PRIMER ON PSYCHOTROPIC DRUGS

Version 38

Matthew L. Israel, Ph.D.
Judge Rotenberg Educational Center
250 Turnpike Street
Canton, MA 02021

June 18, 2009

Introduction

Psychotropic (or psychoactive) drugs are drugs that affect behaviors, feelings, and thinking. My goal in this booklet is to set down in as concise a fashion as possible some key facts about these drugs that would be useful to a clinician, parent, attorney or teacher.

- Chapter 1 presents 24 critical facts about psychotropic drugs in general. These 24 facts are first presented as a group of summary statements on pages 6-8. Following this, each summary statement is repeated with supporting information that is largely composed of quotations from published papers and books. In the electronic version of this document, each summary statement, when first presented on pages 6-8, is linked to its associated supporting information.

- Chapter 2 groups the most commonly used psychotropic drugs into these categories: (1) antipsychotics, (2) antidepressants, (3) stimulants, (4) anticonvulsants, (5) anxiolytics (drugs to alleviate anxiety) and (6) drugs that treat acute extrapyramidal side effects.

- Chapters 3-6 present the key facts concerning the following categories of drugs: Antipsychotics (Chapter 3); Antidepressants (Chapter 4); Stimulants (Chapter 5); and Anticonvulsants (Chapter 6).

- Chapter 7 gives the sources for the information in this booklet as well as recommended readings, web sites and DVDs.

- Appendix A is the list of citations.

- Appendix B presents, for each of the most commonly prescribed psychotropic drugs, the top 20 adverse effects reported to the FDA's voluntary reporting system ("Medwatch"), during 2006-2008, in which the drug was reported to be the primary suspected cause.

- Appendix C is a list of the most commonly used psychotropic drugs, listed alphabetically by both brand name and generic name. For each drug, the following information is provided: category; indications, including age range; normal dosage range; FDA "Black Box" warnings; top 5 adverse effects reported to FDA Medwatch program, 2006-8; number of deaths reported to FDA Medwatch program, 2006-8; and the major problematic side effects reported in textbooks for the category that the drug belongs to.

Table of Contents

Introduction ..... **iii**

Chapter 2. Support for and Explanation of the Critical Facts **5**

Chapter 3. Categories of Psychotropic Drugs **35**

Chapter 4. Antipsychotic Drugs **39**

Chapter 5. Anticonvulsive Drugs **47**

Chapter 6. Antidepressant Drugs **51**

Chapter 7. Stimulant Drugs **55**

Chapter 8. Sources of Information and Recommended Readings, Web Sites and DVDs **59**

Appendix A: Citations **63**

Appendix B: The Most Commonly Prescribed Drugs and the Top 20 Adverse Reactions Reported to the FDA, During 2006-8, for Each **67**

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs **83**

Chapter 1. Critical Facts About Psychotropic Drugs

The following are some critical facts about psychotropic drugs:

(1) It is not true that the introduction into mental hospitals, in the mid 1950's, of certain psychotropic drugs (which were called *neuroleptics* or *major tranquilizers* at the time and which later were called *antipsychotics*) was responsible for the emptying of those mental hospitals and the transfer of the care of many mentally ill persons to the community.

(2) Psychotropic drugs do not correct for "chemical imbalances" in the brain "like insulin for diabetes."

(3) Although psychotropic drugs do not *correct* chemical imbalances in the brain, they do *create* changes and toxic effects on the brain once they are introduced.

(4) The brain tries to compensate for the effects of psychotropic drugs by, for example, changing the number and output of certain receptors that are affected by the drugs.

(5) When a psychotropic drug is withdrawn, the brain—which has previously adapted to the drug by *upregulating* or *downregulating* its receptors for the drug—is often unable to reverse its previous adaptation quickly enough, and this is the origin of "withdrawal" effects.

(6) Psychotropic drugs do not treat or correct the underlying problems that cause mental illnesses such as schizophrenia, depression, anxiety, etc..

(7) Psychotropic drugs produce a wide range of effects on many parts of the body and on many behaviors. Some of these effects may be interpreted by others, or by the patient, as being helpful.

(8) Psychotropic drugs also produce many effects that are harmful, some of which prove to be permanent.

(9) Often the harmful effects of psychotropic drugs are not discovered until years after their introduction, at which point the effects may be irreversible.

(10) The mental illnesses that psychotropic drugs are supposed to treat are not biological "diseases" that have a known biological basis or treatment at this time; instead they are merely collections of behavioral symptoms that are defined by a committee of the American Psychiatric Association which changes the definitions from time to time.

(11) Psychotropic drugs are not specific to certain diseases. Many drugs are prescribed for the same mental illness, and the same drug is used for many different mental illnesses.

(12) Although some studies show temporary improvement in certain symptoms, studies have shown that in the long run the individual is worse off for having taken the psychotropic drug than if she/she had never taken the drug to being with.

(13) The standard basis for prescribing psychiatric drugs, which is the American Psychiatric Association's Diagnostic and Statistical Manual, Version IV, does not clearly distinguish among different mental disorders in an objective and scientific manner.

(14) Psychotropic drugs are often prescribed by psychiatrists and physicians on an "off label" basis, effectively negating the protection of the public, through prior testing and oversight, that the FDA is supposed to exercise..

(15) Even if physicians were to prescribe only according to the FDA label, this would not solve the problems with psychotropic drug prescription. The major problem is that the FDA cannot be relied upon to protect the consumer because the drug manufacturers have been able to use their enormous financial power to keep that agency from being an effective watchdog guarding the public's interest.

(16) The extent of the prescription of psychotropic drugs by physicians has been heavily influenced by the drug companies' ability to influence doctors, patients, legislators, experts and researchers, etc.—all to the detriment of the well being of the patient.

(17) Drug companies tend to downgrade their drugs to doctors when the patent protection is about to run out on them, and then start pushing doctors to prescribe the much more expensive newer drugs. The newer drugs, which can cost 20 times as much as the older ones, often have no real advantages over the older ones, and can even be disadvantageous. This process, combined with drug company-promoted legislation that prevents the government from negotiating the price of drugs with the drug companies, is partly responsible for why medical costs are so high in this country.

(18) One cannot trust the scientific literature or the public media to be a source of accurate information about psychotropic drugs because of the drug companies exert enormous influence on every step of the research, publication and public information process.

(19) The rash of multiple shootings and suicides in schools, colleges, workplaces and elsewhere that America has seen in recent decades is very likely linked, in many cases, to the use of psychotropic drugs by the perpetrators of that violence.

(20) Projects to "screen" children and adults for mental illnesses (such as Columbia University's TeenScreen program) are in large part marketing campaigns supported by drug companies with the purpose of increasing the prescriptions of psychotropic drugs.

(21) The notion that the newer antipsychotic drugs have fewer negative side effects than the older antipsychotics, is largely a myth sponsored by the drug companies.

(22) There are a considerable number of assumptions, notion and procedures that are current in the psychopharmacological literature, but which lack adequate scientific support, including: the adequacy of the double blind

design; the assumption that the patients used in drug trials are representative of the population at large, etc.

(23) Because of the power of the drug companies, the growth and development of non-drug treatment approaches has been largely slowed or stymied.

(24) When the effectiveness of psychotropic drugs has been compared with the effectiveness of behavioral treatment procedures, the latter have consistently proved to be substantially more effective.

Chapter 2. Support for and Explanation of the Critical Facts

1. It is not true that the introduction into mental hospitals, in the mid 1950's, of certain psychotropic drugs (which were called *neuroleptics* or *major tranquilizers* at the time and which later were called *antipsychotics*) was responsible for the emptying of those mental hospitals and the transfer of the care of many mentally ill persons to the community.

> The belief that the introduction of chlorpromazine, marketed in the US as Thorazine, made it possible to empty state hospitals stems from research by Brill and Patton. In the early 1960s, they reported that the patient census at sate mental hospitals in the US declined from 558, 600 in 1955 to 528,800 in 1961. Although they did not compare discharge rates for drug-treated versus placebo-treated patients, they nevertheless concluded that neuroleptics [now called *antipsychotics*] must have played a role in the decline since it coincided with their introduction. The fact that the two occurred at the same time was seen as the proof [9,10] …
>
> …there was one state that did compare discharge rates for schizophrenia patients treated with and without drugs, and its results do not support the historical claim made for neuroleptics…the California investigators determined that neuroleptics, rather than speed patients' return to the community, apparently *hindered* recovery.[13]
>
> The true period of deinstitutionalization in the US was from 1963 to the late 1970s, the exodus of patients driven by social and fiscal policies. In 1963, federal government began picking up some of the costs of care for the mentally ill not in state institutions, and two years later, Medicare and Medicaid legislation increased federal funding for care of mental patients provided they were not housed in state hospitals. Naturally, states responded by discharging their hospital patients to private nursing homes and shelters. In 1972, an amendment to the Social Security act authorized disability payments to the mentally ill, which accelerated the transfer of hospitalized patients into private facilities. As a result of these changes in *fiscal* policies, the number of patients in state mental hospitals dropped from 504,600 to 153, 544 over a 15-year period (1963-1978) [14] (Whitaker[1], 2004, p. 6). [bracketed material supplied]

2. Psychotropic drugs do not correct for chemical imbalances in the brain "like insulin for diabetes."

[1] Mr. Whitaker is a science writer who authored the book, *Mad in America*, a book about America's treatment of the mentally ill throughout its history. This book was picked by *Discover* magazine as one of the best science books of 2002, and the American Library Association named it as one of the best histories of 2002.

No one has discovered any chemical imbalance in the brains of individuals with mental problems such as schizophrenia, prior to the point at which such individuals begin to use psychotropic drugs. (Valenstein, 1988).

In the following interview of Robert Whitaker by a reporter from Street Spirit magazine, Whitaker explains this issue clearly.

Excerpt from *Street Spirit* Interview with Robert Whitaker

SS [the interviewer from Street Spirit Magazine]: Modern psychiatry claims that these psychiatric drugs correct pathological brain chemistry. Is there any evidence to back up their claim that abnormal brain chemistry is the culprit in schizophrenia and depression?

RW [Robert Whitaker]: This is the key thing everyone needs to understand. It really is the answer that unlocks this mystery of why the drugs would have this long-term problematic effect. Start with schizophrenia. They [many researchers] hypothesize that these drugs work by correcting an imbalance of the neurotransmitter dopamine in the brain.

The theory was that people with schizophrenia had overactive dopamine systems; and these drugs, by blocking dopamine in the brain, fixed that chemical imbalance. Therefore, you get the metaphor that they're like insulin is for diabetes; they're fixing the abnormality. With the antidepressants, the theory was that people with depression had too low levels of serotonin; the drugs upped the levels of serotonin in the brain and therefore they're balancing the brain chemistry.

First of all, those theories never arose from investigations into what was actually happening to people. Rather, they would find out that antipsychotics blocked dopamine and so they theorized that people had overactive dopamine systems — same with the antidepressants. They found that antidepressants upped the levels of serotonin; therefore, they theorized that people with depression must have low levels of serotonin.

"But here is the thing that one wishes all of America would know and wishes psychiatry would come clean on: They've never been able to find that people with depression have under active serotonin systems. They've never found consistently that any of these disorders are associated with any chemical imbalance in the brain. The story that people with mental disorders have known chemical imbalances – that's a lie. We don't know that at all. It's just something that they say to help sell the drugs and help sell the biological model of mental disorders.

But the kicker is this. We do know, in fact that these drugs perturb how these chemical messengers work in the brain. The real paradigm is: People diagnosed with mental disorders have no known problem with their transmitter systems; and these drugs perturb the normal function of neurotransmitters. (Whitaker, 2005b) [bracketed material supplied]

3. Although psychotropic drugs do not *correct* chemical imbalances in the brain, they do *create* changes and toxic effects on the brain once they are introduced.

> …a review of the scientific literature shows that the precise opposite [of the notion that drugs correct chemical imbalances in the brain] is true: people diagnosed with mental disorders do not have any known chemical imbalance, and the drugs prescribed for these disorders all work by perturbing—sometimes profoundly—neurotransmitter systems in the brain. These medications actually create "chemical imbalances" in the brain, and once this is understood, it is easy to see why their long-term widespread use has correlated with an astonishing rise in the number of disabled mentally ill adults in the United States in the past fifty years." (Whitaker, 2007, p. 47) [bracketed material supplied].

Peter Breggin (2008) describes psychoactive drugs as disrupting normal brain function and asserts that they all are neurotoxic and cause generalized brain dysfunction, the common result of which he describes as a:

> …lobotomy-like indifference to self and to others—a syndrome that I have called *deactivation*…all of the major categories of psychiatric drugs—antidepressants, stimulants, tranquilizers (antianxiety drugs), mood stabilizers, and antipsychotics—are neurotoxic. They poison neurons, and sometimes destroy them…and share the capacity to produce generalized dysfunction with some degree of impairment across the spectrum of emotional and intellectual function…(Breggin, 2008, p. 2-3).

4. The brain tries to compensate for the effects of psychotropic drugs by, for example, changing the number of receptors for the drug and/or changing the amount of the neurochemical that it produces.

This process is called *upregulating* or *downregulating*. The brain, sensing the drug, responds by increasing decreasing the number of neural receptors and/or the amount of the neurochemical in question that it produces. This process can create additional problems, such as making the individual even more sensitive or less sensitive to the drug in question. Some of these changes may be irreversible. This may be why tardive dyskinesia, a side effect of antipsychotics involving involuntary movements of certain muscle groups, continues indefinitely, even after the drug has been withdrawn for a substantial period of time.

5. When a psychotropic drug is withdrawn, the brain—which has previously adapted to the drug by upregulating or downregulating its receptors for the drug—is often unable to reverse its previous adaptation quickly enough, and this is the origin of "withdrawal" effects.

> The brain does not welcome psychiatric medications as nutrients. Instead, the brain reacts against them as toxic agents, and attempts to overcome their disruptive impact. For example, when Prozac induces an excess of serotonin in the synaptic cleft, the brain compensates by reducing the output of serotonin at the nerve endings, by reducing the number of receptors in the synapse that can receive the serotonin, and by increasing the capacity of the transport system to remove serotonin from the synapse. Similarly, when antipsychotic drugs such as Risperdal, Zyprexa, or Haldol reduce reactivity in the dopaminergic system, the brain compensates, producing hyperactivity in the same system by increasing the number and sensitivity of dopamine receptors. All of these compensatory reactions create new abnormalities in brain function, sometimes causing irreversible disorders, such as antipsychotic drug-induced tardive dyskinesia….
>
> Because the brain attempts to compensate for the effects of most psychoactive drugs, patients can have difficulty withdrawing from them. Physically, the brain cannot recover from the drug effect as quickly as the drug is withdrawn so that the compensatory mechanisms can require weeks or months to recover after the drug has been withdrawn. Sometimes, as in tardive dyskinesia, the brain fails to recover. In some cases, patients who have taken the newer antidepressants such as Prozac, Paxil, Zoloft, and Celexa for months or years cannot withdraw from them owing to the emotional instability and physical symptoms produce by drug-induced changes in the brain."(Breggin, 2008, p. 9)

6. Psychotropic drugs do not treat or correct the underlying problems that cause mental illnesses such as schizophrenia, depression, anxiety, etc.

Scientists have not identified the underlying physiological or biochemical causes of mental illness. They are unable, for example, to do any biochemical test that reveals the presence of mental illness. Consequently it is currently impossible for psychotropic drugs to treat or correct the underlying chemistry or neurophysiology that causes these illnesses.

7. Psychotropic drugs produce a wide range of effects on many parts of the body and on many behaviors. Some of these effects may be interpreted by others, or by the patient, as being helpful.

For example a drug such as Thorazine or Haldol causes many changes in an individual one of which may be sedation. When these drugs are given to a highly aggressive psychotic individual, the sedative effect will make the individual appear calmer, and this may be seen as an improvement by the parent; teacher or caregivers. Because of this drugs have been categorized in terms of the mental illness that they appear to cause improvements in. For example, Thorazine and Haldol are now called "antipsychotics." However, this does not mean that they treat the underlying biological cause of psychosis, and for that reason it is misleading to call such drugs "antipsychotics."

This point can be easily seen in the case of alcohol, which is also a psychotropic drug. It causes a wide range of changes in the individual, one of which is to make the individual less inhibited. For a shy person who ingests alcohol at a party, this could be viewed as a positive result. However, it would be misleading to call alcohol an "anti-shyness" drug.

8. Psychotropic drugs also produce many effects that are harmful, some of which prove to be permanent.

See Chapters 3-6 and Appendices B and C. These harmful effects are generally referred to as "side effects." However, the distinction between "main effects" and "side effects" of psychotropic drugs is quite arbitrary.

It is generally acknowledged that most physicians and psychiatrists do not do a thorough job of explaining the side effects of psychotropic drugs to their patients.

Among the psychotropic drugs, the class of drugs known as the *antipsychotic*s produce some of the most serious side effects. Here is how psychiatrist Grace Jackson has to say about their toxicity:

> With the possible exception of the chemotherapies used in the treatment of cancer, it would be difficult to identify a class of medications as toxic as the antipsychotics. Whether one considers the effects of dopamine antagonists upon the central nervous system or beyond, their proven harmfulness has been an iatrogenic tragedy too often minimized or denied." (Jackson, 2005, p. 14)

About these same antipsychotic drugs, psychiatrist Peter Breggin has this to say:

> … prescribing physicians cannot fully inform patients about the risks associated with neuroleptics because no one except the most self-destructive patient would knowingly take such toxic drugs**.** Doctors have to hide the mountain of risks associated with these drugs in order to get their patients to take them. In this sense, informed consent is largely a sham in regard to antipsychotic drug administration. (Breggin, 2008, p. 112)

A convenient way to find the side effects of a psychotropic drug is to use the web site, www.//emedtv.com. In the search window at the top right, enter a phrase such as "Prozac side effects." Use either the brand or generic name. Side effects of the most commonly prescribed psychotropic drugs can also be found by using the Table in Appendix C.

9. Often the harmful effects of psychotropic drugs are not discovered until years after their introduction, at which point the effects may be irreversible.

> When it comes to the long term effects of drugs, psychotropic or otherwise, industry drug trials tell us little or nothing, for they usually last just 3-6 weeks and

> are designed to paint a rosy picture. Deaths may occur, but such facts rarely get into the drug "insert" that is supposed to be all the patient and family need to know to give informed consent to treat. Rather it is the horror stories that slowly emerge in the press from the "post-marketing" prescription experience that are the facts which should constitute "disclosure" for purposes of informed consent, but never do…
>
> Within the short space of 9 months three FDA-approved drugs have had to be removed from the market due to lethal side effects, that became known not during the pre-marketing safety and efficacy trials, but very soon into their post-marketing, prescription use." (Baughman, 2006, p. 190-191)

The FDA has created a system in which persons such as doctors, nurses, attorneys, patients and others can make voluntary reports to the FDA of serious adverse events that appear to have been caused by the use of a certain drug. Appendix B contains some of this information, derived from the FDA website, for some commonly used psychotropic drugs for the years 2007 and 2008. For each drug a table is provided that lists the top 20 serious adverse reactions for which the drug was reported to be the primary suspected cause. For an interactive online web page in which the user can insert the name of a drug and obtain this same information for these and other drugs, see www.judgerc.org/AdverseDrugReactions .

10. The mental illnesses that psychotropic drugs are supposed to treat are not biological "diseases" that have a known biological basis or treatment at this time; instead they are merely collections of behavioral symptoms that are defined by a committee of the American Psychiatric Association which changes the definitions from time to time.

The reference to mental illnesses as diseases (which therefore require medical or drug treatments) is only a metaphor. Mental illnesses are composed, in large part, of sets of problematic behaviors. Some of these behaviors are outer, observable behaviors, and some are inner, private behaviors that only the individual him/herself can observe. Because of this, the treatment of the behaviors that comprise mental illnesses, through psychosocial approaches such as behavior modification therapy, is the most direct, least toxic and least intrusive way to help the patient improve. Often when the behaviors in question are given effective behavioral treatment, the "illness" vanishes or the "diagnosis" either changes or is no longer necessary.

11. Psychotropic drugs are not specific to certain diseases. Many drugs are prescribed for the same mental illness, and the same drug is used for many different mental illnesses.

Because the drugs do not correct any imbalance and do not address the fundamental biological cause of the mental illness problem, it is misleading to refer to them with names that imply that they treat the condition in question—i.e., with names such as

"antipsychotics," "antidepressants," etc... (Whitaker, 2007). There is no good evidence that the effect of each class of drugs is specific to the mental illnesses that are described by those labels. Support for this assertion can be found in the following areas: (See Moncrieff & Cohen, 2005 for more details. Quotations below are from that article.):

(1) Current theories about the actions of different categories of drugs (e.g. theories about drugs correcting for "excessive dopamine" or "lack of serotonin") are only *assumptions* based on the certain things we know about the mechanisms of the drugs themselves, and are not based on an independent understanding of the fundamental physiological processes that underlie the mental illness.

(2) Evidence to show that one class of drugs produces different and superior clinical effects on a mental illness than does a different class does not exist. "For example, evidence suggesting that antipsychotics are superior to other sedatives in the treatment of psychosis is sparse and inconsistent."

(3) The rating scales commonly used to evaluate the efficacy of drugs "contain items describing behaviour that would not normally be considered a specific part of a disorder being treated and would be expected to respond to non-specific effects of medication. For example, the 17-item Hamilton Rating Scale for Depression contains 7 items on sleep disruption and anxiety, all of which can be expected to respond to sedative effects of drugs."

(4) In practice, psychiatrists use many different categories of drugs to "treat" the same psychiatric illness. They also use the same drug to treat several different types of illnesses.

(5) When psychotropic drugs are given to normal volunteers, the drugs tend to produce the same kinds of effects that they produce on persons with psychiatric illnesses.

Moncrieff and Cohen (2005) point out that there is no more reason to call a neuroleptic an "antipsychotic" drug treatment, because its effects include a lessening of agitation in psychotic persons, than there is call alcohol an "antishyness" drug treatment, because its effects include the lessening of social inhibitions in shy persons.

Breggin states the issue as follows:

> "Despite the deeply convictions of drug proponents, there are no specific psychoactive treatments for specific mental disorders. For example, it will be shown that neuroleptics and lithium affect animals and normal volunteers in much the same way as they affect patients, in part by subduing their overall emotional responsiveness" (Breggin, 2008, p.4)
>
> "It is often said that psychiatry has specific treatments for specific diagnostic categories of patients, for example, neuroleptics for "schizophrenia"; antidepressants for depression; benzodiazepine tranquilizers for anxiety; lithium for mania; and stimulants, such as Ritalin, for attention-deficit hyperactivity. In actual practice, many individual patients are given all of the above categories of drugs at one time or another, and, increasingly so, all at once. Often the

> recommended use of a drug changes over the years. While there is a general tendency for patients labeled schizophrenic to be initially treated with neuroleptics or for depressed patients to be initially prescribed antidepressants, this, in part, a matter of convention within the profession." (Breggin, 2008, p. 8)

Breggin asserts that a psychotropic drug is usually considered to be effective not because it cures or treats the basic mental illness, but rather when "the physician and/or patient prefers a state of diminished brain function, with its narrowed or shallower range of mental capacity or emotional expression." (Breggin, 2008, p. 3) For example, the antipsychotic drugs were shown in short-term studies in the 1960s to reduce, in schizophrenic patients, the expression of hallucinations and delusions and general level of activity —effects which were seen as improvement by the authors of the studies. It is because of these effects that these drugs (which had previously been termed *major tranquilizers*) came to be called "antipsychotic," and not because the drugs reversed the underlying psychotic condition.

Because psychiatric drugs do not treat specific mental illnesses, Moncrieff and Cohen (2005) have recommended that drugs should be categorized not in terms of what illnesses they are used for, but rather by the effects that they tend to produce on the body and behavior—effects such as "sedating" (tranquilizing) or "stimulating."

Evidence that psychotropic drugs are not specific to certain mental illnesses can also be seen in the fact that drug manufacturers sometimes have marketed the same drug for different illnesses. For example, when the patent on fluoxetine (Prozac) expired in 2001, Eli Lilly began to market the same drug under a new name, Sarafem, for a different disorder—premenstrual dysphoric disorder (PMDD). Similarly, GlaxoSmilthKline marketed buproprion HCl both as an antidepressant, under the name Wellbutrin, and as an aid to smoking cessation under the name Zyban. These examples are described by investigative reporter Kelly Patricia O'Meara in her book *Psyched Out.* (O'Meara, 2006, Chapter 6)

12. Although some studies show temporary improvement in certain symptoms, studies have shown that in the long run the individual is worse off for having taken the psychotropic drug than if she/she had never taken the drug to being with.

> "When you look at the research literature, you find a clear pattern of outcomes with all these drugs –- you see it with the antipsychotics, the antidepressants, the anti-anxiety drugs and the stimulants like Ritalin to teach ADHD. All these drugs may curb a target symptom slightly more effectively than a placebo does for a short period of time – say six weeks. An antidepressant may ameliorate the symptoms of depression better than a placebo over the short term.
>
> "What you find with every class of these psychiatric drugs is a worsening of the target symptom of depression or psychosis or anxiety over the long term, compared to placebo-treated patients. So even on target symptoms, there's

> greater chronicity and greater severity of symptoms. And you see a fairly significant percentage of patients where new and more severe psychiatric symptoms are triggered by the drug itself." (Whitaker, 2005b)
>
> **"SS: New psychiatric symptoms created by the very drugs people are told will help them recover?**
>
> **"RW:** Absolutely. The most obvious case is with the antidepressants. A certain percentage of people placed on the SSRIs [a type of antidepressant that includes Prozac, Paxil and Zoloft] because they have some form of depression will suffer either a manic or psychotic attack –drug induced. This is well recognized. So now, instead of just dealing with depression, they're dealing with mania or psychotic symptoms. And once they have a drug-induced manic episode, what happens? They go to an emergency room, and at that point they're newly diagnosed. They're now said to be bipolar and they're given an antipsychotic to go along with the antidepressant; and at that point, they're moving down the path to chronic disability." (Whitaker, 2005b) [bracketed material supplied]

Regarding the long-term effects of antipsychotics on schizophrenia, Whitaker has this to say:

> "Antipsychotics have shown short-term effectiveness in decreasing some symptoms of schizophrenia; however, longer term follow-up studies showed the patients to be worse off than if they had never taken the drugs at all. "..the research record actually is quite consistent. The pivotal NIMH study in the early 1960's found that the drugs had a short-term benefit, but that over the long-term the drug treated patients had higher relapse rates." (Whitaker, 2004)

13. The standard basis for prescribing psychiatric drugs, which is the American Psychiatric Association's Diagnostic and Statistical Manual, Version IV, does not clearly distinguish among different mental disorders in an objective and scientific manner. As psychiatrist Paul McHugh has written, "…a particular patient can satisfy the criteria for several disorders and many dissimilar patients can meet criteria for the same disorder." (McHugh, 2005).

14. Psychotropic drugs are often prescribed by psychiatrists and physicians on an "off label" basis, effectively negating the protection of the public, through prior trials and oversight, that the FDA is supposed to exercise.

Doctors are allowed to ignore the "indications" for a drug (i.e., the psychiatric problems for which the FDA states that the drug is safe and effective treatment) as well as the age limits for which the FDA makes that statement. Drug companies are forbidden to market drugs to doctors for "off-label" uses. However the companies have found numerous ways to get around this prohibition. One way is to do direct-to-consumer advertising, a practice

which is not permitted in most countries and which is permitted only in the United States and New Zealand.

15. Even if physicians were to prescribe only according to the FDA label, this would not solve the problems with psychotropic drug prescription. The major problem is that the FDA cannot be relied upon to protect the consumer because the drug manufacturers have been able to use their enormous financial power to keep that agency from being an effective watchdog guarding the public's interest.

The department within the FDA that oversees the testing and approval of medications is the Center for Drug Evaluation and Research (CDER). CDER conducts no drug tests of its own.

The drug firms pay for and sponsor all tests that the FDA relies upon. Because the drug companies pay for the trials, they make sure that the studies come out favorably to the drug company. User fees, which are collected from the drug companies, now make up over 50% of CDER's budget. As a result, some scientists, advocacy groups and legislators accuse the FDA of treating industry and not the public, as its client.

a. "User fees have undoubtedly constrained the FDA's independence and influenced its decisions." Marica Angell, former editor, *New England Journal of Medicine*, as reported by Cindy Skrzycki, Washingtonpost.com, April 3, 2007.

b. Since 1992, and the birth of user fees, the FDA has slashed its own testing laboratories and network of independent drug safety experts in favor of hiring more people to approve drugs for the pharmaceutical industry (Harris, 2004).

Under the FDA regulations, there are four phases of trials that a drug must undergo:

i. Phase I (1-2 years) The drug is given to 20-80 healthy volunteers to establish safe dosage levels, main adverse effects and "abuse potential."

ii. Phase II (2-3 years) The drug is given to 300-500 people with the illness for which the drug is supposed to be marketed. (Goal is to show a promising therapeutic effect, in order to justify the next phase of the trials.

iii. Phase III (2-4 years). The drug is tested in randomized control trials (RCTs). 1000-3000 diagnosed patients from many sites are randomly assigned to receive either the drug or a placebo. Neither the investigators nor the patients are supposed to know who is receiving what (which is why the procedure is called a "double blind" procedure).

iv. Phase IV. The drug is tested after it has been marketed.

FDA approval requires only 2 Phase III trials that are positive even if most of the trials have been negative.

A positive trial is one in which, on a symptom rating scale (as rated by the researcher) the drug-treated group shows a statistically significant advantage over the placebo-treated group. A drug company is permitted to conduct as many RCT (Random Controlled Trials) in order to come up with 2 trials that are successful. For example, it could conduct 100 RCTs in which the drug fails in 98 trials and succeeds in only 2 trials, and still obtain approval of the drug by the FDA.

So if a drug has shown "efficacy" in its "Phase 3" trials, this means that:

1. The chance that the drug is worse than a placebo is less than 5%.

2. The drug has *not* been shown to help the patient's condition to remit, or to work better than another drug that is already on the market. (Avorn, 2004)

There are many flaws and limitations in the design and conduct of clinical trials of psychotropic drugs that the FDA bases its approval on.[2] As a result, these trials do not provide a firm and scientific basis to determine benefits or risks of the drugs (Cohen, 2002; Safer, 2002), and cause clinicians and policymakers to have false ideas about how medications can harm people. These flaws also mean that FDA approval by itself does not guarantee that a drug is either safe or efficacious for its intended uses. (Strom, 2006).

> ***The trials focus on only a few narrow-chosen behaviors or effects.*** The main psychological alterations caused by the drugs remain unknown. (Jacobs & Cohen, 1999; Cohen & Jacobs, 2007)
>
> ***Most (Phase III) clinical trials last only 3-8 weeks***, and up to 70% of subjects drop out before the trial's end. As a result, only some effects are detected—not those emerging over the longer time periods that are characteristic of the length of time during which users often take the drugs. (Cohen & Jacobs, 2007)
>
> ***All subjects in the clinical trials are wrongly assumed to have the same disorder.*** (Beutler & Malik, 2002, Cohen & Jacobs, 2007; Emslie et al. 2002)
>
> ***Inert pills are inappropriately used as the placebo comparison.***
> This means that in most cases the researcher as well as the subjects know which group is taking the active pill, because of the obvious side effects caused by the active drug, thus breaking the "double blind" control. Active placebos (those that cause some physical sensations) should be used to keep the double blind from being broken. Drug companies do not use them in their clinical trials because active placebos are more effective placebos—i.e., if they were used the difference between the placebo and the active drug would be lessened or even possibly eliminated. (Abboud, 2004, Fisher & Greenberg, 2003).
>
> ***What is called the placebo group is not really a placebo group.*** Usually the subjects in both the placebo group, as well as in the experimental drug treatment group, have previously been on psychotropic drugs and are abruptly taken off

[2] For an excellent exposition of these issues in more detail, see Cohen, 2002.

these drugs for a week or two (called the "washout" period) prior to being placed into either the experimental group or the placebo group. Because psychotropic drugs often have serious withdrawal effects that often take much longer than the brief washout period to leave the body, the placebo group (as well as the experimental group) are both really "drug withdrawal" groups.

After conducting a trial comparing an atypical antipsychotic to a "placebo," the drug's manufacturer declared in its advertising that the side effects of the atypical were "no greater than placebo." The reason that they could claim this was that there was no true placebo group—the placebo group showed the side effects of the withdrawal from the previous drug that these subjects had been on, which was Haldol. The experimental group, which was placed on the atypical antipsychotic, benefited from the fact that antipsychotics tend to mask some of their own side effects—i.e., the side effects do not show up until the drug is withdrawn. As a result, the extent of the side effects in the mislabeled "placebo group"-- caused by withdrawal of the haldol--were approximately the same as the side effects found in the drug group (in which group the side effects were masked by the atypical that the patients in this group were receiving).

The drug companies routinely screen out (exclude) placebo responders (subjects who show a good response to the placebo condition)—an indefensible procedure from a scientific point of view. (Abboud, 2004, Fisher & Greenberg, 2003)

Often higher doses of the comparison drug are used than of the active drug being tested. As a result, the comparison drug produces more side effects, making the newer drug falsely appear to be safer. (Geddes et al., 2000)

Outcomes in the Phase III trials are rated by the researcher rather than by the patient. The problems with this practice are clearly shown in the Phase III pediatric trials of antidepressants. Not one of 10 parent- or child-rated scales showed any advantage for the drug. (Jureidini et al., 2004)

Adverse effects of the drug being tested are carelessly investigated. Most trials elicit side-effects by asking subjects general questions once a week, or waiting for subjects to report them spontaneously. This underestimates the true rates of side effects, especially the psychological and behavioral ones, giving a false impression of the drug's safety. (Greenhill et al., 2000)

Adverse effects are mis-coded, giving a false impression of the drug's safety. The drug company that is sponsoring the trial decides which effects qualify as "adverse drug effects" and how to name them. For example, the following table is an example of mis-coding why patients dropped out of a pediatric trial of the drug Strattera.

What the researcher wrote	How the drug company (sponsor	How it was re-coded after FDA reanalysis

	of study) coded it	
"Parents felt 'too many side effects'; stopped drug early; abdominal pain, nausea, anxiety"	Protocol Violation	Adverse Event
"Increasing behavior problems, worsening oppositional behavior; depression"	Physician Decision	Adverse Event

***Post-treatment ratings by patients are not reported*.** Sponsors gather data for weeks after the subjects stop treatment, but do not submit the data to FDA. The problem is that subjects may rate their treatment differently once they are off drugs from how they rate them while they are still on drugs. (Healy & Farquar, 1998)

***Post-marketing trials are rarely conducted*.** As of 2006, 70% of promised Phase IV trials had not started. (Avorn, 2007)

***Drug companies design their studies solely to get positive results*,** not to assess the drug in an unbiased, scientific manner**.** (Quick, 2001)

i. Negative results, if obtained, are twisted or suppressed.

ii. Sometimes positive results are published multiple times making it appear that the drug has more support in the literature than it really does.

According to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, only 51% were positive when the FDA analyzed the same literature.

Drug companies outsource the conduct of trials to Contract Research Organizations (CROs). This enables the drug companies to shield the trials from public scrutiny.

In 90% of the studies that pit one newer antipsychotic drug against another, the best drug was the study sponsor's drug. (Heres et al., 2006). By contrast, an independent study (NIMH's CATIE study), which compared 5 antipsychotics in the largest schizophrenia trial, showed that the older, cheaper drugs, worked as well (or as poorly) as the newer, more costly antipsychotics. In that study, ¾ of the patients stopped the treatment because they did not improve or had intolerable side effects. (Lieberman et al., 2005).

Because of these flaws in the clinical trials that the FDA requires, the detection of adverse effects of drugs is left largely to "post-marketing surveillance," which itself is very spotty. During the post-marketing period drugs are used for longer periods, in more natural conditions, by more varied the patients.

If the adverse drug reaction is serious enough to require extraordinary monitoring or special screening, the FDA will ask the drug sponsor to insert a "black box warning" in all marketing and product information to alert clinicians and consumers of the nature of the risk.

Examples of the weakness of post-marketing surveillance:

a. Prozac was on the market for 17 years before FDA warned of increased suicidality. Sponsors of several SSRIs have been accused of not disclosing all data from the clinical trials.

b. Vioxx was taken by 20 million Americans before Merck withdrew it after links to heart attacks and strokes. Merck was accused of not disclosing all data from clinical trials.

c. The FDA has a system ("Medwatch") for encouraging persons to report Serious Adverse Events (SAE) that are believed to be caused by drugs. However, only 1% to 10% of drug-related SAEs are reported to the FDA through Medwatch. (Moore, Cohen & Furberg, 2007).

d. Thousands die annually from the effects of drugs. During the 7 years 1998-2005, over 80,000 deaths suspected to have been caused by medications. Twenty-six thousand deaths were suspected to be linked to 15 drugs, including the following 3 antipsychotics and 1 anti-depressant: Clozaril, Risperdal, Zyprexa, and Paxil.

e. The first users of a newly marketed FDA-approved drug are the true research subjects. *Public Citizen* recommends waiting 7 years after marketing to use new drugs.

16. The extent of the prescription of psychotropic drugs by physicians has been heavily influenced by the drug companies' ability to influence doctors, patients, legislators, experts and researchers, etc.—all to the detriment of the well being of the patient.

General Concepts

> "The Food and Drug Administration (FDA), medical and psychiatric associations, experts with vested interest in promoting drugs, and the pharmaceutical industry—the pharmaceutical complex—combine to push doctors to prescribe psychiatric drugs to children and adults." (Breggin, 2008, p. 10)

During the period of patent protection that the drug manufacturer enjoys (approximately 15 years), the manufacturer has every incentive to exaggerate to physicians the benefits and hide the risks of its drugs. During that time brand name drugs receive 40% of the prescription volume and 90% of the revenue. After 15 years, the drug becomes a "generic," it is open to competition from other manufacturers and sells for much less. At

that point the manufacturer may have a new drug it wishes to sell instead of the older one. If so, then, for the first time, it is in the manufacturer's interest to reveal the defects and dangers of the older drug.

Antidepressants, antipsychotics and anticonvulsants are among the top 6 drug classes sold in the US. Psychotropics are popular not because of they are particularly effective, but rather because of the effective marketing campaigns of the drug companies.

Drug companies have successfully promoted the "medicalization" of behavior and psychological problems. Medicalization" means defining a problem as a medical one that requiring a medical (read *drug* solution). Psychiatrists often give first priority to medical (drug) solutions to problems in preference to non-drug solutions such as counseling, diet, behavior modification, exercise, etc.

Influence over Doctors

Drug companies use the following techniques to influence doctors in their prescribing habits.

1. *They make a variety of money payments and gifts to doctors.*

   These take the following forms.
   a. Free lunches. Some drug companies provide free lunches every day to physicians and their office staffs. Such gifts are effective marketing tools even if doctors don't think they are. Studies suggest that that the most powerful form of influence might be small gifts (Reist & VandeCreek, 2004, Dana & Lowenstein, 2003; Oldani, 2004)
   b. They provide free drug samples to physicians. (For every $1 spent on free samples, there is a return of $10 in sales.
   c. They reimburse physicians for continuing medical education courses.
   d. They make payments to doctors for lecturing, consulting and research.

   A sample of physicians showed that:
   a. 83% received food at work
   b. 78% received drug samples
   c. 35% were reimbursed for CME (Continuing Medical Education) courses
   d. 28% were paid to give lectures or to recruit patients into drug trials.

   Minnesota data reported in 2007 showed that 1 in 3 psychiatrists received money from drug makers, including 7 past presidents of the Minnesota Psychiatric Society, 2 drug policy advisors, and 17 faculty psychiatrists at the University of Minnesota.

   Psychiatrists who receive money from drug companies are more likely to prescribe "off-label" antipsychotics to children.

2. *They provide continuing medical education courses at medical conventions that promote their drugs*.

3. *They provide funding for the activities of professional medical and psychiatric organizations*

4. *They support the medical and psychiatric journals with their advertising.*

5. *They pay doctors to serve on "expert committees" that create and promote guidelines for drug treatments used by other doctors.*

6. *They hire attractive young persons to be drug representatives who make constant visits to doctors' offices with their free samples and recommendations.*

   There are 100,000 such reps—1 for every 6 doctors. Doctors who meet frequently with drug reps: (1) increase their prescribing of newer, costlier drugs; (2) reduce the prescribing of generics; (3) increase nonrational prescribing; and (4) use the rep as their main source of information. (Dana & Lowenstein, 2003; Reist & Vandecreek, 2004; Wazana, 2000)

   These drug reps sometimes use statistical tricks to mislead physicians. For example, if a drug A causes 2 deaths in 200 million cases, and drug B causes only 1 death in 200 million cases, the representative, if he is selling drug B will use the relative improvement and will call this a "50%" improvement. On the other hand if the representative is selling drug A, the representative will use the absolute amount of improvement and call the doctor's attention to the fact that drug B's absolute amount improvement is actually "miniscule."

7. *They make use of "prescription tracking" to tailor their marketing pitches to physicians.*

   Health Information organizations combine purchased pharmacy data, AMA physician data, and patient data to determine which drugs individual physicians prefer for which diagnoses and which patient groups, and use this information to tailor their marketing to physicians and to evaluate the effects of their promotions.

Influence over Consumers

Drug companies use the following techniques to influence consumers

1. *They purchase Direct-to-Consumer-Advertising (DCTA) on television and other media.*

DTCA became legal in 1997 and is allowed only in the US and New Zealand. It stimulates the sale of newer, costlier drugs above the older generics.

Between 1995 and 2004, the FDA sent 1,359 warning letters to drug companies for false or misleading advertising. E.g., an FDA letter re a 2007 ad for Geodon (an atypical antipsychotic) asserted that ad was "false and misleading" because efficacy was exaggerated, and no mention was made of risks of neuroleptics malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes.

2. *They sponsor "disease awareness" programs the net effect of which is to encourage persons to purchase their drugs.* An example of the success of these techniques is the current success the drug companies are having in selling "bipolar disorder". The frequency of this diagnosis has skyrocketed in recent years.

> Until recently manic-depressive illness was a rare disorder in the United States, involving only ten per one million new cases each year, or 3,000 new cases per year at the current level of population. The disorder occurred eight times less frequently than schizophrenia. In contrast, bipolar disorder is now thought to affect 5 percent of the people in the United States, or fifteen million Americans. It is now diagnosed as often as depression, and ten times more often than schizophrenia. Clinicians are encouraged to detect and treat it. They are being educated to suspect that many cases of depression, anxiety, or schizophrenia may in fact be bipolar disorder, and to adjust treatment accordingly. (Healy & LeNoury, 2007)

3. *They also engage in "disease mongering," in which they turn ordinary ailments, mild symptoms and risks into full-fledged diseases which require drugs.* An example is the campaign to convince people that they may have "restless leg syndrome" which is then said to require drug treatment.

4. *They fund "patient advocacy" groups which promote the general line that psychological and other problems require a biological solution (drugs).* Drug companies spent $29 million in 2005-2006, but these groups rarely disclose their sources of funding. The groups promote the view of distress as being *chronic brain disease* that requires the latest drugs and neurobiological research.
    a. *National Alliance on Mental Illness* received $11.7 million from 18 drug firms in three years
    b. *Children and Adults with Attention Deficit/Hyperactivity Disorder* is funded by Shire PLC, the #1 ADHD drug maker.
    c. *Depression and Bipolar Support Alliance* receives more than half its funding from drug firms.

    (Philadelphia Inquirer, 2006; Los Angeles Times, 2007)

5. *They provide online medical information and promotions that promote their own drugs and drug use generally.*

Influence over Legislators

Drug companies spend huge amounts of money to influence legislators.

In 2005-2006, drug interests spent $182 million on lobbying, and $100 million on campaign contributions. Drug company lobbyists outnumber Congressmen 2:1. In 2006, drug interests employed about 1,100 lobbyists, including 40 former members of Congress.

PhRMA (Pharmaceutical Researchers and Manufacturers of America), which represents the drug and biotechnology companies in the US, hired hundreds of lobbyists to help pass

Medicare Part D in 2004, which forbids the government from negotiating prices with drug companies.

In 2007 the main lobbying goals of drug companies were (1) to oppose laws that would strengthen FDA's ability to monitor drug safety; and (2) to fight bills that would allow Medicare to negotiate drug prices, which could reduce government drug spending by 60%.;

Influence of Experts and Researchers

Drug companies use the following techniques to influence experts to evaluate their own drugs positively

a. They pay researchers to run clinical trials and develop treatment guidelines
b. They require researchers to signing "secrecy agreements" to conceal negative information that may arise in their drug trials.
c. They pay academics and researchers to lend their names to articles they have not written ("ghostwriting")

Drug companies paid over $1 billion to Medical Education Communication Companies (MECCs) These companies deliver industry-sponsored continuing medical education courses that highlight the sponsor's drugs and are associated with increased prescription of those drugs. (Reiman, 2001; Elliott, 2004, Wazana, 2000).

Drug companies exercise such enormous influence over what is published in medical and psychiatric journals that the journals cannot be relied on for truly scientific articles. For example, drug companies sponsor ghost-written scientific articles and use the power of purchasing reprints to influence journals. They hire MECCs to write academic papers favorable to their products. The MECCs then hire academics to publish the articles under their name without disclosure about their true source. (Moffat and Elliott, 2007). This strategy works because 76% of doctors consider medical journals their most important source of information. (RxPromoROI.org; Fugh-Berman et al., 2006).

A former editor of *British Medical Journal* called journals "extensions of marketing arms" of drug firms and urged journals to stop *publishing all clinical trials* and only evaluate them critically. (Moffat & Elliott, 2007; Smith, 2004; *The New York Times*, 2002)

Even without ghost-writing, a drug firm can influence a journal's publication policies. For example, the drug company may pay a journal $1million for reprints, creating enormous incentive to publish a favorable article.

17. Drug companies downgrade some of their own drugs to doctors only when the patent protection is about to run out on them, at which point competitors can start marketing generic versions of the same drugs at lower costs. At that point, the drug

companies start revealing the true problems with their current drugs and start pushing doctors to prescribe the much more expensive newer drugs that they are about to bring to market.

The newer drugs, which can cost 20 or 30 times as much as the older ones, often have no real advantages over the old ones, and can even be disadvantageous. This process, combined with drug company-promoted legislation that prevents the government from negotiating the price of drugs with the drug companies, is partly responsible for why medical costs are so high in this country.

> The selling of new drugs necessarily involves telling a story that contrasts the new with the old. The worse the old drugs are perceived to be, the better the new drugs will look, and so as the atypicals [the second generation of antipsychotic medications] moved into the marketplace—which meant that drug firms were hiring well-know psychiatrists to serve as consultants and to run clinical trials—researchers started tallying up the shortcomings of standard neuroleptics…
>
> The old drugs, researchers concluded, caused a recognizable pathology, which they dubbed neuroleptic-induced deficit syndrome (NIDS). As would be expected, NIDS was a drug-induced disorder that mimicked natural diseases—like Parkinson's or encephalitis lethargica—that damaged dopaminergic systems. Two thirds of all drug-treated patients, researchers calculated, were plagued by 'persistent Parkinson's.'[Parkinson's disease involves impaired motor movements.] Nearly all patients—some physicians put the figure at 100 percent—suffered from extrapyramidal symptoms (EPS) of some type. (Extrapyramidal symptoms include all of the various motor side effects, such as Parkinson's, akathisia, and muscle stiffness.) As for tardive dyskinesia [sometimes permanent involuntary motor movements, often of the mouth and lips, but of other parts of the body as well], investigators announced that it might be more of a risk than previously thought: It struck up to 8 percent of patients in their *first year* of exposure to a potent neuroleptic like haloperidol [Haldol]. This list of adverse effects attributed to neuroleptics, meanwhile grew to head-spinning length. In addition to Parkinson's, akathisia [severe, sometimes unbearable inner restlessness that has driven some patients to suicide], blunted emotions, TD [Tardive Dyskinesia], and neuroleptic malignant syndrome [a potentially fatal illness in which the body stiffens], patients had to worry about blindness, fatal blood clots, arrhythmia [dangerous change in the heart rhythm], heat stroke, swollen breasts, leaking breasts, impotence, obesity, sexual dysfunction, blood disorders, painful skin rashes, seizures, and, should they have any children, offspring with birth defects. "They have adverse side effect profiles that can affect every physiologic system," said George Arana, a psychiatrist at the Medical University of South Carolina, at a 1999 forum in Dallas. Nor was it just bodily functions so impaired. "Typical antipsychotic medications," Duke University's Richard Keefe told his peers, may "actually prevent adequate learning effects and worsen motor skills, memory function, and executive abilities, such as problem solving and performance assessment."[2]

Researchers also began to admit that neuroleptics didn't control delusions and hallucinations very well. Two-thirds of all medicated patients had persistent psychotic symptoms a year after their first psychotic break. Thirty percent of patients didn't respond to the drugs at all – a "non-response" rate that up until the 1980s had hardly ever been mentioned. Several studies suggested that even this 30-percent figure might be very low and that as many as two-thirds of all psychotic patients could be said to be "non-responders" to neuroleptics.[3] Perhaps the most revealing confession of all came from NIMH scientists: "Our clinical experience is that while the intensity of thought disorder may decrease with medication treatment, the profile of the thought disorder is not altered."[4] The drugs, it seemed, might not be "antipsychotic" medications after all.

As for the patients' quality of life, nearly everyone agreed that neuroleptics had produced a miserable record. More than 80 percent of schizophrenics were chronically unemployed. Their quality of life is "very poor," wrote New York's Peter Weiden. Said Arana: "patients still lie in bed all day. They are suffering." Long-term outcomes with neuroleptics, commented Philip Harvey, from the Mt. Sinai School of Medicine in New York City, were no better than "when schizophrenia was treated with hydrotherapy." Said one physician at the Dallas conference: "We will do a great service to our [first-episode] patients by never exposing them to typical antipsychotic drugs." A 1999 patient survey completed the profile: Ninety percent on neuroleptics said they were depressed, 88 percent said they felt sedated, and 78 percent complained of poor concentration.[5]

All of this was undoubtedly quite true, and yet it had come at a telling time. New drugs were coming to market and such candor about the old ones served as a powerful foil for making the new ones look good. Psychiatrists who came to the Dallas conference, which was sponsored by Janssen, the manufacturer of the atypical drug risperidone, couldn't have missed the message: Those who tended to the severely mentally ill would do well to begin prescribing Janssen's new drug and other atypicals as quickly as possible. The financial forces that helped drive perceptions within psychiatry had changed, and that had led – *within* the medical community – to a rather stunning reassessment of the old.

But what to tell the public? Neuroleptics – billed as antipsychotic medications – had been the mainstay treatment for schizophrenia for forty years. Over and over again the public had been told that schizophrenia was a biological disease and that drugs helped alleviate that biological illness. The drugs were like "insulin for diabetes." What if psychiatry now publicly confessed that the dopamine theory hadn't panned out, that the drugs induced a disorder called NIDS, and that outcomes were no better than when the mad were plunked into bathtubs for hours on end? At least hydrotherapy hadn't caused tardive dyskinesia, Parkinson's, or a host of other side effects. What would the public make of that admission?

A subtler story emerged in public forums. The old drugs were beneficial, but problematic. The new drugs were a wonderful *advance* on the old.
(Whitaker, 2004, p. 255ff) [bracketed material supplied]

18. One cannot trust the scientific literature or the public media to be a source of accurate information about psychotropic drugs because of the drug companies exert enormous influence on every step of the research, publication and public information process.

Drug manufacturers often: determine what studies are done; decide how the research is to be designed; hire the researchers; hire the companies that decide what subjects will be allowed to participate in the research; decide whether or not to submit the studies for publication, if the results are favorable, or to just sit on the results if the results are not;.hire public relations firms to ghostwrite professional articles describing the research studies; hire well-known psychiatrists to put their name to the articles; influence what articles are published by supporting the journals through their advertising and by purchasing huge numbers of reprints; and hire public relations firms who provide news releases that are used by the media to announce the results of their studies to the public.

These practices date all the way back to the 1950's when psychotropic drugs were first introduced. Robert Whitaker tells the story:

> Starting in 1959, Kefauver directed a two –year investigation by the Senate Subcommittee on Antitrust and Monopoly into drug-industry practices, and his committee documented how the marketing machinery of pharmaceutical firms completely altered what physicians, and the general public, read about new medications. Advertisements in medical journals, the committee found, regularly exaggerate the benefits of new drugs and obscured their risks. The "scientific" articles provided a biased impression as well. Prominent researchers told Kefauver that many medical journals "refused to publish articles criticizing drugs and methods, lest advertising suffer." Pfizer physician Haskel Weinstein confessed that pharmaceutical companies ghostwrote many of the laudatory articles:
>
> > A substantial number of the so-called medical scientific papers that are published on behalf of these drugs are written within the confines of the pharmaceutical houses concerned. Frequently the physician involved merely makes the observations and his data, which is sometimes are sketchy and uncritical, are submitted to a medical writer employed by the company. The writer prepares the article which is returned to the physician who makes the overt effort to submit it for publication. The article is frequently sent to one of the journals which looks to the pharmaceutical company for advertising and rarely is the publication refused. The particular journal is of little interest inasmuch as the primary concern is to have the article published any place in order to make reprints available. There is a remarkable attitude prevalent that if a paper is published then its contents become authoritative, even though before publication the same contents may have been considered nonsense.[21]
>
> In its 1961 report, Kefauver's committee also detailed how the pharmaceutical companies manipulated the popular press. Magazines were promised advertising

> revenues if they would publish features mentioning a company's drug in a positive light. Writers could earn extra fees on the side for doing the same, wilth one scribe telling of a potential payoff of $17,000—far more than a year's salary at the time—for a single magazine article. Writers were also bribed with free dinners, limousine rides, and other perks. Weinstein told Kefauver's committee that, as with the scientific literature, "much of what appears (in the popular press) has in essence been placed by the public relations staffs of the pharmaceutical firms. A steady stream of magazine and newspaper articles are prepared for distribution to the lay press.[22] (Whitaker, 2002, p. 149ff)

19. The rash of multiple shootings and suicides in schools, colleges, workplaces and elsewhere that America has seen in recent decades is very likely linked, in many cases, to the use of psychotropic drugs by the perpetrators of that violence.

In her 2006 book *Psyched Out,* investigative reporter Kelly Patricia O'Meara lists the 17 most recent school shootings and writes (see O'Meara, 2006, Chapter 5):

> Of these 17 school shootings, eight of the shooters had a known history of psychiatric mind-altering drug use. Three others—Mitchell Johnson, Ken Bartley Jr. and Michael Carneal—had known histories of psychiatric counseling, which more often than not includes psychiatric drug use. Only one shooter, Charles "Andy" Williams, had been confirmed as having had no psychiatric counseling or psychiatric drug history. What about the others? Despite the fact that nearly half of the recent school shooters were using prescribed psychiatric mind-altering drugs, officials continue to refuse to ask the question. But it goes even deeper: Repeated attempts to obtain the information from family members and attorneys were ignored.

O'Meara has this to say about the reasons for this silence.

> These are important questions that may assist investigators in understanding why children flip out and turn into murderers, but these are questions rarely asked and apparently deemed unimportant by investigators. Making matters worse, because the majority of school shooters are minors, health records (including mental health data) are sealed by the courts, leaving the public at the mercy of news reports that rely on regurgitations of gossip, rumor and opinion. Often what is known, or what is released to the public about the adolescent's mental health state, is as oblique as "the shooter had been receiving psychiatric help." That is not much to go on and, for most Americans, this statement hardly would register as significant on this-is-important-information radar, but for those who closely watch the issue, the more mention of "psychiatric help" is becoming a red flag that psychiatric mind-altering drugs are involved.

20. Projects to "screen" children and adults for mental illnesses (such as Columbia University's TeenScreen program) are in large part marketing campaigns

supported by drug companies with the purpose of increasing the prescriptions of psychotropic drugs.

Such programs often try to enlist public schools in campaigns to screen students for the presence of mental illness. The screening tools are often simple pencil and paper checklists that make use of the indicators for mental illnesses given in DSM IV. Too often these checklist questionnaires can cause a perfectly normal person to believe that he or she is mentally ill. Such screening programs may be associated with a Medication Algorithm Project (MAP) which gives doctors and psychiatrists recommendations as to what drugs to try first, and in what dosages, etc., to treat certain mental illnesses. (See O'Meara, 2006, Chapter 7)

21. The notion that the newer antipsychotic drugs have fewer negative side effects than earlier versions, is largely a myth sponsored by the drug companies.

Excerpt from Robert Whitaker 2007 Affidavit

The following is an excerpt from a 2007 affidavit by Robert Whitaker (Whitaker, 2007) which addresses the claim that the atypical antipsychotics are more effective and safer than the first generation antipsychotics. A link to the complete copy of this affidavit ("Clickable Whitaker Affidavit"), with "clickable" links to the full text of all of the documents underlined in the footnotes to this excerpt can be found on the home page of www.psychrights.org

> 16. The conventional wisdom today is that the "atypical" antipsychotics that have been brought to market—Risperdal, Zyprexa, and Seroquel, to name three—are much safer than Haldol, Thorazine and the other older drugs. However, it is now clear that the new drugs have no such advantage, and there is even evidence suggesting that they are worse than the old ones.
>
> 17. Risperdal, which is manufactured by Janssen, was approved in 1994. Although it was hailed in the press as a "breakthrough" medication, the FDA, in its review of the clinical trial data, concluded that there was no evidence that this drug was better or safer than Haldol (haloperidol). The FDA told Janssen: "We would consider any advertisement or promotion labeling for RISPERDAL false, misleading, or lacking fair balance under section 501(a) and 502(n) of the ACT if there is presentation of data that conveys the impression that risperidone is superior to haloperidol or any other marketed antipsychotic drug product with regard to safety or effectiveness."[3]
>
> 18. After Risperdal (risperidone) was approved, physicians who weren't funded by Janssen were able to conduct independent studies of the drug.

[3] FDA approval letter from Robert Temple to Janssen Research Foundation, December 21, 1993.

They concluded that risperidone, in comparison to Haldol, caused a higher incidence of Parkinsonian symptoms; that it was more likely to stir akathisia; and that many patients had to quit taking the drug because it didn't knock down their psychotic symptoms.[4,5,6,7,8] Jeffrey Mattes, director of the Psychopharmacology Research Association, concluded in 1997: "It is possible, based on the available studies, that risperidone is not as effective as standard neuroleptics for typical positive symptoms."[9]

19. Zyprexa, which is manufactured by Eli Lilly, was approved by the FDA in 1996. This drug, the public was told worked in a more "comprehensive" manner than the standard neuroleptics. However, the FDA, in its review of the trial data for Zyprexa, noted that Eli Lilly had designed its studies in ways that were "biased against haloperidol." In fact, 20 of the 2500 patients treated with Zyprexa in the trials died. Twenty-two percent of the Zyprexa patients suffered a "serious" adverse event, compared to 18 percent of the Haldol patients. There was also evidence that Zyprexa caused some sort of metabolic dysfunction, as patients gained nearly a pound per week. Other problems that showed up in Zyprexa patients included Parkinsonian symptoms, akathisia, dystonia, hypotension, constipation, tachycardia, seizures, liver abnormalities, white blood cell disorders, and diabetic complications. Moreover, two-thirds of the Zyprexa patients were unable to complete the trials either because the drugs didn't work or because of intolerable side effects.[10]

20. There is now increasing recognition in scientific circles that the atypical antipsychotics are no bette4r than the old drugs, and may in fact be worse. Specifically:

a) In 2000, a team of English researchers led by John Geddes at the University of Oxford reviewed results from 52 studies, involving 12, 649 patients. They concluded: "There is no clear evidence that atypical are more effective or are better tolerated than conventional antipsychotics." The English researchers noted that Janssen, Eli Lilly and other manufacturers of atypicals had used various ruses in their clinical trials to make their new drugs look better than the

---

[4] Rosebush, P. "Neurologic side effects in neuroleptic-naïve patients treated with haloperidol or risperidone." *Neurology* 52 (1999):782-785.
[5] Knable, ML. "Extrapyramidal side effects with risperidone and haloperidol at comparable D2 receptor levels." *Psychiatry Research: Neuroimaging Section* 75 (1997):91-101.
[6] Sweeney, J. "Adverse effects of risperidone on eye movement activity." *Neuropsychopharmacology* 16 (1997):217-228.
[7] Carter, C. "Risperidone use in a teaching hospital during its first year after market approval." *Psychopharmacology Bulletin* 31 (1995):719-725.
[8] Binder, R. "A naturalistic study of clinical use of risperidone." *Psychiatric Services* 49 (1998):524-6.
[9] Mattes, J. "Risperidone: How good is the evidence for efficacy?" *Schizophrenia Bulletin* 23 (1997):155-161.
[10] See Whitaker, R. *Mad in America*. New York: Perseus Press (2002):279-281.

old ones. In particular, the drug companies had used "excessive doses of the comparator drug."[11]

b) In 2005, a National Institute of Mental Health study found that there were "no significant differences" between the old drugs and the atypicals in terms of their efficacy or how well patients tolerated them. Seventy-five percent of the 1432 patients in the study were unable to stay on antipsychotics owing to the drugs' "inefficacy or intolerable side effects," or for other reasons.[12]

c) In 2007, a study by the British government found that schizophrenia patients had better "quality of life" on the old drugs than on the new ones.[13] This finding was quite startling given that researchers had previously determined that patients medicated with the old drugs had a "very poor" quality of life.

20. There is also growing evidence that the atypicals may be exacerbating the problem of early death. Although the atypicals may not clamp down on dopamine transmission quite as powerfully as the old standard neuroleptics, they also block a number of other neurotransmitter systems, most notably serotonin and glutamate. As a result, they may cause a broader range of physical ailments, with diabetes and metabolic dysfunction particularly common for patients treated with Zyprexa. In a 2003 study of Irish patients, 25 of 72 patients (34%) died over a period of 7.5 years, leading the researchers to conclude that the risk of death for schizophrenics had "doubled" since the introduction of the atypical antipsychotics.[14]

21 In summary, the research literature reveals the following:

a) Antipsychotics increase the likelihood that a person will become chronically ill.
b) Long-term recovery rates are much higher for unmedicated patients than for those who are maintained on antipsychotic drugs.
c) Antipsychotics cause a host of debilitating physical, emotional and cognitive side effects, and lead to early death.
d) The new "atypical" antipsychotics are not better than the old ones in terms of their safety and tolerability, and quality of lie may even be worse on the new drugs than on the old ones.

---

[11] Geddes, J. "Atypical antipsychotics in the treatment of schizophrenia."*British Medical Journal* 321 (2000):1371-76.

[12] Lieberman, J, et al. "Effectiveness of antipsychotic drugs in patients with schizophrenia." *New England Journal of Medicine* 353 (2005):1209-1233.

[13] Davies, L, et al. "Cost-effectiveness of first- v. second-generation antipsychotic drugs." *The British Journal of Psychiatry* 191 (2007):14-22.

[14] Morgan, M, et al. "Prospective analysis of premature morbidity in schizophrenia in relation to health service engagement." *Psychiatry Research* 117 (2003):127-35.

Excerpt from article by Levitas and Hurley

The following set of questions and answers, in an article by Andrew Levitas, M.D. and Ann DesNoyers Hurley, Ph.D. (Levitas & Hurley, 2006, pp. 97ff.) addresses the issue of whether the atypicals are safer than the first generation antipsychotics.

> **Q.** Would it be true, then, that the SGAs [second generation, or "atypical antipsychotics" currently being prescribed] pose no risk of movement disorder?
>
> **A.** No. They pose less risk than FGAs [first generation antipsychotics, such as Thorazine, Mellaril and Haldol], probably very much less risk. But they pose higher risks of problems seen at much lower frequencies with the FGAs.
>
> **Q.** What problems?
>
> **A.** At the top of the list is Metabolic Syndrome: obesity, diabetes mellitus, and dyslipidemia (abnormal levels of cholesterol and other blood lipids). All are risk factors for cardiovascular disease, one of the major public health problems of our society. …the huge number of studies and the widespread clinical observation of the problem led to a consensus conference of the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists, and the North American Association for the study of Obesity. They identified the risks of metabolic syndrome and its components with each SGA (to the extent permitted by available data), pointed to the resulting risk of eventual consequent cardiovascular disease, and recommended monitoring and treatment guidelines…with our population [referring to individuals with intellectual disabilities] we should be wary of using these drugs casually, without firm indications, and with great caution, in patients for whom obesity and its consequences are particular problems, such as Prader-Willi syndrome and Down syndrome.
>
> **Q.** Are there other problems with SGAs?
>
> **A.** There is the issue of cardiac conduction changes and monitoring the so-called QTc issue. The QTc is an electrocardiographic measure of the electrophysiological changes in the heart tissue. It is a measure of the time from when the heart depolarizes the Q wave until it repolarizes, which is the R, S, and finally T wave. The time between the onset of Q and return to baseline of the T is called the Q-T interval. This is the interval during which the large lower chambers of the heart contract, sending blood around the body. By the time the lowest parts are contracting, the upper parts are repolarizing in preparation for the next contraction, which will begin with the contraction of the heart's upper chambers signaled on the EKG by the P wave. If this wave of contraction, the P wave, reaches the lower chambers before their repolarization, i.e., before the next Q-R-S, disorganization of the heart contraction, or arrhythmia, consequences including sudden death can occur. Any medication that prolongs the Q-T interval risks such an occurrence….

All FGAs and all SGAs are capable of prolonging the QT interval...It is nothing short of an illusion that only thioridazine (Mellaril) is capable of causing this effect.

Exact guidelines on QTc monitoring remain a goal. In the absence of clear guidelines, it is prudent that all patients to be started on any antipsychotic should have baseline cardiac history, chem. Scan, CBS and an EKG….If prolonged Q-T interval is found, re-evaluation of the need for the offending drug should be undertaken, and drug change should be considered.

Q. Are there any other problems?

A. There is the problem of serum prolactin increase, a problem reviewed by Stevens *et al.*[21] Prolactin is the hormone that causes breast growth and lactation; its normal function in pregnant women is to prepare and sustain milk production. Increased prolactin levels suppress estrogen, and thus the menstrual cycle, as long as breastfeeding is active. Dopamine blockade in the hypothalamus [something that antipsychotics are assumed to cause] causes hyperprolactinemia (elevated serum prolactin); FGAs have long been known to cause this effect, signaled by amenorrhea (lack of menses) in female patients, sometimes with galactorrhea (milk production) mimicking a type of ...

Risperidone appears to be the most common cause of hyperprolactinemia among SGAs;[21] I have personally, over the past 10 years, seen four adolescent and young adult males with gynecomastia [female breast growth in a male] and one 30-year old female with amenorrhea[lack of menses]/galactorrhea, all on risperidone [Risperdal, a Second Generation Antipsychotic], and one adolescent male with gynecomastia on olanzapine [Zyprexa, another Second Generation Antipsychotic]. This is a cancer risk in males; recently, FDA researchers began an investigation of reports of galactorrhea in men and children receiving risperidone. Results have yet to be published in a medical journal, but were reported in the Wall Street Journal[2] and reprinted in Psychiatry Drug Alerts,[17] which reported "a high incidence of benign pituitary tumors" among patients receiving risperidone…The matter is still under study…"

22. There are a considerable number of assumptions, notions and procedures that are current in the psychopharmacological literature, but which lack adequate scientific support, including: the adequacy of the double blind design; the assumption that the patients used in drug trials are representative of the population at large, etc.

Seymour Fisher, Ph.D. and Roger Greenberg, Ph.D. have edited an excellent book about psychotropic drugs, *From Placebo to Panacea: Putting Psychiatric Drugs to the Test* (Fisher & Greenberg, 1997). In their concluding chapter, they write the following:

Erroneous Assumptions

Apropos of this matter of uncertainty, the following list is a compilation of assumptions, notions, and procedures current in the psychopharmacology

literature that have directly or indirectly been shown in the preceding chapters to lack dependable and consistent scientific support:

1. The idea that the double-blind design for testing psychotropic drugs effectively eliminates researcher bias.
2. The assumption that the samples of patients evaluated in the typical drug trial are representative of the general clinical population to whom the treatment will be applied.
3. The practice of using an initial washout phase during drug trials, with the intention of eliminating placebo responders and therefore to minimize placebo effects.
4. The assumption that any clear evidence has emerged that the therapeutic power of psychoactive drugs is linked to dose levels in any consistent fashion.
5. The belief that the therapeutic effects of psychoactive drugs are correlated consistently with their plasma levels.
6. The concept that psychotropic drugs produce effects that are more biological than placebo effects.
7. The confident belief that psychotropic drugs are much more therapeutic than placebos. This would be especially true with reference to the antidepressants and anxiolytic agents.
8. The practice of administering psychotropic drugs to children and adolescents to alleviate depression, anxiety, and psychosis.
9. The presumption that psychotropic drugs target specific symptom clusters that are empirically well defined and distinguishable.
10. The practice of testing psychotropic drugs by means of brief trials (e.g.., 4-6 weeks) and assuming such brief evaluations will provide adequate information concerning long-term therapeutic potential.
11. The often promulgated idea that depressed patients can be better prevented from suicide by psychoactive drugs than by other therapeutic techniques.
12. The concept that severe depression (e.g., “endogenous”) is better treated is better treated with antidepressants than with other therapeutic modes.
13. The comfortable self-serving conviction that the side effects of most psychoactive drugs are ephemeral and not of much consequence.
14. The notion that the placebo component of a response to a psychoactive drug can be adequately measured simply by inclusion of a matched placebo control. Since placebos are typically inactive, there is no way of ascertaining whether an enhanced placebo component is linked to the greater stimulation aroused by the active drug.
15. The idea that psychoactive drugs are routinely more effective than psychotherapy treatment or more helpful in preventing relapse.

> This amounts to a litany of weighty problems that plague the psychopharmacological enterprise. As a matter of science, it is appropriate and important to raise these questions. However, what are the practical implications of our observations.
>
> Are we suggesting that psychoactive drugs do not work? No that is not our message. Although such drugs probably often do not work much better than active placebos, many troubled individuals likely have benefited from them. The degree of this benefit, as against no treatment, cannot be scientifically defined at this point in time. Also the issue of how much of the benefit derives from the action of chemical substances (e.g., serotonin, norepinephrine, dopamine) targeted, in terms of theory, to specified CNS systems cannot currently be spelled out. However, in some conglomerate way, different factors unite to impart apparent therapeutic power to the act of an authority figure administering a psychoactive substance to troubled individuals. The complex of ingesting a substance that palpably induces "druglike" body experiences, in the context of personally feeling the need to change or improve, and the added element of receiving authoritative reassurance that now there is a good probability of changing—all seem to offer an opportunity for a therapeutic process to be set in motion. However, we know this only in a diffuse, uncertain fashion. (Fisher & Greenberg, 1997, p. 370-373)

23. Because of the power of the drug companies, the growth and development of non-drug treatment approaches has been largely slowed or stymied.

This story is well told in an article by Stephen Wong, entitled, "Behavior analysis of psychotic disorders: scientific dead end or casualty of the mental health political economy?" Dr. Wong summarizes his answer in the first sentence of this abstract which is "Behavior analysis, once a promising approach to understanding and treating severe mental disorders, has been obscured by the biomedical model of mental illness and its ubiquitous psychotropic drugs." (Wong, 2006).

24. When the effectiveness of psychotropic drugs has been compared with the effectiveness of behavioral treatment procedures, the latter have consistently proved to be substantially more effective.

The evidence for this is summarized and presented very clearly in a book by psychologist Stephen Ray Flora entitled *Taking America off Drugs: Why Behavioral Therapy is More Effective for Treating ADHD, OCD, Depression, and other Psychological Problems* (Flora, 2007).

Chapter 3. Categories of Psychotropic Drugs

I: ANTIDEPRESSANTS

Selective Serotonin Reuptake Inhibitors (SSRIs)

Celexa (citalopram)
Lexapro (escitalopram)
Luvox (fluvoxamine)
Paxil (paroxetine)
Prozac and Sarafem(fluoxetine)
Zoloft (sertraline)

Other Newer Antidepressants

Cymbalta (duloxetine)
Effexor (venlafaxine)
Remeron (mirtazapine)
Symbyax (Prozac plus Zyprexa, a newer antipsychotic)
Wellbutrin and Zyban (bupropion)

Older Antidepressants (Partial List)

Anafranil (clomipramine)
Asendin (amoxapine)
Elavil (amitriptyline)
Norpramin (desipramine)
Pamelor (nortriptyline)
Parnate (tranylcypromine)5
Sinequan (doxepin)
Surmontil (trimipramine)
Tofranil (imipramine)
Vivactil (protriptyline)

II: STIMULANTS

Classic Stimulants

Adderall, Adderall XR (amphetamine mixture)
Desoxyn (methamphetaminej

Other Stimulants

Cylert (pemoline; no longer available)
Strattera (atomoxetine)
Dexedrine (dextroamphetamine)
Focalin, Focalin XR (dexamethylphenidate)
Ritalin, Concerta, Daytrana (methylphenidate)
Vyvanse (lisdextroamphetamine)

III: SEDATIVE, HYPNOTIC, AND ANXIOLYTIC DRUGS (TRANQUILIZERS AND SLEEPING PILLS)

Benzo Tranquilizers

Ativan (lorazepam)
Klonopin (clonazepam)
Librium (chlordiazepoxide)
Serax (oxazepam)
Tranxene (chlorazepate)
Valium (diazepam)
Xanax (alprazolam)

Benzo Sleeping Pills

Dalmane (flurazepam)
Doral (quazepam)
Halcion (triazolam)
ProSom (estazolam)
Restoril (temazepam)

Non-Benzo Sleeping Pills

Ambien (zolpidem)
Lunesta (eszopiclone)
Rozerem (ramelteon)
Sonata (zaleplon)

Barbiturate Sleeping Pills

Butisol (butabarbital)
Carbrital (pentobarbital and carbromal)
Seconal (secobarbital)

IV: ANTIPSYCHOTIC DRUGS (NEUROLEPTICS)

Newer (Second- or Third Generation or Atypical)Antipsychotics 10

Abilify (aripiprazole)
Clozaril (clozapine)11
Geodon (ziprasidone)
Invega (paliperidone)
Risperdal (risperidone)
Seroquel (quetiapine)
Symbyax (olanzapine plus Prozac, an SSRI antidepressant)
Zyprexa (olanzapine)

Older Antipsychotic Drugs

Etrafon (antidepressant plus Trilafon)
Haldol (haloperidol)
Loxitane (loxapine)
Mellaril (thioridazine)
Moban (molindone)
Navane (thiothixene)

Prolixin (fluphenazine)
Serentil (mesoridazine)
Stelazine (trifluoperazine)
Taractan (chlorprothixene)
Thorazine (chlorpromazine)
Tindal (acetophenazine)
Trilafon (perphenazine)
Vesprin (triflupromazine)

Neuroleptics Used for Other Medical Purposes

Compazine (prochlorperazine)
Inapsine (droperidol)
Orap (pimozide)
Phenergan (promethazine) 12
Reglan (metoclopramide)

V: LITHIUM AND OTHER DRUGS USED AS MOOD STABILIZERS

Approved Mood Stabilizers

Depakote (divalproex sodium; antiepileptic drug)
Equetro (extended-release carbamazepine; antiepileptic drug)
Lamictal (lamotrigine; antiepileptic drug)
Lithobid, Lithotabs, Eskalith (lithium)

Off-Label or Unapproved Mood Stabilizers

Catapres (clonidine; antihypertensive drug)
Neurontin (gabapentin; antiepileptic drug)
Tegretol (carbamazapine; antiepileptic drug)
Tenex (guanfacine; antihypertensive drug)
Topamax (topiramate; anti epileptic drug)
Trileptal (oxcarbazepine; antiepileptic drug)

VI. DRUGS DESIGNED TO TREAT ACUTE EXTRAPYRAMIDAL SIDE EFFECTS

Akineton (biperide)
Artane (trihexyphenidyl)
Cogentin (benztropine)
Kemadrin (procyclidine)

Chapter 4. Antipsychotic Drugs

Atypical (Second and Third Generation) neuroleptics: Abilify (ariprazole); Clozaril (clozapine); Geodon (ziparasidone); Invega (paliperidone); Risperdal (risperidone); Seroquel (quetiapine);Symbyax (olanzapine plus Prozac, an SSRI antidepressant); Zyprexa (olanzapine);
Conventional (First Generation, or "Typical") neuroleptics: Etrafon (antidepressant plus Trilafon); Haldol (haloperidol); Loxitane (loxapine); Mellaril (thioridazine); Moban (molindone); Navane (thiothixene); Prolixin (fluphenazine); Serentil (mesoridazine); Stelazine (trifluoperazine); Taractan (chlorprothixene); Thorazine (chlorpromazine); Tindal (acetophenazine); Trilafon (perphenazine); Vesprin (triflupromazine).
Neuroleptics used for non-psychiatric reasons: Compazine (prochlorperazine); Inapsine (droperidol); Orap (prmethazine); Reglan (metocolopramide).

FDA-APPROVED PSYCHIATRIC INDICATIONS FOR ATYPICALS FOR ADULTS

Brand Name	Generic Name	Indication	Ages Approved For
Risperdal (1994)	risperidone	Autism, bipolar mania, schizophrenia	5+
Abilify (2002)	aripiprazole	Schizophrenia	10+
Clozaril (1989)	clozapine	Treatment-resistant schizophrenia	Adults only
Zyprexa (1996)	olanzaine	Bipolar mania, schizophrenia	
Seroquel (1997)	quetiapine		
Geodon (2001)	ziprasidone		
Symbyax			
Invega (2007)	paliperidone		

***** An indication is a diagnosis that is FDA-approved for the use of a medication. Physicians are allowed, however, to use the drug for other purposes (called "off-label" uses).

FDA-APPROVED PSYCHIATRIC INDICATIONS FOR TYPICALS FOR CHILDREN

Orap	pimozide	Tourette's Disorder (for Haldol non-responders)	12+
Haldol	haloperidol	Schizophrenia, Tourette's Disorder	3+
Mellaril	thioridazine	Schizophrenia	2+

FDA BLACK BOX WARNINGS FOR ATYPICALS*

All atypicals	Increased mortality in frail elderly
Clozaril	Serious risk of agranulocytosis (severe drop in white blood cells), seizures, myocarditis, and other cardiovascular and respiratory effects
Seroquel	Risk of suicidality in children and adolescents

* Next to removing a drug from the market, requiring a black box warning is the most severe restriction that the FDA can apply.

EFFECTS

Effects	Notes
1. Sedation, tranquilizing	Due to the various effects listed, there tends to be a decrease, while the drug is used, in psychotic symptoms such as delusions, hallucinations and agitation and in manic symptoms such as euphoria, expansiveness and irritability. This is why these drugs (formerly called "neuroleptics") are called "antipsychotics." It is believed that these effects are due to the dopamine-blocking action of all antipsychotics. (Cohen, 2008, citing Bezchlibnyk-Butler & Jeffries, 2005) When antipsychotics are given in sufficient dosage, they have a stupefying effect. This is why antipsychotics are used to tranquilize wild animals and were used to punish political dissidents in the Soviet Union during the 1960's and 1970's. (Breggin, 2008, p. 39). It also accounts for their impact on acute psychosis (Cohen, 1997, p. 213)
2. Indifference, apathy	
3. Loss of voluntary movement (akinesia)	
4. Reduced spontaneity and affect	
5. Stupefaction	
6. Reduced ability to monitor one's state	
7. Cognitive and motor impairments	
8. Confusion and memory problems	
9. Depression, mood swings,	
10. Inner stress, rocking, pacing & agitation ("akathisia")	Effects 10-13 are called "extrapyramidal symptoms." Because of the possibility of their occurrence, a second drug (an anticholinergic agent, which can have its own negative side effects) is often prescribed as an accompaniment to the antipsychotic. Tardive dystonia can produce bizarre, cramp-like, painful spasms--e.g., facial grimaces or neck distortions.
11. Sudden, bizarre muscle spasms ("dystonia")	
12. Rhythmic, abnormal movements of face, mouth and tongue, sometimes of hands and feet. ("dyskinesia")	
13. Rigid muscles, loss of facial expression, unsteady gait, drooling ("Parkinsonism")	

14. Permanently disfiguring and disabling uncontrollable and repeated movements, of the face or other muscles (tardive dyskinesia)	A dyskinesia that arises after a drug has been used for some times is called a *tardive dyskinesia,* as opposed to an *acute dyskinesia.* These are sometimes permanent and involve a very significant disfiguring of the individual that is often extremely embarrassing to the individual as well as disturbing to others. See examples of this on Youtube at http://www.youtube.com/watch?v=6mXO6khqGKE&feature=related . 12% to 35% of children who receive typical antipsychotics for more than 3 months, acquire tardive dyskinesia. (Cohen, 2008 citing Campbell, Rappaport & Simpson, 1999) Some authors say the highest risk of this is with typicals (1st generation antipsychotics), rather than with atypicals (2d and 3d generation antipsychotics). Others say this is the case only because the amounts of atypical medications used are generally less than the amounts of typicals that were formerly used, and that there are numerous reports of TD with atypicals. (Breggin, 2008, p. 58)
15. Increased compliance	
16. Anxiety	
17. Hostility, aggression	
18. Weight gain	50% of patients on antipsychotics gain 20% of their weight, primarily as fat. Weight gain is linked to "metabolic syndrome" and is a risk factor for diabetes. Zyprexa is notorious for weight gain and its manufacturer, Eli Lilly has paid out 1.2 billion dollars to settle claims relating to its failure to alert users to the problems relating to weight gain, high blood sugar and diabetes.(Cohen 2008, citing Bezchlibnyk-Butler & Jeffries, 2005; Correll & Carlson, 2006, Patel et al. 2005)
19. High blood sugar	
20. Diabetes	
21. Cardiac problems	
22. Liver problems, jaundice	
23. Neuroleptic malignant syndrome	This can occur with any antipsychotic agent, at any dose, at any time. Symptoms: extreme muscular rigidity, high fever & altered consciousness. Chance of occurrence is 1-2% per year of drug usage. Is fatal if not treated.(Cohen, 2008, citing: Bezchlibnyk-Butler & Jeffries, 2005; and Silva et al., 1999)
24. Death	Three atypicals were suspected in nearly 4500 deaths reported to FDA during 1998-2005; Clozaril: 3277 deaths; Risperdal: 1093 deaths; and Zyprexa: 1,005 deaths. (Cohen, 2008 citing Moore, Cohen & Furberg, 2007)
23. Sexual, menstrual and other hormonal disturbances, including infertility, decreased bone density, and breast discharge in males	These and other hormonal dysfunctions are due to the fact that antipsychotics elevate the level of prolactin. (Levitas & Hurley, 2006)

24. Suicidality	The FDA requires a “black box” warning that Seroquel causes suicidality in children and adolescents. Antipsychotics are increasingly being prescribed as mood stabilizers for persons with bipolar disorder. “All studies to date on the treatment of bipolar disorder with mood stabilizers such as Depakote, Zyprexa, and Risperdal show that suicide rate doubles, compared to treatment with placebo.” (Healy & LeNoury, 2007, p. 14)
25. Life-threatening drop in white blood cells (when using Clozaril)	FDA requires that Clozaril have a “black box” warning of the serious risk of agranulocytosis, seizures, myocarditis, and other cardiovascular and respiratory effects.
26. Sudden heart failure	In adults over 30, with no history of previous heart conditions, the risk of sudden heart failure was found to be twice the risk for those who do not take antipsychotics. Risk is 3% for those taking the medication for 10 years, or .003 per year of use. (Carey & Rabin, 2009)
27. Increased mortality in frail elderly (for all atypicals)	FDA requires a “black box” warning of this, also.
28. Reduced life expectancy	This is due, among other causes, to the metabolic effects (see effects 18-20 above) that are associated with heart disease, diabetes, etc.
29. Dysphoria (negative subjective reactions)	Wallace (1994) summarizing topics discussed by thousands of callers to SANELINE (a telephone helpline in the U.K. for people diagnosed or coping with severe mental disorders), writes the following of callers who worry about medication: “Almost all of our callers report sensations of being separated from the outside world by a glass screen, that their senses are numbed, their willpower drained and their lives meaningless. It is these insidious effects that appear to trouble our callers much more than the dramatic physical ones, such as muscular spasms. (pp.34-35). Cohen, (2002).

NOTES

Beginning in the 1950's, certain biochemicals called phenothiazenes--which had previously been used as synthetic dyes and as an insecticide to kill swine parasites, were used to treat psychoses, despite high toxicity and limited effectiveness. These drugs, such as Thorazene, Haldol and Mellaril, which caused apathy, sedation, stupor, among other effects, were at first called "neuroleptics" or “tranquilizers.” Because short-term studies showed a reduction in certain symptoms of psychosis, the drugs were rebranded as "antipsychotics"—probably in large part through the influence of drug company

advertising. In the 1990s newer and much more expensive antipsychotics, such as Risperdal and Zyprexa, were heavily promoted as safer and more effective. The older drugs are now called *typical* (or first generation) antipsychotics and the newer ones are called *atypical* or second- or third-generation antipsychotics. (Cohen, 2008)

Antipsychotics have shown short-term effectiveness in decreasing some symptoms of schizophrenia; however, longer term follow-up studies showed the patients to be worse off than if they had never taken the drugs at all. "..the research record actually is quite consistent. The pivotal NIMH study in the early 1960's found that the drugs had a short-term benefit, but that over the long-term the drug treated patients had higher relapse rates." (Whitaker, 2004)

In 2005, the largest ever schizophrenia treatment study found that atypicals were neither more effective nor better tolerated that the older antipsychotics. Seventy five percent of the patients in this study quit using the drugs due to either inefficacy or intolerable side effects. (Cohen, 2008, citing Lieberman et al, 2005).

There have been few *pediatric* clinical trials of atypicals for any of the FDA-approved indications. As of 2006, only a few studies have reported comparisons between atypicals and placebos with children. Most studies have been only short-term (3-6 weeks) and the results have favored the study funder's drug. (Cohen, 2008, citing McDonagh et al., 20006)

"There are no studies that have shown (atypicals) are safe, or for that matter, that they are effective for children…The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness." Ronald Brown, Chair, 2006 American Psychological Association *Task Force on Psychotropic Drug Use in Children.* (Cohen, 2008, citing 2007 article in the St. Petersburg Times)

Although antipsychotics have been approved by the FDA only for use with schizophrenia, atypicals have been prescribed largely for children who have non-psychotic diagnoses. For example, the diagnoses of Florida Medicaid children who, in 2006, were taking atypical antipsychotics, were as follows: ADHD/Conduct Disorder : 48%; Anxiety, nonpsychiatric diagnosis, or other diagnosis: 27%; Bipolar/Depression: 13%; Schizophrenia/Psychosis: 8%; Autism/Mental Retardation: 4%. (Cohen, 2008, citing 2007 St. Petersburg Times)

Most of the antipsychotics prescribed for children and adolescents have been prescribed for aggression and not for schizophrenia. (Cohen, 2008, citing Patel et al., 2005)

The latest randomized -controlled trial (one that had no drug company sponsorship) found placebo more effective than either a typical (Haldol) or atypical (Risperdal) to reduce aggression in patients with intellectual disability. The authors concluded that "Antipsychotic drugs should no longer be regarded as acceptable routine treatment for aggressive behavior in people with intellectual disability." (Cohen 2008, citing Tyrer et al., 2008).

“With the possible exception of the chemotherapies used in the treatment of cancer, it would be difficult to identify a class of medications as toxic as the antipsychotics. Whether one considers the effects of dopamine antagonists upon the central nervous system or beyond, their proven harmfulness has been an iatrogenic tragedy too often minimized or denied.” (Jackson, 2005, p. 14) [emphasis supplied]

”… prescribing physicians cannot fully inform patients about the risks associated with neuroleptics **because no one except the most self-destructive patient would knowingly take such toxic drugs.** Doctors have to hide the mountain of risks associated with these drugs in order to get their patients to take them. In this sense, informed consent is largely a sham in regard to antipsychotic drug administration.” (Breggin, 2008, p. 112) [emphasis supplied]

“Neuroleptics’ near –sacred reputation as ‘antipsychotics’ is only equaled by their record as one of the most behaviorally toxic classes of psychotropic drugs.” (Cohen, 1997, p. 201) [emphasis supplied]

"These classes of drugs [antipsychotics and anticonvulsants] have dangerous side effects that have led to a doubled mortality rate, shortened lifespan, extreme weight gain and occurrence of type 2 diabetes." (Olfman, 2007) [bracketed material supplied.]

Vioxx was reported, in FDA's after-market adverse incident reporting database, to have caused 937 deaths and was removed from the market. By contrast, three atypicals, which have been suspected of causing nearly 5,377 deaths (Clozaril 3,277, Risperdal 1,093, and Zyprexa 1,007) during the period 1998-2005, are still on the market. (Cohen, 2008, citing Moore, Cohen & Furberg 2007)

"All studies of life expectancy of patients taking antipsychotics show a doubling of mortality rates compared to control groups, and this doubling increases again for every added antipsychotic drug the patient takes. Patients on antipsychotics also have reduced life expectancy. In addition, all studies to date on the treatment of bipolar disorder with mood stabilizers such as Depakote, Zyprexa, and Risperdal show that suicide risk doubles, compared to treatment with placebo." (Healy & LeNoury, 2007, p. 14).

"The anticonvulsants and antipsychotics have simply been rebranded by the pharmaceutical companies as ‘mood stabilizers.’ Both classes of drugs are major tranquilizers and therefore they have a calming effect on agitated or manic patients. But it is important to note that *they do not address an underlying disease process* in the way that an antibiotic does. They treat symptoms not underlying causes." (Olfman, 2007, p. 2).

"…the dopamine blocking capacity of all the newer antipsychotic drugs means that their adverse effects will include the worst effects of the older neuroleptics, including the production of tardive dyskinesia and neuroleptic malignant syndrome…it also helps to account for their primary effect of deactivation. In addition the newer antipsychotic drugs pose even greater risks of causing potentially life-threatening disorders, including marked obesity, elevated cholesterol, and potentially lethal diabetes, cardiovascular disease, and pancreatitis." (Breggin, 2008, p. 25)

"Any difference between the older and the newer antipsychotic dugs in regard to blocking dopamine and causing adverse neurological effects is at best a matter of degree. Seeman (2002), for example, argued that 'the newer, atypical antipsychotics…all bind more loosely" to dopamine than the older neuroleptics. According to this theory, they occupy blockading positions for a briefer period of time, thereby producing fewer adverse effects, such as EPS [extrapyramidal symptoms] Weiden (2007b) noted that ‘in theory' it might be possible to treat patients with the newer atypicals without causing as many EPS effects. But, he concluded, 'In practice, however, EPS remains a significant problem, even in the era of atypical or second generation antipsychotics.’ However, this therapeutic hope assumes that the newer drugs are not being given in larger doses to achieve the same effect as the older drugs, thereby producing the same adverse effects." (Breggin, 2008, p. 53)

"The so-called clinical effect of neuroleptics, their chemical lobotomizing impact, is primarily caused by the blockade of dopaminergic nerves, especially the D_2 receptors, in the ventral striatum…However, blockade of the same D_2 receptors in the dorsal striatum is the probable cause of the extrapyramidal reactions, including TD [tardive dyskinesia]...Hence, as described in chapter 1, the so-called therapeutic effect is inextricably entwined with some of the worst adverse effects." (Breggin, 2008, p. 55) [bracketed material supplied]

"TD often begins with uncontrolled movements of the face, including the eyes (blinking or blepharospasm), tongue, lips, mouth, and cheeks, but it can start with any group of muscles…. The movements displayed are highly variable and include rapid jerking movements (*chorea*) or slower twisting movements (*athetosis*), tics, spasms, and tremors. The person's gait can be badly impaired...Many cases of TD appear to be relatively mild, often limited to movements of the tongue, mouth, jaw, face, or eyelids. Nonetheless, they are frequently disfiguring and often embarrassing. Patients have been known to commit suicide (Yassa et al., 1985)." (Breggin, 2008, p. 56)

"In 1980 the APA [American Psychiatric Association]…task force made it clear that TD is a serious, usually irreversible, largely untreatable, and highly prevalent disease resulting from therapy with neuroleptics." (Breggin, 2008, p. 57)

"…rates for TD among patients treated with antipsychotic drugs are astronomical. Otherwise healthy adults develop TD at the cumulative rate of 3% to 8% per year of exposure to neuroleptics. The elderly (over age 55) develop TD at a cumulative rate that can exceed 20% per year of drug exposure. Children are at high risk as well." (Breggin, 2008, p. 57)

"Atypical neuroleptics cause TD in adults. All the neuroleptics can cause TD, including the atypical neuroleptics such as clozapine (Weller et al., 1993), olanzapine (Herran, 1999), and risperidone (Addington et al., 1995; Buzan, 1996; Kumar et al., 2000); Kwon, 2004). Aripiprazole (Abilify) has been considered one of the safer atypicals, but there are already reports of tardive dyskinesia (Maytal et al., 2006; Oomen et al., 2006). Given that the atypicals, with the exception of clozapine, are all potent D_2 blockers (chapters 2 and 3), it is irrational to anticipate that they will produce a significantly lesser amount of TD when given at equivalent doses to the older neuroleptics." (Breggin, 2008, p. 59).

A key misleading study in 1997 (by Gary Tollefson and Charles Beasley) purported to show that olanzapine had a lower rate of TD than haloperidol over a several-months period. However, the authors (long-time employees of Eli Lilly, the manufacturer of olanzapine, and with a history of defending Lilly's products through purportedly scientific articles) committed the following scientific errors. (1) They failed to annualize the rate of TD on olanzapine. (2) They measured the rate of TD while the patients were still taking olanzapine. Olanzapine masks TD, meaning that one needs to measure its rate only after withdrawing the patients from the drug. (3) They used a relatively low dose of olanzapine compared to the dose they used of haloperidol, "an old trick for making one drug look safer than another...the average physician does not have the time or inclination to analyze a study in the depth with which I have evaluated the Tollefson et al. report. Often physicians will not notice or grasp that the main authors are drug company employees flogging their product under guise of publishing a scientific study." (Breggin, 2008, p. 59-60).

"As of May 2006, two of the more knowledgeable TD experts, Daniel Tarsy and Ross Baldessarini, concluded that the risk of TD with atypicals had not been clearly established to be less than that with the classic neuroleptics and that patients should be treated with atypicals with the usual caution concerning neuroleptic treatment." (Breggin, 2008, p. 60, referring to a study by Tarsy and Baldessarini, 2006) [citation available in Breggin, 2008]

The 2003 edition of The American Psychiatric Publishing Textbook of Clinical Psychiatry recognizes that atypicals can cause TD. "Tardive or withdrawal dyskinesias, some transient but others irreversible, seen in 8%-51% of antipsychotic-treated children and adolescents, mandate caution regarding casual use of these drugs. Tardive dyskinesia has been documented in children and adolescents after as brief a period as 5 months and may appear even during periods of constant medication dose. Cases of tardive dyskinesia have been reported in youths treated with risperidone, indicating that atypical antipsychotics may also cause this serious adverse reaction. (p. 1422)" Breggin, 2008, p. 60.

2007 study at Maryland Psychiatric Research Center showed that 11% of 118 children who had been taking neuroleptics (mostly atypicals) for at least six months, developed TD, compared with 0% of the matched control group. Only 19% of these children had [previously] ever displayed psychotic symptoms. (Breggin, 2008, p. 60) [bracketed material supplied]

"The symptoms of TD are paradoxically masked or suppressed by the drugs that cause them so that the disease symptoms do not fully appear until the patient has been removed from the treatment. For this reason, in addition to using the smallest possible dose for the shortest possible time, whenever possible, patients should periodically be removed from their neuroleptics, if only for a short period, to determine if they are developing TD." (Breggin, 2008, p. 61)

"In the vast majority of cases, TD is irreversible, and there is no effective treatment." (Breggin, 2008, p. 66)

"Atypicals like Risperdal and Zyprexa commonly cause TD in children." (Breggin, 2008, p. 66)

"Worst medically induced catastrophe in history." It is difficult to determine the total number of TD cases. Van Putten (as cited in Lund, 1989) estimated 400,000-1,000,000 in the United States. My own estimate is higher, ranging in the several millions. (Breggin, 1983b). It is no exaggeration to call TD a widespread epidemic and possible the worst medically induced catastrophe in history." (Breggin, 2008, p. 67-8)

"While classic addiction to these substances has not been demonstrated, the antipsychotic drugs can cause severe withdrawal symptoms, making it impossible for patients to stop taking them…individuals often find neuroleptics unpleasant, painful or debilitating, but cannot endure the withdrawal process." (Breggin 2008, p. 73-4)

Chapter 5. Anticonvulsive Drugs

(Anti-convulsives are FDA-approved for treating seizure disorders but not for psychiatric use.)

FDA-APPROVED INDICATIONS FOR PSYCHIATRIC USE[1]

Brand Name	Generic Name	Psychiatric Indication	Age Group
Tegretol, Equetro	carbamazepine	**NO PSYCHIATRIC INDICATIONS**	Any
Gabitril	iagabine		12+
Depakote, Depakene	divalproex sodium, valproate		10+
Topamax	topiramate		
Neurontin	gabapentin		
Lamictal	lamotrigine		3+
Trileptal	oxcarbazepine		2+

FDA BLACK BOX WARNINGS[1,2]

Depakote	**Liver toxicity (particularly for under 2); birth defects; pancreatitis;**
Tegretol	**Aplastic anemia and agranulcytosis (severe reduction of while blood cells which can be life-threatening)**
Lamictal	**Serious rash requiring hospitalization; Stevens-Johnson syndrome for under 16 years of age (fatal sores on mucous membranes of mouth, nose, eyes and genitals).**
All anticonvulsants	**Suicidal ideations and behavior**

[1] Table from Cohen, 2008

[2] Next to removing a drug from market, requiring a black box warning is the most severe restriction the FDA can apply.

EFFECTS

Effects	Comments
Reasons why Physicians Prescribe this Drug "Off Label" (i.e., for reasons other than to reduce seizures)[1]	
To reduce aggression and impulsivity[1]	Use as "mood stabilizer" started in the 1980s-1990s due to dissatisfaction with lithium and antipsychotics, and spread rapidly with the promotion of the expression "mood stabilizer" and of the diagnosis of Bipolar Diagnosis in children. (Cohen, 2008, citing Healy, 2006)
To calm restlessness and excitability[1]	
To serve as "mood stabilizer" in the treatment of Bipolar Disorder	
Undesirable Behavioral Effects[1]	
Depression, sedation	
Hostility, irritability	
Anxiety, nervousness	
Hyperactivity	,
Abnormal thinking	
Confusion, amnesia	
Slurred speech	
Sedation, sleepiness	
Suicide risk	"All studies to date on the treatment of bipolar disorder with mood stabilizers such as Depakote, Zyprexa, and Risperdal show that suicide rate doubles, compared to treatment with placebo." (Healy and LeNoury, 2007, p. 14)
[1] Cohen (2008), citing Bezchlibnyk-Butler and Jeffries (2005).	
Undesirable Physical Effects[1,2]	
Nausea and dizziness	
Vomiting and abdominal pain	
Headaches and tremors	
Fatal skin rashes	
Hypothyroid	
Blood disorders	
Pancreatitis, liver disease	
Birth defects	"Valproate and other anticonvulsant mood stabilizers are among the most teratogenic (damaging to fetal development) in medicine." (Healy and LeNoury, 2007, p. 14)
Menstrual irregularities	
Withdrawal seizures	

[1] Cohen (2008), citing Bezchlibnyk-Butler and Jeffries (2005).
[2] Cohen (2008) citing Gonzalez-Heydrich et al., (2003)

The diagnosis of Bipolar Disorder in the young has increased by a factor of 40 in less than a decade (1994-2003). During 2002 and 2003 more than 1.5 million visits of young persons to physicians were associated with a diagnosis of Bipolar Disorder. (Cohen, 2008, citing Moreno et al., 2007)

Bipolar diagnosis is typically treated with polypharmacy and not with psychotherapy. More than 90% of children diagnosed with Bipolar Disorder received more than 1 psychoactive drug. Less than 40% received psychotherapy. (Cohen, 2008, citing Moreno et al., 2007)

No studies confirm the efficacy and safety of anticonvulsants to treat Bipolar Disorder in children and adolescents. "Despite the frequent use of antiepileptic drugs in the treatment of juvenile bipolar disorder, migraine, and neuropathic pain, the data are insufficient to make recommendations regarding the efficacy of antiepleptics in these conditions in children and adolescents." (Cohen, 2008, citing: Golden et al., 2000; Kowatch et al., 2000, 2005; National Institute of Mental Health, 2000; Ryan, Bhatara & Perel,1999.)

Most trials involving anticonvulsives are open [lacking proper controls], small, and show limited response in youth. Half of all participants in an open trial of lithium, divalproex, or carbamazepine did not respond to treatment. 58% received at least one mood stabilizer *plus* a stimulant, an atypical antipsychotic, or an antidepressant. (Cohen, 2008 citing Lopez-Larsen & Frasier, 2006).[bracketed material supplied]

2008: FDA warns that anticonvulsants *double* risk of suicidal ideation or behavior. Risk is highest in the treatment of epilepsy--which rules out psychiatric status as a confounding variable (Cohen, 2008).

Birth defects concern. Anticonvulsants cross the placenta and increase the risk of fetal malformations and cognitive impairments in children exposed in utero. The highest rates are for valproate and carbamazapine. (Cohen, 2008, citing Adab et al., 2006.)

False confirmation of juvenile bipolar diagnosis by sedative effect of drug. "It is all but impossible for a short-term trial of sedative drugs *not* to significantly lower activity levels in children, resulting in statistically significant rating-scale changes and thereby [falsely] confirming the apparent reality of juvenile bipolar disorder." (Healy & LeNoury, 2007). [bracketed material supplied]

American Academy of Child and Adolescent Psychiatry states that "the diagnostic validity of bipolar disorder [and subsequent pharmacological treatment, often with anticonvulsants] in young children has yet to be established. Caution must be taken before applying the diagnosis in preschool children." (Cohen, 2008) [bracketed material supplied]

"The anticonvulsants and antipsychotics have simply been rebranded by the pharmaceutical companies as 'mood stabilizers.' Both classes of drugs are major tranquilizers and therefore they have a calming effect on agitated or manic patients. But it is important to note that *they do not address an underlying disease process* in the way that an antibiotic does. They treat symptoms not underlying causes." (Olfman, 2007).

"These classes of drugs [antpsychotics and anticonvulsants] have dangerous side effects that have led to a doubled mortality rate, shortened lifespan, extreme weight gain and occurrence of type 2 diabetes." (Olfman, 2007) [bracketed material supplied.]

Chapter 6. Antidepressant Drugs

FDA APPROVED INDICATIONS[1]

Brand Name	Generic Name	Psychiatric Indication	Age Group
Sinequan	doxepin	**OCD**	12+
Anafranil	clomipramine		10+
Luvox	fluvoxamine		8+
Zoloft	sertraline		6+
Tofranil	imipramine		
Prozac	fluoxetine	**Depression, OCD**	7+

[1] Table from Cohen, 2008.

FDA BLACK BOX WARNINGS*

All antidepressants	**"Antidepressants increase the risk of suicidal thinking and behavior in children, adolescents and young adults (18-24 years of age) with Major Depressive Disorder (MDD) and other psychiatric disorders."**

* Next to removing a drug from the market, requiring a black box warning is the most severe restriction that the FDA can apply.

EFFECTS[1]

Short Term Desirable Effects at Usual Doses[1]

Increased physical activity	
Elevated mood	
Decreased expressions of distress such as crying, hopelessness	
Improved sleep and appetite	

[1]. Cohen, 2008, citing Bezchlibnyk-Butler & Jeffries, 2005

Undesirable Behavioral Effects[1]

Anxiety, nervousness	The FDA warns of increased agitation, irritability, aggression, worsening anxiety, severe restlessness, and other unusual behaviors in youth treated with antidepressants. (Cohen, 2008, citing Breggin 2006)
Agitation, irritability	
Aggressiveness	
Mood swings, mania	
Thoughts of suicide	Antidepressants double the risk of suicidality (see Note 1 below for more details).
Attempted or actual suicide	
Gastrointesinal distress (nausea, vomiting, stomach pain, constipation, diarrhea)	

Sexual problems (loss of libido, anorgasmia, erectile dysfunction)	
Sleep disruption (insomnia, hypersomnia)	
Urinary retention	
Blurred vision	
Weight gain	
Headaches, dizziness	
Homicide & other extremely out-of-character actions	Peter Breggin has written a book of case histories of persons who have done such things after taking Prozac (Breggin, 2008b).

[1]. Cohen, 2008, citing Antonuccio et al., 1999, Preda et al, 2001 and Healy, 2003

Withdrawal Effects Likely on Abrupt Discontinuation[1]

Neurosensory (vertigo, tingling & burning)	
Neuromotor (tremor, spasms, visual changes)	
Gastrointestinal (nausea, vomiting, diarrhea, weight loss)	
Neuropsychiatric (anxiety, depression, crying, spells, irritability, suicidal thinking)	
Vasomotor (heavy sweating, flushing)	
Other (insomnia, vivid dreaming, fatigue)	

[1] Cohen, 2008, citing Antonuccio et al., 1999, Preda et al, 2001 and Healy, 2003

NOTES

In Prozac's first two years on the market, the FDA's Medwatch program received more adverse-event reports about this new "wonder drug" than it had for the leading tricyclic antidepressant of the previous twenty years.

Antidepressants are the most prescribed drugs in the United States. The most common newer ones used are the SSRIs (Selective Serotonin Reuptake Inhibitors), such as Prozac, Paxil and Lexapro.

There are very serious questions about whether antidepressants are effective. Meta-analyses of drug vs. placebo studies show 75-82% of the response was duplicated by placebo. 57% of the studies on antidepressants submitted to the FDA failed to show a difference between drug and placebo. (Cohen, 2008, citing Moncrieff et al., 2004, Kirsch et al., 2002, and Sapirstein, 1998)

Evidence of effectiveness of the newer antidepressants (SSRIs) with adults is not impressive. "[I]n 189 trials of 53,048 adult subjects with psychiatric disorders…Approximately 50% of subjects who received active drug and 40% of subjects who received"placebo were designated as responders." (Cohen, 2008, citing Stone & Jones, 2006). “The entire scientific case for antidepressants rests on this 10% difference--which may result from biases in the conduct of clinical trials.”(Cohen, 2008)

Evidence of effectiveness of the newer antidepressants (SSRIs) with children is also lacking. Only 3 of 15 published and unpublished randomized control trials show SSRIs more effective than placebo in depressed children. And none of the studies found drugs better on client- or parent-rated measures. (Cohen, 2008, citing Laughren, 2004)

There is no evidence of effectiveness of the older antidepressants (tryicyclics or MAO inhibitors).. (Cohen, 2008, citing Somers-Flanagan & Somers-Flanagan, 1996)

Antidepressants double the risk of suicidality. In 2005, the FDA issued a "black box" warning of Suicidality in Children and Adolescents. (The black box warning is the most serious action the FDA can take against a manufacturer, short of removing a drug from the marketplace.) Among the quotes from the FDA black box warning: "Antidepressants increase the risk of suicidal thinking and behavior (suicidality)." In 22 random controlled trials testing 9 antidepressants: there was a 2.3% rate of serious suicidal events among drug-treated children vs. 1.2% among placebo treated, with no completed suicides. (Cohen, 2008)

"Several years ago, psychiatrist David Healy, an international expert on mood disorders, discovered that the pharmaceutical industry was suppressing research demonstrating that SSRI antidepressants place children and adolescents at greater risk for suicidal and violent behavior. As a consequence of Healy's advocacy, SSRI antidepressants are now banned in the United Kingdom. (An exception to the ban is Prozac, which can still be prescribed, but only after other interventions, such as psychotherapy, have been tried.)." Olfman, 2007, p.6..

"Activation syndrome" is a more common risk than that of suicidality. In addition to its black box warning, the FDA also warns against agitation, irritability, aggression, worsening anxiety, severe restlessness, and other unusual behaviors in youth treated with antidepressants. (Cohen, 2008, citing Breggin, 2006).

Concern over "Prescription cascade." Continued exposure to antidepressants, such as to the SSRIs, can lead to effects misinterpreted as psychiatric symptoms (such as mania), leading to increases in dosage or additional drugs -- when reducing or stopping the drug would relieve the patient's discomfort(Cohen, 2008, citing Breggin, 2006).

Chapter 7. Stimulant Drugs

FDA APPROVED PSYCHIATRIC INDICATIONS[1]

Brand Name	Generic Name	Indication	Age Group
Adderall, Adderall XR, Dexedrine, Dextrostat	amphetamine, dextroamphetamine	ADHD, narcolepsy	3+
Concerta, Ritalin, Daytrana, Metadate, Focalin, Focalin XR	methylphenidate, dexamethylphenidate	ADHD	6+
Vyanse	lisdextroamphetamine		
Stattera (not considered a stimulant)	atomoxetine		

[1] Table taken from Cohen, 2008

FDA BLACK BOX WARNINGS FOR STIMULANTS*

Adderall, Adderall XR Dexedrine, Dextrostat	DRUG DEPENDENCE "…high potential for abuse. Administration for prolonged periods of time may lead to drug dependence…"
Concerta, Ritalin, Daytrana, Metadate, Focalin, Focalin XR	DRUG DEPENDENCE "…Frank psychotic episodes can occur, especially with parenteral [administration by means other than ingestion] abuse. Careful supervision is required during withdrawal …" [bracketed material supplied]
Strattera (not considered a stimulant)	SUICIDAL IDEATION IN CHILDREN AND ADULTS

* Next to removing a drug from the market, requiring a black box warning is the most severe restriction that the FDA can apply.

DRUG EFFECTS

Effects	Notes
Arousal Effects	
1. Increased alertness	Intensified alertness (#1), increased energy (#2) and intensified focus (#3) explain why amphetamines have been used by pilots and other military personnel to keep themselves alert and focused. These three effects, plus increased repetitive and persistent behavior (#4), increased compliance (#5), social withdrawal (#14), and constriction of affect (#16) may be viewed as therapeutic for a child in school who is fidgety, inattentive, noncompliant, and/or socially disruptive.(Cohen 2008)
2. Increased energy	
3. Intensified focus	
4. Increased repetitive, persistent behavior[2]	
5. Increased compliance[2]	
6. Obsessive-compulsive behaviors	
7. Agitation, nervousness, anxiety, restlessness[1]	

8. Insomnia	
9. Irritability, aggression, hostility[1]	
10. Hypomania, mania and psychosis	If mania occurs, this can lead to a bipolar diagnosis and the prescription of an anti-psychotic, in addition to the stimulant (see below) (Whitaker, 2007)
11. Euphoria (sense of well being)[1]	Ritalin, like cocaine, causes dopamine to increase, although not as quickly. The increase of dopamine is experienced as a "high." Stimulants for children are classified as Drug Enforcement Administration (DEA) "Schedule II Drugs," indicating a high risk of tolerance and dependence.(Cohen, 2008, citing Bezchlibnyk-Butler & Jeffries 2005)

Dysphoric Effects[1]

12. Somnolence	
13. Fatigue, lethargy	
14. Social withdrawal and Isolation	
15. Less exploration, spontaneity & curiosity	
16. Constriction of affect	
17. Apathy	
18. Depression	
19. "Zombie" look	
20. Emotional lability	
21. Psychological dependence[1]	

Other Physical Effects[1]

22. Increased blood pressure[1]	
23. Dizzyness, headaches[1]	
24. Palpitations[1]	
25. Stomach cramps, nausea[1]	
26. Appetite/weight loss[1]	
27. Stunted growth[1]	Average student loses 1/4 inch and 6 pounds. No rebound even 3 yrs after stopping treatment (Cohen, 2008)
28. Cardiac arrest[1]	

[1] Cohen, 2008, citing Bezchliblyk-Butler & Jeffries, 2005

OTHER FACTS

Stimulants produce their short-term effects quickly—within one hour in 60-70% of children who take them. (Cohen, 2008)
Long-term evidence of benefits is doubtful. An American Psychiatric Association report noted lack of data supporting long term efficacy or safety. The report stated that stimulants show minimal efficacy in general life domains of the child, including social and academic success. (Cohen 2008, citing APA Working Group on Psychoactive Medication for Children and Adolescents, 2006 and MTA Cooperative Group, 2004)

2006 FDA warning on stimulants cited: (a) Increased risk of sudden death in patients with heart problems; and (b) increased aggression, mania and/or psychotic symptoms (including hallucinations)
Definite risk of tolerance and dependence. Stimulants prescribed to children are Drug Enforcement Administration (DEA) "Schedule II Drugs," indicating a high risk of tolerance and dependence. (Cohen, 2008)
Diagnosis of ADHD is gateway to diagnosis of bipolar illness and a lifetime of medication: a. Child who is overactive, or shows other behavior problems, is diagnosed as ADHD and prescribed a stimulant such as Ritalin; (b) Ritalin may cause child to have manic episodes, with result that child is now diagnosed with juvenile bipolar disorder; (c) psychiatrist prescribes an antipsychotic as well as a "mood stabilizer" (anticonvulsive drug), possibly as additions to the Ritalin.[5] "One study of bipolar children found that over half were taking at least three psychotropic medications. And once a child is on a drug cocktail that contains an antipsychotic, he is well on his way to a muted and shorted life as a psychiatric patient." (Whitaker, 2007, p. 61)
"Methylphenidate [Ritalin] is a stimulant that blocks the reuptake of dopamine from the synaptic cleft and thus is said to boost dopamine levels in the brain...Cocaine also blocks the reuptake of dopamine from the synaptic cleft, and researchers have reported that methylphenidate's [Ritalin's] potency is equivalent to that of cocaine. The principal difference between the two drugs is that cocaine, when snorted, boosts dopamine levels much more quickly than a methylphenidate tablet does, and cocaine clears from the brain more quickly as well. This quick rush of dopamine is what provides cocaine users with a high, and its quick clearance is what makes the drug addictive." (Whitaker, 2007,p. 57)
"All studies to date on the treatment of bipolar disorder with mood stabilizers such as Depakote, Zyprexa, and Risperdal show that suicide rate doubles, compared to treatment with placebo." (Healey and LeNoury, 2007, p. 14).
Emergency room visits. During 2004, 2,500 children visited emergency rooms after taking stimulants for ADHD, most due to accidental overdoses. One in four children had heart or blood pressure symptoms including palpitations, chest pain or fainting. (Cohen, 2007, citing Walters, 2007)

Chapter 8. Sources of Information and Recommended Readings, Web Sites and DVDs

I began my education in psychotropic drugs by reading articles and a book by Robert Whitaker a science writer who writes with enviable clarity and who has won numerous prizes for his writing, including being a finalist for the Pulitzer prize in the public service area. I highly recommend his writing as a starting point for the reader who wishes to understand more about the points made in the present document. I recommend reading the following items in the order shown:

a. The interview (Whitaker, 2005b) he did which appears in *Street Spirit* magazine, August 28, 2005..

b. The "Whitaker clickable affidavit" (Whitaker, 2007), which is an affidavit he signed in September 2007 in a lawsuit against forced drugging. This affidavit presents his arguments in crystal clear form and has active links to the professional papers that support his points. (Whitaker, 2007)

c. His 2002 book, *Mad in America* (Whitaker, 2002). The chapters of this book are summarized on his web site, www.madinamerica.org , which contains links to the original papers that support the points he makes in *Mad in America*.

d. His 2004 paper, The case against antipsychotic drugs: a 50 year record of doing more harm than good (Whitaker, 2004).

e. His 2005 paper, Anatomy of an epidemic: psychiatric drugs and the astonishing rise of mental illness in America (Whitaker, 2005a).

An indispensable source of information about psychotropic drugs is the writings of Dr. Peter Breggin, a psychiatrist. His 2008 book, *Brain Disabling Treatments in Psychiatry,2d edition* (Breggin, 2008a), contains a wealth of information about the entire field. His 2008 book, *Medication Madness* (2008b), which he co-authored with David Cohen, contains fascinating case histories that illustrate his major points. *Your Drug May be Your Problem* (Breggin & Cohen, 1999) contains practical guidance on how and why to stop taking medications. Dr. Breggin has a website at www.breggin.com which includes interesting film clips of his appearances on national TV programs.

Elliot S. Valenstein's *Blaming the Brain* (Valenstein, 1988) lays to rest the notion that psychotropic drugs correct for chemical imbalances in the brain.

Grace Jackson, a psychiatrist, has contributed the 2005 book *Rethinking Psychiatric Drugs: A Guide for Informed Consent* (Jackson, 2005). She gives a great deal of scientific facts to support her statements. Grace has also written an affidavit (Jackson, 2008) in support of a case against forced drugging. This affidavit provides clear scientific support for the fact that psychotropic drugs produce highly toxic and deadly effects on the brain.

Two other excellent books containing separately authored chapters, both of which were brought to my attention by Robert Whitaker, are *From Placebo to Panacea* (Fisher & Greenberg, 1997) and *Bipolar Children* (Olfman, 2007a).

Dr. David Healy is another psychiatrist who has written authoritatively in this field. His book *Let Them Eat Prozac: the Unhealthy Relationship between the Pharmaceutical Industry and Depression* (Healy, 2004) is fascinating reading.

Dr. Joseph Glenmullen is a practicing psychiatrist in Cambridge, Mass. His book, *Prozac Backlash*: *Overcoming the Dangers of Prozac, Zoloft, Paxil and Other Antidepressants with Safe, Effective Alternatives* (Glenmullen, 2000), presents the issues from the interesting perspective of a practicing psychiatrist.

One of the most important sources of my information is an online training course called "CriticalThinkRx" (Cohen, 2008) written by Dr. David Cohen, Professor of Social Work at Florida International University. See www.criticalthinkRx.org. This free course was made possible by the State Attorneys General Consumer and Prescriber Education Grant Program On May 13, 2004, Warner-Lambert, a division of Pfizer, Inc., entered into an Assurance of Voluntary Compliance/Discontinuance with the Attorneys General of 50 States and the District of Columbia to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin® that violated state consumer protection laws. Among other things, the settlement provides for a $21 million Consumer and Prescriber Education Grant Program and it was this grant program that funded Dr. Cohen's online course. The Grant Program is administered by a Special Committee of State Attorneys General pursuant to an Oregon Court Order. This course is the source of much of the information in Chapters 3-6 and Appendix C.

Dr. Cohen advises me that he is working on a book version of this online course. When it is completed, it is likely to be a valuable accompaniment to the present document. Dr. Cohen has co-authored with J. Moncrieff an important paper on the non-specificity of psychotropic drugs entitled "Rethinking models of psychotropic drug action" (Moncrieff & Cohen, 2005). And his paper "Research on the drug treatment of schizophrenia: a critical appraisal and implications for social work education" (Cohen, 2002) presents, in a very clear and easy to read way, the principal problems that occur when drug companies do their own testing of their own drugs.

Fred Baughman Jr., M.D., a pediatric neurologist has written an important book about ADHD called *The ADHD Fraud: How Psychiatry Makes "Patients" of Normal Children* (Baughman, 2006). For a paper presenting Dr. Bauman's basic points, see his paper "The case against diagnosis and treatment of ADHD and related disorders and their treatment with stimulants" (Baughman, 2001).

Stephen Wong's paper, "Behavior Analysis of Psychotic Disorder: Scientific Dead End or Casualty of the Mental Health Political Economy" (Wong, 2006) points out the financial power of the drug companies has stunted the growth of behavioral approach to treatment of psychosis.

An invaluable web site that contains numerous links to original papers as well as newspaper and magazine articles and other documents is http://psychrights.org/index.htm. This site is sponsored by Law Project for Psychiatric Rights, headed by attorney James Gottstein. Attorney Gottstein is currently suing the State of Alaska for its forced drugging of children in foster homes. I suspect that the "clickable Whitaker Affidavit" and the Grace Jackson affidavit are affidavits taken in connection with this lawsuit, but I have not verified this yet.

Appendix A: Citations

Baughman, F. A. & Hovey, C. (2006). *ADHD Fraud: How Psychiatry Makes Patients of Normal Children.* Oxford, UK: Trafford Publishing.

Baughman, F. A. (2001). The case against diagnosis and treatment of ADHD and related disorders and their treatment with stimulants. http://www.adhdfraud.org/commentary/102604-h.htm. Retrieved February 18, 2009.

Breggin, P. R. (2008a). *Brain Disabling Effects of Psychiatric Drugs.* New York: Springer Publishing Company.

Breggin, P. R. (2008b). *Medication Madness: A Psychiatrist Exposes the Danger of Mood-Altering Drugs*. New York: St. Martin's Press.

Breggin, P. R. & Cohen, D. (1999). *Your Drug May Be Your Problem: How and Why to Stop Taking Psychiatric Medications.* Cambridge, MA: Da Capo Press.

Carey , B. & Rabin, C. (2009, February 19). Study finds Drug Risk with Newer Antipsychotics. *New York Times.* Retrieved February 10, 2009, from http://www.nytimes.com/2009/01/15/health/research/15psych.html.

Cohen, D., (1997). A critique of the use of neuroleptic drugs in psychiatry. In S. Fisher & R. P. Greenberg, (Eds.), *From placebo to panacea: Putting psychiatric drugs to the test.* New York: John Wiley & Sons.

Cohen, D. (2002). Research on the drug treatment of schizophrenia: a critical appraisal and implications for social work education. *Journal of Social Work Education,* 3, 217-239.

Cohen, D. (2008). *CriticalThinkRx.* http://www.criticalthinkrx.org. Retrieved January 6, 2009.

Fisher, S. & Greenberg, R. P. (Eds.) (1997). *From Placebo to Panacea.* New York: Wiley.

Flora, S. R. (2007). *Taking America Off Drugs: Why Behavioral Therapy is More Effective for Treating ADHD, OCD, Depression and Other Psychological Problems.* Albany, NY: SUNY Press.

Glenmullen, J. (2000). *Prozac Backlash: Overcoming the Dangers of Prozac, Zoloft, Paxil, and Other Antidepressants with Safe, Effective Alternatives.* New York: Simon & Shuster.

Healy, D. (2004). *Let Them Eat Prozac: The Unhealthy Relationship between the Pharmaceutical Industry and Depression.* New York: New York University Press.

Healy, D. & LeNoury, J. (2007). Bipolar Syndrome by Proxy?: The Case of Pediatric Bipolar Disorder. In Olfman, S. (Ed.) *Bipolar Children: Cutting-Edge Controversy, Insights, and Research,* pp.12-27. Westport, CT. Praeger.

Jackson, G.E. (2005). *Rethinking Psychiatric Drugs.* Bloomington, IN, Authorhouse.

Jackson, G.E. (2008). Affidavit in North Carolina court suit, Appendix A. Retrieved December 29, 2008 from http://psychrights.org/States/Alaska/CaseXX/3AN-08-493PS/JacksonOnNLtoxicity.pdf

Levitas, A. S. & Hurley, A. D. (2006). The history behind the use of anti-psychotic medications in persons with intellectual disability: Part II. *Mental Health Aspects of Developmental disabilities, 9,* 93-101.

McHugh, Paul (2005). Striving for Coherence: Psychiatry's Efforts Over Classification. *Journal of the American Medical Association.* 293: 2526-2528.

Moncrieff, J. & Cohen, D. (2005). Rethinking models of psychotropic drug action. *Psychotherapy and Psychosomatics,* 74, 145-153.

O'Meara, K. P. (2006). *Psyched Out: How Psychiatry Sells Mental Illness and Pushes Pills that Kill.* Bloomington, IN: Authorhouse

Olfman, S. (Ed.) (2007a). *Bipolar Children: Cutting-Edge Controversy, Insights, and Research.* Westport, CT. Praeger.

Olfman, S. (2007b). Bipolar Children: Cutting Edge Controversy. In Olfman, S. (Ed.) *Bipolar Children: Cutting-Edge Controversy, Insights, and Research,* pp1-11. Westport, CT. Praeger.

Valenstein, E. S. (1988). *Blaming the Brain: The Truth about Drugs and Mental Health.*. New York: The Free Press.

Whitaker, R. (2002). *Mad in America: Bad Science, Bad Medicine, and the Enduring Mistreatment of the Mentally Ill.* New York: Basic Books.

Whitaker, R. (2004). The case against antipsychotic drugs: a 50-year record of doing more harm than good. *Medical Hypotheses,* 62, (5-13). http://www.madinamerica.com/Mad%20In%20America/Documents_files/50-yearrecord.pdf. Retrieved August 27, 2008.

Whitaker, R. (2005a). Anatomy of an epidemic: Psychiatric drugs and the astonishing rise of mental illness in America. *Ethical Human Psychology and Psychiatry,* 7, 2005, (23-35). http://www.madinamerica.com/Mad%20In%20America/Documents_files/Epidemic.pdf Retrieved August 27, 2008.

Whitaker, R. (2005b). Psychiatric drugs: An assault on the human condition. *Street Spirit,* August, 2005. http://www.thestreetspirit.org/August2005/interview.htm. Retrieved August 27, 2008.

Whitaker, R. (2007a). Affidavit of Robert Whitaker, Suffolk County. http://psychrights.org/litigation/WhitakerAffidavit.pdf. Retrieved August 27, 2008.

Whitaker, R. (2007b). Creating the bipolar child: how our drug-based paradigm of care is fueling an epidemic of disabling mental illness in children. In Olfman, S. (Ed.), *Bipolar Children: Cutting Edge Controversy, Insights and Research*. Westport, CT: Praeger.

Wong, S. E. (2006). Behavior analysis of psychotic disorders: scientific dead end or casualty of the mental health political economy? *Behavior and Social Issues, 15,* 152-177.

Appendix B: The Most Commonly Prescribed Drugs and the Top 20 Adverse Reactions Reported to the FDA, During 2006-8, for Each

After a drug is approved for marketing by the FDA and is being prescribed and used, the FDA, as part of its Medwatch program invites members of the public to submit reports on serious adverse reactions that persons suspect the drug of causing. Although the FDA makes this information available on its web site, the information is not in user-friendly form. To remedy this, we have taken the data submitted for 2007 and 2008 and created a table for each drug that shows the top 20 reported adverse events for which that drug was the primary suspected cause. We did this for the 82 most frequently used psychotropic drugs. These tables are presented in this appendix.

Because the FDA reports the information exactly as submitted, some of the suspected effects reported are not always adverse medical or psychological effects but are, instead, other events that the person making the report felt were associated with the use of the psychotropic drug in some way. Some examples are:

Pharmaceutical product complaint	Accidental exposure
Prescribed overdose	Accidental drug taken by child
Pregnancy	Ill-defined disorder
Treatment noncompliance	Condition aggravated
Unevaluable event	Smoker
Poor quality drug administered	Drug ineffective
Drug level decrease/increase	Drug interaction
Medication residue	Fall
Drug screen positive	Drug exposure during pregnancy
Therapeutic response decreased	Caesarean section
Loss of employment	Drug withdrawal syndrome neonatal
Incorrect dose administered	Drug withdrawal syndrome
Intercepted drug administration error	Pre-existing disease

We have eliminated these other reported events from these tables and have left only the adverse medical or psychological effects on the person.

The data included in these tables is also available in a public database at www.Judgerc.org/AdverseDrugReactions. At that site, when the user selects the name of a psychotropic drug from a drop-down menu, a list of the top 20 adverse events reported for that drug appears. The software also allows the user to click on the name of a medical term to obtain, immediately, a brief definition or explanation. Improvement suggestions are invited.

This document contains, for each drug, information about the side effects that are typical for the *class* of psychotropic medications that that drug belongs to. For the side effects that are specific to *each particular drug*, a good online source is www.emedtv.com. In the search engine provided in the upper right of the home page, enter a phrase such as “Prozac side effects” (using the trade name) or “fluoxetine side effects” (using the generic name). This will bring up a number of links. Then click on the link “Prozac side effects” or “fluoxetine side effects.

Abilify
Adderall
Akineton
Ambien
Anafranil
Artane
Asendin
Ativan
Carbrital
Catapres
Celexa
Clozaril
Cogentin
Compazine
Cylert
Cymbalta
Dalmane
Depakote
Desoxyn
Dexadrine
Doral
Effexor
Elavil
Equetro
Etrafon
Focalin
Gabitril
Geodon
Halcion
Haldol
Inapsine
Invega
Kemadrin
Klonopin
Lamictal
Lexapro
Librium
Lithobid
Loxitane
Lunesta
Luvox
Mellaril
Moban
Navane
Neurontin
Norpramin
Orap
Pamelor
Parnate
Paxil
Phenergan
Prolixin
ProSom
Prozac
Reglan
Remeron
Restoril
Risperdal
Ritalin
Rozerem
Serax
Serentil
Seroquel
Sinequan
Sonata
Stelazine
Strattera
Symbyax
Tegretol
Tenex
Thorazine
Tofranil
Topomax
Tranxene
Trilafon
Trileptal
Valium
Vivactil
Vyvanse
Wellbutrin
Xanax
Zoloft

Abilify	
Reaction	**Total**
TREMOR	110
WEIGHT INCREASED	101
TARDIVE DYSKINESIA	100
INSOMNIA	92
NEUROLEPTIC MALIGNANT SYNDROME	79
COMPLETED SUICIDE	76
DEATH	66
AGITATION	65
DYSKINESIA	64
DYSTONIA	62
PSYCHOTIC DISORDER	62
NAUSEA	58
AKATHISIA	56
SOMNOLENCE	54
DELUSION	52
RESTLESSNESS	52
VOMITING	52
ANXIETY	50
CONVULSION	50
HEADACHE	50

Ambien	
Reaction	**Total**
AMNESIA	980
ROAD TRAFFIC ACCIDENT	535
SLEEP WALKING	442
IMPAIRED DRIVING ABILITY	355
SOMNAMBULISM	343
ABNORMAL BEHAVIOUR	268
HALLUCINATION	194
EATING DISORDER	192
ABNORMAL SLEEP-RELATED EVENT	187
CONFUSIONAL STATE	169
LOSS OF CONSCIOUSNESS	161
SOMNOLENCE	142
SLEEP TALKING	118
WEIGHT INCREASED	118
CONTUSION	106
DIZZINESS	99
DEPRESSION	96
PAIN	91
DISORIENTATION	89
AGGRESSION	87

Adderall	
Reaction	**Total**
AGGRESSION	42
INSOMNIA	33
SUICIDAL IDEATION	32
ABNORMAL BEHAVIOUR	30
DRUG ABUSER	30
PSYCHOTIC DISORDER	30
CONVULSION	28
OVERDOSE	28
HEADACHE	25
WEIGHT DECREASED	25
ANXIETY	23
DEPRESSION	19
CHEST PAIN	18
DIZZINESS	18
FATIGUE	18
INTENTIONAL DRUG MISUSE	17
LOSS OF CONSCIOUSNESS	16
NAUSEA	16
TREMOR	16
ANOREXIA	15

Anafranil	
Reaction	**Total**
INTENTIONAL OVERDOSE	6
METABOLIC ACIDOSIS	6
SINUS TACHYCARDIA	6
ELECTROCARDIOGRAM QRS COMPLEX PROLONGED	5
GRAND MAL CONVULSION	5
NEPHRITIS INTERSTITIAL	5
RENAL FAILURE ACUTE	5
BEZOAR	4
CONSTIPATION	4
HAEMODIALYSIS	4
MULTI-ORGAN FAILURE	4
SEROTONIN SYNDROME	4
ANOREXIA	3
ARTHRALGIA	3
COMA	3
DIARRHOEA	3
DRY SKIN	3
HYPERTONIA	3
ILEUS	3
SKIN WARM	3

Akineton	
Reaction	**Total**
NEUROLEPTIC MALIGNANT SYNDROME	27
DELIRIUM	8
CONFUSIONAL STATE	5
ILEUS PARALYTIC	5
PYREXIA	5
RESTLESSNESS	5
BRADYCARDIA	4
COGNITIVE DISORDER	4
MUSCLE RIGIDITY	4
RENAL FAILURE ACUTE	4
RHABDOMYOLYSIS	4
SOMNOLENCE	4
APALLIC SYNDROME	3
BLOOD CREATINE PHOSPHOKINASE INCREASED	3
CARDIAC ARREST	3
DEPRESSED LEVEL OF CONSCIOUSNESS	3
HALLUCINATION, VISUAL	3
MEMORY IMPAIRMENT	3
OVERDOSE	3
SUICIDE ATTEMPT	3

Artane	
Reaction	**Total**
HALLUCINATION	4
NEUROLEPTIC MALIGNANT SYNDROME	4
DELIRIUM	3
DEPRESSED LEVEL OF CONSCIOUSNESS	3
DRUG DEPENDENCE	3
HALLUCINATION, AUDITORY	3
STEVENS-JOHNSON SYNDROME	3
ABNORMAL BEHAVIOUR	2
AMNESIA	2
COGNITIVE DISORDER	2
CONFUSIONAL STATE	2
DELUSION	2
DIABETIC KETOACIDOSIS	2
DISORIENTATION	2
HALLUCINATION, VISUAL	2
HYPERAMYLASAEMIA	2
HYPERTENSION	2
MEMORY IMPAIRMENT	2
PARKINSON'S DISEASE	2
RENAL FAILURE ACUTE	2

Asendin	
Reaction	**Total**
ACUTE RESPIRATORY DISTRESS SYNDROME	2
DRUG TOXICITY	2
ACCIDENTAL DEATH	1
ALANINE AMINOTRANSFERASE INCREASED	1
ALCOHOL USE	1
ANAEMIA	1
ARTERIOSCLEROSIS CORONARY ARTERY	1
ASPARTATE AMINOTRANSFERASE INCREASED	1
CARDIAC FAILURE CHRONIC	1
INTENTIONAL OVERDOSE	1
INTENTIONAL SELF-INJURY	1
LUNG INFILTRATION	1
LYMPHOCYTOSIS	1
PERICARDIAL EFFUSION	1
PLEURAL EFFUSION	1
PROTEIN TOTAL DECREASED	1
PULMONARY CONGESTION	1
PULMONARY OEDEMA	1
PYREXIA	1
SUICIDE ATTEMPT	1

Ativan	
Reaction	**Total**
SUICIDE ATTEMPT	170
SOMNOLENCE	117
MULTIPLE DRUG OVERDOSE INTENTIONAL	91
TACHYCARDIA	91
INTENTIONAL OVERDOSE	68
FATIGUE	54
HYPOTENSION	49
AGITATION	48
ANXIETY	45
CONFUSIONAL STATE	40
VOMITING	39
COMA	36
LOSS OF CONSCIOUSNESS	34
DEATH	33
DYSPNOEA	33
RESPIRATORY FAILURE	33
OVERDOSE	31
DRUG DEPENDENCE	28
DEPRESSED LEVEL OF CONSCIOUSNESS	27
NAUSEA	27

Carbrital	
Reaction	**Total**
AGGRESSION	1
AGITATION	1
CARDIO-RESPIRATORY ARREST	1
COMPLETED SUICIDE	1
FATIGUE	1
ILEUS	1
LETHARGY	1
LOSS OF CONSCIOUSNESS	1
OXYGEN CONSUMPTION DECREASED	1
PARADOXICAL DRUG REACTION	1
PROCEDURAL COMPLICATION	1

Catapres	
Reaction	**Total**
BLOOD PRESSURE INCREASED	148
APPLICATION SITE PRURITUS	114
APPLICATION SITE ERYTHEMA	105
HYPERTENSION	82
APPLICATION SITE RASH	81
BLOOD PRESSURE INADEQUATELY CONTROLLED	66
DIZZINESS	60
SOMNOLENCE	59
APPLICATION SITE IRRITATION	57
HYPOTENSION	55
HEADACHE	33
APPLICATION SITE VESICLES	28
DYSPNOEA	28
BRADYCARDIA	25
OVERDOSE	25
FATIGUE	24
APPLICATION SITE BURN	21
BLOOD PRESSURE DECREASED	21
LETHARGY	21
RASH	20

Celexa	
Reaction	**Total**
COMPLETED SUICIDE	285
DRUG TOXICITY	181
HYPONATRAEMIA	174
SEROTONIN SYNDROME	168
AGITATION	167
DEPRESSION	161
NAUSEA	154
LOSS OF CONSCIOUSNESS	150
ANXIETY	145
CONVULSION	140
OVERDOSE	139
CONFUSIONAL STATE	131
SOMNOLENCE	131
SUICIDAL IDEATION	128
DIZZINESS	127
SUICIDE ATTEMPT	118
VOMITING	118
TREMOR	111
MALAISE	101
DIARRHOEA	93

Clozaril	
Reaction	**Total**
GRANULOCYTOPENIA	627
LEUKOPENIA	253
WHITE BLOOD CELL COUNT DECREASED	185
PYREXIA	176
NEUTROPHIL COUNT DECREASED	167
DEATH	157
TACHYCARDIA	156
PNEUMONIA	150
WHITE BLOOD CELL COUNT INCREASED	144
AGRANULOCYTOSIS	137
MALAISE	120
PSYCHOTIC DISORDER	120
HAEMOGLOBIN DECREASED	119
NEUTROPENIA	117
CONVULSION	112
DYSPNOEA	112
SOMNOLENCE	111
CONSTIPATION	108
VOMITING	108
SEDATION	88

Cogentin	
Reaction	Total
ADVERSE DRUG REACTION	3
COMPLETED SUICIDE	3
CONVULSION	3
CEREBRAL HYGROMA	2
DEMENTIA	2
DIABETIC HYPEROSMOLAR COMA	2
DYSKINESIA	2
DYSTONIA	2
EPISTAXIS	2
LACERATION	2
MUSCLE CONTRACTIONS INVOLUNTARY	2
TREMOR	2
ANXIETY	1
DEREALISATION	1
DISEASE RECURRENCE	1
FATIGUE	1
INSOMNIA	1
NORMAL NEWBORN	1
PALPITATIONS	1
SCHIZOAFFECTIVE DISORDER	1

Cymbalta	
Reaction	Total
NAUSEA	758
DIZZINESS	614
HEADACHE	450
FEELING ABNORMAL	427
INSOMNIA	399
ALANINE AMINOTRANSFERASE INCREASED	396
FATIGUE	395
DEPRESSION	346
ASPARTATE AMINOTRANSFERASE INCREASED	333
BLOOD PRESSURE INCREASED	305
PARAESTHESIA	303
HEPATIC ENZYME INCREASED	300
HYPERHIDROSIS	295
SOMNOLENCE	292
ANXIETY	272
SUICIDAL IDEATION	270
VOMITING	268
TREMOR	267
PAIN	249
DIARRHOEA	247

Compazine	
Reaction	Total
DYSPNOEA	18
TREMOR	17
ANXIETY	12
FEELING ABNORMAL	10
VOMITING	10
DYSTONIA	9
NAUSEA	9
SUICIDAL IDEATION	8
MUSCLE SPASMS	7
RESTLESSNESS	7
AKATHISIA	6
CONVULSION	6
SWOLLEN TONGUE	6
DEPRESSION	5
DIARRHOEA	5
DIZZINESS	5
HEART RATE INCREASED	5
HYPERHIDROSIS	5
PALPITATIONS	5
SPEECH DISORDER	5

Dalmane	
Reaction	Total
SUICIDE ATTEMPT	23
OVERDOSE	15
SOMNOLENCE	11
ALCOHOL USE	7
INTENTIONAL OVERDOSE	7
COMPLETED SUICIDE	6
MULTIPLE DRUG OVERDOSE	6
DRUG TOXICITY	4
SUICIDAL IDEATION	4
AMNESIA	3
HALLUCINATION	3
HYPOTENSION	3
LOSS OF CONSCIOUSNESS	3
PULMONARY CONGESTION	3
PULMONARY OEDEMA	3
ABNORMAL DREAMS	2
ASPARTATE AMINOTRANSFERASE INCREASED	2
CONFUSIONAL STATE	2
DEPRESSION	2
SELF-MEDICATION	2

Cylert	
Reaction	Total
CONVULSION	1
DEATH	1
DRUG ABUSER	1
DRUG DEPENDENCE	1
JAUNDICE	1
LIVER FUNCTION TEST ABNORMAL	1
PSYCHOMOTOR HYPERACTIVITY	1
SUICIDE ATTEMPT	1

Depakote	
Reaction	Total
CONVULSION	93
WEIGHT INCREASED	88
TREMOR	78
ALOPECIA	67
SOMNOLENCE	65
CONFUSIONAL STATE	62
AMMONIA INCREASED	59
DIARRHOEA	47
THROMBOCYTOPENIA	44
VOMITING	44
DEPRESSION	43
RASH	43
NAUSEA	42
HYPERAMMONAEMIA	41
FATIGUE	40
HEADACHE	40
MANIA	37
PLATELET COUNT DECREASED	36
ABNORMAL BEHAVIOUR	35
HALLUCINATION	34

Desoxyn	
Reaction	**Total**
PULMONARY HYPERTENSION	47
DRUG TOXICITY	12
COMPLETED SUICIDE	11
INTENTIONAL DRUG MISUSE	9
CARDIO-RESPIRATORY ARREST	6
DRUG ABUSER	6
MULTIPLE DRUG OVERDOSE	4
POLYTRAUMATISM	4
TRAUMATIC SHOCK	4
CARDIAC HYPERTROPHY	3
DEATH	3
HYPERTHERMIA	3
INTENTIONAL SELF-INJURY	3
OVERDOSE	3
RHABDOMYOLYSIS	3
CARDIOMYOPATHY	2
DISORIENTATION	2
ISCHAEMIA	2
POISONING	2
TACHYCARDIA	2

Effexor	
Reaction	**Total**
SUICIDAL IDEATION	326
NAUSEA	292
DIZZINESS	288
PARAESTHESIA	229
ANXIETY	228
HEADACHE	225
SUICIDE ATTEMPT	200
DEPRESSION	197
INSOMNIA	191
FEELING ABNORMAL	190
TREMOR	185
INTENTIONAL OVERDOSE	174
CONVULSION	151
HYPERHIDROSIS	146
FATIGUE	145
VOMITING	144
COMPLETED SUICIDE	133
CONFUSIONAL STATE	133
AGITATION	130
AGGRESSION	121

Dexedrine	
Reaction	**Total**
FATIGUE	22
INSOMNIA	22
SOMNOLENCE	15
CARDIO-RESPIRATORY ARREST	14
DEATH	14
PALPITATIONS	14
DISTURBANCE IN ATTENTION	13
CHEST PAIN	12
PULMONARY HYPERTENSION	12
AGGRESSION	11
ANXIETY	11
DIZZINESS	11
PYREXIA	11
CARDIOMEGALY	10
HEADACHE	10
VOMITING	10
CARDIAC FAILURE CONGESTIVE	9
COUGH	9
DYSPNOEA EXERTIONAL	9
TRICUSPID VALVE INCOMPETENCE	9

Elavil	
Reaction	**Total**
OVERDOSE	19
SOMNOLENCE	18
CARDIO-RESPIRATORY ARREST	15
CONFUSIONAL STATE	12
INTENTIONAL OVERDOSE	12
HYPOTENSION	11
SUICIDE ATTEMPT	11
DRUG TOXICITY	10
HALLUCINATION	10
CONVULSION	9
DYSPNOEA	9
LOSS OF CONSCIOUSNESS	9
METABOLIC ACIDOSIS	9
MYDRIASIS	9
VENTRICULAR TACHYCARDIA	9
AGGRESSION	8
CARDIAC ARREST	8
COMA	8
VENTRICULAR FIBRILLATION	8
COMPLETED SUICIDE	7

Doral	
Reaction	**Total**
DEPRESSED LEVEL OF CONSCIOUSNESS	5
DISORIENTATION	3
COMA	2
DELIRIUM	2
MULTIPLE DRUG OVERDOSE INTENTIONAL	2
SOMNOLENCE	2
SUICIDE ATTEMPT	2
BLOOD ALKALINE PHOSPHATASE INCREASED	1
BRADYKINESIA	1
HAEMODIALYSIS	1
HALLUCINATION, VISUAL	1
NASOPHARYNGITIS	1
OCULOMUCOCUTANEOUS SYNDROME	1
PLEURAL EFFUSION	1
PORIOMANIA	1
PYREXIA	1
SERUM AMYLOID A PROTEIN INCREASED	1
SPEECH DISORDER	1
SUBDURAL HAEMATOMA	1
THERAPEUTIC AGENT TOXICITY	1

Equetro	
Reaction	**Total**
CONVULSION	102
PYREXIA	89
DRUG RASH W/EOSINOPHILIA & SYSTEMIC SYMPTOMS	79
GRAND MAL CONVULSION	68
DRUG TOXICITY	64
ALANINE AMINOTRANSFERASE INCREASED	63
SOMNOLENCE	59
STATUS EPILEPTICUS	49
OVERDOSE	47
DRUG HYPERSENSITIVITY	46
ASPARTATE AMINOTRANSFERASE INCREASED	45
LYMPHADENOPATHY	44
DIZZINESS	41
GAMMA-GLUTAMYLTRANSFERASE INCREASED	38
PETIT MAL EPILEPSY	38
ELECTROENCEPHALOGRAM ABNORMAL	37
LOSS OF CONSCIOUSNESS	36
EOSINOPHILIA	35
CONFUSIONAL STATE	34
COORDINATION ABNORMAL	34

Etrafon	
Reaction	**Total**
ADVERSE REACTION	1
DYSKINESIA	1
JOINT DISLOCATION	1
MUSCLE SPASMS	1
ROTATOR CUFF SYNDROME	1
TARDIVE DYSKINESIA	1

Geodon	
Reaction	**Total**
TARDIVE DYSKINESIA	92
TREMOR	80
ANXIETY	76
CONVULSION	74
SOMNOLENCE	74
DYSTONIA	64
EXTRAPYRAMIDAL DISORDER	64
INSOMNIA	60
DIZZINESS	55
ELECTROCARDIOGRAM QT PROLONGED	55
DEPRESSION	53
AGITATION	52
MANIA	52
NAUSEA	52
PSYCHOTIC DISORDER	50
NEUROLEPTIC MALIGNANT SYNDROME	49
FEELING ABNORMAL	47
WEIGHT INCREASED	47
SUICIDAL IDEATION	46
WEIGHT DECREASED	46

Focalin	
Reaction	**Total**
CONVULSION	22
HALLUCINATION	19
DEPRESSION	17
HEART RATE INCREASED	13
ABNORMAL BEHAVIOUR	12
AGITATION	11
HEADACHE	11
PSYCHOTIC DISORDER	11
ANXIETY	10
AGGRESSION	9
DIZZINESS	9
CRYING	8
INSOMNIA	8
NAUSEA	8
WEIGHT DECREASED	8
ANOREXIA	7
CHEST PAIN	7
DEPRESSED MOOD	7
HALLUCINATION, AUDITORY	7
VOMITING	6

Halcion	
Reaction	**Total**
SUICIDE ATTEMPT	80
OVERDOSE	40
INTENTIONAL OVERDOSE	34
SOMNOLENCE	31
COMA	29
AMNESIA	19
DEPRESSED LEVEL OF CONSCIOUSNESS	19
INTENTIONAL DRUG MISUSE	17
MULTIPLE DRUG OVERDOSE INTENTIONAL	16
LOSS OF CONSCIOUSNESS	15
BLOOD CREATINE PHOSPHOKINASE INCREASED	13
ABNORMAL BEHAVIOUR	12
DRUG DEPENDENCE	12
MULTIPLE DRUG OVERDOSE	11
RHABDOMYOLYSIS	11
INSOMNIA	10
RESTLESSNESS	10
DEPRESSION	9
ELECTROENCEPHALOGRAM ABNORMAL	9
SUICIDAL IDEATION	9

Gabitril	
Reaction	**Total**
CONVULSION	39
CONFUSIONAL STATE	12
TREMOR	11
GRAND MAL CONVULSION	10
LOSS OF CONSCIOUSNESS	10
STATUS EPILEPTICUS	9
AGITATION	8
DIZZINESS	8
COMPLEX PARTIAL SEIZURES	7
DISORIENTATION	7
PARAESTHESIA	7
MENTAL STATUS CHANGES	6
OVERDOSE	6
AMNESIA	5
CEREBROVASCULAR ACCIDENT	5
HEAD INJURY	5
HEADACHE	5
MUSCLE SPASMS	5
PNEUMONIA	5
SKIN LACERATION	5

Haldol	
Reaction	**Total**
WEIGHT INCREASED	715
EXTRAPYRAMIDAL DISORDER	474
SOMNOLENCE	104
COGNITIVE DISORDER	93
SUICIDE ATTEMPT	70
AKATHISIA	63
NEUROLEPTIC MALIGNANT SYNDROME	62
TREMOR	55
TARDIVE DYSKINESIA	53
AGITATION	44
OVERDOSE	43
DYSTONIA	35
DYSKINESIA	33
TACHYCARDIA	32
PARKINSONISM	30
CONVULSION	29
DYSPNOEA	28
CONFUSIONAL STATE	26
PYREXIA	26
INTENTIONAL OVERDOSE	24

Inapsine	
Reaction	Total
HYPERHIDROSIS	3
TREMOR	3
ATRIAL FIBRILLATION	2
CONVULSION	2
MUSCLE RIGIDITY	2
NAUSEA	2
PROCEDURAL COMPLICATION	2
SEDATION	2
VOMITING	2
DYSKINESIA	1
DYSPNOEA	1
ELECTROCARDIOGRAM ST SGMNT DEPRESSION	1
EPILEPSY	1
FEELING HOT	1
MALAISE	1
NEUROLEPTIC MALIGNANT SYNDROME	1
TACHYCARDIA	1
TORSADE DE POINTES	1
TRISMUS	1
VENTRICULAR TACHYCARDIA	1

Klonopine	
Reaction	Total
COMPLETED SUICIDE	124
CARDIAC ARREST	107
RESPIRATORY ARREST	103
DEATH	92
OVERDOSE	52
CONVULSION	44
ANXIETY	33
CARDIO-RESPIRATORY ARREST	33
DIZZINESS	29
POISONING	28
TREMOR	27
HEADACHE	24
DEPRESSION	22
SOMNOLENCE	22
SUICIDE ATTEMPT	21
AGITATION	20
INSOMNIA	19
AMNESIA	18
CONFUSIONAL STATE	18
DRUG TOXICITY	18

Invega	
Reaction	Total
GALACTORRHOEA	97
EXTRAPYRAMIDAL DISORDER	69
BLOOD PROLACTIN INCREASED	62
WEIGHT INCREASED	61
DYSTONIA	60
TREMOR	52
INSOMNIA	48
SUICIDE ATTEMPT	42
OEDEMA PERIPHERAL	40
AKATHISIA	38
ANXIETY	36
AGGRESSION	35
DYSKINESIA	35
NEUROLEPTIC MALIGNANT SYNDROME	35
CONVULSION	33
RESTLESSNESS	33
SOMNOLENCE	33
TACHYCARDIA	32
DIZZINESS	31
PSYCHOTIC DISORDER	31

Lamictal	
Reaction	Total
RASH	1492
CONVULSION	454
PYREXIA	401
STEVENS-JOHNSON SYNDROME	386
PRURITUS	335
HEADACHE	290
NAUSEA	251
DIZZINESS	236
LYMPHADENOPATHY	202
INSOMNIA	198
FATIGUE	196
VOMITING	189
DEPRESSION	151
ERYTHEMA	150
ANXIETY	147
MOUTH ULCERATION	142
PAIN	141
VISION BLURRED	139
ABORTION SPONTANEOUS	134
SOMNOLENCE	130

Kemadrin	
Reaction	Total
CARDIO-RESPIRATORY ARREST	4
DILATATION VENTRICULAR	4
ASTHENIA	3
CONFUSIONAL STATE	3
VOMITING	3
AMNESIA	2
BLOOD ALCOHOL INCREASED	2
OVERDOSE	2
PULMONARY INFARCTION	2
CARDIOTOXICITY	1
DEATH	1
HAEMOGLOBIN DECREASED	1
HYPONATRAEMIA	1
LUNG DISORDER	1
NEUROTOXICITY	1
POOR PERSONAL HYGIENE	1
RIGHT VENTRICULAR FAILURE	1
SEDATION	1
SUICIDAL IDEATION	1
THERAPEUTIC AGENT TOXICITY	1

Lexapro	
Reaction	Total
COMPLETED SUICIDE	221
CONVULSION	163
DEPRESSION	153
NAUSEA	146
SUICIDAL IDEATION	144
ANXIETY	141
LOSS OF CONSCIOUSNESS	140
DIZZINESS	123
HYPONATRAEMIA	113
TREMOR	105
SUICIDE ATTEMPT	102
INSOMNIA	93
CONFUSIONAL STATE	92
AGITATION	91
HEADACHE	89
FATIGUE	88
ASTHENIA	85
VOMITING	84
SOMNOLENCE	76
DIARRHOEA	72

Librium	
Reaction	Total
CARDIO-RESPIRATORY ARREST	18
DEATH	4
LOSS OF CONSCIOUSNESS	4
CONSTIPATION	3
HYPOTENSION	3
ABDOMINAL PAIN UPPER	2
ALCOHOLISM	2
CARDIAC ARREST	2
COMPLETED SUICIDE	2
DRUG HYPERSENSITIVITY	2
GAIT DISTURBANCE	2
HOMICIDE	2
INTENTIONAL OVERDOSE	2
MENTAL STATUS CHANGES	2
RESPIRATORY RATE INCREASED	2
SOMNOLENCE	2
SUICIDE ATTEMPT	2
TOXIC EPIDERMAL NECROLYSIS	2
VOMITING	2
COAGULATION TIME ABNORMAL	1

Lunesta	
Reaction	Total
DYSGEUSIA	2686
INSOMNIA	2186
MIDDLE INSOMNIA	900
INITIAL INSOMNIA	596
SOMNOLENCE	351
HEADACHE	311
NAUSEA	235
DIZZINESS	201
PARADOXICAL DRUG REACTION	141
NIGHTMARE	104
FATIGUE	95
DRY MOUTH	93
ANXIETY	92
AMNESIA	91
DEPRESSION	87
VOMITING	82
ABNORMAL DREAMS	78
FEELING ABNORMAL	77
HALLUCINATION	73
NERVOUSNESS	66

Lithobid	
Reaction	Total
THERAPEUTIC AGENT TOXICITY	189
TREMOR	113
CONFUSIONAL STATE	84
MANIA	52
HAEMODIALYSIS	50
VOMITING	49
DIARRHOEA	48
SOMNOLENCE	48
NAUSEA	47
RENAL FAILURE	47
BLOOD CREATININE INCREASED	46
DRUG TOXICITY	46
DEHYDRATION	44
NEPHROGENIC DIABETES INSIPIDUS	42
RENAL FAILURE ACUTE	42
DYSARTHRIA	36
HYPERPARATHYROIDISM	36
MENTAL STATUS CHANGES	36
COORDINATION ABNORMAL	35
ASTHENIA	34

Luvox	
Reaction	Total
ALANINE AMINOTRANSFERASE INCREASED	12
IRRITABILITY	12
ASPARTATE AMINOTRANSFERASE INCREASED	11
INSOMNIA	11
ACTIVATION SYNDROME	10
LIVER DISORDER	10
AGITATION	8
ANXIETY	8
DEPRESSION	8
SUICIDAL IDEATION	8
ANOREXIA	7
HEPATIC FUNCTION ABNORMAL	7
SEROTONIN SYNDROME	7
CARDIAC ARREST	6
HOMICIDAL IDEATION	6
SOMNOLENCE	6
TREMOR	6
APATHY	5
BLOOD ALKALINE PHOSPHATASE INCREASED	5
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION	5

Loxitane	
Reaction	Total
DEATH	2
HYPERHIDROSIS	2
MUSCLE RIGIDITY	2
NEUROLEPTIC MALIGNANT SYNDROME	2
DEPRESSED LEVEL OF CONSCIOUSNESS	1
DYSKINESIA	1
EXTRAPYRAMIDAL DISORDER	1
HEAD LAG	1
IRRITABILITY	1
JAW DISORDER	1
PYREXIA	1
RASH	1
SCREAMING	1
SKIN DISCOLOURATION	1
SPEECH DISORDER	1
STUPOR	1
VOMITING	1

Mellaril	
Reaction	Total
TARDIVE DYSKINESIA	4
AGGRESSION	3
BLINDNESS	3
CARDIO-RESPIRATORY ARREST	3
CRYING	3
SOMNOLENCE	3
SUICIDE ATTEMPT	3
WEIGHT DECREASED	3
DEPRESSION	2
INTENTIONAL OVERDOSE	2
NERVOUSNESS	2
NIGHT BLINDNESS	2
SUDDEN DEATH	2
SUICIDAL IDEATION	2
VISION BLURRED	2
DRUG DISPENSING ERROR	1
NAUSEA	1
PARKINSON'S DISEASE	1
RETINOPATHY	1
THROMBOCYTOPENIA	1

Moban	
Reaction	Total
INSOMNIA	1
NEUROLEPTIC MALIGNANT SYNDROME	1
PARANOIA	1
SUICIDAL IDEATION	1
URINARY RETENTION	1

Navane	
Reaction	Total
ANXIETY	1
BLOOD PROLACTIN INCREASED	1
DISTURBANCE IN ATTENTION	1
DRUG DISPENSING ERROR	1
FORMICATION	1
GALACTORRHOEA	1
HALLUCINATION, VISUAL	1
IRRITABILITY	1
MUSCULOSKELETAL STIFFNESS	1
PARANOIA	1
RESTLESSNESS	1

Neurontin	
Reaction	Total
SUICIDE ATTEMPT	592
SUICIDAL IDEATION	390
DEPRESSION	362
COMPLETED SUICIDE	345
PAIN	269
SOMNOLENCE	245
AMNESIA	204
DIZZINESS	199
ANXIETY	184
CONVULSION	179
CONFUSIONAL STATE	166
WEIGHT INCREASED	162
FEELING ABNORMAL	154
INSOMNIA	137
FATIGUE	135
HEADACHE	131
NAUSEA	130
OVERDOSE	128
VISION BLURRED	126
TREMOR	125

Norpramin	
Reaction	Total
AGITATION	4
PANIC ATTACK	4
ANXIETY	3
FLIGHT OF IDEAS	3
HOMICIDAL IDEATION	3
IRRITABILITY	3
MANIA	3
RAPID EYE MOVEMENTS SLEEP ABNORMAL	3
ABNORMAL BEHAVIOUR	2
ANGER	2
DEPRESSION	2
FATIGUE	2
HALLUCINATION, VISUAL	2
NIGHTMARE	2
OVERDOSE	2
SOMNOLENCE	2
TREMOR	2
ABNORMAL SLEEP-RELATED EVENT	1
DEPRESSED MOOD	1
SLEEP DISORDER	1

Orap	
Reaction	Total
HYPOGLYCAEMIA	76
SKIN IRRITATION	64
SUICIDE ATTEMPT	30
BLOOD GLUCOSE INCREASED	28
ANTI-INSULIN ANTIBODY	23
HEPATIC FUNCTION ABNORMAL	22
HYPOGLYCAEMIC COMA	22
BLOOD GLUCOSE FLUCTUATION	21
HYPERGLYCAEMIA	21
DIABETES MELLITUS INADEQUATE CONTROL	17
DYSPNOEA	16
INTENTIONAL OVERDOSE	16
ANTI-INSULIN ANTIBODY INCREASED	15
DIZZINESS	15
LOSS OF CONSCIOUSNESS	15
NAUSEA	14
VOMITING	14
ANTI-INSULIN ANTIBODY POSITIVE	13
BLOOD CREATINE PHOSPHOKINASE INCREASED	12
ALANINE AMINOTRANSFERASE INCREASED	11

Pamelor	
Reaction	Total
COMPLETED SUICIDE	21
HEART RATE INCREASED	7
COMA	5
CONFUSIONAL STATE	5
AGITATION	4
BLOOD PRESSURE INCREASED	4
HYPOTENSION	4
INTENTIONAL DRUG MISUSE	4
PALPITATIONS	4
ASTHENIA	3
BLOOD CREATINE PHOSPHOKINASE INCREASED	3
BRUGADA SYNDROME	3
CARDIO-RESPIRATORY ARREST	3
DRUG ABUSE	3
DRUG TOXICITY	3
DRY MOUTH	3
ELECTROCARDIOGRAM QRS COMPLEX PROLONGED	3
OVERDOSE	3
PUPILLARY REFLEX IMPAIRED	3
SINUS TACHYCARDIA	3

Parnate	
Reaction	Total
ANXIETY	19
HEADACHE	18
SUICIDAL IDEATION	16
INSOMNIA	14
DEPRESSION	13
APATHY	10
HYPOTENSION	10
OVERDOSE	10
DIZZINESS	9
HYPERTENSION	9
MALAISE	7
AGITATION	6
BLOOD PRESSURE INCREASED	6
CHILLS	6
DIARRHOEA	6
HYPERHIDROSIS	6
HYPERTHERMIA	6
SEROTONIN SYNDROME	6
SOMNOLENCE	6
TACHYCARDIA	6

Paxil	
Reaction	Total
CONGENITAL ANOMALY	1765
ANXIETY	1531
SUICIDAL IDEATION	1385
DIZZINESS	1341
NAUSEA	1202
DEPRESSION	983
INSOMNIA	961
ATRIAL SEPTAL DEFECT	946
HEADACHE	937
TREMOR	936
PARAESTHESIA	925
AGITATION	893
HYPERHIDROSIS	826
FATIGUE	815
VENTRICULAR SEPTAL DEFECT	790
AGGRESSION	744
CARDIAC MURMUR	723
HEART DISEASE CONGENITAL	685
IRRITABILITY	654
SUICIDE ATTEMPT	618

ProSom	
Reaction	Total
AGRANULOCYTOSIS	2
DEHYDRATION	2
DRUG TOXICITY	2
CARDIAC FAILURE	1
FEELING ABNORMAL	1
GENERAL PHYSICAL HEALTH DETERIORATION	1
HANGOVER	1
HYPERURICAEMIA	1
INSOMNIA	1
NO THERAPEUTIC RESPONSE	1
PLATELET COUNT DECREASED	1
POOR QUALITY SLEEP	1
SOMNOLENCE	1

Phenergan	
Reaction	Total
PAIN	23
CONVULSION	16
LOSS OF CONSCIOUSNESS	12
VOMITING	12
BURNING SENSATION	11
MENTAL STATUS CHANGES	11
CONFUSIONAL STATE	10
PAIN IN EXTREMITY	10
ANXIETY	9
DYSPNOEA	9
ERYTHEMA	9
HALLUCINATION	9
NAUSEA	9
DYSTONIA	8
INFUSION SITE PAIN	8
MUSCLE SPASMS	8
OEDEMA PERIPHERAL	8
AGITATION	7
PHLEBITIS	7
SPEECH DISORDER	7

Prozac	
Reaction	Total
DEPRESSION	118
COMPLETED SUICIDE	111
SUICIDAL IDEATION	108
CONFUSIONAL STATE	92
AGITATION	83
ANXIETY	78
SEROTONIN SYNDROME	64
INSOMNIA	62
NAUSEA	62
CONVULSION	61
HEADACHE	59
DRUG TOXICITY	57
HYPONATRAEMIA	57
LOSS OF CONSCIOUSNESS	55
VOMITING	55
HYPERHIDROSIS	54
SUICIDE ATTEMPT	54
SOMNOLENCE	51
TREMOR	51
FATIGUE	45

Prolixin	
Reaction	Total
TREMOR	9
BLOOD CREATINE PHOSPHOKINASE INCREASED	6
DYSARTHRIA	6
NEUROLEPTIC MALIGNANT SYNDROME	5
CARDIAC FAILURE	4
CONVULSION	4
INSOMNIA	4
SOMNOLENCE	4
BRADYPNOEA	3
CARDIAC ARREST	3
DYSURIA	3
FATIGUE	3
HYPERHIDROSIS	3
HYPONATRAEMIA	3
HYPOTENSION	3
KETONURIA	3
LETHARGY	3
MUSCLE RIGIDITY	3
PAIN IN EXTREMITY	3
REFUSAL OF TREATMENT BY PATIENT	3

Reglan	
Reaction	Total
TARDIVE DYSKINESIA	63
ANXIETY	41
DEPRESSION	41
TREMOR	38
DYSTONIA	30
EXTRAPYRAMIDAL DISORDER	26
DYSKINESIA	22
INSOMNIA	22
DYSPNOEA	16
AKATHISIA	15
FEELING ABNORMAL	15
NEUROLEPTIC MALIGNANT SYNDROME	15
SUICIDAL IDEATION	15
DYSPHAGIA	14
MUSCLE TWITCHING	14
NAUSEA	14
ASTHENIA	13
BLOOD PRESSURE INCREASED	13
HEART RATE INCREASED	13
NERVOUS SYSTEM DISORDER	13

Remeron	
Reaction	Total
SUICIDE ATTEMPT	7
ANXIETY	6
CONFUSIONAL STATE	6
DEPRESSION	6
DIZZINESS	6
FATIGUE	6
AGITATION	5
HEADACHE	5
INSOMNIA	5
COMA	4
HYPOAESTHESIA	4
INTENTIONAL OVERDOSE	4
LOSS OF CONSCIOUSNESS	4
RESPIRATORY FAILURE	4
WEIGHT INCREASED	4
ASTHENIA	3
ATRIAL FIBRILLATION	3
BACK PAIN	3
ERECTILE DYSFUNCTION	3
WEIGHT DECREASED	3

Ritalin	
Reaction	Total
AGGRESSION	124
DEPRESSION	116
HALLUCINATION	116
HEADACHE	116
AGITATION	95
CONVULSION	95
CHEST PAIN	93
INSOMNIA	93
TACHYCARDIA	91
SUICIDAL IDEATION	90
ABNORMAL BEHAVIOUR	89
ANXIETY	88
PSYCHOTIC DISORDER	82
ANOREXIA	74
SUICIDE ATTEMPT	73
HYPERTENSION	71
VOMITING	68
WEIGHT DECREASED	66
NAUSEA	65
GROWTH RETARDATION	63

Restoril	
Reaction	Total
COMPLETED SUICIDE	23
DEATH	14
DRUG TOXICITY	13
ANXIETY	12
CONFUSIONAL STATE	12
AGITATION	10
POISONING	10
AMNESIA	9
DEPRESSION	9
SOMNOLENCE	8
SUICIDE ATTEMPT	8
AGGRESSION	7
CARDIO-RESPIRATORY ARREST	7
HALLUCINATION	7
INSOMNIA	7
CARDIAC ARREST	6
INTENTIONAL OVERDOSE	6
NIGHTMARE	6
PARANOIA	6
SUICIDAL IDEATION	6

Rozerem	
Reaction	Total
INITIAL INSOMNIA	459
MIDDLE INSOMNIA	377
SOMNOLENCE	234
POOR QUALITY SLEEP	220
INSOMNIA	186
FEELING ABNORMAL	142
FATIGUE	139
DIZZINESS	125
NIGHTMARE	119
ABNORMAL DREAMS	116
HEADACHE	116
NAUSEA	102
ANXIETY	69
HANGOVER	62
FEELING JITTERY	45
AGITATION	41
HALLUCINATION	40
OVERDOSE	39
PALPITATIONS	35
HYPERSOMNIA	32

Risperdal	
Reaction	Total
DIABETES MELLITUS	386
WEIGHT INCREASED	313
DEATH	192
SOMNOLENCE	183
SUICIDE ATTEMPT	173
LEUKOPENIA	138
AGGRESSION	121
TARDIVE DYSKINESIA	121
TREMOR	112
INSOMNIA	108
SUICIDAL IDEATION	108
THROMBOCYTOPENIA	108
EXTRAPYRAMIDAL DISORDER	106
NEUTROPENIA	104
BLOOD PROLACTIN INCREASED	103
PSYCHOTIC DISORDER	103
CONVULSION	99
DEPRESSION	92
ANXIETY	87
PNEUMONIA	87

Serax	
Reaction	Total
CHONDROPATHY	3
CONGENITAL ACROCHORDON	3
DIZZINESS	3
DRUG DEPENDENCE	3
FEMUR FRACTURE	3
INTENTIONAL OVERDOSE	3
SUICIDE ATTEMPT	3
AGITATION	2
ANTINUCLEAR ANTIBODY POSITIVE	2
DERMATITIS BULLOUS	2
DRUG ABUSER	2
EOSINOPHILIA	2
GENERAL PHYSICAL HEALTH DETERIORATION	2
HYPOKINESIA	2
MULTIPLE DRUG OVERDOSE INTENTIONAL	2
PRURIGO	2
BLOOD PRESSURE INCREASED	1
EXTRAPYRAMIDAL DISORDER	1
MIDDLE INSOMNIA	1
SKIN INFLAMMATION	1

Serentil	
Reaction	Total
WEIGHT DECREASED	5
ERECTILE DYSFUNCTION	4
GASTROINTESTINAL DISORDER	4
RENAL DISORDER	4
CHEST PAIN	3
DIABETES MELLITUS	3
HEPATOCELLULAR INJURY	3
LIFE EXPECTANCY SHORTENED	3
MYOCARDIAL INFARCTION	3
REPRODUCTIVE TRACT DISORDER	3
SPERM COUNT ABNORMAL	3
THOUGHT BLOCKING	3
ABDOMINAL PAIN UPPER	2
HEADACHE	2
SLEEP DISORDER	2
ALOPECIA	1
DYSSTASIA	1
HAEMOPTYSIS	1
INCREASED UPPER AIRWAY SECRETION	1
RETCHING	1

Sonata	
Reaction	Total
MIDDLE INSOMNIA	26
SOMNOLENCE	15
SUICIDE ATTEMPT	15
INTENTIONAL OVERDOSE	14
HEADACHE	9
TACHYCARDIA	9
FEELING ABNORMAL	7
HALLUCINATION	7
DIZZINESS	6
INSOMNIA	6
CONFUSIONAL STATE	5
FATIGUE	5
MULTIPLE DRUG OVERDOSE INTENTIONAL	5
DYSARTHRIA	4
HYPERSOMNIA	4
IMPAIRED DRIVING ABILITY	4
NAUSEA	4
NIGHTMARE	4
ROAD TRAFFIC ACCIDENT	4
MEDICAL OBSERVATION ABNORMAL	3

Seroquel	
Reaction	Total
DIABETES MELLITUS	4386
PANCREATITIS	1635
POLYTRAUMATISM	991
DEATH	905
DIABETIC KETOACIDOSIS	798
DIABETIC COMA	546
WEIGHT INCREASED	545
TYPE 2 DIABETES MELLITUS	520
TARDIVE DYSKINESIA	443
HYPERGLYCAEMIA	407
BLOOD CHOLESTEROL INCREASED	378
KETOACIDOSIS	378
SOMNOLENCE	336
CONVULSION	303
OVERDOSE	300
NEUROLEPTIC MALIGNANT SYNDROME	248
DIZZINESS	247
OBESITY	231
SUICIDE ATTEMPT	207
BLOOD TRIGLYCERIDES INCREASED	205

Stelazine	
Reaction	Total
DRUG DISPENSING ERROR	3
AGITATION	2
COMA	2
DRUG DEPENDENCE	2
DRUG WITHDRAWAL HEADACHE	2
DYSKINESIA	2
DYSPNOEA	2
HALLUCINATION	2
INTENTIONAL OVERDOSE	2
MUSCLE SPASMS	2
MYOCARDIAL INFARCTION	2
OEDEMA MUCOSAL	2
ORAL DISCOMFORT	2
TREMOR	2
COMPLETED SUICIDE	1
EXTRAPYRAMIDAL DISORDER	1
HYPERHIDROSIS	1
INNER EAR DISORDER	1
SPEECH DISORDER	1
VOCAL CORD PARALYSIS	1

Sinequan	
Reaction	Total
COMPLETED SUICIDE	31
CARDIAC ARREST	16
RESPIRATORY ARREST	16
CARDIO-RESPIRATORY ARREST	10
SOMNOLENCE	10
DEATH	8
DRY MOUTH	8
DYSPNOEA	8
POISONING	7
DRUG TOXICITY	6
ABDOMINAL PAIN UPPER	5
DISORIENTATION	5
DRUG HYPERSENSITIVITY	5
INTENTIONAL OVERDOSE	5
MULTIPLE DRUG OVERDOSE INTENTIONAL	5
PALPITATIONS	5
AORTIC STENOSIS	4
FACIAL PAIN	4
NAUSEA	4
SUICIDE ATTEMPT	4

Strattera	
Reaction	Total
SUICIDAL IDEATION	161
AGGRESSION	125
SUICIDE ATTEMPT	98
CONVULSION	91
VOMITING	85
NAUSEA	84
ABNORMAL BEHAVIOUR	76
DIZZINESS	76
FATIGUE	75
HEADACHE	74
DEPRESSION	67
ASPARTATE AMINOTRANSFERASE INCREASED	66
LOSS OF CONSCIOUSNESS	66
SYNCOPE	66
ALANINE AMINOTRANSFERASE INCREASED	63
TACHYCARDIA	59
INTENTIONAL SELF-INJURY	53
WEIGHT DECREASED	51
ANXIETY	50
HEART RATE INCREASED	50

Symbyax	
Reaction	Total
DIABETES MELLITUS	2073
WEIGHT INCREASED	999
PANCREATITIS	878
HYPERTENSION	698
HYPERGLYCAEMIA	587
METABOLIC DISORDER	570
DIABETES MELLITUS NON-INSULIN-DEPENDENT	542
DIABETIC KETOACIDOSIS	523
BLOOD TRIGLYCERIDES INCREASED	444
DEATH	394
OBESITY	392
DIABETIC COMA	357
BLOOD CHOLESTEROL INCREASED	330
BLOOD CHOLESTEROL ABNORMAL	307
VISION BLURRED	280
OVERDOSE	263
WEIGHT DECREASED	237
MYOCARDIAL INFARCTION	210
BLOOD GLUCOSE INCREASED	209
RENAL FAILURE	188

Thorazine	
Reaction	Total
LOSS OF CONSCIOUSNESS	10
BLOOD ALKALINE PHOSPHATASE INCREASED	9
ASPARTATE AMINOTRANSFERASE INCREASED	8
ALANINE AMINOTRANSFERASE INCREASED	7
HEART RATE INCREASED	7
LIVER INJURY	7
AMNESIA	6
BLOOD BILIRUBIN INCREASED	6
BLOOD PRESSURE DECREASED	6
PARKINSON'S DISEASE	6
RESPIRATORY RATE INCREASED	6
SOMNOLENCE	6
ACCIDENTAL OVERDOSE	5
CONFUSIONAL STATE	5
METABOLIC ACIDOSIS	5
DIZZINESS	4
HYPOKALAEMIA	4
PRIAPISM	4
RESTLESS LEGS SYNDROME	4
THROMBOCYTOPENIA	4

Tegretol	
Reaction	Total
CONVULSION	244
PYREXIA	209
ASPARTATE AMINOTRANSFERASE INCREASED	131
GAMMA-GLUTAMYLTRANSFERASE INCREASED	127
RASH	127
ALANINE AMINOTRANSFERASE INCREASED	126
DIZZINESS	126
SOMNOLENCE	120
VOMITING	108
MALAISE	106
BLOOD LACTATE DEHYDROGENASE INCREASED	97
HEADACHE	92
BLOOD ALKALINE PHOSPHATASE INCREASED	89
NAUSEA	89
C-REACTIVE PROTEIN INCREASED	80
WHITE BLOOD CELL COUNT INCREASED	78
HAEMOGLOBIN DECREASED	74
PLATELET COUNT DECREASED	71
ASTHENIA	66
LOSS OF CONSCIOUSNESS	65

Tofranil	
Reaction	Total
COMPLETED SUICIDE	25
SUICIDE ATTEMPT	19
DEPRESSION	18
DEPRESSED LEVEL OF CONSCIOUSNESS	16
HEADACHE	16
INSOMNIA	16
TREMOR	16
PYREXIA	15
ASPARTATE AMINOTRANSFERASE INCREASED	14
ALANINE AMINOTRANSFERASE INCREASED	12
BLOOD CREATINE PHOSPHOKINASE INCREASED	12
INTENTIONAL OVERDOSE	12
SOMNOLENCE	12
BLOOD PRESSURE DECREASED	11
HEART RATE INCREASED	11
LIVER DISORDER	11
NEUROLEPTIC MALIGNANT SYNDROME	11
ARRHYTHMIA	10
HYPERHIDROSIS	10
OVERDOSE	10

Tenex	
Reaction	Total
AGGRESSION	2
CONSTIPATION	2
ILEUS	2
ORTHOSTATIC HYPOTENSION	2
VOMITING	2
ABDOMINAL DISTENSION	1
ABDOMINAL PAIN	1
ABDOMINAL TENDERNESS	1
DEHYDRATION	1
DIZZINESS	1
DRUG DISPENSING ERROR	1
DYSGEUSIA	1
GASTROINTESTINAL SOUNDS ABNORMAL	1
ILEUS PARALYTIC	1
IRRITABILITY	1
MANIA	1
RASH	1
RESPIRATORY RATE INCREASED	1
RETCHING	1
THERAPY CESSATION	1

Topomax	
Reaction	Total
CONVULSION	18
ABORTION SPONTANEOUS	13
FAILURE TO THRIVE	10
CONFUSIONAL STATE	9
WEIGHT DECREASED	9
ANGLE CLOSURE GLAUCOMA	8
COMPLETED SUICIDE	8
METABOLIC ACIDOSIS	8
SOMNOLENCE	8
CACHEXIA	6
HEAT STROKE	6
HIP DYSPLASIA	6
LOSS OF CONSCIOUSNESS	6
AMMONIA INCREASED	5
ANOREXIA	5
ASTHENIA	5
DRUG TOXICITY	5
ENCEPHALOPATHY	5
MEMORY IMPAIRMENT	5
VISUAL DISTURBANCE	5

Tranxene	
Reaction	Total
SUICIDE ATTEMPT	3
ABNORMAL BEHAVIOUR	2
COMA	2
DEPRESSION	2
DRUG TOXICITY	2
HYPOTENSION	2
MENTAL DISORDER	2
MULTIPLE DRUG OVERDOSE INTENTIONAL	2
BLOOD ALCOHOL INCREASED	1
DEPRESSED LEVEL OF CONSCIOUSNESS	1
HEADACHE	1
MULTIPLE DRUG OVERDOSE	1
PANCREATITIS ACUTE	1
PNEUMONIA ASPIRATION	1
PNEUMONIA STAPHYLOCOCCAL	1
PRURITUS	1
RASH	1
SOMNOLENCE	1
SPLENIC NECROSIS	1
STOMACH DISCOMFORT	1

Valium	
Reaction	Total
COMPLETED SUICIDE	156
CARDIAC ARREST	154
RESPIRATORY ARREST	153
DEATH	128
OVERDOSE	63
DRUG TOXICITY	59
CARDIO-RESPIRATORY ARREST	45
NYSTAGMUS	40
SOMNOLENCE	40
POISONING	35
DRUG ABUSE	34
DEVELOPMENTAL DELAY	31
CONFUSIONAL STATE	30
INSOMNIA	25
ANXIETY	23
DRUG DEPENDENCE	21
SUICIDAL IDEATION	21
COMA	20
HYPOTENSION	20
NAUSEA	20

Trilafon	
Reaction	Total
DIARRHOEA	2
DYSTONIA	2
EXTRAPYRAMIDAL DISORDER	2
FEELING ABNORMAL	2
MUSCLE RIGIDITY	2
SEDATION	2
TARDIVE DYSKINESIA	2
URINARY INCONTINENCE	2
ASPERGER'S DISORDER	1
BLOOD CREATINE PHOSPHOKINASE INCREASED	1
CRYING	1
DROOLING	1
FLUSHING	1
LIP SWELLING	1
MASTICATION DISORDER	1
PAIN	1
POST-TRAUMATIC STRESS DISORDER	1
PRIAPISM	1
SELF INJURIOUS BEHAVIOUR	1
WEIGHT DECREASED	1

Vivactil	
Reaction	Total
BENIGN PROSTATIC HYPERPLASIA	1
LOSS OF CONSCIOUSNESS	1
URETHRAL OBSTRUCTION	1
URINARY RETENTION	1

Trileptal	
Reaction	Total
CONVULSION	231
HYPONATRAEMIA	128
DIZZINESS	99
DEPRESSION	90
SOMNOLENCE	85
PYREXIA	81
NAUSEA	80
HEADACHE	79
VOMITING	75
ASTHENIA	52
FATIGUE	52
MALAISE	51
TREMOR	51
ANXIETY	49
RASH	48
CONFUSIONAL STATE	44
BLOOD SODIUM DECREASED	43
AGITATION	41
FEELING ABNORMAL	36
SPEECH DISORDER	35

Vyvanse	
Reaction	Total
OFF LABEL USE	116
INSOMNIA	61
AGGRESSION	41
ABNORMAL BEHAVIOUR	40
HEADACHE	32
SUICIDAL IDEATION	31
AGITATION	29
DECREASED APPETITE	27
IRRITABILITY	27
VOMITING	27
NAUSEA	26
PSYCHOMOTOR HYPERACTIVITY	23
ANOREXIA	22
LOGORRHOEA	22
CRYING	20
DYSPNOEA	20
ABDOMINAL PAIN UPPER	19
DISTURBANCE IN ATTENTION	19
FEELING ABNORMAL	19
FATIGUE	18

Wellbutrin	
Reaction	**Total**
INSOMNIA	546
DEPRESSION	505
ANXIETY	464
CONVULSION	410
HEADACHE	378
NAUSEA	342
DIZZINESS	337
TREMOR	281
RASH	255
SUICIDAL IDEATION	250
COMPLETED SUICIDE	244
AGITATION	223
FEELING ABNORMAL	217
URTICARIA	206
TINNITUS	200
FATIGUE	179
IRRITABILITY	179
WEIGHT DECREASED	164
ALOPECIA	156
CRYING	156

Xanax	
Reaction	**Total**
CARDIAC ARREST	125
ANXIETY	124
COMPLETED SUICIDE	123
RESPIRATORY ARREST	121
DEPRESSION	92
SUICIDE ATTEMPT	89
DRUG DEPENDENCE	78
INSOMNIA	77
SOMNOLENCE	71
DRUG TOXICITY	66
POISONING	62
MALAISE	56
HEADACHE	54
OVERDOSE	54
TREMOR	49
SUICIDAL IDEATION	47
CONVULSION	46
LOSS OF CONSCIOUSNESS	46
NAUSEA	46
FEELING ABNORMAL	45

Zoloft	
Reaction	**Total**
DEPRESSION	274
ANXIETY	270
NAUSEA	180
DIZZINESS	173
SUICIDAL IDEATION	164
HEADACHE	163
INSOMNIA	163
TREMOR	155
FEELING ABNORMAL	124
SOMNOLENCE	123
AGITATION	119
COMPLETED SUICIDE	106
VOMITING	102
DIARRHOEA	101
FATIGUE	98
IRRITABILITY	97
ASTHENIA	90
CONVULSION	88
SUICIDE ATTEMPT	86
OVERDOSE	85

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8 (for Top 20 see Appendix B)	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Abilify (aripoprazole)	atypical antipsychotic (newer)	schizophrenia	10+	Increased mortality in frail elderly;	tremor; weight increase; tardive dyskinesia; insomnia; neuroleptic malignant syndrome	70	10 – 15 mg/day (max. 30 mg/day)	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Adderall (amphetamine)	stimulant (classic)	ADHD, narcolepsy	3+		aggression; insomnia; suicidal ideation; abnormal behavior; psychotic disorder	56	10 – 30 mg/day (max. 40 mg/day)	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
Akineton (biperiden)		parkinsonism	not recommended for children		neuroleptic malignant syndrome; delirium; confusional state; restlessness; pyrexia	1	6 – 8 mg/day (max 16 mg/24 hours)	
alprazolam (see Xanax)								
Ambien (zolpidem)	sedative (non-benzo)	Insomnia	adult		amnesia; road traffic accident; sleep walking; impaired driving ability; somnambulism	193	10 mg/day	
amitriptyline (see Elavil)								
amoxapine (Asendin)								
amphetamine (see Adderall)								
Anafranil (clomipramine)	antidepressant (older)	OCD (Obsessive Compulsive Disorder)	10+		Sinus tachycardia; metabolic acidosis; intentional overdose; grand mal convulsion; renal failure acute	14	25-100 mg/day (max 250 mg/day)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
aripiprazole (see Abilify)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Artane (tri-hexyphenidyl)		Parkinsonism			neuroleptic malignant syndrome; hallucination; Stevens-Johnson syndrome; depressed level of consciousness; drug dependence	4	6-10 mg/day	
Asendin (amoxapine)	anti-depressant (older)	depression			acute respiratory distress syndrome; drug toxicity; pleural effusion; pyrexia; pulmonary congestion	2	200-300 mg/day (max. 600/day)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Ativan (lorazepam)	sedative (benzo tranquilizer)	anxiety disorders	18+		suicide attempt; somnolence; multiple drug overdose intentional; tachycardia; fatigue	115	usual dosage 2-6 mg/day (may vary from 1-10 mg/day)	
atomoxetine (see Strattera)								
benztropine (see Cogentin)								
biperiden (see Akineton)								
buproprion (see Wellbutrin or Zyban)								
carbamazepine (see Tegretol or Equetro)								
Carbrital (pentobarbital & carbromal)	sedative (barbiturate)				Aggression; procedural complication; lethargy; fatigue; completed suicide; oxygen consumption decreasedn			
Catapres (clonidine)	anti-hypertensive	hypertension			blood pression increase; application site pruritus; application site erythema; hypertension; application site rash	71	0.2 - 0.8 mg/day (max. 2.4 mg/day)	

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Celexa (citalopram)	anti-depressant (SSRI)		precautions for pediatric use		completed suicide; drug toxicity; hyponatraemia; seratonin syndrome; agitation	626	20-40 mg/day	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
clorazepate (see Tranxene)								
chlordiazepoxide (see Librium)								
chlorpromazine (see Thorazine)								
citalopram (see Celexa)								
clomipramine (see Anafranil)								
clonazepam (see Klonopin)								
clonidine (see Catapres)								
clozapine (see Clozaril)								
Clozaril (clozapine)	antipsychotic (atypical)	treatment-resistant schizophrenia	Adults only	Increased mortality in frail elderly; serious risk of severe drop in white blood cells, seizures, myocarditis, and other cardio-vascular and respiratory effects	Granulocytopenia; leukopenia; white blood cell count decrease; payrexia; neutrophil count decrease	157	300-600 mg/day (max. 900 mg/day)	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Cogentin (benztropine)	treat extrapyramidal side effects	parkinsonism; extra-pyramidal disorders	3+		adverse drug reaction; completed suicide; convulsion; dyskinesia; dystonia	7	1 - 8 mg/day	
Compazine (pro-chlorperazine)	antipsychotic (typical)				dyspnoea; tremor; anxiety; feeling abnormal; vomiting	3	Child: 2.5-10 mg/day (max. 15); Adult: 15-40 mg/day (max.40)	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Concerta (methyl-phenidate)	stimulant (other)	ADHD	6+		aggression; depression; hallucination; headache; convulsion	77	Start at 18–36 mg/day – increases of 18 mg/wk (max 54-72 mg/day)	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
Cylert (pemonline)	stimulant (other)				jaundice; suicide attempt; psychomotor hyperactivity; liver function test abnormal; convulsion			Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
Cymbalta (duloxetine)	anti-depressant (other newer)	depression; anxiety			nausea; dizziness; headache; feeling abnormal; insomnia	410	30-60 mg/day	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Dalmane (flurazepam)	sedative (benzo sleeping pill)	Insomnia	15+		suicide attempt; overdose; somnolence; intentional overdose; alcohol use	8	15 – 30 mg before retiring	
Daytrana (methyl-phenidate)	stimulant (other)	ADHD	6+		aggression; depression; hallucination; headache; convulsion	77	10 – 30 mg/9 hours	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Depakote, Depakene (divalproex sodium, valproate)	anti-convulsive (mood stabilizer)	Seizure disorders (no psychiatric indications)	10+	Suicidal ideations and behavior; liver toxicity	convulsion; weight increase; tremor; alopecia; drug level decrease	105	Initial 25 mg/day – increase to lowest thera-peutic dose (max 60 mg/day)	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
desipramine (see Norpramin)								
Desoxyn (meth-amphetamine)	Stimulant (classic)	ADHD; obesity	6+		pulmonary hypertension; drug toxicity; completed suicide; intentional drug misuse; cardio-respiratory arrest	37	20 – 25 mg/day	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
dexamethylphenidate (see Focalin)								
Dexedrine (dextro-amphetamine)	stimulant (classic)	ADHD; narcolepsy	3+		insomnia; fatigue; somnolence; death; palpitations	20	5 mg/day – raise by 5 mg until optimal response is obtained (max 40 mg/day)	Increa sed repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
dextroamphetamine (see Dexedrine)								
diazepam (see Valium)								
divalproex sodium, valproate (see Depakote, Depakene)								
doxepin (see Sinequan)								
Doral (quazepam)	sedative (benzo sleeping pill)	insomnia	18+		depressed level of consciousness; disorientation; delirium; suicide attempt; coma	0	7.5 – 15 mg/day	
droperidol (see Inapsine)								
duloxetine (see Cymbalta)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Effexor (venlafaxine)	anti-depressant (other newer)	major depressive disorder	Adults only		suicidal ideation; nausea; dizziness; condition aggravated; paraesthesia	320	75 - 225 mg/day (max. 375 mg/day)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Elavil (amitriptyline)	anti-depressant (older)	depression	12+		overdose; somnolence; cardio-respirator arrest; intentional overdose; confusional state; hypotension	42	40 - 100 mg/day	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Equetro (extended-release carbamazepine)	anti-convulsive (mood stabilizer)	acute manic & mixed episodes associated with Bipolar I Disorder	15+		convulsion; pyrexia; condition aggravated; drug rash with eosinophilia and systemic symptoms; grand mal convulsion; drug toxicity	129	400 - 1600 mg/day	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
escitalopram (see Lexapro)								
Eskalith (lithium)	anti-convulsive (mood stabilizer)	manic-depressive illness	12+		therapeutic agent toxicity; tremor; confusional state; mania; haemodialysis	72	900 mg/day (max. 1350 mg/day)	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
eszopiclone (see Lunesta)								
estazolam (see ProSom)								
Etrafon (antidepressant plus Trilafon)	typical antipsychotic (older)				dyskinesia; rotator cuff syndrome; joint dislocation; tardive dyskinesia; muscle spasms	0		Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
fluoxetine (see Prozac)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
fluphenazine (see Prolixin)								
flurazepam (see Dalmane)								
fluvoxamine (see Luvox)								
Focalin (dexamethylphenidate)	Stimulant (other)	ADHD	6+		convulsion; hallucination; depression; heart rate increase; abnormal behavior; headache	2	5 - 20 mg/day	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
gabapentin (see Neurontin)								
Gabitril (iagabine)	anti-convulsive	seizure disorders (no psychiatric indications)	12+	Suicidal ideations and behavior	convulsion; confusional state; tremor; grand mal convulsion; loss of consciousness	6	begin at 4 mg/day; increase weekly by 4-8 mg; child max 32/adult max 56	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
Geodon (ziprasidone)	atypical antipsychotic (newer)	bipolar mania; schizophrenia	Adults only	Increased mortality in frail elderly	tradive dyskinesia; tremor; anxiety; convulsion; somnolence	181	20 to 80 mg BID	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
guanfacine (see Tenex)								
Halcion (trizolam)	sedative (benzo sleeping pill)	insomnia	Adult		suicide attempt; overdose; intentional overdose; somnolence; coma	21	0.25 mg before retiring (max 0.50 mg)	
Haldol (haloperidol)	typical antipsychotic (older)	Schizo-phrenia, Tourette's Disorder	3+		weight increase; extrapyramidal disorder; somnolence; cognitive disorder; suicide attempt	121	Up to 10 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
haloperidol (see Haldol)								
iagabine (see Gabitril)								
imipramine (see Tofranil)								
Inapsine (droperidol)	typical antipsychotic (neuroleptic)	nausea	2+		hyperidrosis; tremor; muscle rigidity; convulsion; nausea	1	Child: 0.1 mg; Adult: 2.5 mg	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Invega (paliperidone)	atypical antipsychotic (newer)	bipolar mania; schizophrenia	Adults only	Increased mortality in frail elderly	galactorrhea; extrapyramidal disorder; blood prolactin increase; weight increase; dystonia	86	3 – 12 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Kemadrin (procyclidine)		Parkinson Disease; parkinsonian symptoms	Recommended for Adults only		cardio respiratory arrest; dilatation ventricular; confusional state; asthenia; vomiting	6	15 30 mg/day	
Klonopin (clonazepam)	sedative (benzo tranquilizer)	seizure disorder; panic disorder			completed suicide; cardiac arrest; respiratory arrest; death; overdose	334	0.5 - 4 mg/day (see FDA label)	
Lamictal (lamotrigine)	anti-convulsive (mood stabilizer)	Seizure disorders	3+	Suicidal ideations & behavior; serious rash requiring hospital; Stevens-Johnson syndrome for under 16 years of age	rash; convulsion; pyrexia; Stevens-Johnson syndrome; pruritus	248	-	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
lamotrigine (see Lamictal)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Lexapro (escitalopram)	anti-depressant (SSRI)	major depressive disorder; generalized anxiety disorder			completed suicide; convulsion; depression; nausea; suicidal ideation	351	10 mg/day (max. 20 mg/day)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Librium (chlor-diazepoxide)	sedative (benzo tranquilizer)	anxiety	6+		cardio respiratory arrest; death; loss of consciousness; constipation; hypotension	27	Child: 10-30 mg/day; Adult: 15-100 mg/day	
lisdextroamphetamine (see Vyvanse)								
lithium (see Lithobid, Lithotabs or Eskalith)								
Lithobid/ Lithotabs (lithium)	anti-convulsive (mood stabilizer)	manic-depressive illness; bipolar disorder	12+		therapeutic agent toxicity; tremor; confusional state; mania; haemodialysis	72	900 – 1200 mg/day; acute mania: 1800 mg/day	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
lorazepam (see Ativan)								
loxapine (see Loxitane)								
Loxitane (loxapine)	typical antipsychotic (older)	schizophrenia	Adults only	Increased mortality in elderly patients	neuroleptic malignant syndrome; hyperhidrosis; death; muscle rigidity; extrapyramidal disorder	2	60 – 100 mg/day (max 250 mg)	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Lunesta (eszopiclone)	sedative (non-benzo sleeping pill)	Insomnia	Adults only		dysgeusia; insomnia; middle insomnia; initial insomnia; somnolence	29	2 – 3 mg before bedtime	

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen-ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Luvox (fluvoxamine)	Anti-depressant (SSRI)	OCD (Obsessive Compulsive Disorder)	8+		Alanine aminotransferase increase; irritability; aspartate aminotransferase increase; insomnia; activation syndrome	4	child: 25-200/300 mg/day (age factor); adult: 50-300 mg/day	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Mellaril (thioridazine)	typical antipsychotic (older)	schizophrenia	2+		tardive dyskinesia; weight increase; aggression; suicide attempt; blindness	5	150-300 mg/day, with a gradual increment to max of 800 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
mesoridazine (see Serentil)								
Metadate (methyl-phenidate)	stimulant	ADHD	6+		aggression; depression; hallucination; headache; convulsion	77	Starting dosage 18–36 mg/day – increases of 18 mg/wk (max 54 [adolescent] -72 [adult])	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
methamphetamine (see Desoxyn)								
methylphenidate (see Concerta, Ritalin, Daytrana, or Metadate)								
metoclopramide (see Reglan)								
mirtazapine (see Remeron)								
Moban (molindone)	typical antipsychotic (older0	schizophrenia	12+	Increased mortality in elderly patients	pranoia; insomnia; urinary retention; suicidal ideation; neuroleptic malignant syndrome	0	Mild: 15-60, Moderate: 30-100; Severe: max 225 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
molindone (see Moban)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Navane (thiothixene)	typical antipsychotic (older)	schizophrenia	12+	Increased mortality in elderly patients	disturbance in attention; paranoia; blood prolactin increased; galactorrhoea; drug dispensing error	0	20 – 30 mg/day (max 60 mg/day)	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Neurontin (gabapentin)	anti-convulsive (off-label or unapproved mood stabilizer)	Seizure disorders (no psychiatric indications)	10+	suicidal ideations and behavior	suicide attempt; suicide ideation; depression; completed suicide; pain	514	People over 12 start on 300 mg/day. Can increase to 1,800 mg/day. Max:3,600 mg/day	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
Norpramin (desipramine)	antidepressant (older)	depression	not recommended for children	suicidal thinking and behavior	panic attack; agitation; anxiety; rapid eye movements sleep abnormal; mania	1	Adole-scent: 25-100 mg/day (max 150); Adult: 100-200 mg/day (max 300)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
nortriptyline (see Pamelor)								
olanzapine (see Zyprexa)								
Orap (pimozide)	typical antipsychotic (neuroleptic)	Tourette's Disorder (for Haldol non-responders)	12+		Hypoglycaemia; skin irritation; suicide attempt; blood glucose increase; anti-insulin antibody	29	0.2 mg/kg/day or 10 mg/day; which ever is less (max 10 mg/day)	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
oxazepam (see Serax)								
oxcarbazepine (see Trileptal)								
paliperidone (see Invega)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Pamelor (nortriptyline)	anti-depressant (older)	depression	not recommended for children		completed suicide; heart reate increase; coma; confusional state; intentioanl drug misuse	26	50 - 150 mg/day	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Parnate (tranyul-cypromine)	anti-depressant (older)	Depression	Adults only	suicidal thinking and behavior	anxiety; headache; suicidal ideation; insomnia; depression	8	30 mg/day (max 60 mg/day)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
paroxetine (see Paxil)								
Paxil (paroxetine)	anti-depressant (SSRI)	depression; anxiety disorders; OCD; panic disorders; PTSD	precautions for pediatric use		congenital anomaly; anxiety; suicidal ideation; dizziness; nausea	833	20 - 50 mg/day (max. 60 mg/day)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
pemoline (see Cylert)								
perphenazine (see Trilfon)								
Phenergan (promethazine)	typical antipsychotic (neuroleptic)	allergy; motion sickness; nausea; sedation	2+	potential for fatal respiratory depression in pediatric patients less than 2 years old	pain; convulsion; vomiting; loss of consciousness; mental status changes	29	Child:12.5 -25 mg/day; Adult: 25-50 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
pimozide (see Orap)								
prochlorperazine (see Compazine)								
procyclidine (see Kemadrin)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Prolixin (fluphenazine)	typical antipsychotic (older)	psychotic disorders	Adults		Tremopr; dysarthria; blood creatine phosphokinase increased; neuroleptic malignant syndrome; somnolence	9	1 – 5 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
promethazine (see Phenergan)								
ProSom (estazolam)	sedative (benzo sleeping pill)	Insomnia	Adults only		agranulocytosis; dehydration; drug toxicity; hangover; somnolence	3	1- 2 mg at bedtime	
protriptyline (see Vivactil)								
Prozac (fluoxetine)	anti-depressant (SSRI)	Depression; OCD (Obsessive Compulsive Disorder);	8+		depression; completed suicide; suicidal ideation; confusional state; agitation	347	20 – 80 mg/day	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
quazepam (see Doral)								
quetiapine (see Seroquel)								
ramelteon (see Rozerem)								
Reglan (metoclo-pramide)	typical antipsychotic (neuroleptic)	Diabetic gastroparesis	Adults only		tardive dyskinesia; anxiety; depression; tremor; dystonia	10	10 mg before each meal and at bedtime	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Remeron (mirtazapine)	anti-depressant (other newer)	depression	precautions for pediatric use		suicide attempt; confusional state; anxiety; fatigue; depression	11	15 - 45 mg/day	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen-ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Restoril (temazepam)	sedative (benzo sleeping pill)	Insomnia	Adults only		completed suicide; death; drug toxicity; anxiety; confusional state	64	15 mg before retiring	
Risperdal (resperidone)	atypical antipsychotic (newer)	autism; bipolar mania; schizophrenia	5+	Increased mortality in frail elderly;	diabetes mellitus; weight increase; death; somnolence; suicide attempt	613	1 mg twice daily. increased gradually to 3 mg twice daily	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
risperidone (see Risperdal)								
Ritalin (methyl-phenidate)	stimulant (other)	ADHD	6+		aggression; depression; hallucination; headache; convulsion	77	20–30 mg/day, although 10–60 mg is not un-common	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
Rozerem (ramelteon)	sedative (non-benzo sleeping pill)	Insomnia	Adults only		initial insomnia; middle insomnia; somnolence; poor quality sleep; insomnia	21	8 mg at bedtime (max 8 mg)	
Serax (oxazepam)	sedative (benzo tranquilizer)	anxiety disorders	12+		intentional overdose; drug dependence; dizziness; chondropathy; suicide attempt	1	30 – 120 mg/day	
Serentil (mesoridazine)	typical antipsychotic (older)	schizophrenia	Adults only		Weight decrease; renal disorder; erectile dysfunction; gastrointestinal disorder; chest pain	0	25 – 200 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Seroquel (quetiapine)	atypical antipsychotic (newer)	bipolar mania; schizophrenia	Adults only	Increased mortality in frail elderly;	diabetes mellitus; pancreatitis; ill-definded disorder; polytraumatism; death	1493	Target dose of 300-400 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
sertraline (see Zoloft)								
Sinequan (doxepin)	anti-depressant (older)	OCD (Obsessive Compulsive Disorder)	12+		completed suicide; respiratory arrest; cardiac arrest; cardio-respiratory arrest; somnolence	57	Started at 30-150 mg/day & gradually increased to 300 mg/day if needed.	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Sonata (zaleplon)	sedative (non-benzo sleeping pill)	insomnia	Adults only		middle insomnia; somnolence; suicide attempt; intentional overdose; tachycardia	2	5 – 10 mg/day (max 20)	
Stelazine (trifluoperazine)	typical antipsychotic (older)	anxiety; schizophrenia	6+		drug dispensing error; oedema mucosal; dyspnoea; dyskinesia; oral discomfort	1	child: up to 15 mg/day; adult: 15 – 40 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Strattera (atomoxetine)	(not considered a stimulant)	ADHD	6+		suicidal ideation; aggression; suicide attempt; convulsion; vomiting	82	40 – 80 mg/day.	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Symbyax (olanzapine/ fluoxetine mixture)	antipsychotic + anti-depressant	bipolar mania; schizophrenia	Adults only	suicidality in children and adolescents	diabetes mellitus; weight increase; pancreatitis; hypertension; hyperglycaemia	1251	3 mg/25 mg – 6 mg/25 mg	
Tegretol or Equetro (carbamaze-pine)	anti-convulsive (off-label or unapproved mood stabilizer)	Seizure disorders (no psychiatric indications)	Any		convulsion; pyrexia; asparate aminotransferase increase; gamma-glutamyltransferase increase; rash	129	400 mg/day. Max: children - 1,000 (12-15) Max: adults - 1,200	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
temazepam (see Restoril)								
Tenex (guanfacine)	anti-hypertensive	high blood pressure	12+		constipation; aggression; ileus; orthostatic hypotension; vomiting	0	3 mg/day	
thioridazine (see Mellaril)								
thiothixene (see Navane)								
Thorazine (chlor-promazine)	typical antipsychotic (older)	schizophrenia	6 months +		loss of consciousness; blood alkaline phosphatase increase; aspartate aminotransferase increase; liver injury; heart rate increase	8	25-100 mg every 6-8 hours (max 800-1200 mg/day)	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Tofranil (imipramine)	anti-depressant (older)	OCD (Obsessive Compulsive Disorder)	6+		completed suicide; auicide attempt; depression; tremor; insomnia	38	Up to 200 mg/day (may go up to 300 mg but only after an EKG is done)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
topiramate (see Topamax)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Topomax (topiramate)	anti-convulsive (off-label or unapproved mood stabilizer)	Seizure disorders (no psychiatric indications)	10+	Suicidal ideations and behavior	convulsion; abortion spontaneous; failure to thrive; weight decrease; confusional state	14	100 – 200 mg/day. (max 1,000 mg/day in divided doses)	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
Tranxene (chlorazepate)	sedative (benzo tranquilizer)	anxiety; anti-convulsant	9+		suicide attempt; mental disorder; coma; abnormal behavior; drug toxicity	1	30 mg/day (max 90 mg/day)	
tranylcypromine (see Parnate)								
triazolam(see Halcion)								
trifluoperazine (see Stelazine)								
trihexyphenidyl (see Artane)								
Trilafon (perphenazine)	typical antipsychotic (older)	Emesis; psychotic disorders	12+		sedation; diarrhea; dystonia; tardive dyskinesia; feeling abnormal	1	12 – 24 mg/day (max 64 mg/day)	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)
Trileptal (oxcarbazepine)	anti-convulsive	seizure disorders (no psychiatric indications)	2+	Suicidal ideations and behavior	Convulsion; hyponatraemia; dizziness; depression; somnolence	49	300 – 600 mg twice per day	Depression, sedation; hostility; anxiety; hyperactivity; abnormal thinking; confusion and amnesia; slurred speech; sedation, sleepiness; nausea, dizziness; vomiting, abdominal pain; headaches, tremors; fatal skin rashes; hypothyroid; blood disorders; pancreatitis, liver disease; birth defects, menstrual irregularities; withdrawal seizures. (Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al, 2003)
Valium (diazepam)	sedative (benzo tranquilizer)	anxiety disorders	6 months +		completed suicide; cardiac arrest; respiratory arrest; death; overdose	471	1 - 40 mg/day	
venlafaxine (see Effexor)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Vivactil (protriptyline)	anti-depressant (older	depression	not recommended for children	suicidality in children and adolescents	Benign prostatic hyperplasia; loss of consciousness; urinary retention; urethral obstruction	0	15 – 40 mg/day (max 60 mag/day)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Vyvanse (lisdextro-amphetamine)	stimulant (classic)	ADHD	6+		off label use; insomnia; aggression; abnormal behavior; headache	0	30 – 70 mg/day	Increased repetitive, persistent behavior; decreased exploration and social behavior; increased compliance; nervousness; insomnia; agitation; depression, "zombie" look; irritability, aggression; mania, psychosis; increased blood pressure; dizziness, headaches; palpitations; stomach cramps, nausea; appetite/weight loss; stunted growth; cardiac arrest. (Bezchlibnyk-Butler & Jeffries, 2005)
Wellbutrin (bupropion)	anti-depressant (other newer)	major depressive disorder	precautions for pediatric use	Suicidality in children and adolescents	insomnia; depression; anxiety; convulsion; headache	360	300 mg/day (max. 450 mg/day)	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
Xanax (alprazolam)	sedative (benzo tranquilizer)	panic disorder	Adults only		cardiac arrest; anxiety; completed suicide; respiratory arrest; depression	305	3 - 6 mg/day	
zaleplon (see Sonata)								
ziprasidone (see Geodon)								
Zoloft (sertraline)	anti-depressant (SSRI)	OCD (Obsessive Compulsive Disorder)	7+		depression; anxiety; pharmaceutical product complaint; nausea; dizziness	328	25 – 50 mg/day	Anxiety; agitation, irritability; mood swings, mania; aggressiveness; suicidal thoughts and actions; nausea, vomiting, stomach pain, constipation, diarrhea; loss of libido, erectile dysfunction, anorgasmia; sleep disruption; urinary retention; blurred vision; weight gain; headaches, dizziness (Antonuccio et al, 1999; Preda et al, 2001; Healy, 2003)
zolpidem (see Ambien)								

Appendix C: Basic Information About the Most Commonly Prescribed Psychotropic Drugs

Name	Category	Indications	Age	FDA Bl'ck Box Warn'gs	Top 5 Adverse Effects Reported to FDA 2006-8	Deaths Rep't'd 2006-8	Recommen -ded Dosage	Problematic Effects for this category of drug, as reported in the literature
Zyprexa (olanzapine)	atypical antipsychotic (newer)	bipolar mania; schizophrenia	Adults only	Increased mortality in frail elderly;	diabetes mellitus; weight increase; pancreatitis; hypertension; hyperglycaemia	1251	Target dose of 10 mg/day	Indifference; sedation; less spontaneity; problems with cognition, memory, heart, liver, sex, menstruation & bone density; confusion, anxiety; depression, mood swings; hostility, aggression; weight gain; diabetes; death; infertility; muscle spasms; tardive dyskinesia; neuroleptic malignant syndrome; parkinsonism. (Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al, 2003; Meyer, 2001)