Psychotropic Medication: Magic Bullet to Treat Mental Illness or Just Another Dangerously Unregulated Industry? Evaluating Whether the Current FDA and Legal Structure is Sufficient to Protect American Consumers of Psychotropic Medication.

Amidst a controversy about whether it is safe to give young children stimulant medication to treat Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD), the National Institute of Mental Health (NIMH), a governmental agency, declared to the public and medical community that Stimulant medications are safe and effective in children. However, a closer look reveals many flaws in the NIMH’s conclusions. Peter Jensen, a consultant to Novartis, the makers of Ritalin, and known drug treatment advocate, was the lead investigator for the study. In fact, the six lead investigators were known advocates of drug treatments for ADD and ADHD and had financial connections to the companies that make the stimulant drugs they were testing.

The NIMH study was a clinic in bad methodology and skewing statistics. The study was billed as the scientific gold standard; a placebo controlled, double-blind, clinical trial, but in practice was anything but the gold standard. The results heavily relied on the evaluations of teachers and parents who were not blind to the treatment. In addition, there was no non-

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1 Peter Breggin, M.D., The NIMH Multimodal Study of Treatment for Attention-Deficit/Hyperactivity Disorder: A Critical Analysis, 13 Int’l Journal of Risk & Safety In Medicine, 15, 15 (2000) (Analyzing the National Institute of Mental Health’s study on the safety and effectiveness of stimulant medication in children by carefully combing through the study’s methodology and results).

2 Id. at 15-16.

3 Duncan, Barry L. et al, Just Say ‘No’ to Drugs as a First Treatment for Child Problems, 13 Psychotherapy in Australia, 32, 37 (August 2007) (Discussing the many problems with over prescribing children psychotropic medication).


5 Id. at15-22.

6 Id. at 16.

7 Id.
Jennifer Olson
treatment control group and 32% of the participants were already on stimulant medication when the study started, making randomization of participants impossible.\textsuperscript{8}

This study was supposed to compare stimulant drug treatment to cognitive behavioral therapy, but the drug treatment was maintained for fourteen months and cognitive behavior therapy was spaced out to once a month during the last few months and stopped early, giving the drug treatment an unfair advantage.\textsuperscript{9} Stimulant drug treatment was given an additional unfair advantage because the type of cognitive behavioral therapy used in the study was developed by Dr. Barkley, who developed and used his brand of cognitive behavioral therapy to show that drug treatments were better.\textsuperscript{10} The National Institute of Mental Health knew that Dr. Barkley’s Cognitive Behavior Therapy was a bad choice and would give the perception of impropriety to the study.\textsuperscript{11} He had recently spoke at the November 1998 National Institute of Health’s Consensus and Development Conference on the Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder and advocated for stimulant drug treatment.\textsuperscript{12}

The National Institute of Mental Health (NIMH) misled the American public by claiming stimulant medication in children was effective because the true methodology and results of their

\textsuperscript{8} Id. at 17.

\textsuperscript{9} Id. at 18.

\textsuperscript{10} Id.

\textsuperscript{11} From the Editors, News Commentary: NIH Consensus Report Highlights Controversy Surrounding ADHD Diagnosis and Stimulant Treatment, 1 Ethical Human Sciences and Services, 9, 9 (1999) (Discussing the National Institute Health’s Consensus and Development Conference on the Diagnosis and Treatment of Attention Deficit and Hyperactivity Disorder, particularly the speakers at the conference, including Dr. Barkley, that advocated for stimulant drug treatment).

\textsuperscript{12} Id.
Jennifer Olson

study, clearly show that stimulant medication had no benefit over cognitive behavior therapy. The long term results showed the clearest picture of the lack effectiveness stimulant medication, yet it went virtually unnoticed after the NIMH’s claims of effectiveness were splashed all over the headlines. After a twenty-four month follow-up, the study showed that the improvements of children on drug treatment deteriorated and the improvements made by children who received cognitive behavior therapy were retained. Further, the only people truly blind to the intervention were the classroom raters, and they found no difference among the intervention groups.

The National Institute of Mental Health is a trusted institution with regard to mental health issues and they misled medical professionals and the public by publishing inaccurate results about the effectiveness of stimulant medication in children. The NIMH’s study of the safety and efficacy of stimulant medications in children to treat ADD and ADHD is a good example of the misinformation and problems facing doctors, patients, and regulators when it comes to psychotropic medications in general. This paper will examine whether psychotropic medications are really “magic bullet” treatments for mental illness or if the pharmaceutical industry is yet another dangerously unregulated industry.

In recent years we have seen what can happen when an industry becomes under regulated. The lack of regulation in the financial sector caused “the great recession” and the lack

13 See generally, Duncan, Barry et al., supra note 3, Just Say ‘No’ to Drugs as a First Treatment for Child Problems, 13 Psychotherapy in Australia, 36-38 (2007) (Explaining the misinformation disseminated by the NIMH when it proclaimed that stimulant medication is a safe and effective treatment for ADD and ADHD).
14 Id. at 37.
15 Id.
16 Id.
of regulation of offshore oil drilling caused the Gulf oil spill. The “great recession” and the Gulf oil spill have revealed a recipe for disaster. In both instances there was a false sense of safety, a relationship between industry and regulators that was too close for comfort, organizational disempowerment of concerned voices, and a large amount of money influencing the regulatory process. This article will examine whether the psychotropic drug industry also has these tell tale signs of disaster, the potential for equally if not more devastating consequences, and will conclude with policy recommendations informed by the mistakes in regulation of the financial and oil industries and tailored to the current regulation of psychotropic drugs in the hope of avoiding another large-scale disaster like the Gulf oil spill and the “great recession.”

FALSE SENSE OF SAFETY

Offshore oil drilling was once seen as “dirty and dangerous,” but as of right before the Gulf oil spill the chances of catastrophe were seen as “infinitesimal.” In the financial sector it was a widely held belief that home prices would not only stay steady, but also continue to rise, until home prices plummeted and many people lost their investments and their homes in “the great recession.” Likewise, psychotropic drugs were not always seen as safe and effective treatments for mental illness, but now, like the recently disproven beliefs about the oil and financial industries, psychotropic drugs are seen as safe and effective and widely used as a first line treatment for mental illness.

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During the 1930’s through the 1950’s, scientists were discovering what they called “magic bullet” medications, like antihistamines and insulin.\textsuperscript{20} During the flurry of drug testing at this time, some drugs were discovered to have side effects that researchers thought could be useful in psychology.\textsuperscript{21} The shift from viewing psychotropic medications as causing potentially useful side effects to treatments of mental illness happened around the time that the Durham-Humphrey Amendment to the Food Drug and Cosmetic Act was passed.\textsuperscript{22} The Durham-Humphrey Amendment made most drugs available by prescription only, making doctors the new gatekeepers for medication.\textsuperscript{23} The American Medical Association (AMA) abandoned its previous drug watchdog role and teamed up with the drug companies to make big money on the newly expanded prescription based system of medicine.\textsuperscript{24} By the mid 1950’s Thorazine Magazine proclaimed that the antipsychotic Thorazine was as important “as the germ-killing sulfas discovered in the 1930’s” and The New York Times called Thorazine “a miracle pill.”\textsuperscript{25} The collision of the new prescription only medical system and the new psychotropic “magic bullets” proved to be a very profitable industry for the drug companies and the AMA.\textsuperscript{26} In 1957 drug company profits reached $1 billion dollars and the AMA’s revenues from drug advertisements reached $10 million by 1960.\textsuperscript{27}

\textsuperscript{20} Id. at 48, 65.
\textsuperscript{21} Id. at 54.
\textsuperscript{22} Id. at 55-56.
\textsuperscript{23} Id. at 57.
\textsuperscript{24} Id.
\textsuperscript{25} Id. at 58-59.
\textsuperscript{26} Id. at 57.
\textsuperscript{27} Id.
There was an important difference between psychotropic drugs and true “magic bullet” medications like insulin and malaria drugs, mainly unlike traditional drugs; psychotropic drugs were created before a disease process was even known. In fact, the theories of the etiology of mental illness developed based on the way the drugs that created side effects on mental status worked. For example the serotonin deficiency theory of depression developed because scientists discovered that antidepressant medications cause serotonin to saturate the synapses.

The backwards and sloppy science that caused the serotonin hypothesis of depression and the dopamine theory of schizophrenia has been called into serious question by independent research, but this has not changed the dominance of these theories in medicine or the use of psychotropic drugs acting on these neurotransmitters. Beginning in 1969 researchers started to look at cerebrospinal fluid in depressed patients to determine if they had low levels of 5-HIAA (metabolized serotonin). Study after study showed no statistically significant or repeatable difference in 5-HIAA levels of depressed and non-depressed participants. The National Institute of Mental Health even did a study in 1984 that showed no relationship between low levels of 5-HIAA and a response to antidepressant medications, but the theory just wouldn’t die. As further evidence of the problems with the serotonin theory of depression, there is a

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28 Id. at 54.
29 CHARLES BARBER, COMFORTABLY NUMB: HOW PSYCHIATRY IS MEDICATING A NATION 95 (Pantheon Books ed., 2008) (Explaining how little we actually know about the human brain and how our current understanding of what brain systems are involved with mental illness are based on how psychotropic drugs work, not on an independent discovery of disease processes).
30 Id.
31 ROBERT WHITAKER, ANATOMY OF AN EPIDEMIC 71 (2010).
32 Id.
33 Id. at 73.
Jennifer Olson

drug on the market in France that reduces the levels of serotonin in the synapse and it has also been shown to treat the symptoms of depression.  

Similar results were found when the dopamine theory of schizophrenia was tested and that theory is also still dominant in medicine. Dr. Elliot Valenstein, a leading neuroscientist at the University of Michigan believes that the serotonin theory of depression is “completely arbitrary” and may have never existed if the first drugs discovered acted on a different neurotransmitter. Some doctors and researchers have gone further by harkening back to the original view of psychotropic drugs as causing side effects not as treatments, like Dr. Breggin, M.D. who believes that “[p]sychiatric drugs don’t correct biochemical imbalances—they cause them.”

Although knowing how the drugs work and the etiology of the illness they purport to treat is not required by the Food and Drug Administration (FDA), safety and efficacy supposedly is. The words safe and effective can be misleading though, because in practice it merely means that drugs may have benefits and may be safe for most people, but by no means safe and effective for everyone. Many people assume that the FDA itself tests the drugs that go onto the


35 ROBERT WHITAKER, ANATOMY OF AN EPIDEMIC 75 (2010) (Revealing that when tested antipsychotics are shown to be not very effect for the people who can withstand the side effects and actually stay on the medication throughout the trial).


38 STEPHEN FRIED, BITTER PILLS: INSIDE THE HAZARDOUS WORLD OF LEGAL DRUGS 29 (Bantam Books ed., 1998) (Explaining that the FDA does not require drug companies to their drugs work, only that they do work and pass a risk benefit analysis for safety).

39 JAY COHEN, OVERDOSE: THE CASE AGAINST THE DRUG COMPANIES 50 (Jeremy P. Tarcher/ Puntam, ed., 2001) (Discussing the misleading nature of the FDA using the term “safe” to describe approved drugs because the drugs
Jennifer Olson

market, but they do not. In fact, they only review summaries of drug safety and efficacy tests conducted by the drug makers.

A look at Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants reveals that although these drugs were approved by the FDA as safe and effective for the treatment of depression, they have a litany of side effects. These side effects include; sexual dysfunction, insomnia, weight gain, agitation, nausea, diarrhea, lethargy, headache, gastrointestinal bleeds, mania, and fatigue. Even though antidepressants were marketed as being withdrawal free and nonaddictive, research has shown what is called “antidepressant discontinuation syndrome.”

As of 2006 the FDA required antidepressants to carry a warning for serotonin syndrome, an overdose of serotonin in the brain that is potentially lethal. Increased risk of suicide caused by antidepressant use has also been well documented. Based on the drug company’s own documents, participants taking Prozac in a FDA approval trial were three to six times more likely to attempt suicide than the participants taking older antidepressants.

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41 Id.


43 Id. at 54, 57, 59.

44 Id. at 55.


46 Peter Breggin, M.D., Suicidality, Violence and Mania Caused by Selective Serotonin Reuptake Inhibitors (SSRIs): A review and Analysis, 16 Int’l Journal of Risk & Safety in Medicine 31, 31 (2003/2004) (Starting almost immediately after Prozac went to market reports of patients increased violence against themselves and others started pouring in anecdotally, to the FDA, and to the British Committee on Safety and Medicine).

47 Id. at 38.
Jennifer Olson

With all of these risks one would hope that these drugs are very effective at treating mental illness, but a real world analysis reveals they are not. In 2006, the government released two studies that showed antidepressants were only effective in around one-third of patients. Antipsychotic medications fared even worse in these studies. A mere one-quarter of the participants remained on the antipsychotic medication throughout the trial. After the widespread introduction of antipsychotics to the market, hospitals coined the term “revolving door syndrome” to describe the large number of patients who were treated with medication, released, and then relapsed, ending up right back in the hospital. The World Health Organization found that countries that use antipsychotic medications have worse outcomes for schizophrenia than developing nations where antipsychotics are only seldomly administered.

Science has shown that like the previously widely held belief that offshore oil drilling and buying real estate were safe, there is a false sense of safety surrounding psychotropic drugs. These drugs have serious side effects and their efficacy is questionable at best. If these drugs were as safe and effective as the drug companies and the FDA claim, then the seriously mentally

48 CHARLES BARBER, COMFORTABLY NUMB: HOW PSYCHIATRY IS MEDICATING A NATION xix (2008) (Discussing the general lack of scientific support for the claim that psychotropic drugs are effective treatments for mental illness. In addition newer psychotropic drugs have not proven to be more effective than first generation drugs, but cost around ten times more. An additional problem with the widespread use of psychotropic drugs is the declining availability of therapy to treat mental illness).

49 Id.

50 Id.

51 Id.

52 ROBERT WHITAKER, ANATOMY OF AN EPIDEMIC 99 (2010) (Discussing a National Institute of Mental Health study of 344 patients that showed patients who received no medication were less likely to be rehospitalized due to mental illness than patients who received antipsychotics. Hospitals also began to notice this trend and coined the term “revolving door syndrome” to describe the roughly 65% relapse rate of people on antipsychotic medication).

53 Stephen Wong, Behavioral Analysis of Psychotic Disorders: Scientific Dead End or Causality of the Mental Health Political Economy?, 15 Behavioral and Social Issues 152, 161 (2006) (Revealing World Health Organization data that found countries that do not use antipsychotic mediation regularly have better outcomes for schizophrenic patients).
Jennifer Olson

ill would not have a decreased lifespan of fifteen to twenty five-years due to an increased number of deaths caused by cardiovascular disease, vascular disease, and diabetes, which are all common side-effect of long term treatment with a cocktail of psychotropic drugs. 54

A RELATIONSHIP BETWEEN THE INDUSTRY AND THEIR REGULATORS THAT IS TOO CLOSE FOR COMFORT

The Minerals Management Service (MMS), a federal regulatory agency like the FDA, was supposed to regulate the oil industry, but in reality the MMS acted as a “rubber stamp” for the oil industry. 55 The regulation of the financial industry suffered from what is known as the “revolving door.” 56 Many government regulators left their government jobs for more lucrative lobbying jobs and many people in the financial industry left their jobs to become regulators of that industry. 57 The FDA suffers from both the “rubber stamp” and the “revolving door” phenomena that contributed to the financial collapse and the Gulf oil spill.

A look at how the FDA regulates psychotropic drugs will be helpful to see why it is so important that regulators are independent from the companies they are regulating. The FDA governs the approval of psychotropic drugs, which is what allows them onto the market. 58 A company that wants a new drug approved fills out an Investigational New Drug Application

54 ROBERT WHITAKER, ANATOMY OF AN EPIDEMIC 211 (2010) (Suggesting that the side effects of mental illness go beyond the immediate discomfort and are shortening the lifespan of the seriously mentally ill).


56 David Miller, Note, Revolving Doors, Accountability and Transparency: Emerging Policy Concerns and Policy Solutions in the Financial Crisis, University of Strathclyde, 603, 607 (2009) (Identifying the “revolving door” syndrome, which happens when industry and regulatory agency employees oscillate between industry and regulation for employment, as one of the causes of the financial crisis).

57 Id.

The company, which is called a sponsor, must meet certain application requirements and provide documentation regarding the testing of the drug. The drug trials go through three phases. Phase I is meant to access the safety and effectiveness of the medication. Phases II and III are meant to expand on these findings and give the sponsor and the FDA a better overall understanding of the drug.

If a life threatening and or adverse drug reaction is found during a study the sponsor is required to immediately report it to the FDA, but a safety report does not reflect or imply a conclusion that the report is an admission that the drug caused or contributed to the adverse experience. Throughout this process the FDA makes clear that they are looking to resolve conflicts with the sponsors. Even if the FDA finds that research was falsified or in other ways incorrect, the law provides a lengthy procedural process including multiple meetings and appeals before they will discontinue a study. Lastly, if a sponsor or researcher is found to have falsified data, all research they are involved in will be reviewed, but not necessarily discontinued.

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62 Id.
63 Id.
67 Id.
After the clinical studies are concluded and the drug has an approval, the process begins to design a label for the drug. The labels are designed by the company and submitted to the FDA for approval. The labeling process is very important because the label is the basis for drug companies’ advertisements to the public. The regulation of prescription drug advertising is the purview of the FDA. Direct to consumer advertisement is clearly very important to the drug companies, as shown by the $2.5 billion spent in the year 2000 on print and television advertising. Direct to consumer advertising is an important tool for drug companies because research shows that the most advertised drugs see large sales increases.

The Food Drug and Cosmetic Act (FDCA) regulates the development, distribution, and promotion of pharmaceutical products. An important part of the FDCA is the prohibition on misbranding. Prior to 1997 the FDCA’s prohibition on misbranding, which requires a “true statement” of the medication, made television advertising more rare than it is today because of

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70 United States General Accounting Office Report to Congressional Requesters, Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations, (October 2002) (Examining the problems with direct to consumer advertising and the FDA’s general lack of power to force drug companies to follow the laws requiring truthful advertising along with the FDA’s reluctance to use the tools they do have to stop misleading advertising).
71 Barbra Adamcik, et al., Monitoring the Regulatory Process of Prescription Drug Advertising, 229 J. Pharmacy & L. 1, 3 (1996) (Discussing the authority of the FDA over direct to consumer advertising and the letter writing process that the FDA initiates when a drug company engages in misleading advertising. The FDA is generally unwilling to go beyond letter writing and take drug companies to court for their violations).
72 Matthew N. Strawn, Note, Recent Developments in Direct to Consumer Advertising of Attention Disorder Stimulants and Creating Limits to Withstand Constitutional Scrutiny, 495 J. Contemp. Health L. & Pol’y 1, 6 (2003) (Discussing the massive impact of direct to consumer advertising on the drug companies budget, profits, and the general trend that the most advertised drugs are the most prescribed and make the most money).
73 Id.
75 21 U.S.C § 331 (2000).
Jennifer Olson

the extensive nature involved in providing all of the relevant information about a medication. However, in 1997 the FDA gave the drug companies a large and lucrative break when it opened up the television advertising market by interpreting the FDCA to allow the “adequate provision” or “true statement” requirement to be met by just providing access to the drug labeling information.

If the FDA finds that a drug company is marketing its drugs in a way that does not give consumers accurate information about side effects or efficacy, the typical response is that the FDA will write a letter telling the company to stop that particular advertisement. The first letter is a “Notice of Violation” letter. If the drug manufacturer does not change their advertisement the FDA sends a second “Regulatory Letter”. If the drug manufacturer still does not comply the FDA can pursue legal action at this point, but it is very rare that the FDA takes drug manufacturers to court for violating advertising requirements. In fact, between 1986 and 1994, the FDA only pursued legal actions against two drug manufactures to halt their advertisements. A former Director of the FDA’s division of Drug Advertising and Labeling has publicly stated, “the FDA continues to be troubled by the selection and poor quality of research or, conversely, the misuse of data from apparently adequate and well controlled studies, 


77 Id.


79 Id.

80 Id.

81 Id.

82 Id.
Jennifer Olson

the extension or distortion of the claim for usefulness beyond those approved, and the use of pharmacokinetic data or blood or tissue levels that suggest clinical significance but are in fact unsupported by substantial clinical experience.”

The scientific standards for FDA approval are not high. The FDA allows drug companies to use what are called “samples of convenience,” which are groups of people who are easy to recruit. The problem with “samples of convenience” are that people with the mental illnesses that these drugs purport to treat safely and effectively are difficult to recruit, meaning they are vastly underrepresented in a “sample of convenience.” In addition, these drugs are only tested for six to eight weeks, and most people who take the drugs will be on them for far longer. For a brief period in 2005 the FDA tried to address the problems associated with having such an arbitrary length for clinical trials by requiring companies to submit both short and long term data on drugs, but this policy was discontinued by a unanimous vote of the FDA advisory panel after hearing testimony from drug companies. Another growing trend in the drug industry is to do the clinical trials that are submitted to the FDA in other countries.

83 Id.

84 CHARLES BARBER, COMFORTABLY NUMB: HOW PSYCHIATRY IS MEDICATING A NATION 34 (2008) (Discussing the problems with the FDA approval process. The FDA allows the research it bases its approval on to be conducted using “samples of convenience,” over very short periods of time that have no relation to the very long period of time most people will actually be on them, and also drug companies are allowed to do their studies in other countries to reduce cost).

85 Id.

86 Id.

87 Id.

88 Id.

89 Id.
Jennifer Olson

A common misconception is that the FDA rigorously reviews the information drug companies submit during the approval process, but the truth is that the FDA reads the summaries that the company provides, offers comments, and at times requests the raw data of the study. The FDA has a very small budget for drug research. The drug companies’ budgets to test and review drugs are in the billions, while the FDA’s budget to study drugs is only in the millions. The FDA is more of a “rubber stamp” for approval than a “watch-dog” of the scientific process.

Although these laws in and of themselves are not particularly strong, they are further weakened by the “rubber stamp” phenomena at the FDA. One of the central focuses during the drug approval process is the development of a drug label or “package insert.” The package insert is very important to the drug companies because it goes into the Physicians’ Desk Reference (PDR) and it governs what information they must provide in advertisements, professional journals, and pharmacy handouts. The drug company initially creates drug labels and then the FDA and drug company negotiate until there is a final label approved. The FDA frequently compromises on the final contents of the label and many of the investigators concerns

90 STEPHEN FRIED, BITTER PILLS: INSIDE THE HAZARDOUS WORLD OF LEGAL DRUGS 35 (1998) (Dealing with his wife’s illness, the author spoke to a former FDA regulator who said that although he was a principle investigator, he saw his job as “pushing papers”).

91 Id. at 70.

92 Id.

93 Id. at 29.


95 Id.
Jennifer Olson

are left out.\textsuperscript{96} This rubber stamping of labels tends to make the drugs look safer and more useful than an objective look at the science would suggest and has created a group of FDA critics.\textsuperscript{97} Marcia Angell, Harvard lecturer and former editor of the New England Journal of Medicine, believes that the FDA is more worried about protecting drug companies than protecting the public’s health.\textsuperscript{98}

The FDA has also become a “revolving door” much like the financial regulatory agencies. Dr. Lumpkin is emblematic of this problem.\textsuperscript{99} He is a known drug treatment advocate within the FDA. He previously worked in the private sector at a drug company before he moved to the FDA.\textsuperscript{100} Dr. Lumpkin is not an exception, reports have shown that as many as half of FDA experts and advisors have financial ties to the drug industry.\textsuperscript{101} This “revolving door” from industry to regulation has likely brought many drug advocates into the FDA and like the financial regulators; the FDA regulators are too close for comfort with the industry they are supposed to be regulating.

Antidepressants are also a good example of the problems with the FDA approval and labeling process. In fact Prozac, the first SSRI to go to market, almost never made it.\textsuperscript{102} Before

\textsuperscript{96} Id.

\textsuperscript{97} Id. at 55.

\textsuperscript{98} Id.

\textsuperscript{99} STEPHEN FRIED, BITTER PILLS: INSIDE THE HAZARDOUS WORLD OF LEGAL DRUGS 59 (1998) (Describing a television appearance on ABC when the author appeared with Dr. Lumpkin, who approved the drug that injured his wife and at that time was the head of the FDA’s anti-infections division. Dr Lumpkin followed a typical path described in this article; he was a former pediatrician and drug company employee, who later moved to the FDA).

\textsuperscript{100} Id.

\textsuperscript{101} JAY COHEN, OVERDOSE: THE CASE AGAINST THE DRUG COMPANIES 13 (2001).

\textsuperscript{102} CHARLES BARBER, COMFORTABLY NUMB: HOW PSYCHIATRY IS MEDICATING A NATION 7 (2008) (Describing the rocky road Prozac had to approval. Eli Lilly almost shelved the drug because at the time there was not a great need seen for antidepressant medication and there were many side effects emerging during testing).
Jennifer Olson

Prozac hit the market psychiatrists did not see much of a need for antidepressants because the prevalence rate of depression in the United States was only approximately 1%. After preliminary clinical trials in Germany the drug was almost shelved by the maker, Eli Lilly, because German regulators believed that there was little benefit to be gained and the risks were too high. The development of Prozac was stopped seven times before it eventually went to market. Now that Prozac and other antidepressants are on the market the prevalence rate of depression is a whopping 15%.

Many of the problems with antidepressants were only revealed to the public through Freedom of Information Requests, leaks, and court cases long after the drugs had been on the market. The concerning issue is that the drug companies knew about the many problems associated with their blockbuster drugs because their own data showed the many side effects of Selective Serotonin Reuptake Inhibitors, in particular the increased risk of suicide, before the drugs were approved by the FDA. Peter Breggin, M.D., discovered through his role as an expert witness in criminal and civil cases involving psychotropic drugs, that the makers of antidepressants skewed the data regarding suicidality before submitting their clinical data to the FDA and an objective look at the science would have revealed that the problem of suicidality


103 Id.
104 Id.
105 Id. at 34.
106 Id. at 7.
107 Peter Breggin, Drug Company Suppressed Data on Paroxetine-Induced Stimulation: Implications for Violence and Suicide, 8 Ethical Human Psychology and Psychiatry 255, 257 (Fall, 2006) (Finding that Paxil, a SSRI antidepressant, increases the risk of suicidality and the makers Glaxo Smith Kline, knew or should have known).
Jennifer Olson

was much larger than the FDA chose to believe. The discovery process in civil suits regarding
death and injury due to antidepressants has also revealed internal drug company memos that
show antidepressant makers’ knowledge of the increased risk of suicidality and the danger being
dismissed and actively kept from the FDA. Shockingly, to cover up the aggression and
suicidality, Eli Lilly’s head scientist, Ray Fuller, modified the rules of the clinical trial of Prozac
and permitted the use of tranquilizers along with Prozac without telling the FDA.

With most, if not all of this information out, the big result was that the FDA issued a
requirement for antidepressants to carry a “Black Box” warning about the increased risk of
suicidality, but only in children. This result was reached after the FDA commissioned an
expert panel, consisting of many experts with ties to pharmaceutical companies, to discuss the
reports of suicidality in people taking antidepressants. One is left to wonder if a panel of truly
objective experts would have suggested such a limited “Black Box” warning with all of the
evidence of increased suicidality and foul play on the part of the drug companies. The

108 Peter Breggin, How Glaxo Smith Kline suppressed Data on Paxil-Induced akathisia: Implications for Suicidality and Violence, 8 Ethical Human Psychology and Psychiatry 91, 91 (Summer 2006). ( Revealing that as an expert witness, Dr. Breggin was able to view Glaxo Smith Kline’s research data that was submitted to the FDA for approval. Glaxo Smith Kline clearly manipulated the numbers by excluding people in the suicide attempt and completion categories that should have been counted).

109 http://breggin.com/index.php?option=com_content&task=view&id=51&Itemid=92 (Making available internal Glaxo Smith Kline memos about the increased risk of suicidality with Paxil. Dr. Breggin first came across these documents as an expert witness in a products liability suit against Glaxo Smith Kline. The documents were later leaked to the British Journal of Medicine and made available to the public through Dr. Breggin’s website).


111 Id. at 44 (Discussing the FDA’s decision in 2005 to approve a “Black Box” warning for Selective Serotonin Reuptake Inhibitor antidepressants that states that there is an increased risk in suicidality for children under eighteen).

112 Id. at 49 (Reviewing the FDA’s decision to limit the “Black Box” warning to children because the scientific studies showed an increased risk of suicidality in all ages. Many of the experts on the panel that issued the warning had ties to drug companies).

113 Id.
effectiveness of the “Black Box” warning was further weakened by the increase in sales after it was required.\footnote{Charles Barber, Comfortably Numb: How Psychiatry Is Medicating a Nation xvi (2008).}

The FDA has become a “rubber stamp” for drug companies and has also had a “revolving door” to the industry. Both of these phenomena have considerably weakened the FDA’s role in regulating the drug companies. If the FDA wants to avoid the disasters that the Oil and Financial industries have created, they should resume their role as regulators by retiring the rubber stamp and closing the revolving door.

**ORGANIZATIONAL DISEMPOWERMENT OF CONCERNED VOICES**

Leading up to the financial crisis and the Gulf oil spill the agencies in charge of regulating the Oil and Financial industries suffered from low moral and concerned voices within the agencies were ignored or silenced. Before the Gulf oil spill, the Mineral Management Service (MMS), the federal agency charged with regulating the oil industry, ranked one hundred and eleventh out of two hundred and sixteen federal agencies in a survey assessing the best federal agencies to work.\footnote{Ed O’Keefe, Survey: MMS a bad place to work, http://voices.washingtonpost.com/federal-eye/2010/05/survey_minerals_management_ser.html} The study also found that MMS supervisors frequently ignored the concerns of staff scientists and the turnover among employees was extremely high.\footnote{Id.} The Securities Exchange Commission (SEC), the agency responsible for regulating the financial industry, also had low morale among regulators before the financial crisis.\footnote{Marisa McQuilken, SEC Enforcement Lawyers say Morale is Up, March 2, 2009, http://www.law.com/jsp/article.jsp?id=1202428712112} One of the biggest reasons for the low morale among regulators was a general distrust in them emanating from
policies that did not allow regulators to negotiate fines with companies and forced them to go through lengthy procedural hurdles to levy fines.  

Like the MMS and SEC before their respective catastrophes, the Food and Drug Administration suffers from low morale and frustration from regulators. In 2006, the FDA studied itself and found that conflict avoidance and waste were big problems. These problems have caused low morale amongst FDA employees. Also in 2006, the Union of Concerned Scientists sent out a questionnaire to FDA scientists asking how to improve the integrity of the Agency. There was a vast sentiment among FDA scientists that politics are put ahead of science and this is a leading cause of the frustration and sense of low morale. One respondent said, “Those who get ahead do so by being yes-men, and by copying and pasting what the drug companies say directly into their reviews.”

This low morale comes from taking scientists and putting them in the position of only being able to work with the labels drug companies give them, not being able to dictate changes in therapy, and being restricted by law from recommending to doctors which drug in a class of drugs is the safest and most effective. Many respected FDA scientists have left the agency

\footnote{118 Id.}

\footnote{119 \textsc{Peter Breggin, M.D.}, Medication Madness: A Psychiatrist Exposes the Dangers of Mood-Altering Medications 55 (2008).}

\footnote{120 \textsc{Charles Barber}, Comfortably Numb: How Psychiatry is Medicating a Nation 35 (2008).}

\footnote{121 Id.}

\footnote{122 Id.}

\footnote{123 Id.}

\footnote{124 \textsc{Stephen Fried}, Bitter Pills: Inside the Hazardous World of Legal Drugs 103 (1998).}
because they have had drugs approved against their recommendations only to see them harm thousands of people.\textsuperscript{125}

FDA officials feel stiffened by politics and many well-respected FDA scientists have left the Agency after their voices were silenced and drugs went to market that harmed people. The FDA is losing good scientists and the ones that remain have well documented low morale. If the FDA wants to be able to take advantage of the many well-trained scientists they have in their employ and effectively evaluate the drugs that they are approving for market, they will need to learn from the mistakes of the financial and oil industries and stop systemically disempowering the voices of concern.

**LARGE AMOUNTS OF MONEY INFLUENCING REGULATION**

The year before the Gulf oil spill, 2009, the Oil industry lobby spent $154 million dollars to influence the legislation regarding energy and climate change by sending a small army of lobbyists to congress.\textsuperscript{126} Similarly, the financial sector lobbied congress to repeal important financial regulation legislation like the Glass-Steagall Act.\textsuperscript{127} The financial and oil industries spent a lot of money on lobbyists before the financial crisis and the Gulf oil spill, and in the end the American public paid the price for the lobbyists’ hard work on deregulation with the “great

\textsuperscript{125} JAY COHEN, OVERDOSE: THE CASE AGAINST THE DRUG COMPANIES 192 (2001).


recession” and the Gulf oil spill.\textsuperscript{128} Last year pharmaceutical companies represented the largest dollar amount spent on lobbying congress.\textsuperscript{129}

Psychotropic drugs are big business. In 2004 alone, approximately thirty three million prescriptions were written for psychotropic medications.\textsuperscript{130} The World Health Organization conducted a study in 2004 and discovered that twenty-six percent of Americans reported having suffered from a mental illness the previous year.\textsuperscript{131} In 2007, the rate of mentally disabled people on SSI or SSDI was one in every seventy-six Americans.\textsuperscript{132} Mental illness is now the leading cause of disability in children.\textsuperscript{133} Depression has increased from a prevalence rate of around one percent for the generation born around World War I, five percent for the generation born around World War II, to an astonishing ten to fifteen percent prevalence rate for the generation born in the 1960’s.\textsuperscript{134} Diagnoses of mental disorders in children have also exploded in recent times.\textsuperscript{135} Approximately one in five times a youth visits a psychiatrist’s office they will be prescribed an

\textsuperscript{128} See generally, \textsc{Peter Breggin, supra notes 107 & 108, Medication Madness: A Psychiatrist Exposes the Dangers of Mood-Altering Medications} 247 (2008).

\textsuperscript{129} \url{http://prescriptions.blogs.nytimes.com/2010/01/30/pro-or-con-lobbying-thrived/}.

\textsuperscript{130} \textsc{Charles Barber, Comfortably Numb: How Psychiatry is Medicating a Nation} 8 (2008).

\textsuperscript{131} \textit{Id.} at 19.

\textsuperscript{132} \textsc{Robert Whitaker, Anatomy of an Epidemic} 7-9 (2010) (Discussing the large increase in the prevalence of depression since the blockbuster Selective Serotonin Reuptake Inhibitor antidepressants have been on the market).

\textsuperscript{133} \textit{Id.}

\textsuperscript{134} \textsc{Charles Barber, Comfortably Numb: How Psychiatry is Medicating a Nation} 106 (2008).

\textsuperscript{135} Susan McBride, Note, \textit{Pharmaceutical Industry Practices and the Medicalisation of Childhood: Is Pathology for Sale?}, 23 Windsor Rev. Legal & Soc. Issues 55, 55 June 2007 (Explaining the disturbing trend of more and more children taking stimulant medication in recent years. This was not always the case and many people are concerned about the long term effects of not only the drugs, but of labeling so many children with a mental illness).
antipsychotic medication.\textsuperscript{136} An emblematic example of the widespread use of psychotropic medications in the United States is the fact that studies have detected drugs like Prozac in the nation’s rivers.\textsuperscript{137} According to author Charles Barber, “Americans have the most luridly expensive urine in the world.”\textsuperscript{138}

The psychotropic drugs that people are taking in record numbers cost money. In 2002, the top ten drug companies put together were more profitable than all other Fortune 500 companies combined.\textsuperscript{139} In 2006 alone, $13.5 billion dollars were spent on antidepressants.\textsuperscript{140} To put that number in perspective, American sales of Zoloft, a Selective Serotonin Reuptake Inhibitor antidepressant, outsold Tide laundry detergent.\textsuperscript{141} In 2006, the American sales of the antipsychotic Zyprexa were greater than the sales of Levi Strauss Co.\textsuperscript{142}

The drug companies are putting all of this money to good use. The drug companies have the largest lobbying effort of any industry.\textsuperscript{143} The result of this massive and record breaking lobbying effort is that drug companies have received industry friendly regulations.\textsuperscript{144} Some of the major accomplishments of these lobbying efforts are the extension of patents for brand name

\textsuperscript{136}Charles Barber, Comfortably Numb: How Psychiatry is Medicating a Nation 92 (2008) (Showing the large amount of money drug companies make in relation to other well known and successful Fortune 500 companies).

\textsuperscript{137}Id.

\textsuperscript{138}Id. at 21.

\textsuperscript{139}Id. at 22.

\textsuperscript{140}Id. at 8.

\textsuperscript{141}Id. at 9.

\textsuperscript{142}Id.

\textsuperscript{143}Id. at 30.

\textsuperscript{144}Id.
Jennifer Olson

drugs and a quicker drug reviewal process with the Prescription Drug User Fee Act (PDUFA).\textsuperscript{145} The PDUFA requires the FDA to evaluate drugs for approval in just two years, saving the drugs companies a vast amount of money.\textsuperscript{146}

The drug companies’ financial influence on regulation is not limited to lobbying efforts. The way the regulatory process is set up, has the drug companies giving money directly to their regulatory agency. In 2007 the big pharmaceutical companies gave the FDA $305 million dollars to review their drugs on an expedited basis.\textsuperscript{147} These numbers represent approximately 20\% of the FDA’s annual budget and half of the FDA’s budget to review drugs.\textsuperscript{148}

After paying the largest lobbying force in the country and paying up to 20\% of the FDA’s drug reviewal budget with expedited drug reviews alone, the pharmaceutical industry has enough money left over to create substantial financial ties with patient and consumer advocacy groups that lobby congress for laxer regulations under the guise of patient advocacy.\textsuperscript{149} The patient advocacy groups that the drug companies sponsor also give out pro drug company information to patients and doctors.\textsuperscript{150} One of the most visible examples of these so called patient advocacy

\begin{footnotes}
\item[145] Id. at 31. (Discussing the vast amount of money drug companies give directly to the FDA to review their drugs on an expedited basis).
\item[146] Id.
\item[147] Id.
\item[148] Id.
\item[149] Susan McBride, Note, Pharmaceutical Industry Practices and the Medicalisation of Childhood: Is Pathology for Sale?, 23 Windsor Rev. Legal & Soc. Issues 59 (2007) (Discussing the many ways that drug companies advertise their drugs beyond advertisements. Drug companies financially support many patient advocacy groups and educational institutions that may otherwise be critical of their drugs).
\item[150] Id.
\end{footnotes}
groups was when Eli Lilly, the makers of Prozac, put together a Prozac support group to appear on the Oprah Winfrey show and discuss how the drug had drastically improved their lives.\textsuperscript{151}

The drug companies have used their massive profits to influence Congress, the FDA directly, and the public at large. The FDA is unlikely to be an effective regulator of the drug industry when the drug industry is literally paying their bills. It is also likely that the industry’s lobby will be effective when the amount of lobbyists out number members of Congress.\textsuperscript{152} As we saw with the financial and oil industries, the deregulation that follows successful lobbying efforts can lead to disastrous effects for the American people.

**POLICY SUGGESTIONS**

The main ways to improve the FDA’s current regulation of psychotropic drugs involves debunking the myths about the safety of psychotropic drugs, breaking up the close relationship between FDA regulators and the pharmaceutical industry, empowering voices of concern, and removing the vast amounts of drug company money from the law making and drug reviewal process. If these suggestions are followed it can save thousand, potentially even millions of people, from suffering from adverse drug reactions, death, and unnecessary permanent changes in brain chemistry.\textsuperscript{153}

One of the major problems with the current widespread use of psychotropic drugs to treat mental illness is the lack of understanding of the etiology of mental illness. As this article previously discussed, the current theories of the causes of mental illness were all developed on the basis of how the drugs that purport to treat them work. However, these theories have not

\textsuperscript{151} Id.

\textsuperscript{152} CHARLES BARBER, COMFORTABLY NUMB: HOW PSYCHIATRY IS MEDICATING A NATION 30 (2008).

\textsuperscript{153} JAY COHEN, OVERDOSE: THE CASE AGAINST THE DRUG COMPANIES 13 (2001). (Noting that 106,000 people die every year from medication side effects, which makes it the fourth leading cause of death ahead of illicit drug use, automobile accidents, AIDS, infectious disease, diabetes, and murder).
been consistently supported by scientific research and significant time and money have not been invested in researching alternative theories.\textsuperscript{154} Psychotropic drugs need to be seen for what they are, and that is drugs that cause abnormalities in brain functioning. Some of the side effects caused by these brain changes may be useful to treat symptoms of mental illness in severe cases when the benefit clearly outweighs the risk. However, if these drugs were seen for what they truly are, drugs causing side effects that should be used only when the benefit outweighs the risks, it is unlikely that up to thirty three million Americans would take at least one of these drugs a year.\textsuperscript{155}

Debunking the myth that psychotropic drugs actually treat mental illness would also have an important impact in the FDA’s safety and efficacy assessments. It is a false assumption that some side effects and adverse drugs reactions are tolerable because of the benefit that these drugs offer to treat mental illness. If the FDA were assessing these drugs with the understanding that these drugs cause an abnormal change in brain chemistry that cause cognitive and behavioral side effects, the balance would less frequently tip in favor of approval. Lastly, the true information about psychotropic medications and the mental illnesses that they claim to treat would allow patients to make informed decisions about whether the risks outweigh the benefits for them.

The close relationship between the FDA and the pharmaceutical industry needs to be broken up. The FDA is charged with a completely different objective than the drug companies they are regulating. The FDA’s main purpose is to protect the American public from unsafe

\textsuperscript{154} \textit{See}, \textsc{Charles Barber}, \textit{supra} note 29. \textit{See also}, \textsc{Robert Whitaker}, \textit{supra} note 31 (Noting the serious logical and methodological flaws with the current theories of mental illness and their resilience despite evidence to the contrary).

\textsuperscript{155} \textsc{Charles Barber}, \textit{Comfortably Numb: How Psychiatry is Medicating a Nation} 8 (2008) (Showing statistics regarding the large amount of Americans that take a prescription psychotropic drug every year).
Jennifer Olson

drugs. The main purpose of the drug companies is to create the maximum profit for their shareholders. The FDA needs independence from the industry it is regulating. The roles of FDA regulators should be clearly defined as different from the role of drug company employees.

The FDA should also develop strict and enforceable ethical guidelines for their employees and experts. USA Today found that more than half of the FDA’s advisory committee experts have financial relationships with the drug companies that they are supposed to be regulating. The revolving door between the FDA and the drug industry should also be closed. FDA scientists and powerful position holders should not be allowed to have financial ties to the drug companies they are regulating. This may mean that the FDA will have to pay their researchers and executives more money, but the budgetary issues of the FDA should not trump the need for independent regulators. Non-disclosure and non-compete agreements are ordinary tools of business and the FDA would be wise to have the appropriate employees sign them. The FDA should also be much more wary about former employees of the drug companies that come to work for the FDA. Their roles in the approval process should be limited until it is clear that they share the interests of the FDA, not the drug companies’ corporate shareholders.

The FDA would greatly benefit from welcoming voices of concern instead of disempowering them. The FDA frequently holds expert panels and hearings on drugs. The expert panels are almost always made up of people with financial ties to the industry and although the hearings are public, the contents of the hearings are generally kept silent by the FDA unless they are forced to release the information due to a Freedom of Information request. If the FDA welcomed experts and scientists without industry ties on their expert panels, and

156 JAY COHEN, OVERDOSE: THE CASE AGAINST THE DRUG COMPANIES 13 (2001) (Finding that the FDA employees have financial relationships with the companies that will be directly helped or hurt by their decisions).
made the public hearings truly public, they would get a much more accurate picture of how the
drugs they have approved are performing on the market.

It is also important to remember that many of the FDA regulators are scientists by
training. They have undergone rigorous academic training to become experts in their fields.
These scientific experts should be given the tools and time to fully and adequately review the
drugs that they are responsible for approving. The scientists’ concerns should be taken seriously
and they should be rewarded for finding safety concerns and creating accurate drug labels, rather
than incentivizing them to rubber stamp approvals and drug labels.

Publicly funded research could solve many of the problems with suppression of
concerned voices and the massive influence of drug company money at the FDA. If the FDA is
conducting the research, they can avoid troublesome and dangerous suppression of adverse drug
reactions and lying about clinical trial methods like we have seen with antidepressants. If the
FDA set the standards for the research and also carried out those studies, the public could be sure
that the drugs they were taking had passed the high scientific bar that the scientific method
offers. This would also boost morale at the FDA. Rather than forcing brilliant scientists to play
politics and rubber stamp drug applications and labels, these scientists could conduct and
evaluate the research that they were trained at elite institutions to do. Public funding of drug
research would take the politics out of the research process. The FDA scientists would be
elevated to their deserved level as scientific experts. They would not have to go back and forth
with the drug companies that pay them, and instead they could approve or reject drugs for market
without fear.

The large influence the drug companies wield through lobbying congress and paying the
FDA for expedited reviews needs to be addressed by the FDA. These are tough economic times
to be calling for a raise in the FDA budget, but the economic problems with this change could be avoided by outlawing drug companies from paying money directly to the FDA. Instead, the federal government should levy a tax on the drug companies and the federal government should pay the FDA. Congress should also fashion stricter rules regarding drug company lobbying of congress members. Congress should be making regulatory decisions based purely on an objective evaluation of the public’s interest and the best science available not sloppy studies done with samples of convenience and in other countries. 157

The role of the FDA in regulating the pharmaceutical industry is particularly important because of the lack of consistent remedies for people and families injured by psychotropic drugs. The state tort law system is currently the only avenue for the consumers of psychotropic medication to hold drug companies accountable for the injuries their products cause. Some states allow punitive damages against the makers of FDA approved drugs, but only if the plaintiff can prove the drug companies acted recklessly, willfully, or wantonly with regard the plaintiff’s rights. 158 The interpretation of reckless, willful, or wanton conduct can vary drastically based on jurisdiction. 159 At least five states allow what it called an “FDA defense,” which means that a drug company cannot be held liable for punitive damages unless the plaintiff can prove that the drug company committed fraud on the FDA. 160 Lastly, at least one state, Michigan, has given drug companies complete immunity from punitive damages regardless of

157 See, CHARLES BARBER, supra note 82 (Describing the many ways the FDA lets the drug companies cut corners during the approval process making the studies drug approvals are based on less valid and reliable).

158 Annette L. Marthaler, Note, The FDA Defense: A Prescription For Easing the Pain of Punitive Damage Awards In Medical Products Liability Cases, Hamline Law Review, 455, 459-462 (Spring,1996) (Discussing the different ways that different states have viewed products liability suits against manufacturers of FDA approved drugs and the inconsistency from state to state of outcomes in like cases).

159 Id.

160 Id.
Jennifer Olson

their conduct.\textsuperscript{161} Due to limited checks on drug company activity through the state tort systems, it is particularly important that the FDA does a better job of regulating the approval and use of psychotropic drugs.

In conclusion, the drug companies seem to be heading down the same dangerous path that the oil and financial industry did. If the lack of regulation by the FDA causes unsafe drugs to be let on the market the consequences will be much larger than the Gulf oil spill or the “great recession.” With millions of Americans taking psychotropic drugs every year, we could be looking at adverse side effects and brain abnormalities in a generation of our population.

Because the stakes are so high when it comes to psychotropic drugs, the laws and regulations governing them need to undergo an overhaul. This overhaul should begin with addressing the myths surrounding psychotropic drugs and then move on to breaking up the close relationship between FDA regulators and the pharmaceutical industry, empowering voices of concern at the FDA, and removing the vast influence of money from the regulation process.

\textsuperscript{161} Amanda Melpolder, A Tragic Blunder Michigan’s Drug Immunity Law Center for Justice and Democracy 1, 1 (2008).