information would likely influence their "prescribing habits." In short, the term "consultant" was a euphemism to cover the collection of purely marketing-related information that was already known and not useful.

v. **Avelox Velocity Challenge.**

321. During certain times, including 2002, Bayer conducted Avelox Velocity Challenge Consultant Meetings for doctors participating in the Avelox Velocity Challenge Clinical Program. As part of the program, Bayer offered free full-regimen samples to physicians who were asked to consider prescribing Avelox to their patients with ABECB or ABS, and then track the patients' improvement during the course of Avelox treatment. Bayer misled the physicians, however, by failing to mention the fact that Avelox is only indicated for a portion of these patients. A targeted portion of these physicians were then invited to attend consultant meetings where the stated purpose included "a review of the latest information on Avelox."

Bayer used funds from the Avelox marketing budget to pay a third-party to organize these meetings, and also used such funds to directly pay each physician $250 as a "consultant" to attend the meeting. In theory, the Avelox Velocity Challenge Consultant Meetings are designed to provide "valuable feedback" to Bayer that would justify payment of such a "consultant fee." This "consulting fee," however, was a facade designed to disguise the purely promotional nature of these meetings, whose primary purpose was to change the prescribing habits of doctors toward more usage of Avelox.

vi. **Testing of New Detailing Approach.**

322. As evidenced by a document entitled "EXECUTIVE SUMMARY, Marketing DSM Tune-In Session" for August 4, 2000, Bayer discussed paying a $100 cash honoraria to
physicians ostensibly in exchange for their feedback on a new visual aid being developed by marketing for detailing Avelox to physicians. The real purpose, however, was to influence the prescribing behavior of the selected physicians, as reflected in the document which states: "In this program, reps would chose [sic] five physicians . . . [t]he message here is that the reps should probably start thinking about those five physicians that they've had a difficult time getting to use Avelox because we want it to be a nonuser targeted approach."

b. **Non-Cash Honoraria.**

323. At various times Bayer paid physicians kickbacks disguised as "honoraria" ostensibly for compensating them for "valuable feedback." The honoraria were in the form of "medically related items" in exchange for the completion of a survey after viewing an electronic presentation or an internet-based interactive learning program, or participating in discussions during a telephonic conference commonly denoted as a telesymposia. The surveys or discussion components were a facade that simply enabled Bayer to compensate physicians under the banner of "market research." The primary purpose of these programs, however, was to influence doctors to prescribe Avelox. These programs included:

a. Telesymposia on the MOSAIC Study published in the March 2004 issue of *Chest*, for which physicians "receive a valuable medical office supply of their choice upon completion of this program and a market research survey." These included a telesymposium entitled "New Evidence in the Antimicrobial Management of Acute Bacterial Exacerbation of Chronic Bronchitis: The MOSAIC Study" a 1-hour program, offered in October - November 2003, January - February 2004 and June 2004.

b. Two interactive Learning Programs on the internet concerning the MOSAIC study in late 2003 and early 2004, respectively, as evidenced by an invitation to go to [http://aveloxusa.medsite.com](http://aveloxusa.medsite.com) and enter invitation code AVY?JNQ7 (2003) and to
http://aveloxusa-2.medsite.com and enter the invitation code AAVX3QAEM9, in order to view the program and "receive a medically relevant item from Medsite Rewards" upon completion of a survey to "help us assess the effectiveness of this program."

c. An interactive Learning Program on the internet, as evidenced by a fax invitation to a Dr. Rizzo on August 2, 2005, which offers to the physician "At the conclusion, you will have the opportunity to complete a short feedback survey and in return receive a clinical practice item through Medsite Rewards."


324. Bayer also employed the use of grants to influence the prescribing behavior of physicians to increase its share of the prescription drug market.


325. Kaiser Permanente, a non-profit Health Maintenance Organization that operates its own facilities, listed Avelox as a non-detectable drug, thereby precluding Bayer sales representatives from going on-site and "detailing" the physicians by providing literature and engaging them in discussions designed to influence their prescribing behavior in favor of Avelox. To get around this restriction, in 2003 Bayer paid $1,000 to Kaiser for the purpose bestowing an honoraria upon a Kaiser-affiliated physician to present information on Avelox at an in-house meeting. Bayer's Avelox financial records from 2003 also show that approximately $30,000 in other direct payments were made to Kaiser entities, excluding any additional payments that may have been made through general Field Force Funds or non-listed Bayer departments. Significantly, this conduct occurred during the same year Bayer entered into the Addendum to its Corporate Integrity Agreement on account of its payment of $100,000 to Kaiser Permanente in connection with sales of Adalat, and Bayer's failure to report "best price" information reflecting private label sales of Adalat and Cipro.
4. **The CME Program.**

326. Bayer frequently sponsored free seminars on Avelox, carried out by third party vendors, which qualified for CME credits for attending physicians, thereby conferring upon physicians a “thing of value” for the purpose of “obtaining or rewarding favorable treatment” in violation of the Anti-Kickback Act of 1986. These programs included:

a. *Antibiotic Selection in the Age of Resistance: A Focus on Newer Agents in Selected Respiratory Tract Infections*, free of charge on Saturday, June 10, 2000, at the Wyncote Golf Club, 50 Wyncote Drive, Oxford, PA. The promotional material for this event included statements that “[t]his CME activity is supported by an unrestricted educational grant from Bayer Corporation” and specifically noted that it qualified for “3.5 hours in category 1 credit towards the AMA Physicians Recognition Award” and “3.5 Prescribed hours by the American Academy of Family Physicians.”

b. *Anti-Infective Explorations*, a CD-ROM containing two self-directed seminars entitled: *Challenges and Change: Exploring Diagnostic Criteria and Treatment Approaches with Acute Sinusitis, Acute Bacterial Exacerbation of Chronic Bronchitis (ABECB), and Community-Acquired Pneumonia (CAP); and Appropriate and Responsible Use of Antibiotics: Clinical and Ethical Considerations*. The promotional material for this free CD-ROM stated that it was “[d]eveloped with national thought leaders” and was approved for “3 category 1 credits toward the AMA Physician’s Recognition Award.”

c. *Turning Patient Expectations into Improved Outcomes: An Analysis of Antibiotic Therapy for Respiratory Tract Infections in the Primary Care Setting*. This free symposium was held at the Long Beach Convention Center, Long Beach, CA, on February 16, 2001 and included a free dinner. The promotional material for this
symposium stated that it was approved for “2.5 hours in category 1 credit toward the
AMA Physicians Recognition Award” and was presented by members of an “Educational
Council,” specifically Antonio Anzucto, MD and Paul Iannini, MD. Both of these
individuals were Key Opinion Leaders paid by Bayer. For example, an Expense
Reimbursement Form from Bayer’s files for Dr. Anzucto’s “services” at a July 31 -
August 3, 2003 PAN meeting in San Francisco indicated that he was paid a $5,000.00
“honoraria” plus $585.00 in travel expenses. Likewise, an entry in the books of Bayer
entitled “Bayer Pharmaceutical North America, Product Avelox, Actual Cost Center
Expense, Y-T-D Jul-2003” evidenced a $1,500.00 honoraria paid to Dr. Iannini on April

d. 2002 National Anti-Infective Forum: Exploring Controversial Topics

Around the Appropriate Use of Antimicrobials, held November 2, 2002 at the Houstonian
in Houston, TX, with satellite locations in seven other cities. Promotional material for
the forum stated that it was approved for “2.75 hours in category 1 credit toward the
AMA Physician’s Recognition Award” and was “supported by an unrestricted
educational grant from Bayer Pharmaceuticals.” Moreover, the “Distinguished Faculty”
included influential physicians such as Sanjay Sethi, MD, a Key Opinion Leader trained
and paid by Bayer. An entry in the books of Bayer entitled “Bayer Pharmaceutical North
America, Product Avelox, Actual Cost Center Expense, Y-T-D Dec-2003” evidenced
payment of $6,171.00, for an honoraria and attendant expenses, to Dr. Sethi on

e. 2003 Infectious Disease Update: Optimizing Antibiotic Management of

Complicated and Uncomplicated Urinary Tract Infection and Respiratory Infections for

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the Primary Care and Hospital-Based Physician, held November 22, 2003 at the Gaylord Opryland Resort and Convention Center. Promotional material for the free symposium stated that it was approved for “2.5 hours in Category 1 credit toward the Physicians Recognition Award of the American Medical Association.”

5. The “Premium” Programs.

Bayer frequently provided funding for CME providers to provide premiums to doctors as an incentive to simply view electronic presentations and/or live CME’s about Avelox. Examples of Avelox educational/promotional programs that offered physicians Bayer-funded compensation for participation included:

a. Thought Leader Telesymposia Series entitled Meet the Investigators/Experts: The Role of a New Antibiotic for the Treatment of Community-Acquired Respiratory Tract Infections,” scheduled for various dates from April 3 - May 31, 2000, July 12 - August 30, 2000, and October 10 - December 4, 2000 involving approximately 120 programs. The promotional material also noted that it was “Sponsored by Bayer Corporation, Pharmaceutical Division” and offered that “Upon completion of the program evaluation, each participant will receive a certificate valued at up to $100 towards the purchase of medically relevant items, such as textbooks or medical supplies.” The investigators/experts were persons such as Dr. Iannini, whom Bayer trained as Key Opinion Leaders and paid substantial honoraria for placing their “expert” imprimatur upon Bayer’s new antibiotic Avelox.

b. Thought Leader Telesymposium entitled: PK/PD Relationships for Differentiation of Fluoroquinolones in Primary Care, scheduled for various dates from December 27, 2000 - February 21, 2001. Promotional material offered both Category 1 credit and noted that “[u]pon completion of the program evaluation, each participant will
also receive a certificate valued at up to $50.00 towards the purchase of medically relevant items, such as textbooks or medical supplies."

c. Telesymposium Series entitled: *New Evidence in the Antimicrobial Management of Acute Bacterial Exacerbation of Chronic Bronchitis: The MOSAIC Study*” offered on various dates in January and February 2001. Promotional materials offer that “Physicians completing this activity will receive a valuable medical office supply of their choice!” The material also clearly shows that the program is offered by Bayer HealthCare in promotion of Avelox and lists as faculty persons such as Dr. Anzueto whom Bayer trained as a Key Opinion Leader and paid a substantial honoraria for placing his “expert” imprimatur upon Bayer’s new antibiotic Avelox.

d. Bayer paid American Health Consultants, a subsidiary of Thomson, to provide an extensive series of CME programs promoting Avelox and CIPRO entitled 2003 *Infectious Disease Update: Optimizing Antibiotic Management of Complicated and Uncomplicated Urinary Tract Infection and Respiratory Infections for the Primary Care and Hospital-Based Physicians*. One of many of these symposia was held November 22, 2003 at the Gaylord Opryland Resort and Convention Center. The brochure for the program advertised “Free Textbook, Fine Dining and Free CME.” Specifically, attendees were offered a free copy of the 2,100 page *Textbook of Adult and Pediatric Emergency Medicine or the Textbook of Primary and Acute Care Medicine*, along with a CD ROM entitled *DrugCHOICE* to assist with antibiotic selection for common infections, which was likely biased towards using Bayer products. Promotional material for the symposium specifically noted that “Attendance at the symposium is required to receive your free textbook.” Sales representatives and Scientific Affairs Liaisons would
frequently distribute invitations to these programs to their high potential physicians.

Bayer paid for this program in the form of an unrestricted educational grant, even though the program’s objectives (as stated in a Thomson proposal to Bayer) were to promote Avelox and Cipro. An updated symposium entitled “2004 Infectious Disease Update” involved 10 large regional programs plus website with an average of 350 physicians attending per program.

e. 2004 Telesymposia Series: Evidence-Based Antimicrobial Treatment of Acute Bacterial Exacerbation of Chronic Bronchitis, Including the Groundbreaking MOSAIC Study Published in the March 2004 issue of Chest, offered at various times on June 23 - 24, 2004. Promotional material for this telesymposium offered that “Physicians completing this activity will receive a valuable medical office supply of their choice!” and also stated that it was “Provided as an educational service by Bayer HealthCare Pharmaceuticals and [wa]s copyrighted to Bayer Pharmaceuticals Corporation.”

C. Bayer’s Unlawful Off-Label Marketing Scheme as to Avelox.

1. Initial Off-Label Marketing.

328. Bayer was permitted to market Avelox only for those uses approved by the FDA. While doctors may prescribe drugs for off-label uses and patients may take drugs for off-label uses, manufacturers are prohibited from marketing or otherwise promoting drugs for off-label uses. In contravention of this prohibition, Bayer made, or caused to be made, false and/or misleading statements in order to promote Avelox for uses not then-approved by the FDA.

329. Bayer’s efforts to promote Avelox for off-label use began with its initial press release on December 13, 1999 announcing FDA approval of Avelox. In that announcement, Bayer downplayed the cardiac hazard warning required by the FDA, downplayed and misled readers concerning interactions with other drugs, and touted Avelox as effective against resistant
pathogens and/or as a drug that addresses the problem of rising bacterial resistance to drugs, and made unsubstantiated claims of superiority. The FDA immediately rebuked these false and/or misleading statements in a warning letter by Tracy Acker, Pharm.D., Branch Chief (Acting), Division of Drug Marketing, Advertising, and Communications to Martina Ziska, MD, PhD, Deputy Director, Regulatory Affairs, Bayer Corporation. In that letter, the FDA specifically noted that "Bayer has not provided substantial evidence to support the use of Avelox against resistant pathogens. Therefore, these suggestions and implications constitute promotion of an unapproved use."

330. Notwithstanding the FDA’s clear admonitions against suggesting or implying that Avelox is useful against drug resistant bacteria, Bayer’s early promotional efforts through symposia and CME programs regularly did precisely that, with offerings such as: *Antibiotic Selection in the Age of Resistance: A Focus on Newer Agents in Selected Respiratory Tract Infections*, offered June 10, 2000 at the Wyncote Golf Club in Oxford, PA, at which Bayer paid attendees a $250.00 "honorarium" as a "consultant to Bayer Corporation."

331. Again, in June 2001 the FDA sent Bayer a warning letter to Martina Ziska at Bayer concerning false and/or misleading statements made by Bayer’s Avelox representative at the American Society of Health-System Pharmacists’ ("ASHP") Annual Meeting that "Avelox can be used to treat penicillin-resistant *Streptococcus pneumoniae* infections." As set forth in the FDA letter, the FDA-approved labeling only noted success against such strains "in vitro" (*i.e.* in the laboratory) but was not approved for such use since no safety and effectiveness in treating "clinical infections" (*i.e.* infected persons) has been established. The FDA considered the incident "evidence of Bayer’s intent to promote Avelox for unapproved uses."
2. **Off-Label Marketing by Promoting “Early” Usage and/or “Everyday” Indications.**
   
a. **Bayer’s Corporate Strategy.**

332. Contrary to FDA approved labeling limiting Avelox to the treatment of certain pathogens established through testing to be present in the patient, by at least 2001 Bayer began using false and/or misleading statements to convince doctors that it was permissible to use Avelox for “everyday” respiratory and skin infections.

333. In a draft of its “2002 US eBusiness Initiatives Analysis and Recommendations,” by T. Almarayati, Bayer’s strategy for Avelox is stated as “Make Avelox appropriate therapy for ‘everyday’ RTI and skin patients” by “Creat[ing] a multifaceted communications program that expands the confidence pillar.” Indeed, at its September 16, 2003 Avelox Team Meeting, Bayer endorsed using Telesymposia to deliver a message to doctors that it is a good practice to “Introduce Avelox early,” *i.e.* before test results confirm the presence of FDA approved indications. Such false and/or misleading statements constituted impermissible marketing of Avelox for uses not approved by the FDA.

334. Furthermore, not all sinusitis or acute exacerbations of sinusitis are bacterial in origin; it takes several days to establish whether or not a patient has bacterial sinusitis. Clearly, starting ABS patients on Avelox early is an off-label use of the product. An April 1, 2004 email from John Daly describing the MOSAIC e-detail stated that one of the key objections that sales representatives heard from physicians was “I have doubts about the bacterial etiology of AEBS,” and sales representatives were instructed how to overcome this objection. Bayer funded these programs and recommended staffing them with Key Opinion Leaders it had trained to deliver its desired message. Such false and/or misleading statements constituted impermissible marketing of Avelox for uses not approved by the FDA.
b. **Off-Label Promoting at Bayer-Funded CMEs.**

335. CME programs were one of the key vehicles for promoting off-label uses. This is because the CME qualification imparted an air of impartiality whereby Bayer could provide false and/or misleading information about off-label uses, such as initiating therapy prior to obtaining lab results and/or for unapproved indications, all under the guise of conveying “scientific data” about Avelox’s effectiveness against particular bacteria not listed in the labeled indications. This data came from laboratory experiments or clinical trials in foreign countries. While the presentation of such material by an impartial source would be permissible, Bayer funded and influenced these CME’s at every level, from developing the content and paying doctors an “honoraria” for delivering the message, to fully funding the CME in order to induce doctors to attend at no charge. Therefore, these CME programs constituted false and/or misleading statements caused to be made by Bayer as part of its efforts to promote off-label uses of Avelox.

c. **Off-Label Promoting by Bayer Sales Representatives.**

336. According to a summary of Avelox market research reports, the following key messages were found to be among the top 3 most effective for selling Avelox: “Most active against the spectrum of relevant respiratory pathogens — including Strep pneumonia, H. flu, M cat, atypicals and anaerobic bacteria” and “Highly active against all respiratory pathogens including Strep pneumonia, H flu, M cat, atypicals and anaerobic bacteria” (emphasis added). These messages included false and/or misleading statements since they overstated that Avelox was appropriate for indications not approved by the FDA. Nonetheless, these messages were recommended to be included in all marketing materials. In another document, Bayer discussed using two sets of messages for Avelox: one for use in visuals (i.e. the copy-approved message), while the other set could only be used in direct, oral communications so as not to leave behind a paper trail of off-label marketing by Bayer sales representatives.

337. Samples were (and continue to be) routinely used in the prescription drug industry to encourage physicians to prescribe new drugs. The whole idea behind samples is to enable the physician to pass the sample on to the patient and begin therapy immediately. In the case of Avelox, however, FDA labeling indicates that therapy should only be initiated after lab results confirm the presence of one of the pathogens for which the drug is approved, or if certain circumstances strongly indicate the presence of the pathogen prior to test confirmation.

338. In an attempt to increase sales of Avelox, Bayer consistently used 70% of its Avelox marketing budget to distribute samples to doctors. In 2003, Bayer gave away 13,534,754 tablets of Avelox, and in 2004 it gave away an estimated 15.6 million tablets valued at $47 million pursuant to the applicable transfer pricing agreement with its parent company in Germany. Assuming an average 8.8 tablets per prescription, these samples represented 1.5 million prescriptions per year — equivalent to 30% of the tablet volume placed into the market. Furthermore, upon information and belief, Bayer used samples and coupons as inducements to managed care groups and physician groups at risk for pharmaceutical costs (among others) to obtain formulary placement and/or increase prescribing of Avelox. Despite the reduction in effective cost of Avelox, samples and coupons were not reported as part of Medicaid Best Prices disclosures and essentially served as “free goods.”

339. Bayer utilized three different programs under the rubric of “samples.” This included: (a) small quantities of samples; (b) “full” prescription samples; and (c) coupons to be passed on to patients.
a. **Small Samples.**

340. Bayer placed samples of various sizes, but less than the full-prescription, in the hands of physicians in order to stimulate physicians to prescribe Avelox. This practice was designed to send a false and/or misleading message to physicians that it was acceptable to initiate treatment immediately, which is contrary to FDA labeling indicating that Avelox therapy should only be initiated after lab results confirm the presence of one of the pathogens for which the drug is approved, or if certain circumstances strongly indicate the presence prior to test confirmation.

b. **“Full Samples.”**

341. Bayer used full supplies of Avelox as part of certain studies, including its “ACES 2000” program which sought to enroll 15,000 patients by the end of June 2000 to “obtain additional safety and effectiveness information on Avelox [for approved uses] in primary care settings.” Bayer designed the clinical trial in a manner that unnecessarily targeted 5,000 physicians with high prescription volumes in order to maximize the marketing and promotional benefit it could derive from the clinical trial, as previously described.

342. Bayer also used full samples for pure marketing purposes, as reflected in a document from a January 15, 2004 meeting in Rochester, NY concerning the “AVELOX Acceleration Project” which reflects the intention that “For Dabblers, replace samples with full-prescription program, including patient feedback mechanism.” This practice was designed to send a false and/or misleading message to physicians that it was acceptable to initiate treatment immediately, which is contrary to FDA labeling indicating that Avelox therapy should only be initiated after lab results confirm the presence of one of the pathogens for which the drug is approved, or if certain circumstances strongly indicate the presence prior to test confirmation. In addition, these samples were of financial benefit to physicians who participated in shared pharmacy risk programs.
c. **Coupons.**

343. According to a comprehensive document used in Bayer’s Avelox Tactics Brainstorming Workshop, dated September 10, 2004, the Managed Market Programs included $15.00 Coupons which were “designed to help sales representatives handle 3rd tier selling objections or help when both Avelox and Levo are third tier.” At the time of the Tactical Plan “11,800 scripts” had been processed since 2003. Similarly, Bayer’s August 18, 2004 Marketing Review, by Stefan Oelrich, reflects the “Avelox Coupon Program” as part of the “2004 Bronchitis Promotional Programs” and describes it as intended to “penetrate the cash paying patient market.”

344. This practice was designed to send a false and/or misleading message to physicians that it was acceptable to initiate treatment immediately, which is contrary to FDA labeling indicating that Avelox therapy should only be initiated after lab results confirm the presence of one of the pathogens for which the drug is approved, or if certain circumstances strongly indicate the presence prior to test confirmation. This practice was also designed to send false and/or misleading messages to patients that the drug is so safe and effective that it is being widely promoted, without disclosing the limited FDA approved uses and the risks of serious complications.

345. Three invoices from PPS Medical Marketing Group, Inc., 264 Passaic Ave., Fairfield, NJ 07004-2593, reflect administration of coupon programs, specifically: invoice 20306019, dated 6/30/03 reflecting processing of 217 “PHARMA-SCRIPTS” for “AVELOX PILOT PATIENT STARTER CERTIFICATE PROGRAM (26-01); and invoices 20306025, dated 6/30/03, and 20308050, dated 8/29/03, reflecting the processing of 775 and 639 “PATIENT REBATES” for “AVELOX COUPON PROGRAM 26-02-01.”
346. To the extent these coupons were used by a beneficiary of a government-funded healthcare program, they constituted the offer or transfer of remuneration to a beneficiary in violation of 42 U.S.C. § 1320a-7a(5).

IX. THE GOVERNMENT HAS BEEN DAMAGED AS A RESULT OF BAYER’S CONDUCT.

347. Bayer knowingly engaged in the fraudulent conduct described in this Complaint to increase its market share and increase revenues. Moreover, Bayer provided false information to the Government to conceal and avoid its obligation to pay larger Medicaid rebates.

348. By paying kickbacks to physicians and hospitals, providing coupons to beneficiaries and promoting off-label uses of Trasylol and Avelox, Bayer violated applicable statutes and regulations, including, but not limited to, the Anti-Kickback Act, the Medicare/Medicaid Anti-Kickback Statute and the False Claims Act. In violating the law, Bayer encouraged over-utilization of potentially unnecessary prescription drugs by doctors, induced excessive payments from the Federal Government-funded health insurance programs, undermined physicians’ and patients’ freedom to choose appropriate drug therapies, which created the potential for patient harm, and generated additional income. In addition, recent clinical trials suggested that the Federal and state governments were also damaged by having to pay for the consequences of inappropriate drug utilization including hospitalization and dialysis expenses for patients suffering from adverse events for Trasylol.

349. Had the Federal Government-funded health insurance programs been aware that Trasylol and Avelox were prescribed as a result of the conduct alleged in this Complaint, they would not have paid the claims that were caused to be submitted as a result of the Defendants’ wrongdoing.
350. On information and belief, in an effort to conceal its actions, Bayer submitted false pricing data to the Government to avoid paying higher Medicaid rebates. As a result, Federal Government-funded health insurance programs paid reimbursements for Bayer prescription drugs that were prescribed by physicians, in part, because of the payment of unlawful kickbacks by Bayer. Moreover, Bayer reaped huge amounts of profit through its off-label promotion scheme which would not have been paid had the Government been aware that it was paying for off-label uses.

X. DEFENDANTS' UNLAWFUL RETALIATION AND CONDUCT.

351. As a result of the concerns expressed by Relator herein and similar concerns expressed by Relator in her capacity as a member of the extended marketing team and marketing research team for Baycol, Relator is informed and believes that Bayer engaged in threats, harassment and discrimination and other negative employment actions with respect to Relator as more particularly described below.

352. Relator told her supervisor, Carol D’Eugenio, Deputy Director in the Strategic Analysis department, that she would not participate in efforts to disguise the Cardiac Team Meetings (“CTM”) as valid market research. D’Eugenio was fully supportive of Relator.

353. Relator also told external Baycol lawyers that she was not happy being asked to work on Trasylol CTMs because they were “basically fraudulent.”

354. Relator complained to Bill Allen (former Trasylol Product Manager), Randy Santiago of Scientific Affairs and others about the fact that the CTMs were being publicly presented as market research or advisory meetings but were, in fact, primarily promotional in nature.

355. During the spring of 2003, Relator again discussed with Carol D’Eugenio her concerns over the fraudulent nature of the CTMs.
356. In June 2003, Relator applied for a Project Manager job for which she was fully qualified. Her application was ignored.

357. In July 2003, Relator learned from Vice President Nancy Bryan that someone in higher management did not want Relator on the New Products Evaluation Team.

358. Relator questioned Carol D'Eugenio as to why she was being blackballed. D'Eugenio agreed with Relator, but could not determine why Relator was being blackballed.

359. In March 2004, Relator requested a meeting and met with Dean Slack, the Director of the Strategic Analysis Department and D'Eugenio's direct supervisor, to again discuss her concerns regarding the fact that the CTM meetings were fraudulent, promotional in nature (including off-label promotion), and involved physician kick-backs. As a result of this meeting, Slack reportedly contacted David Reed, Bayer legal counsel, and also discussed her concerns with Stanley Horton, Director for Trasylol. As a result of these discussions, Slack and Horton apparently agreed upon some changes to an internal CTM justification document to clarify the fact that these meetings were not "market research." Despite these efforts, Relator does not believe that there were any actual changes made to the meetings. In April 2004, Relator was excluded from the Business Plan process for Trasylol, and two unqualified members of the department were listed in her place.

360. In June 2004, Relator attended a CTM which was also attended by Reed, the same internal attorney that Slack had reportedly contacted to discuss Relator's concerns after the March meeting referenced in the preceding paragraph. During discussions with Reed during this June 2004 meeting, Relator made it clear that she still had concerns regarding the CTMs.

361. During about 2004, Relator and Stanley Horton, Director for Trasylol and formerly for Avelox IV, had several interactions where Relator clearly communicated that she
would not support, condone or otherwise enable any behavior that she believed to be fraudulent. On at least two occasions, in response to these discussions, Horton referenced having his bonus tied to the financial success of his products and his desire to get the referenced bonuses. He also stated he thought Relator had the same incentives. These interactions included a meeting in August 2004, at Horton’s request, during which Horton indicated that he needed a market researcher who was going to be “supportive,” and asked if Relator could be trusted to be “supportive.” Relator replied that she was willing to be “supportive” but was unwilling to lie and that she was not willing to support his efforts to cover up what was going on concerning what she considered to be fraudulent behavior.

362. Approximately one month later, in September 2004, Relator was indirectly notified that she was being terminated as part of a workforce reduction implemented as part of a strategic alliance with Schering Plough. Relator was terminated by Bayer effective January 1, 2005.

363. Relator’s job function, however, was not eliminated. Instead, Relator was replaced by another Bayer employee who was less qualified and had less experience in market research and the therapeutic area than Relator (contrary to policies stated in Bayer Human Resources Employee Handbook). Carol D’Eugenio, Relator’s boss (who had just given Relator a good performance appraisal in August 2004 with no areas identified as needing improvement), stated to Relator that she felt Relator’s employment was being terminated because she “stood up to Stan.”
XI. CLAIMS FOR RELIEF.

FIRST CAUSE OF ACTION
False Claims Act: Presentation of False Claims
(31 U.S.C. § 3729(a)(1))

364. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 363 of this Third Amended Complaint as if fully set forth herein.

365. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have "knowingly present[ed], or cause[d] to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval" in violation of 31 U.S.C. § 3729(a)(1); and for which Defendants are liable for treble damages plus a civil penalty of $5,000 - $11,000 for each such claim, pursuant to 31 U.S.C. § 3729(a).

SECOND CAUSE OF ACTION
False Claims Act: Making or Using False Record or Statement to Cause Claim to be Paid
(31 U.S.C. § 3729(a)(2))

366. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 363 of this Third Amended Complaint as if fully set forth herein.

367. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement [i.e., the false certifications and representations made or caused to be made by the Defendants] to get a false or fraudulent claim paid or approved by the Government" in violation of 31 U.S.C. § 3729(a)(2); and for which Defendants are liable for treble damages plus a civil penalty of $5,000 - $11,000 for each such claim, pursuant to 31 U.S.C. § 3729(a).
THIRD CAUSE OF ACTION
False Claims Act: Making or Using False Record or Statement to Avoid an Obligation to Refund
(31 U.S.C. § 3729(a)(7))

368. Relator repeats and incorporates by reference the allegations contained in
Paragraphs 1 through 363 of this Third Amended Complaint as if fully set forth herein.

369. As more particularly set forth in the foregoing paragraphs, by virtue of the acts
alleged herein the Defendants knowingly made, used or caused to be made or used false records
or false statements — *i.e.*, the false certifications made or caused to be made by the Defendants
— to conceal, avoid or decrease an obligation to pay or transmit money or property to the United
States; and for which Defendants are liable for treble damages plus a civil penalty of $5,000
$11,000 for each such claim, pursuant to 31 U.S.C. § 3729(a).

FOURTH CAUSE OF ACTION
False Claims Act: Conspiracy
(31 U.S.C. § 3729(a)(3))

370. Relator repeats and incorporates by reference the allegations contained in
Paragraphs 1 through 363 of this Third Amended Complaint as if fully set forth herein.

371. As more particularly set forth in the foregoing paragraphs, by virtue of the acts
alleged herein the Defendants conspired to get false or fraudulent claims paid by the United
States and performed one or more acts to effect payment of false or fraudulent claims by the
United States; and for which Defendants are liable for treble damages plus a civil penalty of
$5,000 - $11,000 for each such claim, pursuant to 31 U.S.C. § 3729(a).

FIFTH CAUSE OF ACTION
False Claims Act: Retaliation
(31 U.S.C. § 3730(b))

372. Relator repeats and incorporates by reference the allegations contained in
Paragraphs 1 through 371 of the Third Amended Complaint as if fully set forth herein.
373. As more particularly set forth in the foregoing Paragraphs by virtue of the acts alleged herein, and in particular paragraphs 351 to 363, the Defendants discharged, demoted, threatened, harassed and/or discriminated against the Relator in the terms and conditions of her employment after Relator lawfully reported what she believed to be fraudulent conduct or wrongdoing to her superiors in violation of 31 U.S.C. 3730(h). Relator seeks compensatory damages and damages for emotional distress and other appropriate statutory relief pursuant to this section.

**SIXTH CAUSE OF ACTION**

**False or Fraudulent Claims that Were the Product of Violations of the Medicare/Medicaid Anti-Kickback Statute**

374. Relator repeats and reincorporates by reference the allegations contained in Paragraphs 1 through 363 of this Third Amended Complaint as if fully set forth herein.

375. By engaging in the conduct described in the foregoing Paragraphs, Defendants have violated 42 U.S.C. §§ 1320a-7a.

376. In particular, Defendants have knowingly caused physicians and other healthcare providers and/or beneficiaries to present claims to the United States Government and to Medicaid that were the product of the payment of the above-described kickbacks which constitute remuneration to increase the level of business in violation of 42 U.S.C. § 1320a-7a(7) which incorporates by reference 42 U.S.C. §§ 1320a-7b(b)(1)&(2); and for which Defendants are liable for a civil penalty of $50,000 for each act that violated 42 U.S.C. § 1320a-7a(7), pursuant to 42 U.S.C. § 1320a-7a.

377. In further particular, Defendants have knowingly offered or transferred remuneration, in the form of coupons, to beneficiaries of federally funded healthcare programs in violation of 42 U.S.C. § 1320a-7a(5); and for which Defendants are liable for a civil penalty of $10,000 for each act that violated 42 U.S.C. § 1320a-7a(5), pursuant to 42 U.S.C. § 1320a-7a.
378. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks or other prohibited forms of remuneration, the Government would not otherwise have paid for and/or reimbursed.

SEVENTH CAUSE OF ACTION
False or Fraudulent Claims that Were the Product of Violations of the Anti-Kickback Act of 1986

379. Plaintiff repeats and incorporates by reference the allegations contained in paragraphs 1 through 363 of this Third Amended Complaint as if fully set forth herein.

380. By engaging in the conduct described in the foregoing Paragraphs, Defendants have violated 41 U.S.C. §§ 52-53.

381. In particular, Defendants have knowingly caused physicians, other healthcare providers and/or beneficiaries to present claims to the United States Government and to Medicaid that were the product of the payment of the above-described kickbacks. The payment of kickbacks to induce prescriptions constitutes a "thing of value . . . for the purpose of improperly obtaining or rewarding favorable treatment," which were designed to and in fact did increase the level of business in violation of the Anti-Kickback Act of 1986.

382. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.
EIGHTH CAUSE OF ACTION
False or Fraudulent Claims that Were the Product of Off-Label Marketing

383. Plaintiff repeats and incorporates by reference the allegations contained in paragraphs 1 through 363 of this Third Amended Complaint as if fully set forth herein.

384. By engaging in the conduct described in the foregoing Paragraphs, Defendants have violated the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97.

385. In particular, Defendants have knowingly caused physicians, other healthcare providers and/or beneficiaries to present claims to the United States Government and to Medicaid that were the product of the Defendants’ promotion of drugs for off-label uses in violation of 21 U.S.C. § 331 (d) and attendant Federal regulations.

386. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of Defendants’ prohibited off-label marketing, the Government would not otherwise have paid for and/or reimbursed.

NINTH CAUSE OF ACTION
False or Fraudulent Claims that Were the Product of “Misbranding” Drugs

387. Plaintiff repeats and incorporates by reference the allegations contained in paragraphs 1 through 363 of this Third Amended Complaint as if fully set forth herein.

388. By engaging in the conduct described in the foregoing Paragraphs, Defendants have violated the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97.

389. In particular, Defendants have knowingly caused physicians, other healthcare providers and/or beneficiaries to present claims to the United States Government and to Medicaid that were the product of the Defendants’ promotion of drugs for off-label uses in violation of Federal laws including, 21 U.S.C. §§ 331 “Prohibited Acts,” 352 “Misbranded drugs and devices,” 355 “New drugs,” and 360aaa “Requirements for dissemination of treatment
information on drugs or devices,” and attendant Federal regulations. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of Defendants’ prohibited misbranding, the Government would not otherwise have paid for and/or reimbursed.

**TENTH CAUSE OF ACTION**
*California False Claims Act*
*(Cal. Govt. Code §§ 12650 et seq.)*

390. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

391. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Govt. Code §§ 12650 et seq.

392. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the state or of any political subdivision thereof false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

393. The State of California, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

394. By reason of these payments, the State of California has been damaged, and continues to be damaged in a substantial amount.

**ELEVENTH CAUSE OF ACTION**
*Delaware False Claims and Reporting Act*
*(6 Del Code §§ 1201 et seq.)*

395. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.
396. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, 6 Del C. §§ 1201 et seq.

397. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Government false or fraudulent claims for the improper payment or approval of prescriptions for Trasylo1 and Avelox, and used false or fraudulent records to accomplish this purpose.

398. The State of Delaware, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

399. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged in a substantial amount.

**TWELFTH CAUSE OF ACTION**

**Florida False Claims Act**

(Fla. Stat. §§ 68.081 et seq.)

400. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

401. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. §§ 68.081 et seq.

402. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of an agency false or fraudulent claims for the improper payment or approval of prescriptions for Trasylo1 and Avelox, and used false or fraudulent records to accomplish this purpose.

403. The State of Florida, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

404. By reason of these payments, the State of Florida has been damaged, and continues to be damaged in a substantial amount.
THIRTEENTH CAUSE OF ACTION
Georgia False Medicaid Claims Act
(O.C.G.A. §§ 49-4-168 et seq.)

405. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

406. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 et seq.

407. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Georgia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

408. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

409. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

FOURTEENTH CAUSE OF ACTION
Hawaii False Claims Act
(Haw. Rev. Stat. §§ 661-21 et seq.)

410. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

411. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 et seq.

412. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the State of Hawaii false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.
413. The State of Hawaii, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

414. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged in a substantial amount.

**FIFTEENTH CAUSE OF ACTION**

**Illinois Whistleblower Reward and Protection Act**
(740 Ill. Comp. Stat. §§ 175/1 *et seq.*)

415. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

416. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*

417. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the State or a member of the Guard false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

418. The State of Illinois, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

419. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged in a substantial amount.

**SIXTEENTH CAUSE OF ACTION**

**Indiana False Claims and Whistleblower Protection Act**
(In. Code §§ 5-11-5.5 *et seq.*)

420. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

421. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, In. Code §§ 5-11-5.5 *et seq.*
422. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Indiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

423. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

424. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

SEVENTEENTH CAUSE OF ACTION

Louisiana False Claims Act
(46 La. Rev. Stat. Ch. 3 §§ 437.1 et seq.)

425. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

426. This is a claim for treble damages and civil penalties under the Louisiana False Claims Act, 46 La. Rev. Stat. Ch. 3 §§ 437.1 et seq.

427. By virtue of the acts described above, Defendants offered or paid remuneration, including but not limited to kickbacks, directly or indirectly, overtly or covertly, in cash or in kind, for a good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

428. By virtue of the acts described above, Defendants knowingly presented or caused to be presented a false or fraudulent claim to the State of Louisiana.

429. By virtue of the acts described above, Defendants knowingly engaged in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.
430. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged in a substantial amount.

**EIGHTEENTH CAUSE OF ACTION**

**Massachusetts False Claims Act**

(Mass. Gen. Laws ch. 12 §§ 5A et seq.)

431. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

432. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 §§ 5A et seq.

433. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

434. The State of Massachusetts, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

435. By reason of these payments, the State of Massachusetts has been damaged, and continues to be damaged in a substantial amount.

**NINETEENTH CAUSE OF ACTION**

**Michigan Medicaid False Claim Act**

(M.C.L.S. §§ 400.601 et seq.)

436. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

437. This is a claim for civil penalties under the Michigan Medicaid False Claims Act, MCLS §§ 400.601 et seq.

438. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be made to the Michigan Medicaid Program false statements or

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false representations of material fact in the application for Medicaid benefits and for use in
determining rights to Medicaid benefits.

439. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of
the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

440. By reason of these payments, the Michigan Medicaid Program has been damaged,
and continues to be damaged in a substantial amount.

TWENTIETH CAUSE OF ACTION
Montana False Claims Act
(Mont. Code, §§ 17-8-401 et seq.)

441. Plaintiff re-alleges and incorporates by reference herein the allegations previously
alleged.

442. This is a claim for treble damages and civil penalties under the Montana False
Claims Act, Mont. Code §§ 17-8-401 et seq.

443. By virtue of the submissions of non-reimbursable claims described above,
Defendants knowingly caused to be presented to the Montana Medicaid Program false or
fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox,
and used false or fraudulent records to accomplish this purpose.

444. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of
the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

445. By reason of these payments, the Montana Medicaid Program has been damaged,
and continues to be damaged in a substantial amount.

TWENTY-FIRST CAUSE OF ACTION
Nevada False Claims Act
(Nev. Rev. Stat., §§ 357.010 et seq.)

446. Plaintiff re-alleges and incorporates by reference herein the allegations previously
alleged.
447. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 et seq.

448. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

449. The State of Nevada, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

450. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged in a substantial amount.

TWENTY-SECOND CAUSE OF ACTION
New Hampshire Medicaid Fraud and False Claims

451. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

452. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61, et seq.

453. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

454. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.
455. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in excess of $5,000.

**TWENTY-THIRD CAUSE OF ACTION**

*New Jersey False Claims Act*  

456. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

457. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N. J. Stat. Ann. §§ 2A:32C-1 et seq.

458. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an employee, officer or agent of New Jersey, or to any other contractor, grantee or other recipient of New Jersey funds, false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

459. The State of New Jersey, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

460. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged in a substantial amount.

**TWENTY-FOURTH CAUSE OF ACTION**

*New Mexico False Claims Act*  
*(N.M.S.A. §§ 27-14-1 et seq.)*

461. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

462. This is a claim for treble damages and civil penalties under the New Mexico False Claims Act, N.M.S.A. §§ 27-14-1 et seq.
463. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

464. The Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

465. By reason of these payments, the Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-FIFTH CAUSE OF ACTION
New York False Claims Act
(N.Y. Fin. Law §§ 187 et seq.)

466. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

467. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 et seq.

468. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an employee, officer or agent of the state or a local government false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

469. The State of New York, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

470. By reason of these payments, the State of New York has been damaged, and continues to be damaged in a substantial amount.
TWENTY-SIXTH CAUSE OF ACTION

North Carolina False Claims Act

471. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

472. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N. C. Gen. Stat. Ann. §§ 1-605 et seq.

473. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the State of North Carolina false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

474. The State of North Carolina, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

475. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged in a substantial amount.

TWENTY-SEVENTH CAUSE OF ACTION

Oklahoma Medicaid False Claims Act

476. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

477. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. §§ 5053 et seq.

478. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the State of Oklahoma false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.
479. The State of Oklahoma, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

480. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-EIGHTH CAUSE OF ACTION
Rhode Island False Claims Act
(R. I. St. §§ 9-1.1-1 et seq.)

481. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

482. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act, R. I. St. §§ 9-1.1-1 et seq.

483. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the state or a member of the guard false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

484. The State of Rhode Island, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

485. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged in a substantial amount.

TWENTY-NINTH CAUSE OF ACTION
Tennessee Medicaid False Claims Act
(Tenn. Code §§ 71-5-181 et seq.)

486. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

487. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code §§ 71-5-181 et seq.
488. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the state false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

489. The State of Tennessee, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

490. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged in a substantial amount.

THIRTIETH CAUSE OF ACTION
Texas Medicaid Fraud Prevention Law

491. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

492. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001 et seq.

493. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly made or caused to be made false statements or misrepresentations of material fact, and knowingly concealed or failed to disclose information to permit persons to receive benefits or payments under the Medicaid program for Trasylol and Avelox that were not authorized or that were greater than the benefit or payment that was authorized, and used false or fraudulent records to accomplish this purpose.

494. Defendants knowingly paid, charged, solicited accepted or received, in addition to an amount paid under the Medicaid program, a gift, money, a donation or other consideration as a condition to the provision of a service or product or the continued provision of a service or
product where cost of the service or product was paid for, in whole or in part, under the Medicaid program.

495. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

496. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

THIRTY-FIRST CAUSE OF ACTION
Virginia Fraud against Taxpayers Act
(Va. Code §§ 8.01-216.1 et seq.)

497. Plaintiff re-alleges and incorporates by reference herein the allegations previously alleged.

498. This is a claim for treble damages and civil penalties under the Virginia Fraud against Taxpayers Act, Va. Code §§ 8.01-216.1 et seq.

499. By virtue of the submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the Commonwealth false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox, and used false or fraudulent records to accomplish this purpose.

500. The Virginia Commonwealth Government, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

501. By reason of these payments, the Virginia Commonwealth Government has been damaged, and continues to be damaged in a substantial amount.
THIRTY-SECOND CAUSE OF ACTION
Wisconsin False Claims Act
(Wis. Stat. Ann. §§ 20.931 (1) et seq.)

502. Plaintiff re-alleges and incorporates by reference herein the allegations previously
alleged.

503. This is a claim for treble damages and civil penalties under the Wisconsin False

504. By virtue of the submissions of non-reimbursable claims described above,
Defendants knowingly caused to be presented to an officer, employee or agent of Wisconsin
false or fraudulent claims for the improper payment or approval of prescriptions for Trasylol and
Avelox, and used false or fraudulent records to accomplish this purpose.

505. The State of Wisconsin, unaware of the falsity or fraudulent nature of the claims
caused by Defendants, paid for claims that otherwise would not have been allowed.

506. By reason of these payments, the State of Wisconsin has been damaged, and
continues to be damaged in a substantial amount.

THIRTY-THIRD CAUSE OF ACTION
District of Columbia False Claims Act
(D.C. Code §§ 2-308.13 et seq.)

507. Plaintiff re-alleges and incorporates by reference herein the allegations previously
alleged.

508. This is a claim for treble damages and civil penalties under the District of
Columbia False Claims Act, D.C. Code §§ 2-308.13 et seq.

509. By virtue of the submissions of non-reimbursable claims described above,
Defendants knowingly caused to be presented to an officer or employee of the District false or
fraudulent claims for the improper payment or approval of prescriptions for Trasylol and Avelox,
and used false or fraudulent records to accomplish this purpose.
510. The District of Columbia, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

511. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged in a substantial amount.

THIRTY-FOURTH CAUSE OF ACTION

Defendants' Intentional/Reckless Infliction of Severe Emotional Distress upon Plaintiff

512. Plaintiff re-alleges and incorporates by reference the allegations previously alleged herein.

513. Defendants subjected Plaintiff to retaliatory harassment creating a hostile, abusive and intimidating work environment that directly led to her mental and emotional distress;

514. Defendants' conduct is intolerable in a civilized society. As a direct and proximate result of (i) working on products which caused patient injury and deaths, (ii) being aware that Bayer was not doing what was necessary to prevent such injury (iii) objecting to such conduct, and (iv) the retaliatory conduct Plaintiff experienced as a result of expressing her concerns, Plaintiff has suffered and continues to suffer damage in the form of extreme emotional and mental anguish, humiliation, lost income and benefits.

XII. DEMANDS FOR RELIEF.

WHEREFORE, Relator, on behalf of the United States Government, demands judgment against the above-named Defendants, ordering that:

As to the Federal Claims:

a. Pursuant to 31 U.S.C. § 3729(a), Defendants pay: an amount equal to three times the amount of damages the United States Government has sustained as a result of Defendants' actions, which Relator currently estimates to be in the hundreds of millions of dollars; plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C.
§§ 3729, *et seq.*, or such other penalty as the law may permit and/or require for each violation of other laws which governed Defendants’ conduct, *i.e.* $50,000 for each violation of 42 U.S.C. § 1320a-7a(7) of the Medicare/Medicaid Anti-Kickback Statute.

b. Relator be awarded her realtor’s share of the judgment to the maximum amount provided pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. Relator be awarded all costs and expenses of this action, including attorneys’ fees as provided by 31 U.S.C. § 3730(o) and any other applicable provision of the law; and

d. Relator be awarded such relief as is appropriate under the provisions of 31 U.S.C. § 3730(h) of the False Claims Act for retaliatory discharge, including:

1. two times the amount of back pay with appropriate interest;
2. compensation for special damages, including damages for emotional distress, sustained by Relator in an amount to be determined at trial;
3. litigation costs and reasonable attorney’s fees;
4. such punitive damages as may be awarded under applicable law; and
5. reasonable attorney’s fees and litigation costs in connection with Relator’s Section H claim; and

e. Relator and the United States of America be awarded such other and further relief as the Court may deem to be just and proper.

**As to the State Claims:**

f. As provided by:

Cal. Govt. Code §§12650 *et seq.*;
6 Del. C. §§ 1201 *et seq.*;
Fla. Stat. Ann. §§ 68.081 *et seq.*;
O.C.G.A. §§ 49-4-168 *et seq.*;
740 Ill. Comp. Stat. §§ 175/1 et seq.;
In. Code §§ 5-11-5.5 et seq.;
Mass. Gen. Laws Ch. 12 §§ 5A et seq.;
Mont. Code §§ 17-8-401 et seq.;
N.M.S.A. §§ 27-14-1 et seq.;
N.Y. Fin. Law §§ 187 et seq.;
R. I. St. §§ 9-1.1-1 et seq.;
Tenn. Code Ann. §§ 71-5-181 et seq.;
Va. Code Ann. § 8.01-216.1 et seq.;
Wis. Stat. Ann. §§20.931 (1) et seq.; and
D.C. Code Ann. §§ 2-308.13 et seq.;

Relator and each named State Plaintiff be awarded statutory damages in an amount equal to three
times the amount of actual damages sustained by each State as a result of Defendants’ actions, as
well as the maximum statutory civil penalty for each violation by Defendants within each State;
Relator be awarded her relator’s share of any judgment; Relator be awarded all costs and
expenses associated with each of the pendent State claims, plus attorney’s fees.

As provided by MCLS §§ 400.601 et seq., Relator and the State of Michigan be
awarded the maximum statutory civil penalty for each violation by Defendants; Relator be
awarded her relator’s share of any judgment; Relator be awarded all costs and expenses
associated with each of the pendent State claims, plus attorney’s fees

Relator and the State Plaintiffs be awarded such other and further relief as the
Court may deem to be just and proper.
XIII. TRIAL BY JURY.

Relator hereby demands a trial by jury as to all issues.

Dated: New York, New York
February 19, 2010

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