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THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ORANGE

BEVERLY SMITH, on behalf of herself and all others similarly situated and on behalf of the general public,

Plaintiff,

vs.

SMITHKLINE BEECHAM CORPORATION, dba GLAXOSMITHKLINE, a Pennsylvania Corporation, and DOES 1-100, inclusive,

Defendants.

Case No.: 04CC00590

CLASS ACTION COMPLAINT FOR:

1. **UNFAIR AND DECEPTIVE BUSINESS PRACTICES; AND**
2. **FALSE AND MISLEADING ADVERTISING**

Plaintiff, Beverly Smith, brings this action on behalf of the general public and on behalf of herself and all others similarly situated, as members of the proposed Class, defined as follows:

All persons or entities who purchased and/or paid for paroxetine under the trade name Paxil, Paxil CR and/or Paxil Oral Suspension in the states of California, Florida, Massachusetts, Nevada, New Jersey, Pennsylvania, Texas, and Washington for consumption by a minor.

I. JURISDICTION AND VENUE

1. Jurisdiction over this proceeding in California State court is based on activity conducted in the State of California, and in this County, and misconduct alleged herein which was intentionally directed at all residents of the State of California. Accordingly, this Court has jurisdiction of this action under Article VI, section 10 of the California Constitution and section 410.10 of the Code of Civil Procedure.[1]

2. Pursuant to Code of Civil Procedure section 395, venue is proper in this judicial district, as this action concerns acts occurring within this County.

3. Furthermore, Plaintiff is informed and believes (and based thereon alleges) that defendant SmithKline Beecham Corporation, dba GlaxoSmithKline (referred to hereinafter as "SKB") has purposefully availed itself of the benefits and protections of the State of California and/or has had sufficient contact with this County such that maintenance of the action in this locale would be consistent with traditional notions of fair play and substantial justice.

II. THE PARTIES

4. Plaintiff is a resident of the State of California, County of Orange. Plaintiff's minor son was prescribed Paxil and suffered side effects, including self-mutilation, which side effects were not disclosed in Paxil's label. Plaintiff purchased Paxil on her son's behalf. There is no federal jurisdiction over this matter because Plaintiff has not used Paxil and has not suffered any damage in excess of $75,000.

5. SmithKline Beecham Corporation, dba GlaxoSmithKline, is a Pennsylvania corporation. SKB regularly conducts business within the State of California and derives substantial revenues from goods consumed in California.

6. The true names and capacities, whether individual, corporate, associate or otherwise, of defendants Does 1-100, inclusive, are unknown to Plaintiff, who therefore sues such defendants by such fictitious names. Plaintiff will amend this Complaint to show such defendants' true names or capacities when

[1] Unless stated otherwise, all statutory references herein are to California law.

same have been ascertained. Plaintiff is informed and believes and thereon alleges that each of said fictitious named defendants is responsible in some manner for the occurrences herein alleged.

III. NATURE OF THE CASE

7. Plaintiff brings this action for unfair and deceptive business practices. Through this Complaint, Plaintiff alleges the unlawful, unfair business practices and false and misleading statements of SKB in the advertising and marketing of its antidepressant drug paroxetine HCL ("paroxetine") in treating children and adolescents. SKB sells paroxetine in the United States under the trade names Paxil ® and Paxil CR™ (hereinafter referred as "Paxil or "paroxetine"). Until 2003, SKB had market exclusivity for Paxil in the U.S. SKB has marketed and sold Paxil, through the medical community, to the millions of patients and consumers in California, Florida, Massachusetts, Nevada, New Jersey, Pennsylvania, Texas, and Washington since December 1992. Not only are large numbers of medical providers and their minor patients, and their guardians in these states being misled about the drug's true efficacy and risks, but many patients are becoming dependent upon Paxil without warning. Immediate and irreparable harm is occurring daily to these citizens.

8. Plaintiff thus respectfully asks that the Court: (a) enjoin and restrain SKB from disseminating and distributing false and deceptive claims about Paxil and order that this business practice is unfair, deceptive and unlawful; (b) award restitution and/or damages (including treble damages, where appropriate) in the amount that was paid for the minors' Paxil prescriptions, plus interest; (c) order disgorgement relief as appropriate; and (d) award all other costs, including attorneys' fees, available under state law.

IV. CLASS ALLEGATIONS

9. Plaintiff brings this action on behalf of herself and all others similarly situated and on behalf of the general public, defined as follows:

> "All persons or entities who purchased and/or paid for paroxetine under the trade name Paxil, Paxil CR and/or Paxil Oral Suspension in the states of California, Florida, Massachusetts, Nevada, New Jersey, Pennsylvania, Texas, and Washington for consumption by a minor."

10. This action has been brought and may properly be maintained as a class action satisfying the numerosity, commonality, typicality, adequacy, and superiority requirements, because:

a. Individual joinder of Class Members would be impracticable. Plaintiff is informed and believes and based thereon alleges that the class consists of thousands of persons.

b. Common questions of law and fact exist as to all members of the Class that predominate over any question that affects only individual Class Members. These common questions of law and fact include, without limitation:

1) SKB has deceived and continues to deceive the medical community, including those providers who prescribed Paxil to minors, into believing Paxil does not have the harmful properties and the risks which SKB knows it in fact does;

2) SKB has deprived and continues to deprive medical providers the ability to perform the benefit/risk assessment necessary to the proper off label use of Paxil for children and adolescents;

3) By SKB's concealment or provision of inaccurate or biased information that is material to a prescribing decision, it has misled and continues to mislead physicians and patients who rely on that physician's professional judgment;

4) SKB has improperly sought to promote and continues to promote its drug Paxil at the expense of the health and welfare of those children and adolescents who have been prescribed the drug;

5) SKB has prevented and continues to prevent physicians from properly and independently exercising their professional judgment on behalf of their child and adolescent patients;

6) Promoting directly or indirectly that Paxil is either safe or efficacious for treating depression in children and/or adolescents.

7) "Ghostwriting" letters and articles for the signature of "opinion leaders" to be placed in respected medical journals, which downplay Paxil's adverse effects, promoting positive study outcomes and avoiding negative ones.

8) Not permitting clinical trial investigators to have access to the underlying raw data from clinical studies for which they have agreed to sign their names.

9) Hiring prominent psychiatrists around the country to be on-call to address the media when faced with accusations that Paxil is associated with violence and/or suicide and to blame the victim (e.g., by stating "it's the disease, not the drug").

10) Requiring clinical trial investigators to enter into agreements with SKB that they will not publish the results of studies involving Paxil unless SKB agrees to such.

11) By placing clinical trial investigators whose studies demonstrate a lack of efficacy or severe side effects attributable to the drug on "do not use in the future" lists.

12) SKB has hidden the association between Paxil and the side effects referenced above by using such misleading language as "may have no causal relationship to the drug" or "not distinguishable from the natural course of the underlying disease."

13) Mis-coding adverse events.

14) SKB deliberately chose not to use a sufficiently sensitive measure for treatment emergent suicidality in its clinical trials. Such a measure could have enabled SKB to determine the true rate of treatment emergent suicidal behavior, thus enabling SKB to warn physicians of the risk.

15) Drafting expert reports regarding efficacy and safety for regulatory bodies who believed they were the work product and opinion of the expert, not SKB.

16) Intentionally failed to accurately and/or fully report known adverse effects of Paxil.

17) Using "statistical sophistication" to manage unfavorable data from clinical studies.

18) Recommending Paxil for in-patients when SKB knew the drug has never been proven effective for in-patients.

19) Advertising, as if it were a scientifically proven fact, that depression is caused by a "chemical imbalance" of serotonin and that such imbalance will be "corrected" by Paxil, when no such imbalance has ever been proven and it is impossible to test whether anyone is really suffering from such an imbalance.

20) Whether defendant is liable for unfair and deceptive business practices.

c. The representative plaintiff's claims are typical of those of the Class because she is a California resident who purchased and/or paid for Paxil, Paxil CR, Paxil Oral Suspension for consumption by a minor.

d. The representative plaintiff is an adequate representative of the Class because she shares the same interest as all Class Members and because her claims and losses are typical of those of the Class Members. The representative plaintiff has retained competent counsel who are experienced in class action litigation and who will fairly and adequately protect the interests of the Class Members.

e. A class action is superior to other available methods for the fair and efficient adjudication of this litigation, since individual joinder of all persons who purchased and/or paid for Paxil, Paxil CR, and/or Paxil Oral Suspension in the states of California, Florida, Massachusetts, Nevada, New Jersey, Pennsylvania, Texas, and Washington for consumption by a minor is impracticable. Such losses are modest in relation to the expense and burden of individual prosecution of the litigation necessitated by the Defendant's wrongful conduct. It would be virtually impossible for the Class Members to efficiently redress their wrongs individually. Even if all Class Members themselves could afford such individual litigation, the Court system would benefit from a class action. Individualized litigation would present the potential for inconsistent or contradictory judgments. Individualized litigation would also magnify the delay and expense to all parties and to the Court system presented by the issues of the case. By contrast, the class action device presents far fewer management difficulties and provides the benefit of comprehensive supervision by a single Court, as well as economy of scale and expense.

IV. FACTUAL ALLEGATIONS

11. SKB is a pharmaceutical manufacturer with net income (adjusted earnings) in 2002 of nearly $7 billion. SKB has engaged in repeated and persistent fraud by misrepresenting, concealing and otherwise failing to disclose to physicians and other prescribing providers information in its control concerning the safety and effectiveness of Paxil as it relates to minors.

12. Paxil has been approved by the United States Food and Drug Administration ("FDA") as safe and effective for treating various indications in adults, including Major Depressive Disorder ("MDD"), social anxiety disorder ("SAD"), general anxiety disorder ("GAD"), post traumatic stress disorder ("PTSD"), panic

disorder, and obsessive compulsive disorder ("OCD"). Paxil has not been approved for any condition or illness in minors and it is not safe or efficacious for use in minors.

13. Physicians are permitted 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 Paxil for unapproved uses or for minors is off-label use.

14. Over 2 million prescriptions for Paxil 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 Paxil to treat mood disorders in children and adolescents translated into U.S. sales for SKB of approximately $55 million in 2002.

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

16. The FDA does not regulate the practice of medicine. The regulation of the practice of medicine is solely the responsibility of the State.

17. 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.

18. Licensed physicians are permitted 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.

19. In deciding whether to prescribe a drug for an off-label use, physicians typically rely on their assessment of information received about the drug. 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.

20. 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.

SKB's Studies Concerning the Safety and Efficacy of Paxil in Treating Children and Adolescents

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

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

23. SKB has represented that studies 329, 377 and 701 were "well designed and appropriate to investigate whether Paxil was efficacious in children and adolescents with MDD."

24. SKB conducted two additional studies that were extensions of studies 329 and 701. The extension of study 329 (final clinical report approved by SKB 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 SKB on September 16, 2002), was not

randomized, placebo-controlled or blind (all participants received Paxil during the extension) and included participants from completed studies of pediatric patients with MDD (study 701). It examined the longer-term safety of Paxil.

Efficacy

25. SKB's studies did not demonstrate that Paxil is efficacious in treating children and adolescents.

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

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

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

29. Another placebo-controlled trial, study 329, presented a mixed picture of Paxil,'s efficacy in treating MDD in a pediatric population. Before study 329 began, SKB specified seven measures of efficacy, two of which it identified as "primary" endpoints and five as "secondary" endpoints. The efficacy of Paxil was not measured as superior to placebo at a level of statistical significance on either of the primary measures.

Safety

30. SKB's studies showed the possibility of a link between Paxil 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 Paxil 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 Paxil.

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

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

33. In study 377, emotional lability occurred in 4.4 percent of the Paxil group, while it occurred in 3.2 percent in the placebo group. In study 701, emotional lability occurred in 3.6 percent of the Paxil 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.

34. In the 329 extension study, emotional lability was found in 7.7 percent of the youth on Paxil (four individuals) and 3.0 percent of the placebo group. The reported incident for three of the four Paxil 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.

35. 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.

36. In addition, during the course of these trials it was shown that many of the participants (children and adolescents) experienced other serious and/or severe side effects including hyperkinesia [akathisia], hostility, agitation, crying spells, mood fluctuations and self-harm.

37. Even before submitting the clinical trial data related to children and adolescents to the FDA in order to obtain a child/adolescent indication for Paxil, SKB was aware of the risk of treatment emergent hyperkinesia [akathisia], hostility, agitation and suicidal behavior. One of its own expert witnesses, Dr. John Mann, testified in a triple homicide/suicide case (wherein a 60 year old man killed his wife, daughter, baby granddaughter and then himself while on Paxil and which resulted in an 8 million dollar verdict for the Plaintiff): "[A]kathisia has the potential when it is severe of contributing to suicidality and aggression."

38. In addition, in the clinical trials for Paxil, investigators were given a choice as to whether Paxil caused adverse reactions reported by their patients. The choices ranged from "definitely" related to the drug, "possibly," "probably," to "definitely not," and "probably not." SKB's own investigators attributed numerous events, such as hyperkinesia [akathisia], hostility, agitation and suicidal behavior as "definitely" and "probably" related to Paxil.

39. Moreover, the clinical trial data submitted to the FDA by SKB in November1989 for approval of Paxil in adults, initially showed an 8-fold difference in the rates of suicides and suicidal acts on Paxil compared to placebo. Following an exchange with FDA reviewer, Dr. Martin Brecher, SKB submitted a revised set of figures to the FDA. SKB has since admitted that the two sets of figures contain inconsistencies, however, the discrepancy remains unexplained by SKB. The revised figures have appeared widely in the scientific literature notwithstanding, and have consistently been cited as demonstrating Paxil's safety and efficacy. (*See e.g.*, Lopez-Ibor JJ. "Reduced suicidality on paroxetine." European Psychiatry 1993, 8, Supplement 1, 17s-19s; Montgomery SA, Dunner DL, Dunbar G. "Reduction of suicidal thoughts with paroxetine in comparison to reference antidepressants and placebo." European Neuropsychopharmacology 1995, 5, 5-13; Dunner D and Kumar R (1998) "Paroxetine: A review of clinical experience." Pharmacopsychiatry 31: 89-101). It appears that the authors of these studies, at a minimum, never saw the raw data and that SKB may have ghostwritten the articles for their respective signatures. *See* Boseley S, "Scandal of Scientists who take money for papers ghostwritten by drug companies. Doctors named as authors may not have seen raw data." Guardian newspaper, Feb 7th 2002.

SKB's Presentation of Positive Information and Misrepresentation and Suppression of Negative Information Regarding Paxil Usage for Minors

40. Because its studies failed to demonstrate efficacy for Paxil in treating children and adolescents and revealed significant and serious side effects, including the suggestion of a possible increased risk of suicidal thinking and acts for these youths, SKB sought to limit physicians' access to only the most favorable aspects of the data from these studies. To accomplish this, SKB 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.

41. SKB was also aware of a study that analyzed the adult clinical trials submitted to the FDA to establish the efficacy of Paxil (and a number of other SSRI antidepressants), which found "the pharmacological effects of antidepressants are clinically negligible." The Emperor's New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration by Irving Kirsch (University of Connecticut), Thomas J. Moore (The George Washington University School of Public Health and Health Services and Alan Scoboria and Sarah S. Nicholls (University of Connecticut).

42. According to the authors: "Although antidepressant medication is widely regarded as efficacious, a recent meta-analysis of published clinical trials indicates that 75 percent of the response to antidepressants is duplicated by placebo [Kirsch & Sapirstein, G. (1998). Listening to Prozac but hearing placebo: A meta analysis of antidepressant medication. Prevention & Treatment, 1, Article 0002a] ..."

43. In a follow-up article responding to commentaries on the Emperor's New Drugs study ("Antidepressants and Placebos: Secrets, Revelations, and Unanswered Questions"), Kirsch, et al., stated that "there is now unanimous agreement among commentators that the mean difference between response to antidepressant drugs and response to inert placebo is very small. It is so small that, despite sample sizes involving hundreds of participants, 57% of the trials funded by the pharmaceutical industry failed to show a significant difference between drug and placebo. Most of these negative data were not published (see Thase, 2002) and were accessible only by gaining access to U.S. Food and Drug Administration (FDA) documents." The authors went on to state:

> The small difference between the drug response and the placebo response has been a "dirty little secret" (Hollon, DeRubeis, Shelton, & Weiss, 2002), known to researchers who conduct clinical trials, FDA reviewers, and a small group of critics who analyzed the published data and reached conclusions similar to ours (e.g., Greenberg & Fisher, 1989). It was not known to the general public, depressed patients, or even their physicians. We are pleased that our effort facilitates dissemination of this information.

44. An internal FDA memorandum written by Dr. Paul Leber, formerly of the FDA, even warned that the FDA might "come under attack" because it is "not as demanding as it ought to be in regard to its standards for establishing the efficacy of antidepressant drug products."

General Allegations re:

SKB's Manipulation of the Scientific Literature; Ghostwriting, and; Direct to Consumer Promotional Materials Provided Both to Health Care Professionals and to Patients

45. SKB has recruited "opinion leaders" in psychiatry to promote Paxil for use in children and adolescents even though the evidence from company controlled clinical trials demonstrates the drugs are neither safe nor effective.

46. SKB has debased the scientific literature by getting "opinion leaders" to pen their names to company ghostwritten reports that promote unsupportable, off-label prescribing of antidepressants for

children. *See, e.g.* Jon N. Jureidini, Christopher J. Doecke, Peter R. Mansfield, Michelle M. Haby, David B. Menkes, Anne L. Tonkin, "Efficacy and safety of antidepressants for children and Adolescents, British Medical Journal," *see also* Craig J. Whittington, Tim Kendall, Peter Fonagy, David Cottrell, Andrew Cotgrove, Ellen Boddington, "Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data." The Lancet, Volume 363, Number 9418, April 24, 2004; The Lancet Editorial, "Depressing Research," Volume 363, Number 9418, p. 1335. In a June 12, 2004 editorial in The Lancet, SKB's failure to disclose unfavorable studies was sharply criticized. The Lancet stated that SKB "appears to be floundering in the semantic depths. While it has been earnestly parsing the meaning of 'suicidal thinking and acts' and 'publicly,' it appears to have forgotten what lies behind those words–people." The Lancet, Volume 363, Number 9425.

47. SKB also has drafted letters to medical journal editors and "full papers" for the signature of "opinion leaders" and deliberately tried to obscure their true authorship, recognizing that they might draw the suspicion of journal editors.

48. SKB has manipulated the scientific literature, a practice recognized as a growing and serious problem in evidence-based medicine. Several of the most prestigious medical journals in the world, including the New England Journal of Medicine (NEMJ), The Lancet, and the Journal of the American Medical Association (JAMA), stated in a letter published on September 21, 2001, titled: "Sponsorship, Authorship, and Accountability:"

> As editors of general medical journals, we recognize that the publication of clinical-research findings in respected peer-reviewed journals is the ultimate basis for most treatment decisions. Public discourse about this published evidence of efficacy and safety rests on the assumption that clinical-trials data have been gathered and are presented in an objective and dispassionate manner. This discourse is vital to the scientific practice of medicine because it shapes treatment decisions made by physicians and drives public and private health care policy. ***We are concerned that the current intellectual environment in which some clinical research is conceived, study subjects are recruited, and the data are analyzed and reported (or not reported) may threaten this precious objectivity.***"

(Emphasis added.)

> As CROs [Clinical Research Organizations] and academic centers compete head to head for the opportunity to enroll patients in clinical trials, corporate sponsors have been able to dictate the terms of participation in the trial – terms that are not always in the best interests of academic investigators, the study participants, or the advancement of science generally. Investigators may have little or no input into trial design, no access to the raw data, and limited participation in data interpretation. These terms are draconian for self-respecting scientists, but many have accepted them because they know that if they do not, the sponsor will find

> someone else who will. And, unfortunately, even when an investigator has had substantial input into trial design and data interpretation, the results of the finished trial may be buried rather than published if they are unfavorable to the sponsor's product. Such issues are not theoretical. There have been a number of recent public examples of such problems, and we suspect that many more go unreported.
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> . . .
>
> [T]he sponsor must impose no impediment, direct or indirect, on the publication of the study's full results, including data perceived to be detrimental to the product. Although we most commonly associate this behavior with pharmaceutical sponsors, research sponsored by governmental or other agencies may also fall victim to this form of censorship, especially if the results of such studies appear to contradict current policy.

49. According to a study of medical schools involved in industry-sponsored clinical research, published in the New England Journal of Medicine on October 24, 2002, "academic institutions frequently engage in industry-sponsored research that fails to adhere to ICMJE [International Committee of Medical Journal Editors] guidelines regarding trial design, access to data, and publication rights." According to the study: "The integrity of industry-sponsored clinical research has come under increasing scrutiny. Until recently, criticism focused on investigators' financial conflicts of interest with industry sponsors and the publication bias arising from pressure by sponsors to withhold negative research results." The study found that academic researchers rarely have a say in clinical trial design, lack access to data for analysis purposes, and do not have publication rights.

50. Another study on the subject, published in the January 2003 issue of JAMA, titled "Scope and Impact of Financial Conflicts of Interest in Biomedical Research," confirms that "financial relationships among industry, scientific investigators, and academic institutions are pervasive" and "problematic." The study concluded that:

> "Strong and consistent evidence shows that industry-sponsored research tends to draw pro-industry conclusions" and "industry-sponsored studies were significantly more likely to reach conclusions that were favorable to the sponsor than were nonindustry studies."
>
> A number of studies "empirically demonstrated that industry preferentially supports trial designs that favor positive results, such as the use of placebo as the comparison therapy in controlled trials."
>
> "Authors who had financial relationships with pharmaceutical companies were significantly more likely to reach supportive conclusions than authors without such industry affiliations."
>
> "Faculty members with industry relationships are more than twice as likely as those without such funding to take commercial considerations into account when choosing research topics."

"[R]eports suggest that industry may alter, obstruct, or even stop publication of negative studies."

New Engl. J. Med. 2000; 342:1539-1544.

SKB's Release of Study 329 and Concealment of the Unfavorable Studies

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

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

53. 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 SKB employees who authored SKB's final clinical report for study 329.

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

55. While information from study 377 was presented at a medical convention in 1999, neither study 377 nor study 701 were published, and until June 16, 2004, the studies remained unavailable to physicians, as were 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.) As a result of the New York AG's lawsuit and public pressure, SKB published on its website on June 16, 2004, the results of the pediatric clinical trials for MDD only. It has not made available the underlying data. These studies show that Paxil is broadly ineffective in children and adolescents and could increase the risk of suicidal behavior. The incidence of reported suicidal events possibly related to Paxil was 2.4 percent compared to 1.1 percent in patients on the placebo. In a 30-day follow-up trial, that rate increased to 3.4 percent for patients treated with Paxil compared to 1.2 percent in the placebo group.

56. 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 Paxil for a child or adolescent. This is especially true in light of the publication of study 329.

SKB's Provision of Misinformation Regarding Paxil Usage in Minors to its Sales Force–SKB's Liaison to Physicians

57. SKB has repeatedly misrepresented the safety and efficacy outcomes from its studies of Paxil in the pediatric population to its employees who promote Paxil to physicians. These sales representatives are the SKB personnel who routinely have personal contact with the physicians who decide whether to write prescriptions for Paxil.

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

59. 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. SKB 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 Paxil "targets" for psychiatrists who treat only children and adolescents, because SKB informed its sales force that these targets would be eliminated in 2003.

60. In December 1999, Dr. Karen Wagner, one of the authors listed on the published article concerning study 329, spoke at a meeting of SKB Neuroscience consultants, at which she discussed study 329. She was quoted by an internal SKB newsletter as having said, "We can say that Paxil 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.

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SKB's Misrepresentations Regarding Paxil Usage in Minors in its Medical Information Letters: November 2001 through January 2003

61. SKB 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.

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

63. 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 Paxil 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 SKB'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 Paxil. Each of these Medical Information Letters, however, reported open label (non-placebo-controlled) studies with positive efficacy results.

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

65. 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 Paxil group versus 3.0 percent in the placebo group.

SKB's Disclosure of the Studies to Regulatory Agencies and its Admissions Concerning Efficacy and Safety for Paxil Usage in Minors

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

67. The studies raised issues for all the drug-regulatory agencies regarding the efficacy and safety of pediatric use of Paxil.

68. 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"), SKB admitted that studies 329, 377 and 701 "all failed to separate Paxil from placebo overall and so do not provide strong evidence of efficacy in this indication."

69. On June 10, 2003, the MHRA stated that its analyses of SKB's studies suggested the risk of self-harm and potential suicidal behavior of youngsters was between 1.5 and 3.2 times greater for the Paxil 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 patients. The Irish Medicines Board followed suit in December 2003.

70. In response to the MHRA's June 10, 2003 warning, SKB 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."

71. In a press release SKB 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."

72. In a submission SKB made to the EMEA and subsequently sent to the FDA on November 17, 2003, SKB admitted that the risk-benefit balance for treating pediatric patients using Paxil 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, SKB stated, "it must be concluded that the benefit-risk balance is in favour of not treating children and adolescents with paroxetine." SKB 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."

73. On June 19, 2003, the FDA issued a Talk Paper, which stated that it was reviewing the data from studies of Paxil use in children and adolescents 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 Paxil 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 Paxil and an increased risk of suicidal thoughts and acts was under agency review and advised that Paxil 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.

74. On July 15, 2003, after discussions with Health Canada, the Canadian regulatory agency, SKB 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."

75. 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.

SKB's Continued Suppression and Misrepresentations Regarding Paxil Usage in Minors

76. 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 Paxil by children and adolescents, SKB continues to misrepresent and conceal information in an ongoing effort to encourage physicians to prescribe Paxil to these youngsters.

77. For example, SKB 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 Paxil 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.

78. SKB 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 Paxil's efficacy in treating pediatric patients. This Medical Information Letter was specifically focused on the use of Paxil to treat children and adolescents, 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 SKB's position concerning Paxil as a treatment in the pediatric population, suggesting it is safe and effective for this use.

79. SKB further controlled physicians' access to negative information about Paxil as a treatment for children and adolescents by controlling the information provided to its own personnel. While SKB 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.

80. Although, in response to the British and Canadian regulatory actions, SKB distributed letters to the physicians in those countries informing them that clinical studies had failed to demonstrate the efficacy of paroxetine 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 children and adolescents.

81. SKB took affirmative steps to conceal negative information about the use of Paxil to treat children and adolescents from the American public. Unlike SKB's June 10, 2003 press release in Britain, which disclosed that SKB had "seen a difference between [Paxil] and placebo in terms of suicidal thinking or attempts, particularly in adolescents," SKB'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 Paxil trials] committed suicide." The American press release provided no safety or efficacy information material to treatment decisions for pediatric patients.

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

82. Virtually all physicians have access to the results of study 329 through the published article. SKB'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

SKB's control, there is no question about Paxil's safety and efficacy in treating 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 SKB's mis-characterization of much of the information it did disclose, its further concealment and suppression of negative information, and its Paxil-related targeting of psychiatrists who treat only pediatric patients.

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

FIRST CAUSE OF ACTION

FOR UNFAIR AN DECEPTIVE BUSINESS PRACTICES

84. The allegations of each of the preceding and foregoing paragraphs are incorporated by reference as if fully set forth herein.

85. Defendants' actions, as set forth above, constitute unfair and deceptive business practices under the common law and the laws of each included state, including but not limited to California Business and Professions Code §§ 17200, *et seq.*; Florida Stat. Ann. § 501-204, *et seq.*; Massachusetts Regulation of Business Practice and Consumer Protection Act, Mass. Gen. Laws Ch. 93A, § 2, *et seq.*; Nevada Rev. Stat. § 598.360, *et seq.*; New Jersey Unfair Trade Practices Act, N.J. Stat. §§ 56:8-1, *et seq.*; Pennsylvania Unfair Trade Practices and Consumer Protection Law, Pa. Stat. Ann. Tit. 73, § 201-1, *et seq.*; Texas Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. & Comm. Code Ann. § 17.41, *et seq.*; and Washington Consumer Protection Act, Wash. Rev. Code § 19-86-010, *et seq.*

86. In particular, the following acts, among others, constitute unfair and deceptive business practices:

a. SKB has deceived and continues to deceive the medical community, including those providers who prescribed Paxil to minors, into believing Paxil does not have the harmful properties and the risks which SKB knows it in fact does;

b. SKB has deprived and continues to deprive medical providers the ability to perform the benefit/risk assessment necessary to the proper off label use of Paxil for children and adolescents;

c. By SKB's concealment or provision of inaccurate or biased information that is material to a prescribing decision, it has misled and continues to mislead physicians and patients who rely on that physician's professional judgment;

d. SKB has improperly sought to promote and continues to promote its drug Paxil at the expense of the health and welfare of those children and adolescents who have been prescribed the drug;

e. SKB has prevented and continues to prevent physicians from properly and independently exercising their professional judgment on behalf of their child and adolescent patients;

f. Promoting directly or indirectly that Paxil is either safe or efficacious for treating depression in children and/or adolescents.

g. "Ghostwriting" letters and articles for the signature of "opinion leaders" to be placed in respected medical journals, which downplay Paxil's adverse effects, promoting positive study outcomes and avoiding negative ones.

h. Not permitting clinical trial investigators to have access to the underlying raw data from clinical studies for which they have agreed to sign their names.

i. Hiring prominent psychiatrists around the country to be on-call to address the media when faced with accusations that Paxil is associated with violence and/or suicide and to blame the victim (e.g., by stating "it's the disease, not the drug").

j. Requiring clinical trial investigators to enter into agreements with SKB stating that the investigator will not publish the results of studies involving Paxil unless SKB agrees to such.

k. By placing clinical trial investigators whose studies demonstrate a lack of efficacy or severe side effects attributable to the drug on "do not use in the future" lists.

l. Hiding the association between Paxil and the side effects referenced above by using such misleading language as "may have no causal relationship to the drug" or "not distinguishable from the natural course of the underlying disease."

m. Mis-coding adverse events.

n. SKB deliberately chose not to use a sufficiently sensitive measure for treatment emergent suicidality in its clinical trials. Such a measure could have enabled SKB to determine the true rate of treatment emergent suicidal behavior, thus enabling SKB to warn physicians of the risk.

o. Drafting expert reports regarding efficacy and safety for regulatory bodies who believed they were the work product and opinion of the expert, not SKB.

p. Intentionally failed to accurately and/or fully report known adverse effects of Paxil.

q. Using "statistical sophistication" to manage unfavorable data from clinical studies.

r. Advertising, as if it were a scientifically proven fact, that depression is caused by a "chemical imbalance" of serotonin and that such imbalance will be "corrected" by Paxil, when no such imbalance has ever been proven and it is impossible to test whether anyone is really suffering from such an imbalance.

87. The unlawful, unfair and fraudulent business practices and policies of SKB, as described above, present a continuing threat to the targeted members of the public by causing injury and economic damages and loss.

WHEREFORE, Plaintiff prays for judgment against SKB as hereinafter set forth.

SECOND CAUSE OF ACTION

FOR FALSE AND MISLEADING ADVERTISING

88. The allegations of each of the preceding and subsequent paragraphs are incorporated by reference as if fully set forth herein.

89. The misrepresentations and non-disclosures by SKB of the material facts detailed above constitute untrue and misleading advertising.

90. SKB's use of various forms of media to influence prescribing health care providers and advertise, promote and otherwise call attention to Paxil, deceptively misrepresented Paxil's attributes, performance/efficacy, characteristics and risks. Paxil could not and cannot perform as advertised and promoted, and SKB's promotion of Paxil constitutes unfair competition and unfair, deceptive, untrue or misleading advertising. SKB's advertisements to the medical community deceived and continue to deceive

that community and the consuming public. These advertisements and promotional efforts were disseminated for the purposes of unfairly gaining consumer market share by unfair competition. SKB either knew, recklessly disregarded or reasonably should have known that such advertising was untrue and/or misleading.

91. As a result of the conduct described above, SKB has been and will be unjustly enriched at the expense of minor Paxil users, their guardians, and the general public. Specifically, SKB has been unjustly enriched by the receipt of millions of dollars in monies and profits from selling Paxil for and to minors under misleading pretenses.

92. Plaintiff seeks an order of this Court ordering SKB to immediately cease such acts of unfair competition and enjoining SKB from continuing to falsely advertise or conduct business via the unlawful, unfair or deceptive business acts and practices and untrue and misleading advertising complained of herein. Plaintiff additionally requests an order requiring SKB to pay attorneys fees and cost for this suit and to disgorge its ill-gotten gains and awarding all monies wrongfully acquired by SKB by means of such acts of unfair competition and false advertising, for the purpose of restoring all monies paid to purchase Paxil for minors. Minors, their guardians, and the general public may be irreparably harmed and/or denied an effective and complete remedy if such an order is not granted.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff on behalf of minor Paxil users, their guardians, and the general public as applicable, pray for judgment and relief on all Causes of Action for:

1. Restitution and/or damages (including treble damages, where appropriate) in an amount to be determined at trial and/or disgorgement of SKB's' ill-gotten gains to minor Paxil users, their guardians and the general public and to restore to the public all funds acquired by means of any act or practice declared by this Court to be an unlawful, fraudulent or unfair business act or practice, a violation of laws, statutes or regulations, or constituting unfair competition or false, untrue or misleading advertising;

2. A temporary, preliminary and/or permanent order enjoining the above-described wrongful acts and practices of SKB;

3. Plaintiff also requests damages, restitution and distribution of all monies recovered by SKB from sales of Paxil to minors, on behalf of minor Paxil users (past and present), their guardians and the general

public, via fluid recovery or *cy pres* recovery where necessary to prevent SKB from retaining the benefits of their wrongful conduct.

4. An order requiring SKB to provide full access to research findings regarding Paxil's lack of safety and efficacy which may provide vital information about Paxil, which both doctors and patients need;

5. Reasonable attorneys' fees;

6. Costs of this suit;

7. Pre- and post-judgment interest; and

8. Such other and further relief as the Court may deem necessary or appropriate.

Dated: June 17, 2004

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