STATE OF SOUTH CAROLINA	) IN THE COURT OF COMMON PLEAS
	)
COUNTY OF SPARTANBURG	) FOR THE SEVENTH JUDICIAL CIRCUIT
	)
STATE OF SOUTH CAROLINA ex rel. **Alan Wilson,** in his capacity as Attorney General of the State of South Carolina,	)
	)
Plaintiff,	)
	)
vs.	)
	)
GLAXOSMITHKLINE, LLC, formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	) **Case No.** _____
	)
Defendant.	)
_____	)

2011-CP-42-2174

FILED
CLERK OF COURT
SPARTANBURG COUNTY
2011 MAY 17 AM 9:29
HOPE BLACKLEY

CIVIL ACTION COMPLAINT

Plaintiff, the State of South Carolina (hereinafter "the State"), by and through its Attorney General, Alan Wilson, hereby complains of Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"). This is a civil action for damages, restitution, civil penalties, and other legal and equitable relief for violations of S.C. Code Ann. §§ 39-5-10 *et seq.* and 43-7-60 *et seq.* and for other state common law causes of action stated herein brought by the South Carolina Attorney General in the exercise of his constitutional, statutory and common law powers. This action arises out of GSK's wrongful and illegal marketing, sale and promotion of the diabetes medication, rosiglitazone maleate, sold by GSK under the trade names Avandia®, Avandamet® and Avandaryl® (hereinafter referred to as "Avandia").

PARTIES

1. Plaintiff, the State of South Carolina, is a body politic created by the Constitution and laws of the State of South Carolina, and as such, is not a citizen of any State.

2. Attorney General Alan Wilson is the duly-elected and present Attorney General of the State of South Carolina. The Attorney General is statutorily authorized to initiate and maintain this action, and does so, pursuant to S.C. Code Ann. § 1-7-40, S.C. Code Ann. 39-5-10 *et seq.*, and S.C. Code Ann. § 43-7-60(E), 90. This action is also maintained pursuant to the Attorney General's constitutional and common law powers.

3. The Defendant GSK purports to be a limited liability corporation organized and existing under the laws of the State of Delaware but which has its principal place of business at One Franklin Plaza, 200 N. 16th Street, Philadelphia, Pennsylvania 19102. GSK is authorized to conduct business in South Carolina, and its registered agent for service of process is Corporation Service Company, 1703 Laurel Street, Columbia, South Carolina, 29201.

4. At all times material hereto, Defendant GSK was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

5. At all times material hereto, Defendant GSK did business within the State of South Carolina by promoting, marketing, distributing and/or selling Avandia to the State of South Carolina, its departments, agencies, instrumentalities, and/or contractors, and to the general public.

6. Defendant GSK includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors,

successors and assigns and their present officers, directors, employees, agents, representatives, and other persons acting on their behalf.

7. Upon information and belief, in committing the acts alleged herein, each and every managing agent, agent, representative, and/or employee of the Defendant was working within the course and scope of said agency, representation and/or employment with the knowledge, consent, ratification, and authorization of GSK and its directors, officers, and/or managing agents.

8. Upon information and belief, Defendant GSK was formed as a result of the merger of pharmaceutical corporations Glaxo Wellcome, Inc. and SmithKline Beecham, Inc.

JURISDICTION AND VENUE

9. The jurisdiction of this Court is founded upon S.C. Const. Ann. Art. V §11 which gives the Circuit Court general jurisdiction over civil actions.

10. This Court has personal jurisdiction over Defendant because Defendant does business in South Carolina and/or has the requisite minimum contacts with South Carolina necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also being within the contemplation of the South Carolina "long arm" statute, S.C. Code Ann. §36-2-803.

11. Defendant did distribute, supply, market, sell, promote, advertise, warn and otherwise distribute Avandia in South Carolina and specifically in Spartanburg County.

12. Venue in this Court is proper pursuant to the Rules of the South Carolina Supreme Court and the South Carolina Code.

13. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction

pursuant to 28 U.S.C. §1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against Defendant. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy which is founded upon federal law. The issues presented in the allegations of the instant Complaint do not implicate significant federal issues; do not turn on the substantial federal interpretation of federal law; nor do they raise a substantial federal question. Indeed, Plaintiff expressly avers that the only causes of action claimed, and the only remedies sought herein, are for those founded upon the statutory, common, and decisional laws of the State of South Carolina. Further, assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any improvident and dilatory attempt by Defendant to remove this case to federal court would be without a reasonable legal basis in fact or law.

THE STATE'S PROGRAMS

14. The State of South Carolina's Medicaid program provides medical assistance to low income state residents. The primary purpose of the Medicaid program is to enable the State to furnish medical assistance on behalf of families with dependent children and of aged, blind or disabled individuals whose income and resources are insufficient to meet the costs of necessary medical services. The Medicaid program was created under South Carolina state law, and is administered by the South Carolina Department of Health and Human Services.

15. The South Carolina State Health Plan ("SHP") is a State-sponsored program that administers prescription drug benefits for the State's SHP participants. The SHP is a division of the Employee Insurance Program that is run by the South Carolina Budget and

Control Board. The SHP reimburses pharmacies, doctors and hospitals for prescriptions written for and dispensed to SHP participants.

16. The State relies on persons receiving payments and benefits from the Medicaid and SHP programs to "turn square corners" and to provide truthful and accurate information in their dealings with the Medicaid and SHP programs, and to abide by South Carolina law. However, the State's practical ability to monitor or police every one of the millions of claims submitted each year represents a loophole in the structure of the Medicaid and SHP programs.

17. GSK has recognized and aggressively exploited this loophole in several ways. First, GSK has engaged in a direct, illegal, nationwide marketing program to promote the use of Avandia, asserting that Avandia was a "significant advance" in diabetes treatment. GSK affirmatively represented that Avandia was superior to existing drugs, such as metformin and sulfonylureas, at lowering diabetics' blood sugar, a critical goal in diabetes treatment. GSK did not just fail to disclose the potential cardiovascular risks Avandia posed, which include heart attacks and sudden cardiac death, it affirmatively represented that Avandia could reduce diabetics' cardiovascular risks. GSK has conducted this marketing effort knowing that prescriptions for Avandia are generally reimbursed by the South Carolina Medicaid and SHP programs.

18. Upon information and belief, GSK sought to increase the market for Avandia by manipulating South Carolina Medicaid and SHP procedures, and by falsely representing to the State, and to the public in general, the safety and efficacy of Avandia. As a result of GSK's efforts and exploitation of the South Carolina Medicaid and SHP programs, the State has dispensed millions of dollars of Medicaid and SHP funds in purchasing Avandia

prescriptions, for which it must recover under South Carolina law. In addition, under South Carolina law, the State must also recover its costs of care for those Medicaid and SHP participants rendered chronically ill or injured by Avandia's undisclosed side effects, as set forth herein.

FACTUAL BACKGROUND

19. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use the insulin it manages to produce.

20. Avandia, created and marketed by GSK, is purportedly designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby assisting in blood-sugar control. It also is combined with metformin and sold as Advandamet®, and also was developed and sold as Avandaryl®. GSK began developing Avandia in the mid 1990's, and, in 1999, GSK received approval from the FDA to market Avandia in the United States. Avandia is a member of the class of drugs known as thiazolidinediones ("TZDs").

21. GSK's product Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, stroke, and/or severe injury to the heart leading to cardiac arrest and death.

22. GSK knew or should have known about these adverse side effects since before it received FDA approval for Avandia in 1999, but failed to adequately warn the consumer public, prescribers, the FDA, and/or the State of South Carolina of these life threatening cardiovascular risks.

23. In preparation for seeking the FDA's approval to put the drug on the market, GSK

conducted five clinical studies between 1996 and 1998 that revealed a high number of deaths among patients treated with Avandia. Eight Avandia patients suffered heart attacks or cardiac deaths, as compared to only three in the control group. This data alone should have alerted GSK to Avandia's increased cardiovascular risk. Nevertheless, GSK failed to act on this data and continued its plan to seek FDA approval for Avandia.

24. On November 25, 1998, in spite of its knowledge of the drug's increased cardiovascular risks, GSK submitted Avandia's New Drug Application ("NDA") to the FDA.

25. Beginning in early 1999, while Avandia's New Drug Application was under consideration by the FDA, GSK's false and deceptive Avandia marketing campaign took form. GSK's targeted competitor drugs were not only other TZDs. Rather, GSK sought to achieve dominance in the Type 2 diabetes market by becoming the preeminent "first-line" drug of choice. It sought to replace not only other TZDs but also metformin and sulfonylureas—the established, ***much*** safer, and ***much*** cheaper diabetes drugs.

26. GSK manufactured Avandia and marketed it as a "wonder drug." From its launch in 1999 until independent medical studies made public Avandia's true medical risks, GSK successfully executed a massive, aggressive marketing campaign designed to obfuscate the risks of Avandia, asserting that Avandia was a "significant advance" in diabetes treatment. GSK affirmatively represented that Avandia was superior to existing drugs, such as metformin and sulfonylureas, at lowering diabetics' blood sugar, a critical goal in diabetes treatment. GSK did not just fail to disclose the potential cardiovascular risks Avandia posed, which include heart attacks and sudden cardiac death, it affirmatively represented that Avandia could reduce diabetics' cardiovascular risks. GSK knew or should have

known that these representations were not true and likely to deceive. There simply was no scientific support for them. In fact, GSK knew or should have known even before the launch in 1999 that Avandia was no better at lowering blood sugar than existing medications, and that it posed serious increased cardiovascular risks.

27. GSK spent hundreds of millions of dollars in a far-reaching, massive, and widespread promotional campaign to drive Avandia's sales. A highly sophisticated marketer of pharmaceutical products, GSK used its substantial sales, marketing, and public relations machines to create a false and misleading impression of the drug's safety and efficacy among consumers, prescribers, private insurers, public health care providers, public entities, and government payors, including the State of South Carolina.

28. Since 1999, GSK has spent millions of dollars on Direct to Consumer ("DTC") print and television advertising, aimed at convincing patients, including South Carolina Medicaid and SHP participants, to request Avandia from their doctors. GSK's marketing campaign also targeted prescribers as well as the individuals, groups, and entities responsible for selecting the drugs covered by health coverage plans and/or included on pharmacy formularies. GSK sought to influence these targets through, among other tactics, print media, misleading promotional materials, lavish company-sponsored dinners, and "conferences." GSK produced and distributed "studies" whose sole purpose was to advance the company's marketing message and which were intended to, and did, deceive consumers, physicians, private insurers, public health care providers, public entities, and government payors, including the State of South Carolina.

29. GSK's Avandia message had two key components. First, GSK propagated the message that Avandia was better at lowering blood sugar than other established drugs. That

is, Avandia had superior efficacy. GSK also represented that patients could stay on Avandia longer than the older drugs. Second, GSK represented that, unlike the established diabetes drugs, Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks. The notion that Avandia would actually lower diabetics' cardiovascular risk was critical to Avandia's marketing. GSK needed justification for the steep price difference between Avandia and the older established diabetes drugs. GSK, however, knew or should have known that these representations were false, misleading, and likely to deceive. At best, GSK had no data to support these claims. At worst, they were wholesale fabrications.

30. Indeed, upon information and belief, GSK has at all relevant times *known* that it lacked the scientific data to support its efficacy and safety claims. Instead, upon information and belief, GSK's marketing department planned to create scientific evidence to substantiate GSK's marketing claims by conducting company-sponsored "clinical trials" and "studies." On information and belief, company scientists lack the necessary independence in GSK's corporate structure to allow them to create scientific studies that meaningfully assess efficacy and safety; instead, they take direction from GSK's marketing department. On information and belief, GSK's marketing department routinely communicates with GSK scientists, directing them to design studies and trials to yield results that further the drug's product message. Thus, GSK scientists played a central role in GSK's marketing strategy by designing clinical trials and meta-analyses not to advance scientific inquiry into the drug's safety and efficacy, but to produce results consistent with (and hide results inconsistent with) GSK's preexisting advertising messages about Avandia.

31. Another central aspect of GSK's advertising campaign was restricting access to

scientific data about Avandia that would support independent and critical assessments of the drug's safety. On information and belief, when GSK's scientists were unable to obtain the results for Avandia studies that the marketing department ordered, it was company policy to bury the unfavorable data either by not releasing it at all, or by obscuring the data's import by releasing only "summary findings" on the company's website, making the data impossible for independent scientists to analyze effectively.

32. Another vehicle of GSK's tight message construction and control was its use of sales representatives who spread the Avandia message by calling on prescribers throughout the State of South Carolina. GSK even used seemingly independent physicians to disseminate its message. On information and belief, GSK paid doctors to act as speakers to deliver the company's messages about the drug at conferences and in other venues, and as writers who collaborated with GSK representatives in the "ghostwriting" of medical and scientific articles that sought to advance GSK's Avandia marketing agenda. "Ghostwriting" is a particularly insidious practice where a drug company authors a purportedly independent scientific paper and then pays someone else to place ***their*** name on the paper to give the appearance of independence and objectivity by suggesting that the independent person or group, and ***not*** the drug company, performed the research and authored the paper. This aspect of GSK's messaging campaign was particularly far-reaching and effective, as revealed by an independent study authored by doctors at the Mayo Clinic and published in the March 19, 2010 *British Medical Journal* ("BMJ"). The study surveyed 202 articles written about Avandia. The BMJ study found that out of the 31 unique authors who expressed "favourable opinions" of Avandia, 27 of them—an extraordinary 87 percent—had financial ties to GSK.

33. GSK's aggressive marketing campaign did not go unnoticed by the FDA. The FDA cited GSK for engaging in false and deceptive advertising for Avandia **before** the drug was even launched. The FDA cited GSK for precisely the core messages GSK contrived to promote, advertise, and market Avandia. In an April 23, 1999 press release, GSK improperly touted Avandia as "a significant advance in the treatment of diabetes and [as] highly effective in safely and significantly lowering blood sugar." GSK also improperly claimed that Avandia "can help millions of people with Type 2 diabetes lower their blood sugar levels and help prevent life-threatening complications." As the FDA recognized, it is improper for a drug company to "represent in a promotional context that an investigational new drug is safe and effective" before receiving FDA approval.

34. On October 20, 2000, the FDA again found that GSK's promotional materials for Avandia, including print advertisements, were false and misleading. The FDA admonished GSK that "your presentations that Avandia decreases [glucose] by 2.3% are ***misleading*** because they suggest that Avandia is more effective than has been demonstrated by substantial evidence." (emphasis added). The FDA further found that other materials were "***misleading*** because they fail to present risk information with a prominence and readability reasonably comparable with the presentation of information related to the effectiveness of the drug." (emphasis added). In addition, more advertising material was found to "lack fair balance because materials present the product's indication without disclosing risks associated with Avandia."

35. On February 7, 2001, the FDA medical officer reviewing GSK's insulin NDA recommended rejecting the application based on mounting evidence of adverse cardiovascular events, such as heart attacks, linked to Avandia. That same FDA medical

officer concluded that the safety information was "quite troublesome." In addition to mounting safety concerns, GSK continued to receive adverse event reports and other information that confirmed that its claims of Avandia's superior efficacy and greater safety over established diabetes drugs were false. Despite all this, GSK continued its false and deceptive campaign at full speed.

36. On June 28, 2001, the FDA cited GSK for a ***third*** time during its coordinated Avandia marketing campaign, this time for "direct-to-consumer (DTC) broadcast and print advertisements for Avandia that are ***false and misleading.***" (emphasis added). The FDA found these advertisements to be false and misleading because they presented incomplete and deceptive information about the use of Avandia with insulin. Furthermore, the advertisements minimized the required warning information because they failed to use "consumer-friendly language and therefore [were] unlikely to be understood by consumers." The FDA further noted that GSK continually made statements in its advertising that undercut and minimized the FDA-required bolded warnings relating to Avandia.

37. On July 17, 2001, the FDA issued a Warning Letter to Defendant arising from oral misrepresentations made by Defendant at the 10th Annual American Association of Clinical Endocrinologists (AACE) Meeting in San Antonio, Texas, on May 2-6, 2001, which denied the existence of serious new risks associated with Avandia at GSK's promotional exhibit booth. Additionally, GSK displayed exhibit panels (AV013G) at this meeting that minimized new risks associated with Avandia. The FDA found that Defendant's "promotional activities that minimize serious new risks are particularly troublesome because we have previously objected, in two untitled letters, to your dissemination of

promotional materials for Avandia that failed to present any risk information about Avandia or minimized the hepatic risk associated with Avandia. Despite your assurances, such violative promotion of Avandia has continued."

38. The individual violations for which the FDA cited GSK in 2000 and 2001 were not isolated incidents. Instead, they were integral components of GSK's entire coordinated marketing campaign—a campaign that was, as a whole, driven by the aim of misleading the public, the medical community and payors, including the State of South Carolina, about Avandia's efficacy and safety. While the FDA focused on these individual violations, GSK got away with countless other deceptions that contributed to its overarching goal of suppressing adverse information and disseminating false or misleading positive information about Avandia.

39. On March 25, 2008, the FDA sent another Warning Letter to GSK wherein the FDA outlined its findings following an inspection at GSK's corporate headquarters located in North Carolina. The inspection focused on GSK's "compliance with Postmarketing Adverse Drug Experience (PADE) reporting requirements and other postmarketing reporting requirements related to Avandia (rosiglitazone maleate) approved by the FDA on May 25, 1999, under NDA 21-071." The FDA inspection revealed that GSK:

> failed to report data relating to clinical experience, along with other data and information, for Avandia, as required under Section 505(k)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 US.C. §355(k)(1)] and Title 21 of the Code of Federal Regulations (21 CFR) Section 314.80 and 314.81. In particular, the inspection found that your firm failed to report multiple postmarking studies involving Avandia in mandatory Periodic and/or NDA Annual Reports. Failure to comply with Section 505(k) of the Act is a prohibited act under Section 301(e) of the Act [21 U.S.C. § 331(e)].

40. The FDA stated in its Warning Letter that "the specific violations noted in this letter are *serious* and may be *symptomatic* of underlying postmarketing safety reporting failures." (emphasis added). The letter was not an inclusive list of all violations and the FDA reminded GSK that "[i]t is your responsibility to ensure adherence to each requirement of the Act and its regulations." (emphasis added).

41. In addition, GSK threatened and intimidated physicians who were raising concerns regarding the cardiac risk of Avandia.

42. In 1999, John B. Buse, M.D., a diabetes expert and head of endocrinology at the University of North Carolina at Chapel Hill, was involved as an investigator in a rosiglitazone study. Following his investigational efforts, he gave a number of speeches at scientific meetings where he opined that rosiglitazone may carry cardiovascular risks.

43. GSK attempted to silence Dr. Buse by threatening him with a $4 million lawsuit, characterizing him as a liar and telling Dr. Buse's department chair that he was "for sale." In response to GSK's pressure, Dr. Buse sent a three-page letter to the then Chairman of Research and Development, Dr. Tadktaka Yamada. Dr. Buse wrote, "I may disagree with GSK's interpretation of that data...I am not for sale ... Please call off the dogs. I cannot remain civilized much longer under this kind of heat." Eventually, after the intimidation, Dr. Buse signed a statement that GSK used to help ease investor concerns.

44. Nevertheless, on March 15, 2000, Dr. Buse wrote a letter to the FDA again raising concerns about a "worrisome trend in cardiovascular deaths and severe adverse events" associated with Avandia:

> I would like you to know exactly what my concerns are regarding rosiglitazone as a clinical scientist and my approach as a clinician. On the basis of the increase in LDL concentration seen in the clinical trial program

> (whether the number we accept as the truth is the 18.6% at 4 mg bid in the package insert or the "average of 12%" now being discussed) one would expect an increase in cardiovascular events.... Based on studies with statins and plasmapheresis, changes in LDL concentration can be associated with substantial changes in vascular reactivity and endothelial function over a time course of days to weeks.
>
> In short, the lipid changes with troglitazone and pioglitazone can only be viewed as positive. They are very similar in nature.... As mentioned above, I remain concerned about the lipid changes with rosiglitazone....Rosiglitazone is clearly a very different actor. I do not believe that rosiglitazone will be proven safer than troglitazone in clinical use under current labeling of the two products. In fact, rosiglitazone may be associated with less beneficial cardiac effects or even adverse cardiac outcomes.

45. After hearing allegations that Dr. Buse was intimidated, the United States Senate Committee on Finance ("Senate Finance Committee") began an investigation and "intensive review" of documents and found that "it is apparent that the original allegations regarding Dr. Buse and GSK's attempts at silencing him are true; according to relevant emails, GSK executives labeled Dr. Buse as a "renegade" and silenced his concerns about Avandia by complaining to his superiors and threatening a lawsuit."

46. The Senate Finance Committee stated in its report that "[t]he documents in the Committee's possession raise serious concerns about the culture of leadership at GSK. Even more serious perhaps is our fear that the situation with Dr. Buse is part of a more troubling pattern of behavior by pharmaceutical executives."

47. The Senate Finance Committee noted that "[t]he effect of silencing this criticism is, in our opinion, *extremely serious.* At a July 30, 2007, safety panel on Avandia, FDA scientists presented an analysis estimating that Avandia caused approximately 83,000

excess heart attacks since coming on the market. Had GSK considered Avandia's increased cardiovascular risk more seriously when the issue was first raised in 1999 by Dr. Buse, instead of trying to smother an independent medical opinion, some of these heart attacks may have been avoided."

48. GSK's marketing strategy was wildly successful. Through 2007, GSK's U.S. Avandia sales topped $7 billion. But as Avandia revenue streamed into GSK, additional information began to come to light that belied GSK's claims of Avandia's superiority over the older and cheaper diabetes drugs and of its purported ability to reduce diabetics' cardiovascular risks. Indeed, GSK, through its own internal studies and reports from the field (called serious adverse event reports, or "SAEs"), collected reams of data showing that Avandia dramatically ***increased*** diabetics' cardiovascular risks. But rather than informing the public about these dangers, GSK suppressed the data and studies for fear they would undermine the drug's core marketing messages.

49. As serious cardiac adverse event reports continued to pour in, GSK decided that, in addition to its policy of concealing the data on Avandia's increased cardiovascular risks, it needed to prepare for offensive action to convince diabetics, the U.S. medical community, and payors, including the State of South Carolina, that Avandia was safe. Thus, in 2004 it began marshalling, filtering, and selectively disseminating the data and studies it had been collecting regarding Avandia's cardiac risks.

50. In 2005, GSK concluded its own meta-analysis of data concerning Avandia's effect on diabetics' risk of heart attacks. Stunningly, GSK's own meta-analysis found that Avandia increased diabetics' risk of heart attacks by at least ***an additional 31%***. Yet, when GSK informed the FDA about its meta-analysis in September 2005, it minimized the

significance of its own conclusions by stating merely that they "may" signal an increased risk for heart attacks in diabetics. GSK did not inform the State of South Carolina of GSK's now undeniable knowledge of the increased cardiovascular risk associated with the use of Avandia. Instead, its false and deceptive marketing campaign continued full speed ahead.

51. In August of 2006, GSK finally sent to the FDA and the European Medicines Agency ("EMEA") the results of its 2005 meta-analysis showing that use of Avandia caused a 31% increase in diabetics' already elevated heart attack risk. Within two months, the EMEA ordered GSK to put the results of its meta-analysis on its warning label. Meanwhile, in the United States, GSK continued to minimize Avandia's risks.

52. While intentionally failing to warn of Avandia's known increased cardiovascular risks, GSK continued to tout "studies" consistent with its marketing message. On September 23, 2006, GSK published the results of its DREAM (Diabetes Reduction Assessment with Rampiril and Rosiglitazone Medication) study. The DREAM study allegedly investigated whether Avandia could prevent diabetes by examining the effect of Avandia on non-diabetics. While treatment with Avandia was associated with a lower risk of diabetes for pre-diabetic subjects as compared to a placebo, subjects taking Avandia had a higher incidence of heart attacks than the control group. Some scientists sharply criticized the DREAM study, noting that GSK appeared to be focused largely on marketing questions by focusing on a pre-disease state and not concentrating on addressing the pressing questions surrounding Avandia's increased risk of heart attacks for the population to whom the drug was actually marketed.

53. In December 2006, GSK released the results of its ADOPT (A Diabetes Outcome Progression Trial) study in the New England Journal of Medicine (*"NEJM"*). As an integral part of GSK's marketing campaign, the ADOPT study compared Avandia to metformin and another drug called glipizide (also known as glyburide) to "compare" their glycemic control efficacy. GSK had promised the FDA that ADOPT would study, among other things, the long-term safety of Avandia, including cardiovascular risks. However, cardiovascular events were neither identified nor recorded in a systematic fashion in the ADOPT study. Heart failure was the only outcome it reviewed and measured. GSK ignored data about other cardiovascular events, such as non-fatal heart attacks—data that would have been valuable in assessing Avandia's cardiovascular risks. GSK knew there were many serious cardiovascular issues associated with Avandia aside from heart failure, but it failed to investigate these risks even when it had the opportunity to do so. Nonetheless, as two prominent researchers observed in an editorial in the *NEJM,* "even though misclassification and incomplete ascertainment of events effectively reduce the ability of a study to detect a difference in event rates, [Avandia] in ADOPT was associated with a higher risk of cardiovascular events, including heart failure, than glyburide."

54. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the NEJM of his analysis of 42 studies comprising of approximately 28,000 people who took Avandia. These were on-line databases of GSK studies that were available on the Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse effects at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr.

Nissen's analysis showed a 64% elevated risk of death from cardiovascular causes.

55. In the same *NEJM* issue, two other prominent scientists stated in an editorial that, "[i]insofar as the findings of Nissen...represent a valid estimate of the risk of cardiovascular events, rosiglitazone represents a major failure of the drug-use and drug-approval process in the United States." GSK had all this data available at its fingertips for years, but it had at a minimum ignored the data, or at worst covered it up. Although GSK scientists had the ability and duty to analyze this data, GSK failed to take any action, all the while aggressively marketing Avandia. Indeed, internal GSK e-mails show that GSK's own scientists ***confirmed*** the accuracy and validity of the Nissen analysis.

56. In a December 2007 floor speech, Senator Grassley, the Chairman of the Senate Finance Committee, revealed that Dr. Steve Haffner, a professor of medicine at the University of Texas Health Sciences Center, San Antonio, and a consultant for GSK, had leaked to GSK a draft of the Nissen article before it was published by the *NEJM.* Dr. Haffner was entrusted with a confidential copy of the manuscript draft because he was peer-reviewing the study for the *NEJM.*

57. According to documents produced by GSK to the Senate Finance Committee, the leaked manuscript was widely disseminated within the Company, allowing GSK to launch a public relations plan in an effort to protect Avandia. The Senate Finance Committee staff reviewed documents showing that over forty executives at GSK received and/or learned of the results in the leaked study, including then CEO Dr. Jean-Pierre Garnier; head of research, Dr. Moncef Slaoui; Vice President of Corporate Media Relations, Nancy Pekarek; and GSK Senior Advisor, Sir Collin Dollery.

58. Before Dr. Nissen's study on Avandia was published, GSK's statistical experts were examining the study for potential flaws. In addition, GSK officials were drafting "key messages" to undermine the main conclusion of the Nissen study. One day after receiving the unpublished study from Dr. Haffner, GSK produced a detailed, 8-page analysis of Dr. Nissen's paper, weeks before the paper's public release. The GSK statistician attempted to find deficiencies in Nissen's meta-analysis but noted, "[t]he selection of trials therefore appears to be thorough, though others more familiar with the trials can comment more knowledgeably."

59. The GSK statistician also performed a regression analysis on each study that Dr. Nissen used in his meta-analysis to see if the effects of myocardial infarction and/or cardiovascular death would still appear. The statistician stated, "[t]hese results are very similar to the conclusion from the [Nissen] paper using the Peto method. As such there is no statistical reason for disregarding the findings as presented."

60. On May 9, 2007, Sir Colin Dollery, a senior consultant to GSK, laid out many of the problems with Avandia in an email to Dr. Slaoui and others. He wrote:

> To a great extent, the numbers are the numbers, the [Nissen] analysis is very similar to our own . . . We cannot undermine the numbers but I think they can be explained so we must concentrate on effective risk management.

61. After the publication of the Nissen study, GSK went on the offensive. On May 21, 2007, *NEJM* published online Dr. Nissen's meta-analysis that found a link between Avandia and heart attacks. That same day, GSK responded via press release and via a letter to healthcare providers stating that, "GSK strongly disagrees with the conclusions reached in the *NEJM* article, which are based on incomplete evidence and a methodology that the

author admits has significant limitations." Instead, GSK highlighted the results of company sponsored trials like RECORD (Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes) as "the most scientifically rigorous way to examine the safety and benefits of a medicine." In a subsequent letter to *The Lancet*, GSK maintained that the RECORD trial is "compelling evidence" for the safety of Avandia, and that "the independent data safety monitoring board for RECORD recently reviewed an interim analysis of unblinded cardiovascular endpoints and confirmed that the trials should continue."

62. On June 5, 2007, GSK published the "interim results" of the RECORD study. The GSK study authors concluded that the data was "insufficient" to find a link between Avandia and heart attacks. It was no coincidence that GSK had these results prepared and ready for public dissemination so quickly after the publication of the Nissen article. Internal GSK emails indicate that GSK executives, not the study's independent steering committee, made the final decision to publish the RECORD trial results. Yet, in talking points created for its sales force, GSK stated, "because of the widespread media coverage of the *NEJM* [Nissen] meta-analysis and the confusion it has created, the RECORD Steering Committee decided it was important to publish the interim analysis in the interests of patient safety."

63. The Senate Finance Committee further noted that, based on a review of emails, the authors of the RECORD trial appeared more concerned about countering claims that Avandia may be associated with heart attacks, than in trying to understand the underlying science. While circulating a draft of a manuscript on the RECORD trial, one of the authors

wrote to his colleagues, "[W]hat's to stop [Nissen] adding the events from RECORD to his meta-analysis and re-enforcing his view?"

64. The RECORD study's stated purpose was to examine whether the "promising' impact of thiazolidinediones on insulin sensitivity and cardiovascular risk factors would translate into an improvement in cardiovascular clinical outcomes." The study also sought to "address concerns over cardiac failure[;] confirm that the better outcomes associated with improved glucose control, as reported by the UKPDS [the United Kingdom Prospective Diabetes Study], are applicable to this group of drugs; and allay concerns based on LDL [low-density lipoprotein] cholesterol concentrations rather than LDL particle atherogenicity." The publication of the RECORD study's interim results in June 2007 was the first that anyone in the United States, other than GSK, knew of the study's existence. GSK had failed to even report this study's existence to the FDA. GSK released these "interim results" (the study had not been completed), to give a "complete picture" of Avandia's cardiovascular risks. In fact, RECORD's results showed that GSK's claims about Avandia's superior efficacy and safety were both false. The RECORD study confirmed that Avandia offered no superior efficacy over established diabetes drugs. RECORD's "interim results" also showed that Avandia was associated with a 30% increased risk of heart failure. Minimizing and concealing the true results of its own RECORD study, GSK continued to claim that that the data was insufficient to support any conclusion about an increased risk of heart attacks.

65. The release of RECORD's "interim results" by GSK was calculated to prematurely publicize "conclusions" that were unsupported and, in fact, contradicted by the data from the study. Thus, for many scientists, RECORD raised more questions than it answered. As

one researcher noted in an editorial in the *NEJM,* RECORD "seem[ed] to reflect a company-oriented posture regarding rosiglitazone, rather than a neutral scientific inquiry." Further, the study had far too few participants, or "power," to extrapolate the study's findings beyond the study itself. In fact, GSK had been aware since at least 2004 that the RECORD trial was statistically inadequate or "underpowered" to answer questions regarding cardiovascular safety.

66. Despite GSK's best efforts, it could not stem the tide of data exposing Avandia's dangers. On July 30, 2007, the FDA released its own meta-analysis of 42 studies. Like the Nissen study, the FDA's analysis drew largely on raw data of which GSK had known for years. Like Nissen, the FDA's study found that Avandia significantly increased diabetics' risk of heart attacks and other serious cardiovascular events. The FDA's scientists found that Avandia use increased diabetics' already increased risk of serious cardiovascular events by ***an additional 42%***.

67. On the same day, the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA met jointly to examine the cardiovascular risks of Avandia. At that meeting, the FDA's Director for Science and Medicine in the Office of Surveillance and Epidemiology, Dr. David Graham, concluded that Avandia should be pulled from the market. His detailed presentation tracked a combination of results from long-term, placebo-controlled studies and meta-analyses to conclude that Avandia's benefits did not outweigh its cardiovascular risks. After the close of testimony, the two FDA committees officially concluded that Avandia posed greater cardiovascular risks than placebo.

68. The proceedings' chairman, Clifford M. Rosen, M.D., wrote in the August 9, 2007 edition of the *NEJM* that:

> The basic plot of the [Avandia] story quickly became obvious to the advisory committee: a new "wonder drug," approved prematurely and for the wrong reasons by a weakened and underfunded government agency subjected to pressure from industry, had caused undue harm to patients.

69. On August 14, 2007, the warnings, precautions and contraindications sections of the Avandia label were changed regarding the potential increased risk of heart failure, and the following new black box warning was added to the label:

WARNING: CONGESTIVE HEART FAILURE

> Thiazolidinediones, including rosiglitazone, cause or exacerbate congestive heart failure in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patient carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered.
>
> AVANDIA is not recommended in patients with symptomatic heart failure. Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated. (See CONTRAINDICATIONS and WARNINGS.)

70. On September 23, 2007, a third independent meta-analysis was published, this time by the Journal of the American Medical Association ("*JAMA*"). This analysis confirmed both the Nissen and the FDA's results, showing a 42% increase in heart attacks associated with Avandia use. The *JAMA* study concluded that Avandia "significantly increased the risk of myocardial infarction." Also in September 2007, a study published in the *Annals of Internal Medicine* concluded that, compared "with newer, more expensive agents [like

Avandia], older agents (second-generation sulfonylureas and metformin) have similar or superior effects on glycemic control, lipids, and other intermediate endpoints."

71. On or about November 14, 2007, the warnings, precautions, and indications sections of the Avandia label were changed regarding the potential risk of myocardial ischemia, and the following language was added to the black box warning:

> WARNING: CONGESTIVE HEART FAILURE AND MYOCARDIAL ISCHEMIA
>
> A meta-analysis of 42 clinical studies (mean duration 6 months; 14,237 total patients), most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14,067 patients), comparing AVANDIA to some other approved antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

72. Despite the evidence establishing otherwise, GSK continued to deny evidence of the increased cardiovascular risks associated with Avandia. In December 2007, in response to the *JAMA* meta-analysis, GSK baldly stated in a press release that "there is no consistent or systematic evidence that [Avandia] increases the risk of myocardial ischemic events or deaths in comparison to other anti-diabetic agents."

73. In February 2010, following a two-year investigation that involved the review of over 250,000 pages of documents provided by GSK, the FDA, and others, the Senate Finance Committee published its "Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia." Among other things, the report concluded:

> The totality of the evidence suggests that GSK was aware of the possible cardiac risks associated with Avandia years before such evidence became public. Based on this knowledge, GSK had a duty to sufficiently warn patients

> and the FDA of its concerns in a timely manner. Instead, GSK executives intimidated independent physicians [and] focused on strategies to minimize findings that Avandia may increase cardiovascular risk . . .

74. The Senate Finance Committee's investigation revealed that, as far back as 2000, internal emails show that GSK executives sought to downplay scientific findings, which raised questions about the safety of Avandia. For example, in an internal email sent on October 23, 2000, a GSK executive sought to downplay the fact that Avandia gave a worse lipid profile than Actos. At the time, GSK executives were concerned about a GSK study of Actos, called Study 175. In that email, a GSK executive wrote, "This was done for the US business, way under the radar and we lost in terms of LDL and Tgs . . . Per Sr. Mgmt request, **these data should not see the light of day** to anyone outside of GSK." (emphasis supplied).

75. In another email sent on July 6, 2001, GSK executives discussed not wanting to do a head to head trial between Avandia and Actos because of Study 175. In that email, a GSK executive wrote, "I agree that there is no benefit in doing a head to head study with [ACTOS] as the best result would be equivalence.

76. The Senate Finance Committee expressed concern that Study 175 was not turned over to the FDA in a timely manner. A deputy director at the FDA Office of Drug Safety was asked whether it would "have been important . . . to know that in 2001 GlaxoSmithKline found that they lost against its competitor Actos" and responded:

> . . . any information pertaining to a serious adverse event, such as myocardial infarction, and especially death, is a high alert for any safety officer at the FDA. So any information, including something like this, because the lipid profile go to some biological mechanism by which maybe one drug may have more safety – adverse event than another within the same drug class, it would be

> extreme [sic] important information for someone in my position to consider.

77. On a separate occasion, GSK executives discussed, in email, whether to publish two GSK studies that also found problems with Avandia. In an email sent on July 20, 2001, a GSK executive responded, "Not a chance. These put Avnadia [sic] in quite a negative light when folks look at the response of the [Avandia] arm. It is a dificult [sic] story to tell and we would hope that these do not see the light of day. We have already published the better studies."

78. GSK created a sophisticated ghostwriting program called CASPPER. The Senate Finance Committee also discovered that Avandia was part of GSK's CASPPER program. For example, in an email sent on August 13, 2001, a GSK employee wrote, "[S]ee attached manuscript that has been ghostwritten for Haffner." Further down, the email continued, "Please find attached the Haffner manuscript... The manuscript is currently in a rough format that has not gone to the author yet." In an internal GSK memo written on September 13, 2000, GSK explained the value of CASPPER. According to the document:

> CASPPER provides you the ability to offer assistance in the preparation and publication of case studies and other short communications relevant to the clinical use of Avandia . . . Your participation can help establish or enhance your relationships with your physicians or other healthcare professionals.

79. In response to several document requests made to the FDA, the Senate Finance Committee also received and reviewed an analysis conducted by two FDA safety officials, Dr. David J. Graham, and Dr. Kate Gelperin. This analysis, conducted in October 2008, reviewed all available studies comparing Avandia (rosiglitazone) to Actos (pioglitazone). These FDA officials concluded:

> The risks of rosiglitazone use are serious and exceed those for pioglitazone. Rosiglitazone confers no unique and medically important benefit that distinguishes it from pioglitazone. The risks of rosiglitazone use exceed its benefits compared to pioglitazone. Rosiglitazone should be removed from the market.

80. In a study published in February 2010 in the journal for the American Diabetes Association, *Diabetes Care,* researchers at Harvard University sought to "identify potential association(s) of diabetic medications with myocardial infarction (MI)." As GSK purported to do in the ADOPT and RECORD studies, the researchers compared Avandia to the established and much cheaper drugs metformin and sulfonylureas. They also included Actos. The study reviewed the charts for groups of 11,200, 12,490, 1,879, and 806 patients who were prescribed sulfonylurea, metformin, Avandia, or Actos, respectively. The Harvard study found that, compared to sulfonylurea, Avandia increased a diabetic's heart attack risk by an additional 30%. Significantly, when contrasted with GSK's claims to the contrary, the Harvard study showed that when compared to metformin, the "gold standard" in diabetes treatment, Avandia more than doubled a diabetic's risk of heart attack, increasing the risk by 120%. This led the authors dryly to conclude that "[o]ur results are consistent with a relative adverse cardiovascular risk profile for rosiglitazone." This is hardly the "significant advance" in diabetic care that GSK represented Avandia would be beginning in 1999 and continuing thereafter.

81. Despite the overwhelming evidence to the contrary, GSK has continued to deny that Avandia increases the risk of cardiac events, including at the FDA's Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, held on July 13-14, 2010. However, at that meeting, FDA reviewer Dr. Marciniak reported that RECORD "was inadequately designed and

conducted to provide any reassurance about the CV safety risk of rosiglitazone." Dr. Marciniak also made the startling finding that the number of adverse cardiac events was not accurately reported in the RECORD study. Dr, Marciniak commented that "one does not have to be a mathematician or to perform calculations" to come to the conclusion that a combined look at at all of the trials of Avandia would demonstrate that it causes heart attack. At the conclusion of that meeting, 22 out of 33 panel members voted to recommend to the FDA that Avandia should either be withdrawn from the market or have sales severely restricted.

82. On September 23, 2010, the FDA imposed strict restrictions on the further use of Avandia. The FDA required that GSK develop a restricted access program for Avandia under a risk evaluation and mitigation strategy, or REMS. The REMS requires the following elements to assure safe use of Avandia:

(a) Provision of complete risk information to each patient and documentation in their medical record that the information has been received and understood;

(b) Documentation from health care providers that each patient receiving Avandia falls into one of two categories: (I) patients currently taking Avandia, or (ii) patients not already taking Avandia who are unable to achieve glycemic control on other medications and, in consultation with their health care professional, decide not to take Actos® for medical reasons;

(c) Documentation from health care providers that the risk information has been shared with each patient; and

(d) Physician, patient, and pharmacist enrollment in the REMS program.

In addition, the FDA halted the controversial Thiazolidinedione Intervention with Vitamin D Evaluation ("TIDE") clinical trial comparing Avandia to Actos®. *Id.* On that same date,

European regulators stopped all sales of Avandia in Europe. Also on that same date, GSK announced that it would voluntarily cease promotion of Avandia in all the countries in which it operates.

83. As shown herein, GSK's corporate strategy and business model is dictated not by science, but by sales and marketing. At GSK, marketing and commercial personnel exert extensive control over scientific and medical decisions, such as the initiation of clinical trials, the types of trials done, the design of those trials, and the reporting and publication of the data, all with the ultimate goal of producing further support for GSK's marketing messages and bolstering sales of Avandia. For example, on information and belief, GSK actively sought to create the impression that Avandia was better at lowering blood sugar than metformin, but intentionally avoided studying these two drugs head-to-head because it knew that if it did so, the studies would show GSK's claims to be false. GSK also obscured or failed to report important safety information specifically relating to Avandia's cardiovascular risk, because doing so would jeopardize sales of Avandia and would be inconsistent with GSK's key marketing and sales messages—such as GSK's claim that Avandia, even though more expensive, ultimately was more cost effective than other type 2 diabetes therapies. Defendant failed to disclose Avandia's known side effects in the drug's package inserts and promotional materials. Instead, Defendant trained and encouraged its sales representatives to make false statements concerning the safety and efficacy of Avandia. GSK's top priority is neither science nor safety, but rather marketing. Marketing concerns infected and distorted GSK's entire Avandia scientific program.

84. Likewise, GSK maintained a marketing-based publication strategy to misleadingly influence the medical and scientific literature by promoting the publication of medical and

scientific articles that would support its marketing message about Avandia's safety and efficacy and/or suggest dissatisfaction with competing therapies. On information and belief, this strategy included practices such as ghostwriting articles and hiring outside ghostwriting companies, giving GSK's marketing personnel editorial and substantive input into decisions about what scientific studies to publish and the actual content of such publications, and forming misleading financial and promotional relationships with authors, "opinion leaders" and other physicians. GSK gave its marketing department extensive control over the company's research and publication decisions so that medical and scientific publications could be used as tools to promote its marketing messages about Avandia. Defendant's contrived, self-funded studies were materially misleading in that they failed to employ proper scientific methodology, clinical research techniques, and data interpretation, neglected to accurately report results in conducting these studies to support their promotional campaign, and distorted the data derived from their flawed studies in their publication of that data.

85. GSK's far-reaching, massive, and widespread promotional campaign to drive Avandia's sales was specifically directed at and did influence the State of South Carolina. GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists" presented false and misleading information regarding the safety and efficacy of Avandia which was reasonably relied upon by the State of South Carolina.

86. In addition, GSK, through its control and manipulation of studies and research publications, its sponsorship of medical education programs, its submission of false and misleading information to the FDA, its use of GSK "opinion leaders", its failure to adequately warn of Avandia's true risks in its labeling and other marketing materials, and

its false and deceptive marketing conducted by GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists", caused false and misleading information regarding the safety and efficacy of Avandia to be reasonably relied upon by the State of South Carolina.

87. GSK engaged in a premeditated program to influence consumers, prescribers, Medicaid and SHP participants, and the State of South Carolina to believe that Avandia was a superior drug when it was not, and to believe that Avandia was cardio-protective when it was not.

88. Moreover, from the time it first went on the market, Avandia's price was grossly inflated compared to older diabetic drugs.

89. The financial toll that GSK's false and deceptive marketing of Avandia has had on the State of South Carolina has been dramatic. Relying upon GSK's promises of superior treatment and better cardiovascular outcomes compared with the older diabetes drugs, such as metformin and sulfonylureas, the State of South Carolina paid a hefty premium for a drug that in truth was no more efficacious than far cheaper drugs, but was far more dangerous to South Carolina Medicaid and SHP participants.

90. As the diabetes problem has grown in South Carolina, the State of South Carolina has had to shoulder an increasing share of the burden of treating diabetics, particularly in indigent and low-income populations, and the weight of that responsibility continues to grow. The State of South Carolina seeks the most effective and safest treatment for its residents and relies on pharmaceutical companies to fairly and accurately represent the safety and efficacy of their products. GSK has wholly violated that trust, and instead has perpetrated its fraudulent scheme to defraud the State of South Carolina, and has bilked the

State of South Carolina out of millions of dollars by making false representations that Avandia was better at lowering blood sugar than existing medications, and could decrease diabetics' cardiovascular risks.

91. To treat patients with Type 2 diabetes, the State of South Carolina purchased millions of dollars' worth of Avandia starting in 1999, relying on GSK's false and misleading representations that Avandia was a safe and effective treatment for Type 2 diabetes. GSK's deception increased the costs to the State of South Carolina through the higher price of Avandia when cheaper and safer alternatives were available. Further the State of South Carolina bears the additional treatment and hospitalization costs of the heart attacks and other cardiovascular problems caused by Avandia to its Medicaid and SHP participants, including, but not limited to, heart attacks, strokes, and sudden cardiac death. GSK could have prevented these increased costs had it been forthcoming with the State of South Carolina, the medical and scientific community, and consumers about the risks of Avandia.

92. GSK's false, misleading, and deceptive marketing of Avandia resulted in millions of dollars of Avandia sales to the State of South Carolina, sales that otherwise would not have been made. GSK was unjustly enriched and profited from the suppression of the truth and misleading promotion of Avandia.

93. GSK's false, misleading and deceptive marketing of Avandia also resulted in those South Carolina Medicaid and SHP participants who took Avandia experiencing cardiovascular side effects including, but not limited to, heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, stroke and/or severe injury to the heart leading to cardiac arrest, and death, requiring otherwise avoidable hospitalizations

and medical care and treatment. As a result, the State of South Carolina has borne and will bear additional costs for the care and treatment of these undisclosed increased cardiovascular risks.

94. This Complaint is based solely upon the laws of the State of South Carolina, and contains causes of action found within those laws. To the extent that the Defendant asserts that any claim contained herein raises a substantial question of federal law or a federal cause of action, Plaintiff hereby disavows any such claim.

COUNT I

Equitable Tolling of Applicable Statutes of Limitations

95. Plaintiff repeats and reiterates the allegations previously set forth herein.

96. The running of any statute of limitations has been tolled by reason of GSK's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff the true risks associated with taking Avandia.

97. As a result of GSK's actions, Plaintiff and, upon information and belief, South Carolina Medicaid and SHP participants, and prescribers within the State of South Carolina, were unaware, and could not reasonably have known, have ascertained, or have learned through reasonable diligence, the true risks associated with taking Avandia and/or the damages resulting from the Defendant's wrongful acts, and/or that the concealment of those risks were the direct and proximate result of Defendant's acts and omissions.

98. Furthermore, GSK is estopped from relying on any statute of limitations because of its fraudulent concealment of the true character, quality and nature of Avandia. Defendant was under a duty to disclose the true character, quality and nature of Avandia because this

was non-public information over which the Defendant had and continues to have exclusive control, and because the Defendant knew that this information was not available to the Plaintiff, South Carolina Medicaid and SHP participants, and prescribers within the State of South Carolina. In addition, the Defendant is estopped from relying on any statute of limitations because of its intentional concealment of its wrongful and fraudulent conduct.

99. Plaintiff had no knowledge that the Defendant was engaged in the wrongdoing and unlawful conduct alleged herein. Because of the fraudulent acts of concealment of wrongdoing and unlawful conduct by the Defendant, the Plaintiff could not have reasonably discovered the wrongdoing and unlawful conduct, nor was the damage resulting from the Defendant's wrongful acts capable of ascertainment by the Plaintiff, nor, upon information and belief, South Carolina Medicaid and SHP participants, and/or prescribers within the State of South Carolina. Also, the economics of this fraud should be considered. The Defendant had the ability to and did spend enormous amounts of money in furtherance of its purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff, South Carolina Medicaid and SHP participants, and prescribers within the State of South Carolina could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on the Defendant's representations.

COUNT II

Submission of False and Fraudulent Claims Under the Medicaid Program

100. Plaintiff repeats and reiterates the allegations previously set forth herein.

101. S.C. Code Ann. §43-7-60 provides as follows:

(B) It is unlawful for a provider of medical assistance, goods, or services to knowingly and wilfully make or cause to be made a false claim, statement, or representation of a material fact: (1) in an application or request, including an electronic or computer generated claim, for a benefit, payment, or reimbursement from a state or federal agency which administers or assists in the administration of the state's medical assistance or Medicaid program; or (2) on a report, certificate, or similar document, including an electronic or computed generated claim, submitted to a state or federal agency which administers or assists in the administration of the state's Medicaid program in order for a provider or facility to qualify or remain qualified under the state's Medicaid program to provide assistance, goods, or services, or receive reimbursement, payment or benefit for this assistance, goods or services.

For purposes of this subsection, each false claim, representation or statement constitutes a separate offense.

(C) It is unlawful for a provider of medical assistance, goods, or services knowingly and willfully to conceal or fail to disclose any material fact, event or transaction which affects the (1) provider's initial or continued entitlement to payment, reimbursement, or benefits under the state's Medicaid plan; or (2) amount of payment, reimbursement, or benefit to which the provider may be entitled for services, goods or assistance rendered.

For purposes of this subsection, each fact, event, or transaction concealed, or not disclosed constitutes a separate offense.

102. As a person who has provided goods, services, or assistance, and who has received reimbursement, payment and/or benefits for services, goods, or assistance rendered under the State's Medicaid program, Defendant is a "provider" within the meaning of S.C. Code Ann. §43-7-60(A)(1).

103. In representing that Avandia had superior efficacy than other established drugs, that patients could stay on Avandia longer than the older drugs, that Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks, and in failing to disclose the true facts regarding safety and efficacy of Avandia, GSK committed violations of subsections (B) and (C) of S.C. Code Ann. §43-7-60 in connection with the State's Medicaid program. On information and belief, GSK's clinical research and publication

strategies were directed and influenced largely by marketing concerns rather than by medical or safety concerns, and GSK's management allowed marketing personnel to direct the company's so-called scientific research rather than enabling independent analysis. GSK repeatedly failed to disclose important safety information; it improperly and deceptively influenced the medical and scientific literature and the perception of Avandia within the medical community; it consistently downplayed Avandia's risks; it formed deceptive and misleading financial and promotional relationships with "opinion leaders," speakers and other physicians for the purpose of promoting the product; it engaged in misleading sales training, sales tactics, and marketing to prescribers, Medicaid participants, and/or the State of South Carolina that misrepresented the safety and efficacy of Avandia; it engaged in the ghostwriting of medical and scientific articles; and it engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described herein.

104. GSK's far-reaching, massive, and widespread promotional campaign to drive Avandia's sales was specifically directed at and did influence the State of South Carolina. GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists" directly communicated with the State of South Carolina, and in connection therewith, presented false and misleading information regarding the safety and efficacy of Avandia which was reasonably relied upon by the State of South Carolina.

105. In addition, GSK, through its control and manipulation of studies and research publications, its sponsorship of medical education programs, its submission of false and misleading information to the FDA, its use of GSK "opinion leaders", its failure to adequately warn of Avandia's true risks in its labeling and other marketing materials, and its false and deceptive marketing conducted by GSK sales representatives, lobbyists, GSK

"opinion leaders," and company "scientists,", caused false and misleading information regarding the safety and efficacy of Avandia to be reasonably relied upon by the State of South Carolina.

106. GSK's aggressive, illegal promotions have induced a misallocation of State Medicaid funds through a pattern of fraudulent conduct. GSK made or caused false claims, statements and representations of material fact to be made to the State in connection with the South Carolina Medicaid program. In addition, Defendant knowingly and willfully concealed or failed to disclose material facts, events and/or transactions which affected Defendant's entitlement to payment, reimbursement, or benefits under the State's Medicaid plan and/or the amount of payment, reimbursement, or benefit to which the Defendant was entitled for services, goods or assistance rendered. Defendant's scheme included the implementation of intentionally deceptive marketing practices. Defendant intended that its fraudulent promotion result in the reimbursement of prescriptions by the South Carolina Medicaid program.

107. As a result of GSK's fraudulent marketing of Avandia, the State of South Carolina has paid millions of dollars for Avandia and has paid excessive prices for Avandia. As a result, GSK has been illegally enriched at the expense of the State. Further, the State has been required and will be required to pay the costs of treatment for state residents actively harmed by GSK's actions.

108. In making representations that Avandia had superior efficacy over other established drugs, that patients could stay on Avandia longer than the older drugs, and that Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks, GSK acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance

or reckless disregard of the truth or falsity of the information. GSK's wrongful conduct resulted in charges to the State for goods or services that were so deficient as to be worthless.

109. Defendant fraudulently caused physicians to prescribe an expensive and unsafe medication, thereby wrongfully resulting in the State's payment for this expensive and unsafe medication.

110. Accordingly, pursuant to subsection (E) of S.C. Code Ann. §43-7-60, the Attorney General on behalf of the State is entitled to recover damages equal to three times the amount of overstatement or overpayment, and in addition, the Court should impose a civil penalty of two thousand dollars for each false claim, representation, or overstatement made to the State in connection with the Medicaid program.

COUNT III

Strict Products Liability—Failure to Warn

111. Plaintiff repeats and reiterates the allegations previously set forth herein.

112. Defendant GSK is the manufacturer and/or supplier of Avandia.

113. The Avandia manufactured and/or supplied by Defendant GSK was and is unaccompanied by proper warnings or packaging regarding all possible side effects associated with the drug. GSK failed to warn of the comparative severity, incidence, and duration of such adverse effects. The warnings given to the State, prescribers, and Medicaid and SHP participants did not accurately reflect the signs, symptoms, incidents, or severity of the side effects of Avandia.

114. The method by which Avandia was marketed in South Carolina rendered it

defective and unreasonably dangerous.

115. Avandia is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Avandia greatly outweigh any claimed utility of Avandia to the State and its Medicaid and SHP participants.

116. Avandia reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Defendant. At the time Avandia was sold or placed on the market, it was in a defective condition and unreasonably dangerous to South Carolina Medicaid and SHP participants.

117. South Carolina Medicaid and SHP participants, and their physicians used Avandia in the manner in which it was intended to be used, without any substantive alteration or change in the product.

118. GSK failed to adequately test Avandia. Such testing would have shown that Avandia possessed serious potential side effects, of which full and proper warnings should have been made.

119. The Avandia manufactured or supplied by GSK was defective due to inadequate post-marketing warnings, packaging, or instructions. After GSK knew or should have known of the risks of injury from Avandia, it failed to provide adequate warnings to prescribers, Medicaid and SHP participants, or the State as the prescribers, users, and financially responsible party, respectively. Further, GSK continued to aggressively market Avandia in spite of these defects and risks.

120. Based on information and belief, GSK actually knew of the defective nature of Avandia, but continued to market and sell Avandia without proper warning, so as to maximize sales and profits in conscious disregard for the foreseeable harm caused by

Avandia.

121. As result of Avandia's defective nature, certain South Carolinians whose care is provided by Medicaid and SHP were injured.

122. The State was forced and/or will be forced to expend significant sums of money, through its Medicaid and SHP programs, to treat Medicaid and SHP participants who sustained and/or will sustain Avandia-related injuries.

123. The State is entitled to recover the costs of such treatment that has been incurred and that will be incurred by the State.

124. GSK's wrongful conduct resulted in charges to the State for goods or services that were so deficient as to be worthless.

125. As a proximate cause and legal result of GSK's failure to warn of known and reasonably knowable dangers associated with the use of Avandia, the State of South Carolina has suffered and will continue to suffer damages and is entitled to recover those damages.

COUNT IV

Strict Products Liability - Design Defect

126. Plaintiff repeats and reiterates the allegations previously set forth herein.

127. At all times material and relevant to this action, Avandia was defective in design, and was so at the time it was prescribed by physicians treating patients that were participating in the South Carolina Medicaid and SHP programs. Avandia was defective and unreasonably dangerous in that it caused serious injuries and illness when used for its intended and foreseeable purpose.

128. The defects in Avandia were known to GSK at the time of approval by the FDA.

The required disclosures from GSK were inaccurate, incomplete, misleading, and fraudulent. These misrepresentations were material to the State.

129. GSK knew Avandia would be used by consumers without inspection for defect and that the State, prescribers, and users of Avandia were relying upon GSK's representations that the product was safe.

130. The design of Avandia rendered it a dangerously defective drug in that its use causes dangerous, and potentially life-threatening, medical conditions when taken as recommended by Defendant and such risks were not generally known by South Carolina physicians, the State and/or South Carolina Medicaid and SHP participants.

131. Avandia was a dangerously defective drug in that Defendant failed to conduct adequate testing, notwithstanding the known side effects associated with Avandia. Adequate testing would have revealed the full extent of the dangers of Avandia, and would have shown that Avandia could cause extensive medical complications and injuries.

132. Avandia is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Avandia greatly outweigh any claimed utility of Avandia to the State and Medicaid and SHP participants.

133. Avandia reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Defendant. At the time Avandia was sold or placed on the market, it was in a defective condition and unreasonably dangerous to South Carolina Medicaid and SHP participants.

134. South Carolina Medicaid and SHP participants, and their physicians used Avandia in the manner in which it was intended to be used, without any substantive alteration or change in the product.

135. As result of Avandia's defective nature, certain South Carolinians whose care is provided by Medicaid and SHP were injured.

136. The State was forced and/or will be forced to expend significant sums of money, through its Medicaid and SHP programs, to treat Medicaid and SHP participants who sustained and/or will sustain Avandia-related injuries.

137. The State is entitled to recover the costs of such treatment that has been incurred and/or that will be incurred by the State.

138. GSK's wrongful conduct resulted in charges to the State for goods or services that were so deficient as to be worthless.

139. As a proximate and legal result of the design defect, as well as GSK's failure to adequately test the product, the State of South Carolina has suffered and will continue to suffer damages and is entitled to recover those damages.

COUNT V

Fraud and Negligent Misrepresentation

140. Plaintiff repeats and reiterates the allegations previously set forth herein.

141. GSK's warnings of Avandia's side effects contained false representations and/or failed to accurately represent the material facts of the full range and severity of risks and adverse reactions associated with the product.

142. GSK's Avandia-related claims and assertions to the State of South Carolina, prescribers, and Medicaid and SHP participants contained false representations as to the safety of Avandia and its defective design.

143. GSK was negligent in not making accurate representations regarding the side effects

and adverse medical conditions associated with the use of Avandia.

144. GSK knew or reasonably should have known through adequate testing that the claims made to the State with regard to the safety and efficacy of Avandia were false or incomplete, and misrepresented the material facts of Avandia's unsafe and defective condition.

145. The State, through its Medicaid and SHP programs, expended millions of dollars for Avandia prescriptions which were directly caused by the fraudulent and misleading statements of the Defendant.

146. Defendant willfully, knowingly and deceptively withheld material facts regarding the risks and side effects associated with Avandia from the State of South Carolina, prescribers, and Medicaid and SHP participants.

147. Defendant intentionally withheld information regarding the safety risks and side effects associated with Avandia with the intent to induce the State of South Carolina, prescribers and Medicaid and SHP participants.

148. The State of South Carolina, prescribers and Medicaid and SHP participants were justified in their reliance on Defendant to educate them as to the risks and dangerous and potentially life-threatening side effects associated with Avandia use.

149. GSK's far-reaching, massive, and widespread promotional campaign to drive Avandia's sales was specifically directed at and did influence the State of South Carolina. GSK sales representatives, lobbyists, GSK "opinion leaders", and company "scientists" directly communicated with the State of South Carolina, and in connection therewith, presented false and misleading information regarding the safety and efficacy of Avandia which was reasonably relied upon by the State of South Carolina.

150. In addition, GSK, through its control and manipulation of studies and research publications, its sponsorship of medical education programs, its submission of false and misleading information to the FDA, its use of GSK "opinion leaders", its failure to adequately warn of Avandia's true risks in its labeling and other marketing materials, and its false and deceptive marketing conducted by GSK sales representatives, lobbyists, GSK "opinion leaders," and company "scientists,", caused false and misleading information regarding the safety and efficacy of Avandia to be reasonably relied upon by the State of South Carolina.

151. GSK's aggressive, illegal promotions have induced a misallocation of State Medicaid and SHP funds through a pattern of fraudulent conduct which caused false claims to be submitted to the South Carolina Medicaid and SHP programs. Defendant executed and conspired to execute a plan to defraud the South Carolina Medicaid and SHP programs in connection with the delivery of or payment for Avandia. Defendant's plan included the implementation of intentionally deceptive marketing schemes. Defendant intended that its fraudulent promotion result in the reimbursement of prescriptions by the South Carolina Medicaid and SHP programs.

152. Each of the Defendant's misleading and deceptive statements, representations and advertisements related to Avandia were material to the State's reimbursement of Avandia.

153. As a proximate and legal result of GSK's fraudulent misrepresentations, the State of South Carolina has suffered and will continue to suffer damages, and is therefore entitled to recover for those damages.

COUNT VI

Negligence

154. Plaintiff repeats and reiterates the allegations previously set forth herein.

155. GSK owed a duty to exercise reasonable care in the testing, marketing, manufacture, sales, labeling, and/or distribution of Avandia, including a duty to ensure that users would not suffer from unreasonable, dangerous, undisclosed, or misrepresented side effects. GSK owed this duty to the State of South Carolina, as the State funded the distribution of Avandia to South Carolina Medicaid and SHP participants.

156. GSK breached this duty, as it was negligent in the testing, marketing, manufacture, sale, labeling and distribution of Avandia.

157. Defendant further negligently, carelessly, recklessly, willfully and/or intentionally engaged in the following conduct:

(a) Failing to adequately train its sales force;

(b) Supplying a product that it knew, or should have known, contained inadequate warnings of side effects and risks that were known to, or based on facts available to the Defendant;

(c) Supplying a product lacking sufficient warnings and/or instructions when it knew, or should have known, the side effects associated with Avandia were not generally known by South Carolina physicians treating Medicaid and SHP participants;

(d) Misrepresenting the safety and efficacy of Avandia;

(e) Representing that Avandia was safer and more effective than cheaper, safer and equally (or more) effective diabetes medications;

(f) Failing to disclose the true facts regarding the safety and efficacy of Avandia;

(g) Bringing Avandia to market when it knew or should have known of the dangerous and defective condition of Avandia;

(h) Failing to remove Avandia from the market when it knew or should have known of the dangerous and defective condition of Avandia; and

(i) Continuing to promote, market and sell Avandia after it knew, or should have known, of the serious side effects and risks associated with Avandia use.

158. Defendant's negligent, careless, reckless, willful and/or intentional conduct was the proximate cause of the injuries and damages sustained by the State.

159. At all relevant times, Defendant knew, or should have known, that Avandia was and is hazardous to human health.

160. Avandia is abnormally and unreasonably dangerous as marketed in that the health risks and costs associated with Avandia greatly outweigh any claimed utility of Avandia to Medicaid and SHP participants.

161. As a direct result of the unreasonable marketing practices of Defendant, Avandia was, and is, defective and unreasonably dangerous.

162. Avandia reached the users and consumers thereof in substantially the same condition as when originally manufactured, distributed and sold by Defendant. At the time Avandia was sold or placed on the market, it was in a defective condition and unreasonably dangerous to Medicaid and SHP participants.

163. South Carolina Medicaid and SHP participants used Avandia in the manner in which it was intended to be used, without any substantive alteration or change in the product.

164. Due to the negligent, careless, reckless, willful and/or intentional conduct of the Defendant, as set forth above, the State dispensed millions of dollars of Medicaid and SHP funds in purchasing Avandia prescriptions and was also forced and will be forced to expend

significant sums of money for the care and treatment of South Carolina Medicaid and SHP participants injured by Avandia, all of which was foreseeable to Defendant.

165. As a direct and proximate result of Defendant GSK's negligence, the State of South Carolina has suffered and will suffer damages and is therefore entitled to recover those damages.

166. The reprehensible nature of the Defendant's conduct further entitles the State to an award of punitive damages.

COUNT VII

Breach of Express Warranty

167. Plaintiff repeats and reiterates the allegations previously set forth herein.

168. In marketing Avandia and promoting its use in the South Carolina Medicaid and SHP programs, Defendant GSK expressly warranted to the State, prescribers, and Medicaid and SHP participants that Avandia was safe, effective, and fit for its intended use. These express warranties were created by and through statements made by Defendant's authorized agents or sales representatives, orally and in publications, package inserts, and in other written materials intended for the State, prescribers and Medicaid and SHP participants.

169. The State, prescribers, and Medicaid and SHP participants relied on these express warranties.

170. GSK breached these express warranties due to Avandia's defective nature and the fact that the drug was not safe, effective, or fit for its intended use. Rather, Avandia carries unreasonable and undisclosed risks in breach of the express warranties.

171. The State dispensed millions of dollars of Medicaid and SHP funds in purchasing

Avandia prescriptions and was also forced and will be forced to expend significant sums of money for the care and treatment of South Carolina Medicaid and SHP participants injured by Avandia, all of which was foreseeable to Defendant. The State's expenses were caused and will be caused by Defendant's breach of its express warranties.

172. As a direct and legal result of Defendant's breach of express warranties, the State of South Carolina has suffered and will continue to suffer damages and is entitled to recover for those damages.

COUNT VIII

Breach of Implied Warranty

173. Plaintiff repeats and reiterates the allegations previously set forth herein.

174. Through the manufacture, marketing, and sale of Avandia, Defendant GSK impliedly warranted to the State of South Carolina, prescribers, and Medicaid and SHP participants that Avandia was of merchantable quality - safe and fit for its intended use.

175. At all times relevant to this action, Defendant GSK also had reason to know of the particular purpose for which the State, prescribers, and Medicaid and SHP participants were purchasing and using Avandia, i.e., for the treatment of diabetes. Therefore, Defendant GSK impliedly warranted to the State of South Carolina, prescribers, and Medicaid and SHP participants that Avandia was fit for that particular purpose.

176. Defendant GSK had reason to know through actual or constructive knowledge that the State of South Carolina, prescribers, and Medicaid and SHP participants were reasonably relying upon the skill, judgment, and implied warranties of Defendant in approving, prescribing, and using Avandia.

177. Defendant GSK breached the implied warranties of merchantability and of fitness for a particular purpose in that Avandia is not of merchantable quality, not safe for its intended use, and not safe for its particular purpose. This is because Avandia had dangerous and undisclosed propensities when ingested, resulting in severe illness and injury to many of its users.

178. The State dispensed millions of dollars of Medicaid and SHP funds in purchasing Avandia prescriptions and was also forced and will be forced to expend significant sums of money for the care and treatment of South Carolina Medicaid and SHP participants injured by Avandia, all of which was foreseeable to Defendant. The State's expenses were caused and will be caused by Defendant's breach of its implied warranties.

179. As a direct and legal result of this Defendant's breach of its implied warranties, the State of South Carolina has suffered and will continue to suffer damages and therefore is entitled to recover those damages.

COUNT IX

Unjust Enrichment

180. Plaintiff repeats and reiterates the allegations previously set forth herein.

181. Defendant knowingly, willfully and intentionally marketed and promoted Avandia in a false and deceptive manner.

182. Defendant knowingly, willfully and intentionally withheld information from the State, prescribers and Medicaid and SHP participants regarding the risks associated with Avandia use.

183. The State paid, reimbursed or otherwise conferred a benefit upon Defendant that directly resulted from the Defendant's fraudulent marketing practices.

184. Further, Defendant has been unjustly enriched as a result of its fraudulent marketing practices.

185. Plaintiff is entitled to restitution to the extent of the increased revenue received by the Defendant from Avandia prescriptions that were reimbursed by the State and which resulted from Defendant's deceptive and illegal marketing program.

COUNT X

Violations of the South Carolina Unfair Trade Practices Act

186. Plaintiff repeats and reiterates the allegations previously set forth herein.

187. GSK constitutes a "person" within the meaning of S.C. Code Ann. §39-5-10(a).

188. The State also constitutes a "person" within the meaning of S.C. Code Ann. §39-5-10(a).

189. GSK has repeatedly engaged in conduct which constitutes unfair and deceptive acts and practices, and violations of the South Carolina Unfair Trade Practices Act ("SCUTPA"), including:

(a) Making false and misleading misrepresentations of fact regarding Avandia's safety and efficacy;

(b) Misrepresenting and concealing material facts and/or failing to inform and educate South Carolina physicians and Medicaid and SHP participants as to the risks and dangers associated with Avandia use when such facts were well known to, or readily ascertainable to, Defendant;

(c) Misrepresenting and concealing material facts which were known to Defendant and unknown to South Carolina physicians, when Defendant knew that South Carolina physicians rely on such facts when deciding to prescribe Avandia to their patients;

(d) Misrepresenting that Avandia was a "significant advance" in diabetes treatment;

(e) Misrepresenting that Avandia was superior to existing drugs at lowering diabetics' blood sugar;

(f) Misrepresenting that Avandia could reduce diabetics' cardiovascular risks;

(g) Failing to disclose that Avandia posed serious increased cardiovascular risks; and

(h) In otherwise failing to disclose the true facts regarding the safety and efficacy of Avandia.

190. Defendant made orally, and in writing, false, misleading or deceptive misrepresentations in advertisements, promotions, marketing materials, statements, and product labeling, and otherwise disseminated false, misleading and deceptive information that had a tendency to deceive and did deceive the State, physicians, and Medicaid and SHP participants regarding the health risks and benefits associated with Avandia in violation of the SCUTPA §39-5-110.

191. The Attorney General seeks a civil penalty in the amount of up to $5000 for each method, act or practice deemed to violate the SCUTPA.

192. As a consequence of Defendant's illegal and deceptive sales and marketing practices, the State made monetary expenditures on behalf of South Carolina Medicaid and SHP participants who were prescribed Avandia when safer, less expensive and equally (or more) effective diabetes medications were readily available.

193. As a further consequence of Defendant's illegal and deceptive sales and marketing practices, many South Carolina Medicaid and SHP participants were prescribed Avandia by their physicians and sustained serious and potentially life-threatening side effects.

194. The State was forced to expend and will be forced to extend significant sums of money for the treatment of those South Carolina Medicaid and SHP participants who have

sustained serious and potentially life-threatening injuries as a result of using Avandia.

195. The Attorney General has determined that the imposition of an injunction against Defendant prohibiting the conduct set forth herein is in the public interest.

196. The State seeks the entry of a permanent injunction prohibiting Defendant's unlawful and deceptive conduct and the imposition of all appropriate remedies available under the SCUTPA, including restitution of all sums paid by the State for Avandia as a result of Defendant's violations of the SCUTPA.

197. Defendant acted knowingly and willfully in committing the violations of the SCUTPA described herein.

198. Each Avandia prescription written in South Carolina without an adequate warning constitutes a separate and distinct violation of the SCUTPA.

199. Each piece of marketing material used or disseminated in South Carolina which contained false or deceptive material constitutes a separate and distinct violation of the SCUTPA.

200. In addition to civil penalties sought under the SCUPTA §39-5-110, the State also seeks actual damages for the ascertainable losses incurred in connection with the Medicaid and SHP programs as a result of the Defendant's violations of the SCUTPA, together with three times the actual damages sustained by the State as allowed under §39-5-140(A) of the SCUTPA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the State of South Carolina, prays for judgment against GSK as follows:

1. For all damages sustained by the State in connection with the Medicaid and SHP

programs;

2. For restitution for Avandia prescriptions that were paid by the State in connection with the Medicaid and SHP programs and which resulted from Defendant's deceptive and illegal marketing program;

3. For treble damages pursuant to S.C. Code Ann. § 39-5-140(a);

4. For a civil penalty in the amount of up to $5000 for each method, act or practice deemed to violate the SCUTPA, and as allowed by S.C. Code Ann. § 39-5-110;

5. For treble damages pursuant to S.C. Code Ann. § 43-7-60(E);

6. For a civil penalty of $2000 for each false claim, representation or overstatement made to the State in connection with the Medicaid program, and as allowed by S.C. Code Ann. § 43-7-60(E);

7. For punitive damages;

8. For injunctive relief; and

9. For such other and further relief as may be justified and which Plaintiff may be entitled to by law or equity including, but not limited to, all attorneys' fees, investigative fees, court costs, witness fees, and deposition fees.

REQUEST FOR JURY TRIAL

The State respectfully requests that all issues presented by its above Complaint be tried before a jury, with exception of those issues that, by law or equity, must be tried before the Court.

Respectfully submitted,

STATE OF SOUTH CAROLINA
OFFICE OF THE ATTORNEY GENERAL

ALAN WILSON
Attorney General of South Carolina
JOHN W. McINTOSH
Chief Deputy Attorney General
C. HAVIRD JONES, JR.
Assistant Deputy Attorney General
Post Office Box 11549
Columbia, South Carolina 29211
(803) 734-3970 (Telephone)
(803) 734-3677 (Facsimile)
agsjones@scag.gov

By: John W. McIntosh
Chief Deputy Attorney General

HARRISON, WHITE, SMITH & COGGINS, P.C.

By: s/John B. White, Jr.

John B. White, Jr.
State Bar No. 5996
178 West Main Street (29306)
PO Box 3547
Spartanburg, SC 29304
(864) 585-5100 (Telephone)
(864) 591-0491 (Fax)

HEARD, ROBINS, CLOUD & BLACK, L.L.P.

Bill Robins III
Justin R. Kaufman
300 Paseo de Peralta, Suite 200
Santa Fe, New Mexico 87501
(505) 986-0600 (Telephone)
(505) 986-0632 (Facsimile)

L. MICHAEL MESSINA, P.A.

L. Michael Messina
2219 Vista Larga NE
Albuquerque, New Mexico 87106
(505) 243-0503 (Telephone)
(505) 243-3329 (Facsimile)

CHARLIE CONDON LAW FIRM, LLC

Charlie Condon
880 Johnnie Dodds Boulevard, Suite 1
Mount Pleasant, South Carolina 29464
(843) 884-8146 (Telephone)
(843) 884-6595 (Facsimile)

SIMMONS LAW FIRM, LLC

John S. Simmons
1711 Pickens Street
Columbia, South Carolina
(803) 779-4600(Telephone)
(803) 254-8874 (Facsimile)