SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK, :
by ELIOT SPITZER, Attorney General of the :
State of New York, :

Plaintiff,

against -

COMPLAINT
Index No.

GLAXOSMITHKLINE, plc.,
d/b/a/ GlaxoSmithKline,

SMITHKLINE BEECHAM CORPORATION,
d/b/a/ GlaxoSmithKline,

Defendants. :

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TO: THE SUPREME COURT OF THE STATE OF NEW YORK

The People of the State of New York, by their attorney, Eliot Spitzer, Attorney General of the State of New York, allege the following upon information and belief:

PRELIMINARY STATEMENT

1. GlaxoSmithKline, plc and SmithKline Beecham Corporation (doing business as GlaxoSmithKline and together referred to as "GSK") are collectively a pharmaceutical manufacturer with net income (adjusted earnings) in 2002 of over $6.9 billion. GSK has engaged in repeated and persistent fraud by misrepresenting, concealing and otherwise failing to disclose to physicians information in its control concerning the safety and effectiveness of its antidepressant medication paroxetine HCL ("paroxetine") in treating children and adolescents with Major Depressive Disorder ("MDD"). GSK sells paroxetine in the United States under the names Paxil® and Paxil CR™. Until 2003, GSK had market exclusivity for paroxetine in the US.

2. Paroxetine has been approved by the United States Food and Drug Administration ("FDA") as safe and effective for treating various indications in adults, including MDD, social anxiety disorder, general anxiety disorder and obsessive compulsive disorder ("OCD"). Paroxetine has not been approved for any condition or illness in children or adolescents. However, New York, like other states, permits physicians to prescribe FDA-approved drugs for conditions or diseases for which FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines the drug in question is an appropriate treatment for an individual patient. This practice is referred to as "off-label" use, and prescribing paroxetine for children and adolescents is an off-label use.

3. Approximately 2.1 million prescriptions for paroxetine were written for children and adolescents in the United States during 2002. Nearly 900,000 of these prescriptions were for youngsters whose primary diagnosis was a mood disorder, the most common of which is depression. It is estimated that one-third of such prescriptions are written by non-psychiatrists, many by family practitioners and pediatricians. Prescriptions for paroxetine to treat mood disorders in children and adolescents translated into US sales for GSK of approximately $55 million in 2002

4. GSK has misrepresented information concerning the safety and efficacy of paroxetine for treating MDD in children and adolescents. GSK has allowed positive information about pediatric use of paroxetine to be disclosed publically, but has withheld and concealed negative information concerning the safety and effectiveness of the drug as a treatment for pediatric MDD. Thus, GSK has prevented physicians from properly and independently exercising their professional judgment on behalf of their child and adolescent patients with MDD. GSK's acts have deprived these youngsters of the benefit of their physicians' independent professional judgment.

5. The Attorney General of the State of New York brings this action to stop GSK's illegal and deceptive actions, to obtain restitution for the New York children and adolescents with MDD for whom paroxetine has been prescribed, for disgorgement of profits, and for all other proper relief.

JURISDICTION AND PARTIES

6. The Attorney General is authorized to seek a judgment which enjoins repeated or persistent fraudulent or illegal business acts or practices, including any misrepresentation, concealment or suppression of a material fact, and which awards damages and restitution for such acts. N.Y. Executive Law § 63(12).

7. GlaxoSmithKline, plc is a public limited company organized under the laws of England and Wales. SmithKline Beecham Corporation is a Delaware corporation, which is a wholly owned subsidiary of GlaxoSmithKline, plc. (Defendant GlaxoSmithKline, plc includes all of its predecessors and its past and current components, including SmithKline Beecham Corp.) GSK regularly conducts business within the State of New York and derives substantial revenues from goods consumed in New York.

FACTUAL ALLEGATIONS

Background

8. The FDA approves drugs for human use, based on whether they are safe and effective as determined through scientifically conducted clinical studies. Efficacy is assessed by whether the drug is superior to placebo (dummy pills) and whether that superiority is statistically significant, *i.e.*, the difference in the outcome could not be explained by chance alone. To provide solid evidence of a drug's efficacy, and therefore its benefit to patients, a study needs to be randomized, placebo-controlled and double-blind. The FDA approves a drug for specific

conditions or diseases and for specific populations, such as children and adolescents ("pediatric population") or adults.

9. The FDA has approved paroxetine as safe and effective in treating various indications in adults, but not for any illness or condition in children and adolescents.

10. The FDA does not regulate the practice of medicine. Within New York, as in other states, the regulation of the practice of medicine is solely the responsibility of the State.

1. New York physicians, like other physicians, owe their patients fiduciary and professional obligations to exercise their independent professional judgment in making treatment recommendations and to recommend only those treatments that are appropriate for the individual patient. Conversely, patients (and, in the case of children and adolescents, their parents and guardians) rely on the professional judgment of their physicians in deciding whether to consent to and purchase a treatment.

12. The State of New York, like other states, permits licensed physicians who practice medicine within its borders to prescribe a drug for conditions or diseases for which FDA approval has not been obtained when, in the physician's professional judgment, it is an appropriate treatment for the individual patient, provided the drug has already been approved by the FDA for some other use. This judgment is based on the balance between (a) the benefit the patient is likely to derive from the treatment, including the harm or benefit, if any, of providing no treatment or an alternative treatment, and (b) the risk that the proposed treatment will cause the patient harm and the nature and severity of that harm.

13. In deciding whether to prescribe a drug for an off-label use, physicians usually rely on their assessment of information received from other sources. Such information must be accurate and provide an unbiased picture of a drug's safety and efficacy in treating a condition. If the information is false or misleading, the physician cannot accurately assess the crucial risk-

benefit balance for the patient or exercise professional judgment that is independent. Consequently, the physician cannot act in accordance with the professional and fiduciary obligations owed to the patient.

14. Concealing or providing inaccurate or biased information that is material to a prescribing decision misleads the physician and the patient who relies on that physician's professional judgment.

GSK's Studies Concerning the Safety and Efficacy of
Paroxetine in Treating Children and Adolescents with MDD

15. GSK conducted three randomized, placebo-controlled, double-blind clinical studies to assess the safety and efficacy of paroxetine in treating children and adolescents diagnosed with MDD. These studies are referred to by GSK as studies 329, 377 and 701

16. GSK management approved the final clinical reports for studies 329 and 377 in 1998 and for study 701 on July 31, 2001

17. GSK has represented that studies 329, 377 and 701 were "well designed and appropriate to investigate whether paroxetine was efficacious in children and adolescents with MDD." The FDA has also referred to them as "well-controlled trials."

18. GSK conducted two additional studies that were extensions of studies 329 and 701. The extension of study 329 (final clinical report approved by GSK on October 31, 2001), which included only youngsters with MDD, was not randomized. It was designed to evaluate relapse rate and longer-term safety, not efficacy. Study 716 (final clinical report approved by GSK on September 16, 2002), was not randomized, placebo-controlled or blind (all participants received paroxetine during the extension) and included participants from completed studies of pediatric patients with MDD (study 701) or OCD. It examined the longer-term safety of paroxetine.

a. Efficacy

19. GSK's studies did not demonstrate that paroxetine is efficacious in treating children and adolescents with MDD.

20. Two of the three GSK placebo-controlled studies (377 and 701) failed to show that paroxetine was more effective than placebo or that there was any evidence of efficacy for treating MDD in children and adolescents.

21. Study 377 found that "[n]o clinically or statistically significant differences were detected between paroxetine and placebo in either of the [two] primary efficacy variables," or on any of the secondary measures.

22. In study 701, placebo actually outperformed paroxetine on the primary efficacy measure and there were no statistically significant differences between paroxetine and placebo on any of the secondary measures.

23. Another placebo-controlled trial, study 329, presented a mixed picture of paroxetine's efficacy in treating MDD in a pediatric population. Before study 329 began, GSK specified seven measures of efficacy, two of which it identified as "primary" endpoints and five as "secondary" endpoints. The efficacy of paroxetine was not measured as superior to placebo at a level of statistical significance on either of the primary measures. It was measured as superior to placebo on three of the five secondary ones, as well as on an endpoint that was added to the analysis.

b. Safety

24. GSK's studies showed the possibility of a link between paroxetine and an increased risk of suicidal thoughts and acts in adolescents. Combined, studies 329, 377, and 701 showed that certain possibly suicide-related behaviors were approximately two times more likely

in the paroxetine group than the placebo group. The extension phase of study 329 and study 716 provided support for the presence of such a risk in youngsters taking paroxetine.

25. In the five studies (329, 377, 701, 329-extension and 716), GSK coded suicidal thinking and acts, as well as mood swings, crying and similar behaviors, as "emotional lability."

26. In study 329, emotional lability was recorded for 6.5 percent of the participants on paroxetine (for five of six of these youngsters, the events were classified as "serious") and only 1.1 percent in the placebo group (also "serious").

27. In study 377, emotional lability occurred in 4.4 percent of the paroxetine group, while it occurred in 3.2 percent in the placebo group. In study 701, emotional lability occurred in 3.6 percent of the paroxetine group participants who remained in the study for the tapering-off or follow-up periods, while it occurred in 1.4 percent of the same group of participants who took placebo.

28. In the 329 extension study, emotional lability was found in 7.7 percent of the youth on paroxetine (four individuals) and 3.0 percent of the placebo group. The reported incident for three of the four paroxetine youngsters was intentional overdose, and the youth from the placebo group was reported as suicidal and homicidal. The adverse events for these four participants were categorized as serious.

29. In study 716, which had no placebo group, emotional lability occurred in 6.8 percent of the participants (children and adolescents) with a primary diagnosis of MDD and in 12.5 percent of the adolescents with MDD.

GSK's Presentation of Positive Information and
Misrepresentation and Suppression of Negative Information

30. Because its studies failed to demonstrate efficacy for paroxetine in treating MDD in children and adolescents and suggested a possible increased risk of suicidal thinking and acts

for these youth, GSK sought to limit physicians' access to only the most favorable aspects of the data from these studies. To accomplish this, GSK embarked on a campaign both to suppress and conceal negative information concerning the drug and to misrepresent the data it did reveal concerning the drug's efficacy and safety.

a. GSK's Release of Study 329 and Concealment of the Unfavorable Studies

31. An internal GSK document from 1998 concluded that, in light of the mixed efficacy outcomes from study 329 and the entirely negative results of study 377, GSK's "target" was "[t]o effectively manage the dissemination of these data in order to minimise any potential negative commercial impact."

32. As part of its campaign to "manage the dissemination of these data," the document recommended that GSK prepare and cause the publication of a full article on the only study with some favorable conclusions, study 329.

33. Thereafter, and in accordance with the recommended plan, an article that described and analyzed the results of study 329 was published in a professional journal. The authors of this article included two GSK employees who authored GSK's final clinical report for study 329.

34. Although it allowed the data from study 329 to be published, GSK concealed and suppressed studies 377 and 701, which failed to show that paroxetine was more effective than placebo in treating MDD in children and adolescents.

35. While information from study 377 was presented at a medical convention in 1999, neither study 377 nor study 701 has ever been published, and they remain unavailable to physicians, as are the results of the extension phase of study 329 and study 716. (Interim results from study 716 were presented at a medical conference in 2002.)

36. The data in studies 377 and 701, as well as the data from the extension phase of study 329 and study 716, are material to the risk-benefit balance and, therefore, to a physician's decision whether to prescribe paroxetine for a child or adolescent with MDD. This is especially true in light of the publication of study 329.

b. GSK's Provision of Misinformation to its Sales Force, Which Is the Company's Liaison to Physicians

37. GSK has repeatedly misrepresented the safety and efficacy outcomes from its studies of paroxetine as a treatment for MDD in a pediatric population to its employees who promote paroxetine to physicians. These sales representatives are the GSK personnel who routinely have personal contact with the physicians who decide whether to write prescriptions for paroxetine.

38. On a cover memo that transmitted the published article concerning study 329 to "All Sales Representatives Selling Paxil," Zachary Hawkins, GSK Paxil Product Management, stated, "***Paxil* demonstrates REMARKABLE Efficacy and Safety in the treatment of adolescent depression.**" (Type face as in original.)

39. Study 329 did not demonstrate remarkable efficacy and safety in treating adolescent depression. Although the memo contained the boiler-plate language, "FYI *Article will be stamped: This article is for pharmaceutical consultants' Information only. Do not use it with, or distribute it to physicians*," it is clear that this was the intent. GSK would have had no reason to provide this information to sales representatives other than to use it to falsely characterize study 329 in their communications with physicians. Indeed, it appears that these sales representatives had paroxetine "targets" for psychiatrists who treat only children and adolescents, because GSK informed its sales force that these targets would be eliminated in 2003.

40. In December 1999, Dr. Karen Wagner, one of the authors listed on the published article concerning study 329, spoke at a meeting of GSK Neuroscience consultants, at which she discussed study 329. She was quoted by an internal GSK newsletter as having said, "We can say that paroxetine has both efficacy and safety data for treating depression in adolescents." Although study 377 had also been completed when this newsletter was distributed, its negative results were not mentioned.

c. GSK's Misrepresentations in its Medical Information Letters: November 2001 through January 2003

41. GSK provides information concerning off-label uses of its drugs to physicians through its Medical Information Letters, but only when the physician makes an unsolicited request for the information.

42. As of November 2001, GSK had completed and approved the final clinical reports on studies 329, 377 and 701, and the extension phase of study 329. GSK issued Medical Information Letters in November 2001 and January 2003, both of which misrepresented the information concerning the safety and efficacy of paroxetine for treating MDD in children and adolescents as GSK knew it at the time. GSK enclosed the published article concerning study 329 with some of the Medical Information Letters.

43. Neither of these Medical Information Letters reported the four efficacy outcomes from study 329 that were not statistically significant. Nor did the Medical Information Letters refer to the fact that study 329 had an extension phase in which the rate of relapse did not differ between the paroxetine and placebo groups. While all of the efficacy outcomes from study 377 were negative, the Letters only reported one of them, stating it was numerically superior to placebo but not statistically significant. The Medical Information Letters failed to communicate GSK's own conclusion that there was no clinical significance, as well as no statistical

significance, in the outcomes from study 377. Nor did these Medical Information Letters include any reference to study 701 in which placebo outperformed paroxetine. Each of these Medical Information Letters, however, reported open label (non-placebo-controlled) studies with positive efficacy results.

44. GSK reported emotional lability data from its MDD paroxetine studies in only one of the two Medical Information Letters it sent to physicians during this period. Even when GSK reported the emotional lability information in one Letter, which was exclusively from study 329, it did so only for the paroxetine group. Without the comparative data from the placebo group, these data on possibly suicide-related thinking and acts lost much of their meaningfulness.

45. The Medical Information Letter that reported emotional lability data from study 329 also provided information on other categories of adverse events observed during study 716. This Letter, however, did not inform physicians that in study 716 emotional lability was experienced by 6.8 percent of the participants (children and adolescents) with a primary diagnosis of MDD and in 12.5 percent of the adolescents with MDD. Extension study 329 was not mentioned in any of the Medical Information Letters, although in this study emotional lability was observed in 7.7 percent of the paroxetine group versus 3.0 percent in the placebo group.

GSK's Disclosure of the Studies to Regulatory
Agencies and its Admissions Concerning Efficacy and Safety

46. In 2002, as part of its application for FDA approval of paroxetine to treat OCD in children and adolescents, GSK submitted the final clinical reports for studies 329, 377 and 701, which assessed the safety and efficacy of paroxetine in the treatment of MDD in pediatric patients. GSK subsequently provided these materials to the drug-regulatory agencies of other countries.

47. The studies raised issues for all the drug-regulatory agencies regarding the efficacy and safety of pediatric use of paroxetine for treating MDD.

48. In documents submitted in response to safety and risk-benefit issues raised by various drug-regulatory agencies, including the FDA, the UK's Medicines and Healthcare products Regulatory Agency ("MHRA") and the European Agency for the Evaluation of Medicinal Products ("EMEA"), GSK admitted that studies 329, 377 and 701 "all failed to separate paroxetine from placebo overall and so do not provide strong evidence of efficacy in this indication."

49. On June 10, 2003, the MHRA stated that its analyses of GSK's studies suggested the risk of self-harm and potential suicidal behavior of youngsters with MDD was between 1.5 and 3.2 times greater for the paroxetine group than for placebo. The MHRA reported that its Committee on Safety of Medicines advised that paroxetine "should not be used in children and adolescents under the age of 18 years to treat depressive illness." The agency also added a contraindication for this use on the paroxetine labeling in the UK, which would substantially curtail its use as a treatment for pediatric MDD. The Irish Medicines Board followed suit in December 2003.

50. In response to the MHRA's June 10, 2003 warning, GSK admitted in a letter to physicians in the UK that the "clinical trials in children and adolescents under 18 years of age failed to demonstrate efficacy in Major Depressive Disorder and that there was a doubling of the rate of reporting of adverse events in the paroxetine group compared with placebo, including ... emotional lability."

51 In a press release GSK issued in the UK, the company admitted that, in its studies of youngsters with depression, it had observed "a difference between [paroxetine] and placebo in terms of suicidal thinking or attempts, particularly in adolescents."

52. In a submission GSK made to the EMEA and subsequently sent to the FDA on November 17, 2003, GSK admitted that the risk-benefit balance for treating pediatric MDD patients using paroxetine was unfavorable. Citing the overall lack of statistical significance in the efficacy outcomes from studies 329, 377 and 701 and the possibly increased risk of suicidal thinking and acts for these youth, especially for older adolescents, GSK stated, "it must be concluded that the benefit-risk balance is in favour of not treating children and adolescents [diagnosed with MDD] with paroxetine." GSK also stated in this submission, "in view of a safety signal concerning a possible increase in suicidal behaviour, particularly in adolescents with MDD, the use of paroxetine in children and adolescents with MDD cannot be recommended."

53. On June 19, 2003, the FDA issued a Talk Paper, which stated that it was reviewing the data from studies of paroxetine use in children and adolescents with MDD to assess possible increased risk of suicidal thinking and attempts in this population. Noting the absence of evidence of efficacy, the FDA also stated that although the review of the safety data was not complete, "FDA is recommending that Paxil not be used in children and adolescents for the treatment of MDD." In a second Talk Paper in October 2003, the FDA did not retract its finding that "***three*** well-controlled" clinical trials of paroxetine did not establish its efficacy in treating MDD in the pediatric population, but it noted the scientific fact that the lack of evidence of efficacy in any "***particular***" study is not "***definitive***" evidence that the drug is not effective. (Emphasis added.) It also stated that the possibility of a link between paroxetine and an increased risk of suicidal thoughts and acts was under agency review and advised that paroxetine and other drugs in its class (Selective Serotonin Reuptake Inhibitors or "SSRIs") be used with caution. The FDA strengthened its advice to use SSRIs with caution in a third FDA Talk Paper issued March 22, 2004.

54. On July 15, 2003, after discussions with Health Canada, the Canadian regulatory agency, GSK issued a public advisory "alerting patients, their parents or guardians, and healthcare professionals that until further information is available Paxil should not be given to pediatric patients (children and adolescents under 18 years of age), due to concerns of a possible increased risk of suicidal thinking, suicidal attempts or self-harm. Paxil must not be used in pediatric patients with major depressive disorder, due to the additional fact that studies have failed to show that Paxil was effective in this patient population."

55 On April 22, 2004, the Committee for Proprietary Medicinal Products of the EMEA announced that, following its review of scientific data, it was recommending to the European Commission that paroxetine not be prescribed for pediatric patients.

GSK's Continued Suppression and Misrepresentations

56. Despite its 2003 admissions to regulatory agencies and to the public in the UK and Canada, and despite the agencies' negative assessment of efficacy and articulated safety concerns about the use of paroxetine by children and adolescents with MDD, GSK continues to misrepresent and conceal information in an ongoing effort to encourage physicians to prescribe paroxetine to these youngsters.

57. For example, GSK revised its Medical Information Letter three times after the FDA's first Talk Paper in June 2003. While these Letters included all of the data from study 329, none cited the existence of the extension phase of this study, which showed no difference in relapse rate between paroxetine and placebo. One of these three 2003 Medical Information Letters did not report any additional information concerning emotional lability beyond what was reported in the earlier Medical Information Letters that pre-dated any of the Talk Papers. None of the Letters reported the particularly negative emotional lability data from study 329-extension and

study 716, although they cited other non-randomized studies that had no placebo control. Moreover, all of these communiques to physicians referenced the FDA Talk Papers, but one failed to acknowledge the absence of evidence of efficacy from the clinical studies, which the FDA's first Talk Paper had noted.

58. GSK also issued a fourth Medical Information Letter explicitly responding to the FDA's first Talk Paper, which omitted any reference to the agency's finding of no evidence of paroxetine's efficacy in treating MDD in a pediatric population. This Medical Information Letter was specifically focused on the use of paroxetine to treat children and adolescents with MDD, and stated: "GlaxoSmithKline stands firmly behind Paxil as a safe and effective medication that continues to help millions of patients suffering from mood and anxiety disorders. We will continue to work with the FDA on the safety evaluation." In the context of this document, the quoted statement appeared to announce GSK's position concerning paroxetine as a treatment for MDD in a pediatric population, suggesting it is safe and effective for this use.

59. GSK further controlled physicians' access to negative information about paroxetine as a treatment for MDD in children and adolescents by controlling the information provided to its own personnel. While GSK attached the FDA's June 19, 2003 Talk Paper to a July 15, 2003 internal company newsletter, it instructed the sales representatives that the copy of the Talk Paper was "**for your information only, and it** [sic] **not to be used with your customers.**" (Emphasis in original.) This 2003 newsletter also informed the sales personnel, who communicate directly with physicians, that study 329, as described in the published article, was able to establish efficacy despite a high placebo-response rate. At most, study 329 presents a mixed picture on efficacy.

60. Although, in response to the British and Canadian regulatory actions, GSK distributed letters to the physicians in those countries informing them that clinical studies had

failed to demonstrate the efficacy of paroxetine in MDD in the pediatric population and that there was a doubling of the rate of reporting of adverse events, including emotional lability, it did not provide American physicians with this same information. Instead, it sent the Medical Information Letters, with their omissions of material information, to only those physicians who specifically requested information concerning paroxetine use as a treatment for MDD in children and adolescents.

61 GSK took affirmative steps to conceal negative information about the use of paroxetine to treat MDD in children and adolescents from the American public. Unlike GSK's June 10, 2003 press release in Britain, which disclosed that GSK had "seen a difference between [paroxetine] and placebo in terms of suicidal thinking or attempts [in its MDD studies] particularly in adolescents," GSK's June 19, 2003 American press release noted only that "there is no evidence that Paxil is associated with an increased risk of suicidal thinking or acts in adults" and that "not a single person [who participated in the pediatric paroxetine trials] committed suicide." The American press release provided no safety or efficacy information material to treatment decisions for pediatric patients with MDD.

GSK's Prevention of Physicians' Exercise of
Independent Professional Judgment on Behalf of Their Patients

62. Virtually all physicians have access to the results of study 329 through the published article. GSK's failure to disclose to these physicians the findings of studies 377 and 701 and the safety outcomes of studies 329-extension phase and 716, created the false impression that, based on the scientific evidence in GSK's control, there is no question about paroxetine's safety and efficacy in treating MDD in children and adolescents and, therefore, the risk-benefit balance is well settled and generally favorable for this off-label use. This impression was reinforced by GSK's mischaracterization of much of the information it did disclose, its further

concealment and suppression of negative information, and its paroxetine-related targeting of psychiatrists who treat only pediatric patients.

63. GSK misled and deceived physicians and consequently the patients who relied on their professional judgment. GSK deprived physicians of the information needed to evaluate the risks and benefits of prescribing paroxetine for children and adolescents with MDD. By doing so, GSK deceived these physicians, irrespective of whether or not they would have prescribed paroxetine if GSK had disclosed the material facts that were known at the time.

CAUSE OF ACTION
REPEATED AND PERSISTENT FRAUD

64. Executive Law § 63(12) authorizes the Attorney General to bring an action to enjoin and obtain restitution and damages for "repeated fraudulent acts or ... persistent fraud .. in the carrying on, conducting or transaction of business," including "any deception, misrepresentation, concealment [or] suppression" of a material fact.

65. By engaging in the acts and practices described above, GSK has engaged in and continues to engage in repeated fraudulent acts or persistent fraud in violation of Executive Law § 63(12).

PRAYER FOR RELIEF

WHEREFORE, the People of the State of New York respectfully request that a judgment and order be entered that:

A. Permanently enjoins GSK from engaging in the deceptive, fraudulent and unlawful practices alleged herein;

B. Directs GSK to pay restitution and damages to all aggrieved consumers, including those not known at the time the order is entered, which restitution and damages shall include, but

not be limited to, disgorgement of all profits GSK derived from the sale of Paxil® or Paxil CR™ in the State of New York for a child or adolescent with depressive disorder;

C. Awards Plaintiffs costs, including additional costs in the amount of $2,000 pursuant to C.P.L.R. § 8303(a)(6); and

D. Grants all other relief that is just and proper.

Dated: New York, New York
June 2, 2004

Respectfully submitted,

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