Ronald L. M. Goldman, Esq. (Bar No. 33422)
Karen Barth Menzies, Esq. (Bar No. 180234)
Jessica R. Dart, Esq. (Bar No. 225054)
BAUM, HEDLUND, A Professional Corporation
12100 Wilshire Boulevard, Suite 950
Los Angeles, California 90025
Telephone (310) 207-3233
Telefax (310) 820-7444

Attorneys for Plaintiff

THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

ROBERTA MADISON, Dr. P.H.,

Plaintiff,

vs.

PFIZER, INC., a New York corporation, and DOES 1-100, inclusive,

Defendants.

Case No.: BC318871

COMPLAINT

[B&P Code §§ 17200 & 17500]

Plaintiff, Roberta Madison, Dr. P.H., by her attorneys, brings this action as a private attorney general on behalf of all Zoloft users (past and present) whether adults or minors (through their guardians), in the state of California and the general public of the State of California ("General Public"), on information and belief alleges as follows:

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 Los Angeles County, and misconduct alleged herein which was intentionally directed at all residents of the State of California. Accordingly, this Court has jurisdiction

over this action under Article VI, § 10 of the California Constitution and § 410.10 of the Code of Civil Procedure.[1]

2. Pursuant to Code of Civil Procedure § 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 Pfizer, Inc. (referred to hereinafter as "Pfizer") has purposefully availed itself of the benefits and protections of the State of California and/or have 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 Los Angeles. There is no federal jurisdiction over this matter because Plaintiff has not used Zoloft, is not making a claim for personal injury in this action and has not suffered damage in excess of $75,000.

5. Pfizer, Inc. is a New York corporation. Pfizer regularly conducts business within the State of California and derives substantial revenues from drugs consumed in California. Pfizer is engaged in the business of research, development, testing, manufacturing, promoting, marketing, distributing and selling pharmaceutical drugs, including the drug Zoloft (generically known as sertraline), which are distributed throughout California, including Los Angeles County.

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

7. At all times pertinent, all defendants, their aggregates, corporations, associates, and partners, and each of them, were the agent, servant, employee, assignee, successor in interest, or joint venturer of each other and were acting within the course or scope of such agency or employment; and

[1] All statutory references herein are to California law.

all acts or omissions alleged herein of each defendant were authorized, adopted, approved, or ratified by each of the other defendants.

8. At all times pertinent, all defendants, and each of them, were fully informed of the actions of their agents and employees, and thereafter no officer, director, or managing agent of defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and then all defendants, and each of them, thereby ratified those actions.

III. NATURE OF THE CASE

9. Plaintiff brings this action pursuant to California Business & Professions Code §§ 17200 and 17500, et seq. Throughout this Complaint, Plaintiff alleges the unlawful, unfair business practices and false and misleading statements of Pfizer in the advertising and marketing of its antidepressant drug sertraline in treating adults, children and adolescents. Pfizer sells sertraline in the United States under the trade name Zoloft (hereinafter collectively referred to as "Zoloft" or "sertraline")[2]. Pfizer has marketed and sold Zoloft, through the medical community, to millions of California patients and consumers since December 1991. Not only are large numbers of California medical providers and their patients, including the guardians of minors, being misled about the drug's true nature, efficacy and risks, but many patients are becoming dependent upon Zoloft without warning. Immediate and irreparable harm is occurring daily to these citizens.

IV. FACTUAL ALLEGATIONS

10. Pfizer has engaged in repeated and persistent false and misleading conduct by misrepresenting, concealing and otherwise failing to disclose to physicians and other prescribing health care providers information in its possession, custody or control concerning the safety and effectiveness of Zoloft as it relates to use for adults and minors.

11. Zoloft has been approved by the United States Food and Drug Administration ("FDA") as allegedly safe and effective for treating various indications in adults. Zoloft has not been approved

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[2] Zoloft is a member of a class of drugs known as "selective serotonin reuptake inhibitors," or "SSRI's" which include other similar drugs such as Paxil (which has nearly identical methods of action and side-effect profile). Pfizer secured FDA approval to market Zoloft as an antidepressant in late 1991.

for any condition or illness in minors other than Obsessive-Compulsive Disorder ("OCD") and it has been proven to be unsafe and ineffective for use in minors diagnosed with depression. In fact, Zoloft has been declared to be contra-indicated for use by minors in the United Kingdom.

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

13. The State of California, 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. This practice is referred to as "off-label" use, and prescribing Zoloft for unapproved uses or for minors (other than OCD) is an example of off-label use.

14. Pfizer has misrepresented information concerning the nature, safety and efficacy of Zoloft. For instance, Pfizer has arranged for positive information about adult and pediatric use of Zoloft to be disclosed publically (including for use by prosecutors' offices around the country in criminal cases where the defendant was on Zoloft at the time of the alleged criminal act). However, Pfizer has intentionally withheld and concealed negative information concerning the safety, effectiveness and side effects of the drug. Thus, Pfizer has prevented health care providers, including physicians, from properly and independently exercising their professional judgment on behalf of their adult, child and adolescent patients. Accordingly, Pfizer's acts have deprived these patients of the benefit of their health care providers' independent professional judgment.

15. California health care providers, including 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 efficacious and 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 purchase and undertake treatment.

16. In deciding whether to prescribe a drug for an off-label use, health care providers, including physicians, usually rely on their assessment of information received about the drug from various sources, such as journal articles, company literature and discussions with Pfizer sales people. 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.

17. Concealing adverse information and 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. This is exactly what Pfizer has done and continues to do on a daily basis. This misleading information, along with omissions of material facts related to Zoloft's side effects and effectiveness, cause health care providers, patients and the general public to be misled about Zoloft's risks and benefits.

18. Pfizer is aware of and has conducted many randomized, placebo-controlled, double-blind clinical studies to assess the safety and efficacy of Zoloft in treating adults, children and adolescents diagnosed with various conditions.

19. The large majority of the early Zoloft efficacy studies proved to be negative, failed[3] or were neutral. Pfizer has assiduously suppressed this vital information, all the while knowing that this information is of great importance to prescribing physicians in conducting the necessary risk/benefit analysis in treating their patients.

20. Many Pfizer studies not only failed to demonstrate that Zoloft is efficacious, they clearly demonstrated that Zoloft is associated with serious, severe, and sometimes fatal side effects.

[3] For example studies wherein the volunteers experienced such severe side effects that the studt was terminated.

21. In the majority of the efficacy studies, there were no clinically or statistically significant differences detected between Zoloft and placebo.

22. Studies have shown that placebo actually outperformed Zoloft. Other studies have shown that exercise is more effective than Zoloft in relieving depression.

23. Pfizer's studies also showed an association between Zoloft and increased suicidal thoughts and acts in both adults and children/adolescents.

24. In addition, during the course of clinical trials, many of the participants (including children and adolescents) experienced other serious or severe side effects of Zoloft including hyperkinesia/akathisia, hostility, agitation, crying spells, mood fluctuations, mania, hypomania, convulsions, panic attacks, anxiety, increased depression, impulsivity, hallucinations, insomnia, liver failure, psychosis, aggressive reaction, thoughts and acts of self-harm and harm to others, as well as withdrawal reactions upon stopping the drug or reducing the dosage.

Pfizer's Presentation of Positive Information and Misrepresentation and Suppression of Negative Information Regarding Zoloft

25. Because many of its studies failed to demonstrate efficacy for Zoloft in treating adults, children and adolescents and revealed significant and serious side effects, including the suggestion of a possible increased risk of suicidal thinking and acts, Pfizer sought to limit health care providers' access to only the most favorable aspects of the data from these studies. To accomplish this, Pfizer embarked on a campaign and took actions to suppress and conceal negative information concerning the drug and to misrepresent the data it did reveal concerning the drug's efficacy and safety by, among other acts:

a. "Ghostwriting" letters and articles for the signature of "opinion leaders" to be placed in respected medical journals, suppressing information about Zoloft's adverse effects, promoting positive study outcomes while avoiding negative ones, and communicating marketing messages designed to get health care providers, including physicians, to prescribe Zoloft for off-label uses;

b. Not permitting clinical trial investigators to have access to the underlying raw data from clinical studies despite their names were on the published results of the studies;

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

d. Secretly assisting criminal prosecutors to prosecute criminal defendants when Pfizer learns that the defendant was under the influence of Zoloft at the time of the alleged crime when there is a possibility that the criminal defendant may assert the "Zoloft-defense," including provision of a specially prepared "Prosecutors' Manual." In doing so, Pfizer provides select information about Zoloft to prosecutors and suppresses and conceals negative information about the drug, including Zoloft's potential to induce violent or bizarre behavior;

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

f. Requiring clinical trial investigators to enter into agreements that they will not publish the results of studies involving Zoloft unless Pfizer agrees to such;

g. 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;

h. Mis-coding adverse events;

i. Deliberately choosing not to use a sufficiently sensitive measure for treatment emergent suicidality in its clinical trials. Such a measure could have enabled Pfizer to determine the true rate of treatment emergent suicidal behavior, thus enabling Pfizer to warn health care providers, including physicians, of the risk;

j. Drafting expert reports regarding the efficacy and safety of Zoloft for regulators, which regulators then believed were the work product and opinion of the expert, not Pfizer;

k. Intentionally failing to accurately and/or fully report known adverse effects of Zoloft;

l. Using statistical sophistication and mathematical trickery to manage unfavorable data from clinical studies;

m. Recommending Zoloft for patients hospitalized for severe depression when it knew the drug has never been proven effective for in-patients;

n. 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 Zoloft, when no such imbalance has ever been scientifically proven and it is impossible to test whether anyone is really suffering from such an imbalance[4];

o. Deliberately failing to investigate the frequency and severity of Zoloft-induced adverse reactions, including, but not limited to, suicidal risk and withdrawal reactions;

p. Adopting a corporate position of deception regarding adverse events associated with Zoloft; and

q. Advertising Zoloft as "non-habit forming" when Pfizer knows that Zoloft can cause withdrawal reactions and dependence.

26. The purpose of these actions was to try to minimize any potential negative commercial impact to Pfizer and to create and exploit the market for its drug Zoloft.

27. As a result, Pfizer misled and deceived health care providers, including physicians, and consequently the patients who relied on their professional judgment. Pfizer deprived health care

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[4] In May 2003, the maker of the SSRI Paxil, GlaxoSmithKline ("GSK"), announced that it was **withdrawing** claims contained in its promotional material for Paxil (called Seroxat in Ireland and the UK) that the drug worked by normalizing levels of serotonin. GSK acknowledged that the link between depression and serotonin levels is unproven and that such claims "were not consistent with the scientific literature."

providers, including physicians, of the information needed to evaluate the risks and benefits of prescribing Zoloft. By doing so, Pfizer deceived these health care providers, including physicians, irrespective of whether or not they would have prescribed Zoloft if Pfizer had disclosed the material facts that were known at the time. Further, patients and the public have been deceived and misled by Pfizer's direct-to-consumer advertising such as television ads, magazine advertisements, and patient pamphlets, tapes and brochures.

FIRST CAUSE OF ACTION

FOR VIOLATIONS OF BUSINESS & PROFESSIONS CODE § 17200

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

29. By engaging in the acts and practices described above, Pfizer has engaged in and continues to engage in repeated violations of Bus. & Prof. Code§ 17200, *et seq.*;

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

a. Pfizer has deceived and continues to deceive the medical community, including those health care providers who believed that Zoloft does not possess the harmful properties and risks which Pfizer knows it in fact possesses;

b. Pfizer has deprived and continues to deprive health care providers the ability to perform the benefit/risk assessment necessary to the proper use of Zoloft, thus preventing them from properly and independently exercising their professional judgment on behalf of their patients, including on behalf of their child/adolescent patients;

c. Pfizer has misled and deceived and continues to mislead and deceive patients and the public directly through its direct-to-consumer advertisements and promotion of Zoloft.

d. As a result of Pfizer's concealment, or providing inaccurate or biased information that is material to a prescribing decision, Pfizer has misled and continues to

mislead health care providers, including physicians, and patients who rely on their physicians' professional judgment concerning Zoloft's risks and lack of efficacy;

e. Pfizer has improperly sought to promote and continues to promote its drug Zoloft at the expense of the health and welfare of those who have been prescribed the drug;

f. Pfizer has promoted directly or indirectly to health care providers, including physicians, patients and the general public that Zoloft is safe and efficacious for treating depression when it is not;

g. Pfizer has consistently, persistently and knowingly made false statements about Zoloft and misrepresented (by affirmative statements and omissions) its true nature, safety and efficacy. Pfizer has done this by, among others things:

1. Claiming that depression is caused by a chemical imbalance and that Zoloft corrects this imbalance, however, there is no reliable scientific evidence that such an imbalance exists nor proof that Zoloft or any other SSRI "corrects" this alleged imbalance[5];

2. Arguing that warning health care providers, including physicians, and patients of the reasonably associated risks of Zoloft will scare patients away from taking it, while knowing that Zoloft's lack of efficacy coupled with the potential risks would be the actual cause of many patients choosing not to take the drug, thus reducing Pfizer's income;

3. "Educating" health care providers to tell their patients that they should continue taking Zoloft even if they feel worse, thus, (a) dooming many to continue with a treatment that may have little or no benefit, (b) that may have caused them to feel worse, and; (c) that may cause them great harm, including death;

4. Conducting the marketing of Zoloft in a way that encourages prescribers to increase the dose of Zoloft when patients "fail to respond" or feel worse, while

[5] See footnote 4, ante.

knowing that increasing the dose does not increase efficacy, but only increases side effects;

5. Claiming depression is an extreme health burden that health care providers, including physicians, must treat with medication such as Zoloft, while knowing that in the majority of cases, depression is short-lived and resolves spontaneously without the need for any treatment;

6. Claiming that Zoloft is effective for the treatment of males with Post Traumatic Stress Disorder ("PTSD") when it has been shown to be ineffective in this population;

7. Failing to inform the medical community that Zoloft has never been shown to be effective in the treatment of in-patient depression;

8. Failing to inform health care providers, including physicians, that Zoloft causes akathisia, even though this fact is well-known to Pfizer's physicians, scientists and researchers and has been known for many years;

9. Marketing Zoloft as "selective," meaning that it acts only on one neurotransmitter (serotonin), in order to capitalize on the belief that low serotonin levels cause depression (an unproven theory), while avoiding problematic ones (such as dopamine, which is associated with movement disorders), knowing that Zoloft acts on numerous neurotransmitters, including dopamine, not just serotonin;

10. Marketing and advertising Zoloft as "non-habit forming," all the while knowing that Zoloft causes withdrawal reactions and dependence;

11. Failing to inform health care providers, including physicians, that Zoloft was only tolerated by many volunteers in clinical trials because they were co-administered others drugs, such as sedatives, to help counteract the severity of Zoloft-induced side effects. In fact, Zoloft was only approved with sedatives, not by itself;

12. Failing to warn that Zoloft can cause severe agitation-type adverse events and thoughts and/or acts of self-harm or harm to others, despite the FDA's request that it do so[6];

13. Using "opinion leaders" to publish ghostwritten medical letters, articles and reports, thus misleading the medical community into thinking that these so-called "opinion leaders" actually reviewed the raw data, had personal experience with the drug and wrote the letters, journal articles and/or reports themselves. In fact, it has been Pfizer employees and agents who have written much of the material promoting the virtues of Zoloft and Pfizer employees who have then decided who should/would be the authors;

14. Stating that Zoloft's side effects are "mild," when internally-acknowledged side effects include severe and often times deadly side effects;

15. Failing to inform the medical community and the public that continued long term use of Zoloft correlates with an increased risk of breast cancer;

16. Convincing health care providers, including physicians, that Zoloft is "effective" when in the majority of clinical trials for Zoloft, it proved no more effective than placebo (an inert substance like a sugar pill);

17. Publishing only selected results from clinical trials, knowing that publication of all of the data shows Zoloft in a different and negative light;

18. Failing to warn health care providers, including physicians, patients and the general public that Zoloft can cause an up to two-fold increase in suicidality than normal;

19. Deliberately mis-coding or failing to report thousands of instances of severe side effects in order to make Zoloft appear "safe";

[6] Pfizer is well aware of this risk as evidenced by its recent warnings issued in Canada, a copy of which is attached as Exhibit 1.

20. Expressing side effects in terms of number per "patient years" knowing that this would mislead those who reviewed such statistics;

21. Failing to warn that Zoloft can cause side effects such as emotional blunting, depersonalization, and akathisia, which alone or in combination with other side effects, are associated with acts of self-harm;

22. Falsely promoting that randomized controlled clinical trials are the only way to determine whether side effects related to Zoloft, such as Zoloft-induced acts of self-harm, are causally related to Zoloft, thus trying to hide behind convoluted statistical analyses and deceiving the medical community and the public generally thereby;

23. Aggressively promoting Zoloft to non-psychiatric medical doctors (the group that Pfizer has targeted for its promotional activities[7]) while acknowledging that a general practitioner's knowledge, training, and ability to diagnose and treat Zoloft side effects is inadequate, and;

24. Over-promoting Zoloft in order to increase its sale by sponsoring award/incentive programs for doctors; and conducting and sponsoring campaigns to increase the diagnosis of depression by general practitioners; sponsoring lectures and seminars under the guise of education when its true purpose was to increase the sales of Zoloft; and

25. Failing to register clinical trials of Zoloft as required by law.

31. Each of the above acts and all of the misrepresentations and conduct of defendants, and each of them, as alleged in this complaint was and is intended by defendants and each of them to induce

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[7] Pfizer's promotion of Zoloft to treating physicians is intense. Sales people from at least four different divisions of Pfizer, i.e., Roerig, Pratt, Alta and CNS, each visit the same group of doctors within a given geographic area at different times and promote Zoloft over and over again. Their promotional tactics include giving doctors promotional drug starter kits. Pfizer's promotional efforts extend to recruiting and paying physicians to give lectures sponsored by Pfizer. Pfizer encourages doctors to prescribe Zoloft by misrepresenting the efficacy and "safety" of the drug and failing to fully inform them of the side effects that must be closely monitored, such as those set forth herein.

reliance by health care providers, including physicians, patients and the public to prescribe, accept and urge treatment with Zoloft.

32. Health care providers, including physicians, patients and the general public relied upon the acts and conduct of defendants, and each of them, alleged in this complaint in prescribing, accepting and urging treatment with Zoloft.

33. As a direct result of the above, Pfizer has promoted a drug of questionable efficacy, which can cause grave side effects, and created an environment where doctors feel free to distribute Zoloft to their patients as if it were virtually free from serious side effects. Pfizer's actions have stripped the standard safeguards that would normally protect consumers from the adverse effects of Zoloft. In fact, Pfizer has perpetrated a massive fraud upon California consumers in that most of them, including their doctors, believe that Zoloft is a highly effective medication for the treatment of a number of mental disorders and that the side effects are rare and/or mild and, on the most part, are not life threatening.

34. These unlawful, unfair and fraudulent business practices and policies of Pfizer, 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 Pfizer as hereinafter set forth.

SECOND CAUSE OF ACTION

FOR FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17500, *ET SEQ.*

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

36. The misrepresentations and non-disclosures by Pfizer of the material facts detailed above constitute false and misleading advertising and therefore constitute violations of Business & Professions Code §17500, *et seq.*

37. Pfizer has used various forms of media to advertise and promote Zoloft and otherwise influence the prescribing practices of health care providers in California. In doing so, Pfizer has deceptively misrepresented Zoloft's attributes, performance/efficacy, characteristics and risks. Zoloft

does not perform as advertised and promoted, and Pfizer's promotion of Zoloft constitutes unfair competition and unfair, deceptive, untrue, false or misleading advertising within the meaning of Business & Professions Code §17500, *et seq*. Pfizer's advertisements to the medical community have deceived and continue to deceive that community and the consuming public. These advertisements and promotional efforts were disseminated for the purpose of unfairly gaining consumer market share by unfair competition. Pfizer either knew, recklessly disregarded or reasonably should have known that such advertising was untrue and/or misleading. Such conduct also constitutes a violation of Business & Professions Code §17200, *et seq*.

38. As a result of the conduct described above, Pfizer has been and will be unjustly enriched at the expense of California Zoloft users, the general public and those entities that have paid for Zoloft prescriptions. Specifically, Pfizer has been unjustly enriched by the receipt of hundreds of millions of dollars in monies and profits from selling Zoloft to Californians under misleading pretenses.

39. Pursuant to Business & Professions Code §§17203 and 17535, Plaintiff seeks an order of this Court ordering Pfizer to immediately cease such acts of unfair competition and enjoining Pfizer from continuing to falsely advertise or conduct business in this State via the unlawful, unfair or deceptive business acts and practices and untrue and misleading advertising complained of herein. Plaintiff also seeks an order requiring Pfizer to fully disclose the true nature of its misrepresentations, and engage in a corrective advertising campaign to disclose that Zoloft does not preform as advertised. Plaintiff additionally requests an order requiring Pfizer to disgorge its ill-gotten gains and awarding all monies wrongfully acquired by Pfizer by means of such acts of unfair competition and false advertising, for the purpose of restoring all monies paid by California Zoloft users to purchase Zoloft and to pay attorneys' fees and costs for this suit. California Zoloft users, including minors through 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, Roberta Madison, Dr.P.H., on behalf of California Zoloft users and the general public as applicable, pray for judgment and relief on all Causes of Action for:

1. Restitution in an amount to be determined at trial and/or disgorgement of Pfizer's ill-gotten gains to Zoloft users, including minors, 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. Restitution and distribution of all monies recovered by Pfizer from sales of Zoloft to California Zoloft users (past and present) and the general public, via fluid recovery or *cy pres* recovery where necessary to prevent Pfizer from retaining the benefits of their wrongful conduct.

3. An order requiring Pfizer to provide full public access to research findings regarding Zoloft's lack of safety and efficacy which may provide vital information about Zoloft, which both doctors and patients desperately need;

4. A temporary, preliminary and/or permanent order enjoining the above-described wrongful acts and practices of Pfizer

5. Reasonable attorneys' fees as appropriate under applicable law;

6. Costs of this suit;

7. Pre- and post-judgment interest as allowed by law; and

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

Dated: July 23, 2004

Ronald L. M. Goldman, Esq.
Karen Barth Menzies, Esq.
Jessica R. Dart, Esq.
BAUM HEDLUND, A Professional Corporation

Attorneys for Plaintiff

Health Canada Endorsed Important Safety Information on ZOLOFT (sertraline hydrochloride)

Pfizer Canada Inc.

May 26, 2004

Subject: **Stronger WARNING for SSRIs and other newer antidepressants regarding the potential for behavioural and emotional changes, including risk of self-harm**

Dear Healthcare Professional,

Pfizer Canada Inc., following discussions with Health Canada, would like to inform you of important safety information regarding the possibility that SSRIs (selective serotonin reuptake inhibitors) and other newer antidepressants may be associated with behavioural and emotional changes, including risk of self-harm.

The new Class warning incorporated in the Product Monograph of ZOLOFT* (sertraline hydrochloride) capsules is provided below.

POTENTIAL ASSOCIATION WITH THE OCCURRENCE OF BEHAVIOURAL AND EMOTIONAL CHANGES, INCLUDING SELF-HARM.

Pediatrics: Placebo-Controlled Clinical Trial Data

- **Recent analyses of placebo-controlled clinical trial safety databases from SSRIs and other newer antidepressants suggest that use of these drugs in patients under the age of 18 may be associated with behavioural and emotional changes, including an increased risk of suicidal ideation and behaviour over that of placebo.**

- **The small denominators in the clinical trial database, as well as the variability in placebo rates, preclude reliable conclusions on the relative safety profiles among these drugs.**

Adult and Pediatrics: Additional data

- **There are clinical trial and post-marketing reports with SSRIs and other newer antidepressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or harm to others. The agitation-type events include: akathisia, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment.**

Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behavior is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes.

Discontinuation Symptoms

Patients currently taking sertraline hydrochloride should NOT be discontinued abruptly, due to risk of discontinuation symptoms. At the time that a medical decision is made to discontinue an SSRI or other newer antidepressant drug, a gradual reduction in the dose rather than an abrupt cessation is recommended.

It should be noted that a causal role for SSRIs and other newer antidepressants in inducing self-harm or harm to others has not been established. The possibility of a suicide attempt is inherent in depression and other psychiatric disorders, and may persist until remission occurs. Therefore, high-risk patients should be closely supervised throughout therapy with appropriate consideration to the possible need for hospitalization. The updated warning informs practitioners that all patients being treated with SSRIs and other newer antidepressants should be rigorously monitored for clinical worsening, or onset/ worsening of agitation-type adverse events, or other indicators of potential for suicidal behaviour.

Sertraline hydrochloride is not indicated for use in the pediatric population

New Information Added to the Consumer Information Section
The Consumer Information Section of the Product Monograph has been updated to reflect this new Class warning, and to advise patients that treatment with SSRIs and other newer antidepressants is most safe and effective when there is good communication with the treating physician about how the patient is feeling.

Background
In February 2004, a scientific advisory panel set up by Health Canada was asked to provide the clinical practice perspective on the pediatric clinical trial safety data, and the spontaneous post-marketing reports for SSRIs and other newer antidepressants. The panel agreed that a contraindication was not warranted for these medications, and supported Health Canada's recommendation for stronger warnings, while providing suggestions and comments. The record of proceedings, and other information about the panel, can be found on Health Canada's website at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/sap_ssri_2004-02-20_rop_e.html.

Pfizer Canada Inc. continues to work closely with Health Canada to monitor adverse event reporting and to ensure that up-to-date information regarding the use of ZOLOFT (sertraline hydrochloride) is available.

The identification, characterization and management of drug-related adverse events are dependent on the active participation of healthcare professionals in adverse drug reaction reporting programs. Healthcare professionals are asked to report any suspected adverse reactions in patients receiving ZOLOFT (sertraline hydrochloride) directly to Pfizer Canada Inc. or Health Canada at the following addresses:

Pfizer Canada Inc.
Medical Information
P.O. Box 800
Pointe-Claire, Quebec
H9R 4V2
1 800 463-6001

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866 234-2345
Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

For other inquiries: please refer to contact information.

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties.*

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.html
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.html

Your professional commitment in this regard has an important role in protecting the well-being of your patients by contributing to early signal detection and informed drug use.