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# PSYCHIATRIC ETHICS AND EMERGING ISSUES OF PSYCHOPHARMACOLOGY IN THE TREATMENT OF DEPRESSION

*John Alan Cohan\**

## INTRODUCTION

One of the principal purposes of psychiatric treatment is to do good and avoid harm - the central aims of Hippocratic treatment ethics.<sup>1</sup> At the same time, psychiatrists seek to help their patients feel better. In fulfilling the latter function, there can be conflicts with the Hippocratic duty. At times psychiatrists might abandon the ethical traditions of their profession by prescribing "feel good" drugs that, while fulfilling the goal of making the patient "feel" better, may be fundamentally flawed in terms of doing harm in the long run, or even in the short run.

Many aspects of psychotherapy do not involve making the patient "feel good." Psychoanalysis often involves varying degrees of intrusive examination of a patient's innermost thoughts and motivations, and the questions a therapist asks can often make patients feel uncomfortable. The psychiatric profession justifies the painful aspects of psychotherapy as being "worth it" in the same way that a painful procedure, such as chemotherapy for cancer, is justified by the benefits the treatment produces.

While the number of Americans who are in psychotherapy increased slightly from 1987 to 1997, the average length of time patients spent on the couch dropped significantly over the same period, with a substantial increase in the proportion of patients receiving

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1. According to Robert M. Veatch, "the core of professional physician ethics, the core of the Hippocratic tradition" is a commitment by physicians "to producing good for their patient and to protecting that patient from harm." ROBERT M. VEATCH, *A THEORY OF MEDICAL ETHICS* 22 (1981).

antidepressants and other psychiatric drugs.<sup>2</sup> The trend to depart from traditional psychotherapy was noted even before then by Anna Freud, who remarked in a lecture delivered on the occasion of the 112th anniversary of her father's birth, the extent to which people had become alienated from psychoanalysis.<sup>3</sup>

In 1997, 9.69 million people visited psychotherapists - or 3.59% of the nation's population.<sup>4</sup> The percentage of patients who saw therapists for more than twenty sessions dropped to 10.26% in 1997 from 15.69% in 1987, and slightly over 33% attended only one or two sessions.<sup>5</sup> On the other hand, the percentage of patients who took psychiatric medication increased to 61.52% in 1997 from 31.52% a decade earlier.<sup>6</sup> The most common diagnoses for patients who received psychotherapy in 1997 were depression, manic-depression, and other mood disorders.<sup>7</sup> Almost 39.09% of patients were diagnosed with depression, compared to 19.51% ten years earlier.<sup>8</sup>

When a patient has symptoms of depression, psychiatrists are faced with many ethical dilemmas. In this article I will bring forth various issues for consideration by the psychiatric community and other health care professionals pertaining to the treatment of depression. I will discuss emerging ethical problems with respect to the prescription and use of antidepressants known as selective serotonin reuptake inhibitor antidepressants, or "serotonin blocker" drugs (SSRIs) such as Prozac, Paxil, Zoloft, Luvox, and Celexa. What is the truth regarding the side effects of antidepressants? There are certain side effects admitted by drug manufacturers, yet many other side effects discussed in scientific studies and revealed through anecdotal evidence are cause for concern. Some side effects have become separate mental syndromes in their own right, listed in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV-TR), published by the American Psychiatric Association. There are additional and serious side effects associated with withdrawing from taking antidepressants. I will also discuss the question of prescribing SSRIs for use by children, not only for depression, but for what people have described as "attention deficit" disorder. To what extent, if at all, is this "disorder" an abnormality

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2. Erica Goode, *Psychotherapy Shows a Rise Over Decade, But Time Falls*, N.Y. TIMES, Nov. 20, 2002, at A21.

3. See LIONEL TRILLING, *SINCERITY AND AUTHENTICITY* 56 (1972).

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

that requires remediation through drugs? I will then turn to a discussion of whether SSRIs are any more effective than placebos. Various scientific studies have brought into doubt the efficacy of SSRIs over placebos, based on reports from large samplings of patients. This discussion brings to issue a further question of the paradigm, not often questioned, that supposes mental abnormalities are tied to a “biochemical imbalance” in the brain. To what extent is this true, or is it somewhat of a myth? I will then turn to a discussion of the suicide cases that have plagued the pharmaceutical firms that produce SSRIs, and trace some of the lawsuits and report on their current status. When unusual cases of suicide occur in people who previously had no suicide ideation, and when the onset of suicidal symptoms occurs upon taking SSRIs, there is indeed a significant concern of causation, not merely correlation. My discussion will then turn to what has become a popular culture topic in criminal law: “the Prozac defense.” Various criminal attorneys and a number of judges have taken this matter to heart, opening a wedge that will no doubt continue to impact criminal jurisprudence for some time to come. Next, I will discuss some of the ethical concerns of studies that appear with respect to objectivity in scientific journals. These issues include ghost-writing of scientific articles by pharmaceutical companies, and the failure of scientific authors to disclose significant financial ties to the firms for whose drugs they are writing a favorable endorsement. Finally, I will turn to a discussion of cosmetic pharmacology, questioning the ethics of prescribing drugs simply to alter one’s conception of self, to alter one’s personality, to get a competitive edge on others, or to provide other cosmetic uses that will make one “normal,” that is, competitive with others who are also using drugs to enhance their apparent ability to cope in the workplace and in other social settings. I will then provide some concluding remarks, including a sense of how Aristotle, Bruno Bettelheim, and Robert Nozick would regard the efforts to alter a person’s sense of well-being through drugs.

## II. IS THERE A TREND TO TREAT DEPRESSION WITH DRUGS RATHER THAN BY COGNITIVE THERAPY?

Antidepressants known as selective serotonin reuptake inhibitor antidepressants, or “serotonin blocker” drugs (SSRIs) such as Prozac, Paxil, Zoloft, Luvox, and Celexa, are said to enhance serotonin function. The chemical compound fluoxetine hydrochloride (“fluoxetine”), commonly known as Prozac, was developed by Eli Lilly scientists in the 1970s, and was initially touted as a treatment for

depression.<sup>9</sup> This compound is believed to selectively inhibit the brain's reuptake of serotonin, which is a neurotransmitter, a substance that allows individual neurons to communicate with one another. Because scientists believed there was a correlation between the level of serotonin in the brain and mood, many claimed that this compound might be efficacious in the treatment of depression. "By crossing the synapses between neurons, serotonin and other neurotransmitters" are said "to trigger neural responses that ultimately influence thoughts and emotions."<sup>10</sup> Prozac and other SSRIs are thought to inhibit the central nervous system neuronal uptake of serotonin, thus assuring that more of the neurotransmitter is available for triggering neurons.<sup>11</sup>

These drugs are being prescribed not only for psychotic illnesses but other conditions such as manic depression, Alzheimer's, personality disorders, and nonpsychotic depression.<sup>12</sup> Prozac is also prescribed for obsessive-compulsive disorder. Brain imaging shows that obsessive compulsive disorder is associated with functional hyperactivity of the caudate nucleus, a structure buried beneath the cerebral cortex.<sup>13</sup> Some researchers claim that the caudate is part of a subcortical circuit that acts to screen out superfluous thoughts and impulses. The subcortical circuit of obsessive compulsive disorder patients malfunctions, allowing the repetitive thoughts to reach the cortex and intrude themselves into one's conscious awareness. In addition, patients with obsessive-compulsive disorder have altered serotonic function compared with normal controls.<sup>14</sup>

It is now increasingly recognized that successful cognitive therapy and successful pharmacological treatment produce similar changes in the brains of patients with obsessive-compulsive disorder and other disorders. For example, a study by Dr. Lewis Baxter at the UCLA School of Medicine examined PET scans of patients with obsessive-compulsive disorder who responded to either a reuptake inhibitor like Prozac or cognitive behavior therapy after a ten-week period.<sup>15</sup> Both

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9. UNITED STATES CONVENTION, INC., THE COMPLETE DRUG REFERENCE 580 (1991).

10. Michael D. Tomatz, *Prozac: Is it the Next Rising Giant in Products Liability?*, 12 REV. LITIG. 704, 705 (1993).

11. Tomatz, *supra* note 10.

12. See Alex Berenson, *Trial Lawyers Are Now Focusing On Lawsuits Against Drug Makers*, N.Y. TIMES, May 18, 2003, at A1.

13. *Id.*

14. *Id.*

15. Richard A. Friedman, *Like Drugs, Talk Therapy Can Change Brain Chemistry*, N.Y. TIMES, Aug. 27, 2002, at F5.

patient groups showed virtually identical changes in their brains, namely decreases in the activities of the caudate nuclei.

Studies of patients with depression, reported in *The Archives of General Psychiatry*, showed similar results.<sup>16</sup> Two studies compared the effects of interpersonal psychotherapy with an antidepressant on brain function, as observed in PET scans. In one study, one group of depressed patients received interpersonal therapy, a short-term talk treatment that focused on the effects of social relationships and major life events on mood. Another group of depressed patients received an SSRI, Paxil, in a twelve-week trial. The depressed patients who responded to either treatment had nearly identical changes in the abnormally high activity seen in the prefrontal cortex before treatment.<sup>17</sup> In the second study, one group of depressed patients received interpersonal therapy and another group received Effexor, an antidepressant that enhances both serotonin and norepinephrine, and there were similar, although not identical results.<sup>18</sup>

Based on these and other similar studies, the question arises that if cognitive therapy, which focuses on changing distorted patterns of thinking, results in the enhancement of neurotransmitter serotonin, whose activity is often abnormal in people with obsessive-compulsive disorder and depression, then why not bypass such therapy altogether and achieve the “same” result, that is, the same changes toward normal brain functioning, by pharmacological means?<sup>19</sup>

The answer can be seen in the statistics: Last year over 15 million prescriptions were written for the two leading antipsychotic drugs, Zyprexa and Risperdal.<sup>20</sup> “National sales of antipsychotic medications reached \$6.4 billion in 2002, making them the fourth-highest-selling

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16. *Id.*

17. *Id.*

18. *Id.* This second study showed that patients “with interpersonal therapy but not Effexor also had activation of a brain area called the cingulate gyrus, which responds to serotonin in the brain and has a role in regulating mood.” *Id.*

19. The work of Dr. Eric Kandel, a Nobel Prize-winning psychiatrist and neurobiologist, showed that, with respect to the well-mapped nervous system of sea slugs, learning leads to the production of new proteins and, in turn, to the remodeling of neurons. Sea slugs exposed to the controlled-learning condition that produced long-term memory ended up with double the number of neuronal connections as the untrained animals. The implication of this and similar studies for humans is that learning literally changes the structure and function of the brain. *Id.*

20. See Erica Goode, *Leading Drugs for Psychosis Come Under New Scrutiny*, N.Y. TIMES, May 20, 2003, at A1.

drugs, behind cholesterol-lowering drugs, ulcer drugs and antidepressants . . . .”<sup>21</sup>

### III. WHAT IS THE TRUTH REGARDING SIDE EFFECTS OF ANTIDEPRESSANTS?

The maxim *primum non nocere* is usually applicable to the physician-patient relationship where the harms to be avoided are side effects, complications, or other adverse medical events that could involve damage or injury that are more or less directly attributable to medical acts.

Some of the nation’s leading trial lawyers are sponsoring complicated and well-financed plaintiffs’ suits against drug manufacturers, claiming that the companies have hidden the addictive dangers and side effects of antidepressant drugs.<sup>22</sup> Lawyers involved in current litigation claim that pretrial discovery reveals that some companies have hidden the serious risks of not only psychotropic medications, but of such popular drugs as Baycol, a cholesterol-lowering drug.<sup>23</sup>

Researchers are increasingly questioning whether antidepressants are as effective or as benign as originally advertised, and whether the benefits of these drugs are outweighed by their side effects. There is a growing consensus that serious side effects are commonplace, particularly in the form of Type II and Type I diabetes, hyperglycemia, and excessive weight gain.<sup>24</sup>

The fact that a drug is approved for marketing by the FDA does not in fact mean that the drug is truly safe and efficacious, but simply that the drug meets minimal standards addressed by the FDA. Often the evidence of side effects emerges well after a drug enters the marketplace. The reporting of side effects after a drug is marketed is only tentative because it is voluntary on the part of doctors, making it hard to know what the true numbers are. According to the FDA, the reports it receives on a drug’s side effects after a drug is marketed represent perhaps ten percent of the actual number of adverse reactions.<sup>25</sup>

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21. *Id.*

22. *See* Alex Berenson, *supra* note 12.

23. *See id.*

24. *See id.* In Japan and Europe some drugs, including Zyprexa and Seroquel, already carry warning labels about the associated risk of diabetes. *See id.*

25. *See* Erica Goode, *supra* note 20.

The Supreme Court has held that the regulation of product safety in products liability cases is a matter of state prerogative, so that a drug company's approval by the FDA is not dispositive of any legal issues pertaining to products liability.<sup>26</sup>

#### A. Side Effects Admitted by Drug Manufacturers

The list of side effects admitted by the drug manufacturers is staggering. For example, Eli Lilly's warnings indicate a range of side effects including the development of restlessness, gritting of teeth, tremors, decreased sexual interest, seizures, and more. Under the "PRECAUTIONS" section of the company's description of Prozac on its website, insomnia was reported by twelve percent to thirty percent of patients, depending on whether they were taking the drug for depression, obsessive compulsive disorder, or bulimia; and altered appetite and weight, including significant weight loss, was noted particularly in underweight depressed or bulimic patients, ranging from eleven percent to seventeen percent, depending on the condition for which the patient was being treated. Activation of mania/hypomania as well as seizures was noted in only 0.1% to 0.2% of patients.<sup>27</sup>

Additional side effects, not mentioned in the company's literature, are nonetheless well documented. It is well established that "prolonged treatment with any of the classes of antidepressants causes changes in brain tissue, including a decreased number of receptors for" serotonin.<sup>28</sup> Some theorists claim that it is this deterioration of brain cells, not the drug itself, which may actually result in an antidepressant effect.<sup>29</sup> In addition, a recent study raises the possibility that even some of the newer psychiatric drugs are linked to pancreatitis.<sup>30</sup>

Various lawsuits claim that Lilly intentionally marketed a high dosage of Prozac. "[D]uring the clinical trials, Lilly scientists proposed

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26. *Blowers v. Eli Lilly & Co.*, No. CV00 00008 ACK FIY ¶27 (D. Haw. filed), available at [www.justiceseekers.com/files/NLPP00000/013.pdf](http://www.justiceseekers.com/files/NLPP00000/013.pdf) (last visited Feb. 8, 2004) [hereinafter *Blowers Complaint*].

27. ELI LILLY & CO., PROZAC DESCRIPTION 9-10, at <http://pi.lilly.com/prozac.pdf> (last visited Feb. 8, 2004) [hereinafter PROZAC DESCRIPTION].

28. Cathrine M. Vale, *The Rise and Fall of Prozac: Products Liability Cases and "The Prozac Defense" in Criminal Litigation*, 12 ST. LOUIS U. PUB. L. REV. 525, 528 (1993); see O.S. RAY & CHARLES KSIR, *DRUGS, SOCIETY & HUMAN BEHAVIOR* (6th ed. 1993).

29. Vale, *supra* note 28, at 528.

30. See Goode, *supra* note 20.



a 5 or 10 mg dose regimen [of Prozac], but they were countermanded by the CEO of the company.”<sup>31</sup> Thus, the company, in its fervor to produce a best seller, marketed a twenty milligram, “one size-fits-all” pill so that prescribing physicians would not have to worry about dose selection and so that patients would get a “quicker hit.”<sup>32</sup> One of the concerns of this large dose is that some individuals simply do not metabolize Prozac as well most people do, and the rapid accumulation of Prozac in the body can exacerbate side effects.<sup>33</sup> Later, Lilly manufactured a ten milligram pill, but by that time the twenty milligram dose had been established as the “standard” dose for physicians to prescribe.<sup>34</sup> The significance of this is that adverse drug reactions are generally dose related.<sup>35</sup> Moreover, this plays into the hands of critics who deride a trend in psychiatry to over-medicalize, and to invent new categories of mental illness: “This has led to the risk of inappropriate medicalization, with associated abuse of drug treatment so as to achieve societal control.”<sup>36</sup> Lilly could have manufactured a lower, safer dose in a “once a week” design, something that appeared to be effective in a Lilly-sponsored trial in the United Kingdom.<sup>37</sup> Lilly, however, did not start marketing a once-a-week Prozac until its patent rights had come to a close and other manufacturers were poised to market a generic formulation of fluoxetine hydrochloride.<sup>38</sup>

### *B. Side Effects Reported by Anecdotal Evidence and Scientific Journals*

Anecdotal evidence, not acknowledged by pharmaceutical firms, as well as studies in peer review science journals, also point to a host of additional side effects associated with the use of SSRIs. Such anecdotal evidence consists of reports of mind racing, inability to

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31. Cole v. Eli Lilly & Co., No. 02-2484-DV ¶ 13 (W.D. Tenn. Filed June 2002), available at [www.justiceseekers.com/files/NLP00000/060.pdf](http://www.justiceseekers.com/files/NLP00000/060.pdf) (last visited Feb. 8, 2004) [hereinafter Cole Complaint].

32. *Id.*

33. Blowers Complaint, *supra* note 26, at ¶20.

34. *See id.*

35. *See id.* at ¶15.

36. PAUL BROWN, *Ethical Aspects of Drug Treatment in PSYCHIATRIC ETHICS* 167, 171 (Sidney Bloch & Paul Chodoff eds., 2d ed. 1991).

37. Cole Complaint, *supra* note 31, ¶14.

38. *Id.*

control thoughts, panic attacks, hot surges, nightmares, lack of empathetic feelings or emotions, feelings like being a zombie, numbness in limbs, dizziness, feeling disconnected from others, heart palpitations, uncontrollable flashes of memories and images from the past, agoraphobia, feeling drugged out, feeling urges to jump out of fast moving cars, extreme head pain, increased depression, nose bleeds, loss of sex drive, memory loss, sudden and excessive weight gain, hating people, not wanting to be around people, tremors, sudden jerky movements of muscles, inability to focus or concentrate, breathing difficulty, uncontrollable bouts of anger, self-mutilation, and much more.<sup>39</sup> In addition, the antidepressant Serzone, which has been banned in Europe, is now the subject of a campaign by a consumer advocacy group known as Public Citizen, to remove it from sale in the United States because of cases of deadly liver failure among users of the drug.<sup>40</sup> A new analysis of the FDA Adverse Event Reports Database found that from April 1, 2002, through May 12, 2003, there were thirty-three additional reports of liver failure – including nine deaths – for a total of fifty-five patients with liver failure.<sup>41</sup> The Canadian government has announced that it has now banned the drug.<sup>42</sup>

A 1998 article in the *Journal of Psychopharmacology* reported that when taken in tandem with other substances that increase serotonergic activity in the brain, Prozac can lead to a condition called serotonin syndrome, which is characterized by cognitive behavioral changes (confusion, hypomania, and agitation) as well as delusions and hallucinations.<sup>43</sup> “Neurological disorders including disfiguring facial and whole body tics, indicating potential brain damage, are an increasing concern with patients on the drugs. . . . With related drugs targeting serotonin, there is evidence that they may effect a ‘chemical lobotomy’ by destroying the nerve endings that they target in the

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39. See Real Side Effects of SSRI's, at <http://www.prozactruth.com/sideeffects.htm> (last visited Feb. 8, 2004).

40. See Associated Press, *Testimony on Antidepressant*, N.Y. TIMES, Oct. 30, 2003, at A25.

41. See Public Citizen Renews Call to Ban Antidepressant Serzone; Canadian Ban, New Data Strengthen Case, available at [www.citizen.org/pressroom/release.cfm?ID=1567](http://www.citizen.org/pressroom/release.cfm?ID=1567) (last visited Feb. 8, 2004).

42. See *id.*

43. Roger M. Lane, *SSRI-Induced Extraphramidal Side-effects and Akathisia: Implications for Treatment*, 12 J. PSYCHOPHARMACOLOGY 192, 203 (1998).

brain.”<sup>44</sup> Peter Breggin, M.D., a well-known critic of SSRIs, says of these minor tranquilizers, “As with most psychiatric drugs, the use of the medication eventually causes an increase of the very symptoms that the drug is supposed to ameliorate . . . .”<sup>45</sup>

Prozac and other SSRIs, which the psychiatric profession initially prescribed for symptoms of depression, can often create a worsening of depression. “In a seemingly paradoxical effect, antidepressants can cause or worsen depression. In controlled clinical trials for Prozac . . . depressed patients taking Prozac attempted suicide more frequently than depressed patients taking placebo (sugar pill) or older antidepressants.”<sup>46</sup> It has also been noted that one of the effects that Prozac has on a person’s mood is to diminish one’s sense of rejection, sensitivity, and vulnerability; as well as enhancement of hedonistic behavior. These traits, if multiplied on a collective level could depersonalize society so that people will be motivated only by self-interest and become disconnected from a larger sense of community.

The suffering that patients might feel with depression or with other disabling symptoms “cannot be dulled without harming other functions such as concentration, alertness, sensitivity, and self-awareness.”<sup>47</sup> The authors of one study say: “Do not let anyone pressure you into starting or continuing psychiatric drugs. As a competent adult, you have the ethical and legal right to make your own decisions about taking psychiatric drugs.”<sup>48</sup>

The July 15, 2002 *Newsweek* magazine reported that a new study by University of Connecticut psychologist Irving Kirsch titled “The Emperor’s New Drugs” found that antidepressant drugs “may have no meaningful pharmacological effect at all.”<sup>49</sup> Kirsch pooled data from thirty-eight studies on six antidepressant drugs approved by the FDA (Prozac, Zoloft, Paxil, Serzone, Celexa, and Effexor) and found “that people who got placebos fared almost as well as those getting real drugs.”<sup>50</sup> He found that on the fifty-point Hamilton Depression Scale,

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44. JOSEPH GLENMULLEN, PROZAC BACKLASH: OVERCOMING THE DANGERS OF PROZAC, ZOLOFT, PAXIL, AND OTHER ANTIDEPRESSANTS WITH SAFE, EFFECTIVE ALTERNATIVES 8 (2000).

45. PETER BREGGIN, TOXIC PSYCHIATRY 246 (1991).

46. *Id.*

47. *Id.* at 36.

48. PETER R. BREGGIN, M.D. and DAVID COHEN, Ph.D., *Your Drug May Be Your Problem: How and Why to Stop Taking Psychiatric Drugs* 29 (1999).

49. David Noonan & Geoffrey Cowley, *Prozac vs. Placebos*, NEWSWEEK, July 15, 2002, at 48-49.

50. *Id.*

people getting real drugs improved ten points, while people getting placebos improved eight points. The article quotes clinical psychologist David Antonuccio of the University of Nevada School of Medicine as saying, "One day we may look back and marvel at the stroke of marketing genius that led to calling these medications antidepressants in the first place."<sup>51</sup> In fact, as early as 1994 *Newsweek* had already reported that "[Prozac] . . . and its chemical cousins Zoloft and Paxil are no more effective than older treatments for depression."<sup>52</sup>

The author of *Listening to Prozac*, Peter D. Kramer, who is now a clinical professor of psychiatry at Brown University, said in a letter to the *New York Times*:

[Your article] may give the misimpression that my 1993 book, "Listening to Prozac," claimed that the new antidepressants were miracle drugs. In fact, I wrote that Prozac was no more, and perhaps less, effective in treating major depression than prior medications. The book was early to identify Prozac's undesirable effects, including 'burnout' and sexual dysfunction. I argued that the theories of brain functioning that led to the development of Prozac must be wrong or incomplete.<sup>53</sup>

A recent article in *Barron's* reported that "Antidepressant sales in the U.S. jumped to \$12.5 billion in 2001 from \$1.5 billion in 1991, making them the largest profit driver for the pharmaceutical industry in the 1990s" and "[b]etween 1991 and 2001, global sales of antidepression drugs rose ten-fold, to over \$11 billion, making this sector the drug industry's chief profit driver in the decade."<sup>54</sup> The article cited Forrest Laboratories, which got sixty-eight percent of its \$1.6 billion in revenue in 2001 from its new antidepressant, Celexa. The article stated, "Paxil, the No. 1 drug on the market . . . brought in \$2.7 billion in revenues last year."<sup>55</sup> The article goes on to say, "Depression is caused by an imbalance of chemicals in the brain," which is asserted as a claim without argument.<sup>56</sup> Then the article claims, inconsistently:

Ironically, clinicians still don't understand exactly how these drugs work. For while they increase the levels of serotonin in

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51. *Id.*

52. Geoffrey Cowley, *The Culture of Prozac*, NEWSWEEK, Feb. 7, 1994, at 41.

53. Peter R. Breggin, *Fighting the Darkness in the Mind*, N.Y. TIMES, July 7, 2002, §4, at 8.

54. Jay Palmer, *After the Boom, No Reason to Smile*, BARRON'S, May 20, 2002, at 25-26.

55. *Id.*

56. *Id.*

the brain very quickly, they can take three to six weeks to kick in and start lifting depression. . . . What's more, it's a common finding that between 30% and 50% of patients taking any one of the new antidepressants fails to get any benefit from that particular drug. They must try a second, and maybe even a third, before they find one that works.<sup>57</sup>

*C. Side Effects That Have Become Separate Mental Syndromes Listed in the DSM-IV-TR*

The *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV-TR), published by the American Psychiatric Association, includes several syndromes that are neuroleptic-induced, that is, side effects that develop within a few days of starting or rapidly increasing the dose of neuroleptic medications.<sup>58</sup> Neuroleptic medications are defined as antipsychotropic drugs as well as major tranquilizers.<sup>59</sup> A large number of drugs are classified as neuroleptic, including numerous antidepressants such as Prozac, Luvox, Effexor, Xanax, and numerous other drugs.<sup>60</sup> These neuroleptic drugs are known to induce detailed side effects that are serious enough that the American Psychiatric Association has seen fit to specify these side effects as separate syndromes under the DSM-IV-TR. In other words, the psychiatric community is sufficiently familiar with the side effects of antidepressant drugs so that they have defined separate mental syndromes that are caused by the very drugs prescribed for the "cure" of other mental syndromes. Bizarre as it seems, the American Psychiatric Association has decided to classify the side effects of taking various psychiatric drugs as separate mental syndromes in their own right. One of the results of classifying the side effects of psychiatric drugs as separate mental syndromes is this: These side effects, constituting separate mental syndromes, may be treated as further symptoms that merit further treatment to counteract the drug-induced symptoms - with further drugs!

I will briefly discuss these well-established side effects, which as mentioned have become separate mental syndromes in their own right.

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57. *Id.*

58. See, e.g., AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS § 333.7 (4<sup>th</sup> ed. Text rev. 2000) [hereinafter DSM-IV-TR].

59. See COMPREHENSIVE HANDBOOK OF PSYCHOPATHOLOGY 804 (Patricia B. Sutker & Henry E. Adams eds., 3d ed. 2001).

60. See *id.* at 805, tbl. 3.

These side effects, known as extrapyramidal effects, result from dopamine blockade, and are divided into four major categories:

1. Neuroleptic-induced Acute Dystonia<sup>61</sup> occurs within seven days after administering the drug. This involves abnormal postures or muscle spasms that develop in association with use of the drug. Symptoms include abnormal positioning of the head and neck, spasms of the jaw muscles, impaired swallowing, speaking, or breathing (potentially life-threatening), and thickened or slurred speech. Fear and anxiety often accompany the onset of this dystonia. Patients often mistakenly regard the symptoms as part of their mental disorder.

2. Neuroleptic-Induced Acute Akathisia<sup>62</sup> is a very unpleasant sensation of restlessness, resulting in an inability to stay still, characterized by fidgety movements, swinging of the legs while seated, pacing to relieve restlessness, the inability to stand still for at least several minutes, and a sense of inner restlessness. SSRI-induced akathisia is "an internal sensation of agitation or discomfort that drives a person to move about, and also to lose impulse control. During akathisia, the inner sense of agitation includes many unusual physical feelings such as electricity in the head or body."<sup>63</sup> Symptoms can occur within four weeks of initiating the drug or increasing the dose, or following the reduction or withdrawal of the medication. The DSM-IV-TR says that the subjective distress can be severe enough to result in patients increasing their medication dose, or to result in aggression or suicide attempts.<sup>64</sup> The symptoms of akathisia range from twenty-five percent to seventy-five percent in patients taking neuroleptic drugs. These symptoms persist for as long as the medication is continued, and can persist after the drugs are stopped. "Serotonin-specific reuptake inhibitor antidepressant medications may produce akathisia that appears to be identical in phenomenology and treatment response to Neuroleptic-Induced Acute Akathisia."<sup>65</sup> Some studies indicate that some of the newer drugs carry a lower risk of tardive dyskinesia, but other studies claim that overall, side effects are about the same.<sup>66</sup> A study financed by the British government and published in the British Medical Journal in 2000, claimed that there was no

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61. See DSM-IV-TR, *supra* note 58, § 333.7.

62. See *id.* § 333.99.

63. Peter R. Breggin, *Paxil Withdrawal Suit Resolved*, in PSYCHIATRIC DRUG FACTS, at <http://www.breggin.com/paxilwithdrawalsuit1.html> (last visited Feb. 8, 2004) [hereinafter *Paxil Withdrawal Suit Resolved*].

64. See DSM-IV-TR, *supra* note 58, § 333.99.

65. *Id.*

66. See *Paxil Withdrawal Suit Resolved*, *supra* note 63.

difference in effectiveness between the newer generation of antipsychotic drugs and older drugs.<sup>67</sup>

3. Neuroleptic-Induced Tardive Dyskinesia<sup>68</sup> involves abnormal, involuntary movements of the tongue, jaw, trunk, or extremities as side effects of neuroleptic medication. The symptoms can occur both at the onset of taking the medication or with the withdrawal of the medication. The symptoms are worsened by stimulants and emotional distress. Psychiatrists are advised that the symptoms can be reduced by “increased doses of neuroleptics or sedatives.”<sup>69</sup> About twenty percent to thirty percent of patients are subject to these symptoms. With older patients, the norm is about fifty percent.

4. Medication-Induced Postural Tremor<sup>70</sup> is a postural tremor developed in association with the use of antidepressants, other neuroleptic medications, and other drugs. The tremor involves a regular, rhythmic oscillation, most commonly of the hands and fingers, head, mouth, or tongue, with a frequency of eight and twelve cycles per second.

In addition, the DSM-IV-TR lists a disorder known as Substance-Induced Anxiety Disorder,<sup>71</sup> which involves anxiety symptoms evoked by various medications, including antidepressant drugs. Symptoms under this disorder include panic attacks and obsessions or compulsions, and the “disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.”<sup>72</sup>

There is also what is known as SSRI-induced obsessive-compulsive behavior that motivates violence toward oneself or others.<sup>73</sup>

Thus, the DSM-IV-TR directly acknowledges a multiplicity of side effects serious enough to warrant separate categories of discussion in the manual, while the warnings that accompany the packaging of these drugs fail to provide this information. Many doctors do not realize that the toxic side effects of SSRIs can surface just after the first or second dose, while the “therapeutic effect” of any antidepressant usually takes several weeks or more to kick in.<sup>74</sup>

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67. *See id.*

68. *See DSM-IV-TR, supra* note 55, § 333.82.

69. *Id.* (emphasis added).

70. *Id.* § 333.1.

71. *Id.* at 479.

72. *Id.* at 483.

73. *See Paxil Withdrawal Suit Resolved, supra* note 63.

74. *Id.*

#### D. Side Effects Associated With Withdrawing from the Drugs

In addition to side effects of the kinds discussed above, there is a separate type of side effect associated with withdrawal from the use of SSRIs. Among the lawsuits against drug manufacturers of Prozac and other SSRIs are allegations that the drug companies failed to warn the public about the dangers of withdrawing from antidepressant drugs. According to a growing consensus of medical experts, all of the SSRIs can cause serious withdrawal reactions. A common mantra concerning psychiatric drugs is this: "All psychiatric drugs can cause problems during withdrawal,"<sup>75</sup> and the longer a patient takes a psychiatric drug, the more difficult withdrawal will be. The earliest mention of the dangers of SSRI withdrawal appear to have been expressed by Peter R. Breggin, M.D., in his book, *Talking Back to Prozac*,<sup>76</sup> and in two more recent books, *Brain-Disabling Treatments in Psychiatry*<sup>77</sup> and *The Antidepressant Fact Book*.<sup>78</sup>

Paxil, because of its intense impact and short duration of action, causes the most severe withdrawal reactions.<sup>79</sup> In December 2001, most likely in response to a pending settlement of a California lawsuit, Glaxo SmithKline revised its label for Paxil with a specific mention of the danger of Paxil's withdrawal reactions.<sup>80</sup> The revised label refers to "discontinuation" rather than "withdrawal" symptoms. Discontinuation is an industry euphemism for withdrawal that avoids the negative connotations associated with addiction, dependency, or withdrawal syndrome.<sup>81</sup> "By using the term discontinuation instead of withdrawal, the drug company obscures the potential severity of these symptoms and their tendency to force patients to continue taking the drug."<sup>82</sup> Withdrawal symptoms of SSRIs include abnormal dreams, paresthesia (abnormal sensations), sensory disturbances such as electric shock sensations, agitation, anxiety, nausea, sweating, painful

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75. BREGGIN & COHEN, *supra* note 48, at 16.

76. See generally PETER R. BREGGIN, M.D. & GINGER BREGGIN, *TALKING BACK TO PROZAC* (1994).

77. See generally PETER R. BREGGIN, M.D., *BRAIN-DISABLING TREATMENTS IN PSYCHIATRY: DRUGS, ELECTROSHOCK AND THE ROLE OF THE FDA* (1997).

78. See generally PETER R. BREGGIN, M.D., *THE ANTIDEPRESSANT FACT BOOK* (2001).

79. See *Paxil Withdrawal Suit Resolved*, *supra* note 63.

80. *Id.*

81. *Id.*

82. *Id.*



internal sensations, various manifestations of emotional distress, and dizziness.<sup>83</sup> Of particular concern are the withdrawal symptoms of anxiety and agitation, as these can contribute to aggressive, violent, or suicidal behavior.

Many more people are taking prescription drugs than used to be the case. No medicine is completely safe for everyone. Even the safest drugs have side effects. Because clinical trials for new drugs are conducted on only a few thousand subjects, the tests do not always discover rare but danger side effects that might affect one in a million users. Generally, the number of reported cases of serious side effects is relatively small. Quite plausibly, drug makers may find it strategic to introduce a “new generation” of psychotropic drugs, claiming some improvement, just in time to accommodate the fact that the patent on the older formula is about to expire.

#### IV. THE RISKS ASSOCIATED WITH SSRI USE BY CHILDREN

The risks become a more pressing issue when SSRIs are prescribed for children.

The number of children and adolescents who take a wide range of psychiatric drugs more than doubled between 1987 and 1996, according to researchers at the University of Maryland who studied 900,000 children and adolescents.<sup>84</sup> According to the study, the most commonly prescribed psychiatric drugs for children are antidepressants and Ritalin (for attention deficit disorder).<sup>85</sup> In addition, the drug clonidine is often prescribed for children as an antihypertensive for the insomnia produced by Ritalin or other stimulants.<sup>86</sup> Other conditions for which pediatricians and child psychiatrists are increasingly turning to pharmacology include severe anxiety, obsessive disorder, manic depression, and other conditions.<sup>87</sup> Earlier this year, the FDA approved Prozac to treat depression in children from ages seven to seventeen.<sup>88</sup> The problem with this trend is

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83. *Id.*

84. Erica Goode, *Study Finds Jump in Children Taking Psychiatric Drugs*, N.Y. TIMES, Jan. 14, 2003, at A21.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

that little research is available to show the long-term effects of psychiatric drugs on children, and this concern is exacerbated by the fact that animal studies suggest that some psychiatric drugs have lasting effects on the brain when given before puberty.<sup>89</sup>

Recently, British drug regulators sent a letter to doctors and other health care professionals advising against the use of all antidepressants except Prozac for the treatment of depressed children under eighteen.<sup>90</sup> The government regulators contend that the safety and effectiveness of SSRIs indicates that their benefits do not outweigh their potential risks.<sup>91</sup>

Moreover, little research is available to show whether psychiatric drugs are being prescribed in a responsible manner, or whether they are being over-prescribed, given that health insurance companies are known to be reluctant to pay for “talk” therapy and other non-medication treatments for the amelioration or cure of mental illness symptoms.<sup>92</sup> Finally, there is little guidance in establishing the effective doses and duration of psychiatric medications for children.<sup>93</sup> I believe that it is a disturbing medical trend to medicate children with serious, or perhaps not-so-serious, mental health needs, particularly in the face of limited scientific and clinical data that address the potential lasting impacts on the brain of children.

There has been a 1,100% increase in Attention Deficit Hyperactivity Disorder (ADHD) diagnoses in American children between 1987 and 2001.<sup>94</sup> Many claim that it is invalid to classify ADHD as a mental illness in the first place. For example, the Commission on Human

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89. *Id.*

90. See Erica Goode, *British Warning on Antidepressant Use for Youth*, N.Y. TIMES, Dec. 11, 2003, at A1. For a summary of the British government drug agency's findings, see MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY [MHRA], SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIs): OVERVIEW OF REGULATORY STATUS AND CSM ADVICE RELATING TO MAJOR DEPRESSIVE ORDER (MDD) IN CHILDREN AND ADOLESCENTS INCLUDING A SUMMARY OF AVAILABLE SAFETY AND EFFICACY DATA, available at [http://medicines.mhra.gov.uk/ourwork/monitorsafeequalmed/safetymessages/ssriooverview\\_101203.htm](http://medicines.mhra.gov.uk/ourwork/monitorsafeequalmed/safetymessages/ssriooverview_101203.htm) (last visited Feb. 8, 2004) [hereinafter MHRA].

91. See Goode, *supra* note 90, at A1; MHRA, *supra* note 90.

92. See Goode, *supra* note 90, at A1; MHRA, *supra* note 90.

93. See Goode, *supra* note 90, at A1; MHRA, *supra* note 90.

94. CITIZENS COMMISSION ON HUMAN RIGHTS INTERNATIONAL, CHILD PSYCHIATRY PUT ON NOTICE DUTCH COMMISSION FINDS PSYCHIATRIC CLAIM IS FALSE—ADHD IS NOT A BRAIN DISORDER, available at [http://www.prozactruth.com/add\\_adhd.htm](http://www.prozactruth.com/add_adhd.htm) (last visited Feb. 8, 2004).

Rights argues that it is fraudulent for psychiatrists to claim that ADHD is neurobiological.<sup>95</sup> The DSM-IV-TR itself declares that “it must be admitted that no definition adequately specifies precise boundaries for the concept of ‘mental disorder.’”<sup>96</sup> The DSM-IV-TR further admits that attention-deficit is a commonplace occurrence in *most people*, stating as follows: “Although most individuals have symptoms of both inattention and hyperactivity-impulsivity, there are some individuals in whom one or the other pattern is predominant.”<sup>97</sup> The psychiatric community admits that a diagnosis of ADHD is in effect not susceptible to scientific confirmation. The Associated Laboratory findings section states, “There are no laboratory tests that have been established as diagnostic in the clinical assessment of Attention-Deficit/Hyperactivity Disorder.”<sup>98</sup> The discussion further states:

It is very unusual for an individual to display the same level of dysfunction in all settings or within the same setting at all times. Symptoms typically worsen in situations that require sustained attention or mental effort or that lack intrinsic appeal or novelty (e.g., listening to classroom teachers, doing class assignments, listening to or reading lengthy materials, or working on monotonous, repetitive tasks). Signs of the disorder may be minimal or absent when the person is under very strict control, in a novel setting, is engaged in especially interesting activities, in a one-to-one situation (e.g., the clinician’s office), or while the person experiences frequent rewards for appropriate behavior.<sup>99</sup>

And the DSM-IV-TR discussion suggests that the “disorder” goes away as children mature:

As children mature, symptoms usually become less conspicuous. By late childhood and early adolescence, signs of excessive gross motor activity (e.g., excessive running and climbing, not remaining seated) are less common, and hyperactivity symptoms may be confined to fidgetiness or an inner feeling of jitteriness or restlessness.<sup>100</sup>

It seems to fly against common sense to claim that something is a mental disorder if the symptoms go away as the child matures. What are we to see next? Perhaps the next edition of the DSM will

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95. *Id.*

96. *See* DSM-IV-TR, *supra* note 58.

97. *Id.* at 80.

98. *Id.* at 81.

99. *Id.* at 79.

100. *Id.* at 81-82.

categorize the tendency of prepubescent boys' voices to undergo changes in tone as a mental syndrome, notwithstanding that they, too, "outgrow" the "symptoms." In light of the DSM-IV-TR's own admissions, it would seem to be a common sense matter to place children who really have a problem with attention-deficit and hyperactivity in settings where they are least likely to manifest the "disorder," and to give them material that has an intrinsic appeal rather than material that lacks intrinsic appeal in their daily activities. Moreover, if children display symptoms of hyperactivity that becomes a problem for others around them, this may plausibly be, very simply put, an occasion to exercise proper control over them by parents and teachers. The signs of the "disorder" may go away when children are under appropriate classroom discipline or are engaged in especially interesting activities.

#### V. ARE SSRIs SIGNIFICANTLY MORE EFFECTIVE THAN PLACEBOS?

It is one thing to examine whether a drug is safe, and an entirely separate matter to determine whether a drug is therapeutically effective. Some scientists think that the efficacy of antidepressant drugs is extremely dubious, and that "no significant progress in the pharmacological treatment of depression has occurred since the introduction of imipramine in 1958."<sup>101</sup> This notion is echoed by Peter Breggin, M.D., who famously asserts:

The most fundamental point to be made about the most frequently used major antidepressants is that they have no specifically antidepressant effect. Like the major tranquilizers to which they are so closely related, they are highly neurotoxic and brain disabling, and achieve their impact through the disruption of normal brain function. . . . Only the "clinical opinion" of drug advocates supports any antidepressant effect.<sup>102</sup>

Even lithium, which is said to be helpful for people whose mood repeatedly changes from manic to depressive and back again, and widely used psychiatric drugs called minor tranquilizers, including Valium, Librium, Xanax, and Halcion, are supposed to provide a calming, anti-anxiety, panic-suppression remedy, but many regard

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101. RICHARD ABRAMS, M.D., *ELECTROCONVULSIVE THERAPY* 7 (1988).

102. PETER R. BREGGIN, M.D., *PSYCHIATRIC DRUGS: HAZARDS TO THE BRAIN* 160, 184 (1983).

them to be ineffective and dangerous. A 1993 *Consumer Reports* article stated that these so-called minor tranquilizers do not cure anything, but are principally brain-disabling drugs that produce in the majority of cases "memory loss, depression and paranoia."<sup>103</sup>

Many have questioned whether the taking of antidepressants is any better than taking a placebo. According to critics of antidepressant drugs, FDA studies on Prozac "underscored the drug's lack of effectiveness and recent analyses of literature indicate that antidepressants in general are no better than placebo."<sup>104</sup> In an article entitled *No Prescription for Happiness*, journalist Thomas Moore reviewed the FDA studies in connection with the approval of Prozac, and said:

Lilly [manufacturer of Prozac] had conducted 10 such clinical trials for Prozac, according to FDA records. However, in six of these trials no measurable overall difference could be detected between those treated with Prozac and those who got the placebo. . . . Failure to produce a measurable effect is a routine event in the testing of drugs for depression.<sup>105</sup>

While about sixty percent of patients report that they experience relief of their symptoms of depression, bulimia, and obsessive-compulsive disorder - the three main illnesses for which Prozac and other anti-depressant drugs are approved - a small but significant percentage of patients actually become worse on Prozac.<sup>106</sup>

In one study, researchers found that Zoloft, a commonly prescribed antidepressant, was only ten percent more effective than placebos for treatment of depression in children and teenagers, a margin deemed to be rather small.<sup>107</sup> A researcher involved in the findings said that the large number of subjects who improved while taking placebos "does seem to support the idea that children and adolescents may be more responsive to environmental effects."<sup>108</sup>

Another comment on the placebo effect is noted as follows:

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103. LAWRENCE STEVENS, J.D., PSYCHIATRIC DRUGS: CURE OR QUACKERY?, available at <http://www.antipsychiatry.org/drugs.htm> (last visited Feb. 8, 2004).

104. BREGGIN & BREGGIN, *supra* note 76, at 57.

105. Douglas A. Smith, *Book Review*, available at <http://www.antipsychiatry.org/br-pibp.htm> (last visited Feb. 8, 2004) (reviewing COLIN A. ROSS, M.D., & ALVIN PAM, PH.D. ET AL., PSEUDOSCIENCE IN BIOLOGICAL PSYCHIATRY (1995)).

106. Vale, *supra* note 28, at 525.

107. Erica Goode, *Researchers Find Zoloft, a Popular Antidepressant, to be Effective in Treating Children*, N.Y. TIMES, Aug. 27, 2003, at A18.

108. *Id.*

Despite a hugely successful promotional campaign by drug companies and biological psychiatry, the effectiveness of most or all psychiatric drugs remains difficult to demonstrate. The drugs often prove no more effective than sugar pills, or placebos - and to accomplish even these limited positive results, the clinical trials and data that they generate typically have to be statistically manipulated.<sup>109</sup>

According to some studies and anecdotal evidence, Prozac actually is claimed to be effective in the treatment of a number of disorders having nothing to do with depression, including body dysmorphic disorder, trichotillomania (pulling out of one's hair), writer's block, alcoholism, pathologic jealousy, attention deficit hyperactivity disorder, panic disorder, premenstrual tension, chronic pain, dementia, gambling, and fear of public speaking.<sup>110</sup> Does it not seem odd that a drug, originally approved as an antidepressant, has become a drug of choice for a wide variety of completely unrelated disorders? How could it be that a psychiatric drug designed for a specific treatment would be equally suited for such an array of disorders - unless in fact its effectiveness is the placebo effect?

The "biochemical imbalance" myth: There are various explanations of why placebos would be just as effective as drugs for "treating" certain symptoms. First, many disagree with the theory of the biological causation of mental illnesses. There is a growing movement to discredit the idea that depression or other mental disorders are the result of a biological abnormality or a "chemical imbalance," rather than being caused by events, environmental circumstances, or personal relationships that have no basis in the annals of science.<sup>111</sup> That is, many believe that the notion that numerous mental syndromes are neurobiological diseases or based on brain dysfunction is just false. Such critics argue that psychiatric disorders are caused by life experience rather than by the theoretical biological abnormalities that the pharmacology industry would want psychiatrists to believe. In *Pseudoscience in Biological Psychiatry*, the authors, Colin A. Ross, M.D. and Alvin Pam, Ph.D., claim that biological psychiatry, presently the dominant force within the psychiatric community, relies on a scientific methodology that is "sufficiently flawed as to call into doubt

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109. BREGGIN & COHEN, *supra* note 48, at 37.

110. Colleen Cebuliak, *Life as a Blonde: The Use of Prozac in the '90s*, 33 ALBERTA L. REV. 611, 612-613 (1995).

111. See LAWRENCE STEVENS, J.D., THE MYTH OF BIOLOGICAL DEPRESSION, available at <http://www.antipsychiatry.org/depressi.htm> (last visited Feb. 8, 2004).

the preponderance of its accepted findings . . . .”<sup>112</sup> In fact, the authors find that

[t]he history of biological psychiatry can be depicted as a tale of “promising” leads, closure on slender evidence, hyperbole as initial reception to new work, and ultimately unproductive results. . . . [F]ollowing about a century of effort, a harsh assessment would be that no substantive results have been tendered for the pathogenesis of any major psychiatric disorder.<sup>113</sup>

The authors claim that “biological psychiatry does not come close to meeting scientific standards,”<sup>114</sup> and that “[a]t the present time, there is no proof that biology causes schizophrenia, bipolar mood disorder, or any other functional mental disorder.”<sup>115</sup> The trouble with biological psychiatry is that the locus of blame for disturbed behavior is the body rather than the family, society, or other social conditions that give rise to pathologies. “This perspective lets the social surround escape unscathed from any blame or responsibility, no matter how much psychological disorder is in its midst.”<sup>116</sup>

The controversial belief in biological causation has spawned the growth of the pharmaceutical industry’s otherwise unjustifiable biological “treatments” for depression, based on the idea that unhappiness is caused by biological malfunction rather than by life experiences. Many claim that there is no convincing evidence that depression is *ever* biologically caused.<sup>117</sup> For example, in her book, *The Broken Brain: The Biological Revolution in Psychiatry*, University of Iowa psychiatry professor Nancy Andreasen, M.D., Ph.D., expresses her skepticism this way: “The older term *endogenous* implies that the depression ‘grows from within’ or is biologically caused, with the implication that unfortunate and painful events such as losing a job or lover cannot be considered contributing causes.”<sup>118</sup> A panel of experts assembled by the U.S. Congress Office of Technology Assessment in 1992 discredited the theory that depression is “caused” by lowered levels or abnormal use of the brain chemical serotonin, stating,

112. COLIN A. ROSS, M.D. & ALVIN PAM, PH.D., PSEUDOSCIENCE IN BIOLOGICAL PSYCHIATRY 8 (1999).

113. *Id.* at 42.

114. *Id.* at 69.

115. *Id.* at 90.

116. *Id.*

117. See STEVENS, *supra* note 111.

118. NANCY ANDREASEN, M.D., PH.D., THE BROKEN BRAIN: THE BIOLOGICAL REVOLUTION IN PSYCHIATRY 203 (1984).

“Currently, no clear evidence links abnormal serotonin receptor activity in neurotransmitter levels or for disruption of normal receptor activity.”<sup>119</sup>

Adding to the chorus of concern about the medicalization of mental disorders are Peter R. Breggin, M.D. and David Cohen, Ph.D., authors of *Your Drug May Be Your Problem: How and Why to Stop Taking Psychiatric Drugs*.<sup>120</sup> The authors claim that no matter what one’s “psychiatric problem” may be, whether depression, manic-depression, anxiety, or even schizophrenia, one is better off without psychiatric drugs. They claim:

No psychiatric drug has ever been tailored to a known biochemical derangement. . . . [N]o biochemical imbalances have ever been documented with certainty in association with any psychiatric diagnosis. The hunt goes on for these illusive imbalances; but their existence is pure speculation, inspired by those who advocate drugs.<sup>121</sup>

They further say:

Although medication advocates often speak with seeming confidence about how psychiatric drugs can correct biochemical imbalances in the brain, they are merely indulging in pure speculation. There’s little evidence for the existence of any such imbalances, and no way to demonstrate how drugs would affect them if they did exist.<sup>122</sup>

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Advocates of psychiatric drugs often claim that the medications improve learning and the ability to benefit from psychotherapy, but the contrary is true. There are no drugs that improve mental function, self-understanding, or human relations. Any drug that affects mental processes does so by impairing them.<sup>123</sup>

Critics also argue that no physical cause can be proven for today’s mental illnesses. The commonly prescribed psychiatric drugs appear to disable the brain in a generalized way. None of today’s psychiatric drugs have the sort of specificity for depression, for anxiety, or for obsessive-compulsive behavior that is often claimed for them. Rather, as critics point out, psychiatric drugs manifestly interfere with a normal biological function, to wit, normal neuroreceptor functioning, and take

119. *Id.* (citing UNITED STATES CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *THE BIOLOGY OF MENTAL DISORDERS* (1992))

120. BREGGIN & COHEN, *supra* note 48.

121. *Id.* at 35.

122. *Id.* at 33-34.

123. *Id.* at 97-98.



away from mental capabilities a patient would have in the absence of the drug.

Ross and Pam also claim that psychiatry is related to oppression: "Biological psychiatry redefines social deviance as a medical problem. By doing so, it transforms social norms, which are subjective and political, into medical norms, presumed to be objective and scientific. . . . Medicalization of social deviance allows us a pretense of humanitarianism" for coercive measures against people whose behavior "deviates from expectations based on the dominant social class's ideology and viewpoint."<sup>124</sup> The authors go on to say, "Psychiatry redefines a great deal of normal human behavior as medically deviant by pathologizing people who are socially marginal in any way."<sup>125</sup> Peter Breggin, M.D., claims, "When mental health professionals point to spurious genetic and biochemical causes" of depression, and prescribe drugs rather than fostering more authentic cures, "they encourage psychological helplessness and discourage personal and social growth" of the type that is crucial to lead a happy and meaningful life.<sup>126</sup> Dr. Breggin adds this:

Nothing has harmed the quality of individual life in modern society more than the misbegotten belief that human suffering is driven by biological and genetic causes and can be rectified by taking drugs or undergoing electroshock therapy. . . . If I wanted to ruin someone's life, I would convince the person that biological psychiatry is right - that relationships mean nothing, that choice is impossible, and that the mechanics of a broken brain reign over our emotions and conduct. If I wanted to impair an individual's capacity to create empathetic, loving relationships, I would prescribe psychiatric drugs, *all* of which blunt our highest psychological and spiritual functions.<sup>127</sup>

The unanimous bias of the pharmaceutical industry is that emotional states are assimilated into brain states; that is, the former are reducible

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124. ROSS & PAM, *supra* note 112, at 22. An example of this pertains to homosexuals, who, prior to 1974, were deemed socially marginal people when homosexuality was defined by the American Psychiatric Association as a mental disorder. Another example occurred in the Soviet Union, where political dissidents were famously relegated to mental hospitals and treated as schizophrenics because they opposed Communism.

125. *Id.* at 228.

126. Peter Breggin, M.D., *Another View: Talking Back to Prozac*, PSYCHOLOGY TODAY, July/Aug. 1994, at 72.

127. Peter R. Breggin, M.D., *Forward* to WILLIAM GLASSER, REALITY THERAPY IN ACTION xi (2000) (emphasis added).

to or dependent on the latter. Even if there were some truth to the idea that some biological condition is associated with depression, the question remains whether this is a cause or an effect of the depression. One brain-scan study found that simply asking normal people to imagine or recall a situation that would make them feel sad resulted in significant changes in blood flow to the brain.<sup>128</sup> In other words, research suggests that emotions cause biological changes in the brain rather than the other way around.

One of the reasons I think the biological cause of depression is so popular is that there are times when people are depressed for reasons that are not at all apparent. That is precisely what Freud suggested in his elucidation of the unconscious mind. Freud compared the mind to an iceberg, largely submerged and invisible, and claimed that the greater part of the mind is irrational and unconscious, and that this part is "more important in guiding our lives than the rational part, even though we deceive ourselves into believing it is the other way around."<sup>129</sup> Moreover, Freud did not believe it was possible to reduce human emotions to chemical or physiological causes. If people are given an enhanced sense of well-being through drugs, they will not be motivated to explore and tackle the source of their previous discontent. By promoting a distorted view of reality, Prozac in a real way distances people from reality. If a large segment of society is on Prozac or similar drugs, the very notion of "reality" will take on a different, surrealistic, aura.

Many scientists criticize the very notion of "normality," and whether and how the psychiatric community can scientifically categorize various symptoms as constituting mental illness. In the book, *Myths of Madness*, Don D. Jackson, M.D. says:

On that day when it is generally recognized that "normality" is a myth, that mankind does not divide into sane and insane, that mental disorder is not an intractable unalterable ogre unrelated to ordinary human nature, we will look with more optimism toward the future. We will recognize that man is fantastically adaptable (especially when he is given adequate opportunities) and that most people contribute something to the world. We

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128. ANDREASEN, *supra* note 118 (citing Jose V. Pardo, M.D., Ph.D. et al., *Neural Correlates of Self-Induced Dysphoria*, AM. J. PSYCHIATRY 713 (May 1993)).

129. See *id.* (citing ALICE KAHN LADAS ET AL., *THE G SPOT AND OTHER RECENT DISCOVERIES ABOUT HUMAN SEXUALITY* 6-7 (1982)).

will know that men and women, strangers or neighbors, are not “less normal” or “more inferior” than we are - just different.<sup>130</sup>

## VI. THE CONTROVERSY OVER WHETHER SSRIs ENTAIL SIDE EFFECTS THAT PRECIPITATE SUICIDE

In the early 1990s Eli Lilly faced over 200 lawsuits from people claiming that Prozac made them harm themselves or others.<sup>131</sup> The number of lawsuits has increased, with claims that the drug manufacturer knew for years that the drug poses an unreasonable risk of violent, homicidal, and suicidal behavior for a small but significant percentage of patients, but that it failed to conduct appropriate tests to generate the necessary scientific data regarding this linkage and has failed to warn of these dangers and/or to institute measures in order to ameliorate the risk.<sup>132</sup> Initially, the only acknowledged side effects stated by Lilly included “anxiety, diarrhea, drowsiness, headaches, increased sweating, and nausea.”<sup>133</sup> Lilly revised its Prozac literature in May of 1990 to inform physicians of the purported association of suicidal ideation and Prozac, while denying that there is such an association in fact.<sup>134</sup> Litigants have claimed that Lilly knew that there were at least one or two ways that the design of the chemical fluoxetine, the drug’s chief ingredient, “could have been modified to make [Prozac a safer drug], but that it chose not to pursue such reasonable alternative designs.”<sup>135</sup>

Until recently, the majority consensus of the scientific community was that there appeared to be “no definitive findings that Prozac results in the development of suicidal ideation or violence in those taking the drug.”<sup>136</sup> However, the suicide cases subject to litigation have a unique signature or profile, somewhat distinctive from that of

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130. DON D. JACKSON, M.D., MYTHS OF MADNESS: NEW FACTS FOR OLD FALLACIES 169 (1964).

131. See, e.g., Cole Complaint, *supra* note 31, ¶22 (citing “Privilege and Redaction Log” in the case of Forsyth v. Eli Lilly, Civil CV00-00401 (D. Haw. filed), available at <http://www.justiceseekers.com/files/NLPP00000/060.PDF>).

132. *Id.*

133. Tomatz, *supra* note 10, at 707.

134. See Anastasia Toufexis, *Warnings About a Miracle Drug: Reports of Suicide Attempts in Prozac Users Raise Doubts About the Popular Antidepressant*, TIME, July 30, 1990, at 54.

135. Cole Complaint, *supra* note 31, ¶2.

136. Vale, *supra* note 28, at 527.

the suicidality otherwise noted in depressed patients. The phenomenon has four distinctive attributes:

- (a) either *de novo* thinking about suicide or, an incremental or quantum increase in the severity of a patient's suicidality (like a progression from "passive" thoughts of suicide to an "active" suicidal plan or attempt);
- (b) an "obsessional" quality where the ideas about suicide "seem to intrude" into the person's mind;
- (c) the thoughts, attempt or suicidal act were of a violent nature; and
- (d) then, finally, the most difficult term to describe is that they were egodystonic--they were egodystonic and/or discord. [sic] They were not wanted --did not seem to fit with the rest of the ways that the individual patients were thinking, certainly not something they were truly planning to do . . . . Foreign to the person and also not a true intent of the person.<sup>137</sup>

The first postulation of suicidal ideation associated with Prozac was reported by Dr. Martin H. Teicher et al., who noted that six depressed patients who never before had suicidal ideation, developed intense and violent suicidal preoccupation at a mean of twenty-six days after treatment with Prozac commenced.<sup>138</sup> There was no evidence

that strong preexisting self-destructive urges were activated and energized by fluoxetine. No patient was actively suicidal at the time fluoxetine treatment began. Rather, all were hopeful and optimistic, and the strong obsessive suicidal thoughts emerged *de novo* after weeks or months of treatment. In four patients . . . , these thoughts were accompanied by abject acceptance and detachment. Two patients . . . tried to conceal their suicidal feelings and impulses and to continue fluoxetine treatment, believing that the drug would eventually enable them to successfully kill themselves!<sup>139</sup>

Dr. Teicher also was amazed at how violent the patients' suicidal ideations were:

Two patients fantasized, for the first time, about killing themselves with a gun . . . , and one patient . . . actually placed a loaded gun to her head. One patient . . . needed to be physically restrained to prevent self-mutilation. . . . [Another patient], who

137. Cole Complaint, *supra* note 31, at ¶ 9.

138. Martin H. Teicher et al., *Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment*, 147 AM. J. PSYCHIATRY 2, 207, 209 (1990).

139. *Id.* at 209.

had no prior suicidal thoughts, fantasized about killing himself in a gas explosion or a car crash.<sup>140</sup>

The Teicher study was criticized in subsequent publications.<sup>141</sup> Skeptics generally argued that for findings to be conclusive on the question of suicidal ideation, a double-blind, randomized trial design would be necessary.<sup>142</sup> At the same time, others have opined that the frequent development of akathisia reported in patients taking Prozac and other antidepressants could be implicated as the specific cause of new-onset suicidal ideation and violence.<sup>143</sup> And at present, over a decade after the Teicher study, there are numerous scientific studies and anecdotal reports that lend credence to the theory that Prozac and other SSRIs cause suicidal ideation and homicidal behavior.<sup>144</sup>

During the first testing of fluoxetine hydrochloride on animals in 1977, Lilly's scientists discovered that the drug suppressed deep sleep and hence suppressed rapid eye movement (REM) in the subject animals. But more alarmingly, Lilly's scientists wrote:

By the fourth day of drug treatment the cats receiving the larger doses, which had been friendly for years, began to growl and hiss. . . . After cessation of the drug treatment, the cats returned to their usual friendly behavior in a week or two; those on the higher doses recovering more slowly.<sup>145</sup>

Similar aggressive behavior was noted in dogs receiving high doses.<sup>146</sup>

In 1986, the German government rejected Lilly's application to market Prozac there, in part because of its evaluation of evidence that suggested the drug posed an increased risk of suicide in those who

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140. *Id.*

141. *See* Vale, *supra* note 28, at 534.

142. *Id.* (citing Charles M. Beasley, *Fluoxetine and Suicide: A Meta-Analysis of Controlled Trials of Treatment for Depression*, 303 *BRIT. MED. J.* 685 (1990)).

143. Vale, *supra* note 28, at 535 (citing R.A. King et al., *Emergence of Self-Destructive Phenomena in Children and Adolescents During Fluoxetine Treatment*, 30 *J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY* 179 (1991)); William C. Wirshing, *Fluoxetine, Akathisia, and Suicidality: Is There a Causal Connection?*, 49 *ARCHIVES GEN. PSYCHIATRY* 580 (1992).

144. *See* Eric W. Fine, M.D., *Selective Serotonin Reuptake Inhibitors (SSRIs) and Cases of Alleged Related Violence*, 23 *AM. J. FORENSIC PSYCHIATRY* 5 (2002) (concluding that cases involving Prozac-induced suicide and homicide cannot be ignored and that each individual case requires careful and comprehensive evaluation on its merits).

145. Cole Complaint, *supra* note 31, ¶ 15.

146. *Id.*

otherwise had no suicidal tendencies.<sup>147</sup> The question of whether Prozac causes suicide ideation came to public attention in the United States in a February 1990 article entitled "Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment," by Harvard psychiatrists Martin Teicher, Jonathan Cole and Nurse Carol Glod.<sup>148</sup>

According to critics of Prozac, Eli Lilly, in its zeal to produce a blockbuster drug, manipulated results of clinical trials by controlling the design of the studies and making public only positive data. For example, it has been documented that in the clinical trials, approximately 5.3% of patients dropped out because of side effects involving akathisia (a turmoil or state of agitation which, when drug induced, is accompanied with panic and an awareness of strange and unusual impulses that the affected individual does not ordinarily have)<sup>149</sup> or an incipient serotonin syndrome. In other words, the group of patients who experienced the most serious side effects dropped out of the trials and as a result their side effects were not reported in the study.<sup>150</sup> The FDA noted in a Memorandum dated November 13, 1994, "This Agency must inform Lilly early on that we have problems with their analysis because of the large number of dropouts."<sup>151</sup> Moreover, Lilly allowed clinicians conducting the trials to administer sedatives to other patients to mask side effects pertaining to violence or suicide ideation.<sup>152</sup> An FDA epidemiologist, Dr. David Graham, stated that "the firm's analysis of suicidality does not resolve the issue," and that "because of apparent large scale under reporting, the firm's analysis cannot be considered as proving that fluoxetine and violent behavior are unrelated."<sup>153</sup>

Many believe that the FDA did not receive a full picture of the available research in 1991 when the FDA examined the question of suicide ideation associated with Prozac. FDA procedures required Lilly to inform the agency of any concerns about Prozac raised by other national health authorities, but Lilly never told the FDA or the

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147. *Id.* at ¶ 11.

148. See Martin Teicher, Jonathan Cole & Carol Glod, *Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment*, 147 AM. J. PSYCHIATRY 2 (1990).

149. See Robert Lane, *SSRI-Induced Extraphramidal Side-effects and Akathisia: Implications for Treatment*, 12 J. OF PSYCHOPHARMACOLOGY 2 (1998).

150. See Blowers Complaint, *supra* note 26, at ¶ 9.

151. *Id.* at ¶ 28. Under the FDA's own analysis of its statistical system, there have been approximately 20,000 Prozac related suicides since 1987. *Id.* at ¶ 30.

152. See *id.* at ¶ 28.

153. *Id.*

expert panel that German regulators initially refused to approve Prozac's sale in 1986 because of concerns over a link with suicide.<sup>154</sup> German authorities had noted that Prozac seemed to have caused a substantial increase in suicide among patients using the drug.<sup>155</sup> Eventually, the drug was approved in Germany with a warning that physicians should consider using sedatives for patients at risk of suicide.<sup>156</sup> In the United States, no such warning is included in Prozac's literature, although the risk of suicidal ideation is listed among the drug's side effects.<sup>157</sup>

How SSRIs contribute to suicide ideation is not entirely clear, but some researchers suggest that one possibility is that the drugs produce restlessness, impulsiveness, agitation, or manic episodes – akathisia - in many patients that could lead to self-destructive behavior.

The questions regarding the safety of Paxil, Prozac, and Zoloft continue to be disturbing. In June 2003, British drug authorities reported that unpublished studies about Paxil show that it carries substantial risk of suicide ideation in teenagers and children.<sup>158</sup> The report said that nine studies of Paxil revealed 3.2 times the likelihood of suicidal thoughts or suicide attempts among teens and children given the drug compared to patients given a placebo.<sup>159</sup> This concern was echoed a week later by the Food and Drug Administration.<sup>160</sup> In addition, the studies found that Paxil was no more effective than a placebo in treating depression in youngsters. Since all the SSRIs act similarly in the body, these concerns about Paxil extend to the other antidepressant drugs.<sup>161</sup>

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154. Gardiner Harris, *Debate Resume on the Safety Of Depression's Wonder Drugs*, N.Y. TIMES, Aug. 7, 2003, at A1.

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.*

159. *See id.*

Even in adults, SSRIs have been found to offer only modest benefits. In about one-half of all adult tests, the drugs prove no more effective than placebos. . . . According to a survey in 2000 of studies used by the F.D.A. in approving the drugs, . . . on average, they reduce symptoms of depression by about 41 percent on a weekly used scale, compared to a 31 percent reduction among those taking placebos.

*See id.*

160. *Id.*

161. *Id.*

The threat of suicide in patients who take SSRIs was weighed and rejected by regulators in past years. The latest findings give fresh urgency to claims of plaintiffs' lawyers who assert that drug makers withheld evidence of the SSRIs' suicide risk from regulators.<sup>162</sup> Of the ten American members of an ad hoc FDA panel that had cleared the drugs from being a suicide risk in 1991, seven now say that the new information would prompt them to reconsider that decision.<sup>163</sup> One of the members, Dr. Jeffrey A. Lieberman, said, "In 1991, we said there wasn't sufficient evidence to support a link between these drugs and suicide. Now there is evidence, at least in children, and I wouldn't rule out that it's in adults, too."<sup>164</sup>

At the time of publication of this article, the FDA announced it was convening a panel to meet in February 2004 to re-examine the relationship between suicide and SSRIs.<sup>165</sup> The panel will consider whether the drugs should be prescribed to teenagers and children, whether warnings accompanying the drugs should be changed, and what studies should be conducted to determine if there really is a link between suicide in youngsters and the use of SSRIs.<sup>166</sup> In preparation for the meeting, the FDA is reviewing pediatric studies. Studies of Paxil showed that children taking the drug were more likely to attempt suicide than those taking placebos, and that Paxil did not improve symptoms of depression in the subjects who were studied.<sup>167</sup>

According to Dr. Graham Emslie, professor of psychiatry at the University of Texas Southwestern Medical Center, who was a researcher in four of GlaxoSmithKline's studies of Paxil, some companies have withheld negative findings pertaining to SSRIs: "I know of at least a half-dozen other studies of antidepressant treatments in children and adolescents that have been completed but as yet have not been published. More than enough time has passed for these to be published at least in abstract form."<sup>168</sup>

It might be conceded that there is an inherent difficulty in pinpointing the cause of suicide committed by seriously depressed patients. Fifteen percent of those who are seriously depressed patients

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162. *Id.*

163. *Id.*

164. *Id.*

165. See Gardiner Harris, *F.D.A. Intensely Reviews Depression Drugs*, N.Y. TIMES, Oct. 28, 2003, at A1.

166. *See id.*

167. *See id.*

168. *Id.*



commit suicide,<sup>169</sup> and at the same time millions of depressed individuals take Prozac every year. Although many risk factors for suicidality are well known, there is no clinical test, technique, or biological marker sufficiently trustworthy to support an accurate short-term prediction of suicide in individual patients.<sup>170</sup> Thus, it is a daunting challenge to determine whether certain depressed people take their lives as a result of taking Prozac or other SSRIs, rather than as a result of their disease. Frederick K. Goodwin, a government psychiatrist who specializes in depression, says, "It wouldn't be surprising over time to see thousands of suicides among more than three million depressive patients."<sup>171</sup> In addition, many people taking SSRIs have suffered years of mental disturbances and even severe depression, making it difficult to attribute specific cases of suicidal ideation to the drug itself. Untreated depression results in a higher risk of suicide, so refusing treatment with Prozac because of its negative portrayal could ironically result in a higher risk of suicide, thereby exacerbating the very risk that the patient is trying to avoid.

On the other hand, in situations where suicidal ideation is a *de novo* symptom, particularly where this is temporally close in time to the onset of taking an antidepressant, there could be strong circumstantial evidence of causation. Further, given the wealth of published epidemiological data in scientific journals asserting a connection between Prozac and suicidal ideation, as discussed above, expert testimony supporting causation may likely be submitted to a jury.

There appears to be ample reason for physicians to be mindful of the strands of evidence, both anecdotal and scientific, outlined above, and to be particularly vigilant in prescribing antidepressants to patients who may have a pre-existing tendency towards suicidal ideation.

## VII. THE STATUS OF THE "PROZAC DEFENSE" IN CRIMINAL LAW

The so-called "Prozac defense" in criminal cases, once ridiculed, actually is becoming a legally cognizable defense. The theory behind the defense is that the drug causes involuntary conduct as a side effect, and that the drug in fact caused a given defendant to kill or commit

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169. See Tracy Schroth, *Defending Prozac: Divide, Discover, and Conquer*, LEGAL TIMES, Dec. 16, 1991, 2, 13.

170. See Fine, *supra* note 144, at 7.

171. Thomas M. Burton, *Anti-Depression Drugs of Eli Lilly Loses Sales After Attack By Sect*, WALL ST. J., Apr. 19, 1991, at A1.

some other crime at issue.<sup>172</sup> Proponents of the “Prozac defense” argue that during an SSRI-induced mania a person can make elaborate plans, including robberies and other crimes, and that sometimes the mania is exacerbated by psychotic features such as hallucinations or delusions.<sup>173</sup> “Drug-induced mania can cause many expressions of disinhibited or out-of-control behavior, including sexual acting out, road rage, buying sprees and shoplifting. Drug-induced mania, even when seemingly not intense, can ruin marriages and destroy careers.”<sup>174</sup>

The “Prozac defense” relies on the doctrine of involuntary intoxication. Generally, the defense of involuntary intoxication is a complete defense in jurisdictions that have adopted the *M’Naghten* definition of insanity.<sup>175</sup> The general view is that intoxication resulting from medication that “has been prescribed (and taken as prescribed) or administered by a physician, is involuntary intoxication.”<sup>176</sup> As early as 1915 the idea of involuntary intoxication due to drugs entered into jurisprudence in the case of *Perkins v. United States*,<sup>177</sup> where a Federal appellate court said:

A patient is not presumed to know that a physician’s prescription may produce a dangerous frenzy. . . . If [the defendant] was so frenzied by a portion of the medicine innocently taken under the direction of the physician that he was thrown into a mental state which placed him beyond his own control and beyond the realization of what might be the ill effect of an overdose, he would not be legally responsible.

The notion of involuntary intoxication takes into account that patients have no duty to discover that a drug is defective or unreasonably dangerous, nor to guard against its existence.<sup>178</sup> Certain products are regarded as unavoidably unsafe products. That is, they are products that “are quite incapable of being made safe for their intended and ordinary use.”<sup>179</sup> If Prozac is in fact an unavoidably

172. See *Garza v. State*, 829 S.W.2d 291 (Tex. App. 1992) (ruling that the trial court did not err in overruling the defendant’s requested instruction of involuntary intoxication because the defendant had not raised the defense at trial).

173. See *Paxil Withdrawal Suit Resolved*, *supra* note 63.

174. *Id.*

175. WAYNE R. LAFAVE & AUSTIN W. SCOTT, *CRIMINAL LAWS* § 4.10(f), at 393-94 (2d ed. 1986).

176. Phillip E. Hassman, Annotation, *When Intoxication Deemed Involuntary so as to Constitute a Defense to Criminal Charge*, 73 A.L.R.3d 195, §7(a) (1977).

177. *Perkins v. United States*, 228 F. 408, 415-16 (4<sup>th</sup> Cir. 1915).

178. RESTATEMENT (SECOND) OF TORTS, §402A cmt. n (1965).

179. RESTATEMENT (SECOND) OF TORTS, §402A cmt. k (1965).

unsafe product, the manufacturer would need to provide an adequate warning to physicians and patients that its use may cause destructive, suicidal, or homicidal urges in some of its users.<sup>180</sup> According to comment “j” of Section 402A of the *Restatement (Second) of Torts*, if the seller knows or “by the application of reasonable, developed human skill and foresight should have knowledge” of a danger, then the seller must warn against it.<sup>181</sup> Furthermore, “a product sold without such a warning is in a defective condition.”<sup>182</sup> This provision is interpreted to mean that a drug manufacturer is held to be an expert in its own field and presumed to keep abreast of scientific data pertaining to its product.<sup>183</sup> In addition, “if a substantial number of doctors or consumers had complained to a drug manufacturer of an untoward effect of a drug, that would have constituted sufficient information requiring an appropriate warning” by the company.<sup>184</sup>

Under this legal backdrop, to what extent has Eli Lilly been provided notice about the possible dangers of using Prozac? Mounting scientific and anecdotal evidence, plus individual reports and general post-marketing monitoring, suggest that the manufacturer should by now be apprised of a risk that (to put it in the most charitable light) it may not have known existed at the time the drug was manufactured. This information would appear to support the need of a suicidal ideation warning.

After the Wesbecker rampage in Louisville, in which a man with a history of depression who was taking Prozac shot and killed co-workers and himself (see discussion below), Eli Lilly began to mention the episode in its May 1991 package insert, but the company failed to provide a general warning about suicidal and homicidal tendencies.<sup>185</sup> The company’s refusal to provide a more concrete warning is consistent with its overall position that there is no causal connection between Prozac and self-destructive behavior. Still, there is authority for the proposition that “under a strict liability theory, a manufacturer must warn of dangers and risks, whether or not a causal relationship between use of the product and various injuries has been definitively established at the time of the warning.”<sup>186</sup> Under this rule, a

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180. See Tomatz, *supra* note 10, at 717.

181. RESTATEMENT (SECOND) OF TORTS, §402A cmt. j (1965).

182. RESTATEMENT (SECOND) OF TORTS, §402A cmt. h (1965).

183. Tomatz, *supra* note 10, at 718.

184. Feldman v. Lederle Lab., 479 A.2d 374, 387 (N.J. 1984).

185. Tomatz, *supra* note 10, at 719.

186. Hamilton v. Hardy, 549 P.2d 1099, 1108 (Colo. Ct. App. 1976). See also Feldman, 479 A.2d at 389 (citing *Hamilton* with approval).

manufacturer cannot interpose the defense that it did not warn because causation had not been conclusively established between a drug and the onset of suicidal ideation or homicidal tendencies. Moreover, drug manufacturers must warn of dangers even where the deleterious effect occurs in only a handful of "idiosyncratic or hypersensitive users."<sup>187</sup>

As mentioned above, Lilly does provide certain warnings. The company notes, for example, that the drug is eliminated relatively slowly so that its active ingredients can accumulate in the body. "The long elimination half-lives of fluoxetine . . . assure[s] that, even when dosing is stopped, active drug substance will persist in the body for weeks (primarily depending on individual patient characteristics, previous dosing regimen, and length of previous therapy at discontinuation)."<sup>188</sup> Some of the warnings given by the company are in fact nothing more than direct quotes from the *Physician's Desk Reference (PDR)*. For example, the only mention of suicide ideation is this: "The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy."<sup>189</sup> In fact, this statement is lifted directly from the *Physician's Desk Reference (PDR)*.<sup>190</sup> The company's warnings also has a section entitled "Interference With Cognitive and Motor Performance," in which it states, "Any psychoactive drug may impair judgment, thinking, or motor skills, and patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that the drug treatment does not affect them adversely."<sup>191</sup> This is nothing more than a general advisory somewhat similar to that found on over-the-counter night time cold remedies. The company also discloses adverse events including anxiety, nervousness, tremor, nausea, dry mouth, and decrease of libido reported by a significant number of patients.<sup>192</sup>

Lilly probably does not want to provide a more detailed warning because it could frighten consumers. However, comment "k" of the *Restatement (Second) of Torts* sets forth what is known as the risk

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187. *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 430 (2d Cir. 1969).

188. PROZAC DESCRIPTION, *supra* note 27.

189. *Id.* at 9.

190. See MEDICAL ECONOMICS DATA, PHYSICIANS' DESK REFERENCE 921 (1992).

191. PROZAC DESCRIPTION, *supra* note 27, at 10.

192. *Id.* at 15, Tbl. I.

utility doctrine, and provides an example of a safe haven for useful products that involve risk:

An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.<sup>193</sup>

Under this risk utility doctrine Eli Lilly could provide a more detailed warning and thereby be exempted from strict liability, assuming that Prozac's usefulness outweighs the known risks. That is, the risk utility analysis strives to balance the apparent benefits of a drug with the known risks as set out in the warning information.

The fact that the FDA has approved the language on a warning label is "not necessarily conclusive on the question of the adequacy of the warnings."<sup>194</sup> Manufacturers have a duty to monitor information about their products, and FDA warnings are considered adequate only if the manufacturer is not privy to information pointing to a greater danger.<sup>195</sup> Interestingly, the FDA reviewed escalating reports of suicidal ideation, and its Psychopharmacologic Advisory Committee released its report in September 1991. The ten-member committee "unanimously declined to recommend any change in warning or prescription practice on Prozac."<sup>196</sup> The committee found "no credible evidence" supporting the reports that there was a causal connection between Prozac and suicidal or violent behavior in its users.<sup>197</sup> This must have fueled Lilly's consistent position that there is no connection between Prozac and self-destructive or violent behavior, so that there is nothing to warn about.<sup>198</sup>

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193. RESTATEMENT (SECOND) OF TORTS, § 402A cmt. k (1965).

194. *Brochu v. Ortho Pharmaceutical Corporation*, 642 F.2d 652, 658 (1<sup>st</sup> Cir. 1981) (quoting *Chambers v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1095 (D. Md. 1986)).

195. *Id.*

196. Charles Petit, *Tough Times for an Anti-Depressant*, S.F. CHRON., Sept. 25, 1991, at A1.

197. Schroth, *supra* note 169, at 14.

198. ELY LILLY & CO., 1991 SECOND-QUARTER REPORT 6 (1991) (company argues that negative thoughts occur as a concomitant to depression, and since

Recently, the defense of involuntary intoxication in connection with prescription drugs gained credibility in *Minneapolis v. Altimus*,<sup>199</sup> where the defendant claimed that by taking Valium he was unexpectedly intoxicated. The Minnesota Supreme Court established three criteria for interposing a successful defense of involuntary intoxication caused by ingestion of a prescription drug: (1) “the defendant must not know, or not have reason to know, that the prescribed drug is likely to have an intoxicating effect”; (2) “the prescribed drug, and not some other intoxicant, is in fact the cause of the defendant’s intoxication at the time of the alleged criminal” act; and (3) “the defendant, due to involuntary intoxication, must be temporarily insane.”<sup>200</sup>

Some courts have in fact accepted the involuntary intoxication defense in connection with Prozac or other SSRIs, apparently following the three-prong criteria just mentioned. In effect the courts are finding that the involuntary use of the drug or drugs created a state of mind equivalent to insanity or temporary insanity. In Connecticut a judge acquitted a defendant, Christopher DeAngelo, of first-degree robbery based on the finding that the defendant was unable to appreciate the wrongfulness of his conduct or to control his conduct within the requirements of law, and that this impaired state was specifically attributable to his taking Prozac and Xanax.<sup>201</sup> The defendant had committed several robberies over the course of a few days, including the bank where his wife worked, and was easily recognized in the course of these episodes because of a vintage car he drove.<sup>202</sup> The defendant had no prior history of any criminal or aggressive behavior; he had no financial problems, and was considered a very responsible person by co-workers, family, and friends. The judge in that case relied on a forensic psychiatrist’s report stating that the defendant experienced disinhibition (i.e., paradoxical behavior) and mania induced by the Prozac and Xanax. The report said, “Both syndromes are characterized by lack of self-control, judgment, and insight,” that both “can cause or include out-of-character, irrational, senseless, impulsive, bizarre and destructive behavior,” and “they can produce criminal actions that make no sense in terms of the

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Prozac users often suffer from depression in the first instance, it is the depression and not the drug that causes destructive urges).

199. *Minneapolis v. Altimus*, 238 N.W.2d 851, 854 (Minn. 1976).

200. *Id.* at 857.

201. See COURT FINDS PROZAC AND XANAX CAUSE CRIMINAL CONDUCT, available at <http://www.breggin.com/deangelo.html> (last visited Feb. 8, 2004).

202. Fine, *supra* note 144, at 27.

individual's self-interest, and which are bound to be discovered."<sup>203</sup> The psychiatric report concluded that if the defendant had not been taking Prozac and Xanax, "he would almost certainly never have committed these crimes."<sup>204</sup>

In another Prozac defense case a Georgia man accused of robbery was diagnosed with a Prozac and Xanax induced Mood Disorder with Manic Features, and the prosecution agreed to a plea bargain as a result of a forensic psychiatrist's report, dropping nine counts of robbery and four counts of kidnapping.<sup>205</sup> In another case, a Virginia man, charged with assault against the police, was acquitted on grounds of involuntary intoxication with psychiatric drugs, based on forensic psychiatric testimony.<sup>206</sup>

In 1999 an Australian court ruled that the defense of diminished responsibility applied to David John Hawkins, who has confessed to strangling his wife of fifty years despite the loving relationship that had existed between them even at the time of the homicide. The judge in the case *Regina v. David John Hawkins*<sup>207</sup> opined that the defendant was under the influence of a prescription for Zoloft, which he had started taking only one day before the homicide. The defendant pled guilty to the reduced charge of manslaughter on the grounds of diminished responsibility.<sup>208</sup> The defendant had no prior history of violence. The judge, relying on statistics from the Australian Department of Health and Aged Care, as well as forensics reports, stated in his opinion:

The effective drug in Zoloft is capable of causing sleeplessness, agitation, confusion, hallucination and psychosis. Furthermore, because responses to antidepressants can be idiosyncratic the effect of a given dose on one particular individual may be more profound than on another or even on a statistically "average" person.<sup>209</sup>

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203. *Id.*

204. *Id.*

205. *See Paxil Withdrawal Suit Resolved*, *supra* note 63.

206. CENTER FOR THE STUDY OF PSYCHIATRY AND PSYCHOLOGY, ASSAULT CHARGES DISMISSED ON GROUNDS OF INVOLUNTARY INTOXICATION WITH PSYCHIATRIC DRUGS, at <http://www.breggin.com/invintoxication.html> (last visited Feb. 8, 2004).

207. *Regina v. Hawkins* (2001) N.S.W.S. Ct. Cas. 420, available at <http://www.justiceseekers.com/files/NLPP00000/052.PDF>.

208. Fine, *supra* note 144, at 26.

209. *Regina v. Hawkins* (2001) N.S.W.S. Ct. Cas. 420, ¶ 34.

...Zoloft can cause agitation and a certain amount of disinhibition so that some individuals engage in aggressive or dangerous behaviours without due regard for the consequences and in a manner that is out of character for them. Behaviour of such a kind is sometimes described in terms "that suggest manic or psychotic reactions". Zoloft can also lead to suicide. In this regard it should be noted that when medically examined shortly after his arrest the prisoner was found to be "acutely suicidal".<sup>210</sup>

The manifestations of aggression, agitation, confusion and hallucination experienced by the prisoner are thus readily able to be explained by reference to the Zoloft which he had ingested in the early hours of 1 August, 1999.<sup>211</sup>

The judge quoted from portions of the forensics reports, including the following:

The unusual factor in my opinion was the fact that [the prisoner] was taking Zoloft at the time and this produced a strange and unusual state of mind in him involving akathisia and possibly also emotional blunting and psychotic decompensation and this led directly to his behaviour on . . . August 1st 1999. In my opinion had he not been taking Zoloft the events of that night would not have happened. The temporal association between his intake of Zoloft and these events and the congruence of this time frame with the time frame reported in the literature argue strongly for an SSRI (Selective Serotonin Re-uptake Inhibitor) induced problem.<sup>212</sup>

One forensic expert stated that SSRIs can cause one in four healthy volunteers to exhibit moderate to severe agitation, which "could lead to violent behavior."<sup>213</sup>

The judge nevertheless sentenced the defendant to three years in prison with a non-parole period of two years, meaning that he would be in prison for only a short time. The judge imposed some prison time because the defendant had previously taken Zoloft and then stopped because he had been aware that it had an adverse effect on him; the dose taken by him at the time of the homicide was several times in excess of what had been prescribed; and while his responsibility was diminished, it was not entirely eliminated.<sup>214</sup>

210. *Id.* at ¶38.

211. *Id.* at ¶39.

212. *Id.* at ¶43.

213. Fine, *supra* note 144, at 26.

214. Regina v. Hawkins (2001) N.S.W.S. Ct. Cas. 420, ¶ 72.



In a federal civil suit based on product liability, a Wyoming jury found that Paxil caused Donald Schell to shoot and kill his wife, daughter, and granddaughter, as well as commit suicide, and awarded eight million dollars in damages to his heirs, saying that Paxil “can cause some individuals to commit suicide and/or homicide.”<sup>215</sup> Schell took one tablet of Paxil daily for just two days before the fatal incident. The question before the jury was whether taking one tablet of Paxil daily for two days caused Donald Schell to commit murder and suicide, or whether the extreme aggression and violence was caused by his clinical depression. The jury deliberated for five hours and found the defendant eighty percent liable and Donald Schell twenty percent liable.<sup>216</sup> The plaintiffs’ attorney made the argument that the jury should consider a broader question, namely, whether it is possible that the drug produces a violent reaction in some people.<sup>217</sup> The case focused on allegations that SmithKline never fully tested the propensity of Paxil to cause violence or suicide, and that they took affirmative steps to mislead the public and the medical profession about this problem.<sup>218</sup> Schell had a past history of five previous bouts of depression that were severe enough to keep him from work, and he had sporadic psychiatric treatment.<sup>219</sup> He had a history of taking other antidepressants, including Prozac.<sup>220</sup>

This case set a legal precedent in that it was the first time a jury found a pharmaceutical firm liable for a death caused by a patient taking an antidepressant.<sup>221</sup> The case implies that other SSRI antidepressants could be implicated by association. Part of the discovery in the case revealed that GlaxcoSmithKline was “aware that a small number of individuals had become agitated or violent while taking Paxil.”<sup>222</sup>

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215. *Tobin v. SmithKline Beecham Pharmaceuticals*, No. 00-CV-0025-Bea (D. Wyo. Filed May 8, 2001), available at <http://www.justiceseekers.com/files/NLPP000/042.PDF>. See also Fine, *supra* note 144, at 22-23.

216. Fine, *supra* note 144, at 24.

217. *Id.* at 23.

218. See *id.* at 24.

219. See *id.*

220. See *id.*

221. *Id.* at 22.

222. Fine, *supra* note 144, at 23. GlaxcoSmithKline’s clinical trial of 2000 healthy volunteers who were given either Paxil or a placebo showed that [m]any of the subjects developed adverse reactions, ranging in severity from mild anxiety to, in a very small number, suicidal ideation. Some of them experienced anxiety, nightmares, hallucinations and other side-

The jury's verdict suggests that "a warning about possible suicide, violence or aggression should have been included in the warning insert" for Paxil.<sup>223</sup> "None of the manufacturers of SSRIs have issued such a warning."<sup>224</sup> According to one attorney familiar with the ongoing litigation with respect to SSRIs, Pfizer, which manufacturers Zoloft, and Eli Lilly had internal documents indicating they had knowledge of these side effects.<sup>225</sup>

Some people question whether the internal documents of GlaxoSmithKline are scientifically helpful in ascertaining the effects of antidepressants on patients who have clinically significant major depressive disorder, since the subjects who participated in the study were healthy volunteers and did not receive

the kinds of comprehensive psychiatric evaluations that inquire, at a meaningful level, about past histories of violent behavior or past psychosocial stressors and their impact on their coping mechanism. . . . Drawing conclusions from the effects of antidepressant medications on healthy volunteers . . . does not seem a very scientifically accurate way to draw conclusions that these drugs cause aggressive or violent behavior.<sup>226</sup>

However, the judge in the *Schell* case, U.S. Magistrate William C. Beaman, issued a thirty-one page opinion in which he denied the defendant's motion to exclude or limit plaintiffs' experts' testimony. One of plaintiffs' experts, John T. Maltzburger, said this in his report:

It is generally understood by most psychiatrists that a certain number of patients, perhaps five percent, will develop restlessness and anxiety when prescribed selective serotonin uptake inhibitor drugs (SSRIs) of which Paxil is an example. . . . Furthermore, a certain number of depressed patients are known to "switch" in to hypomanic states when treated with antidepressant drugs. When a patient has a hypomanic history . . . or already exhibits akathisia symptoms . . . , SSRI compounds should not be prescribed because they have the potential to make the anxiety much worse, indeed, to make it unbearable. There are credible reports of patients becoming suicidal and

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effects within two days of taking Paxil, and one experienced akathisia after four days. Two volunteers attempted suicide after 11 and 18 days respectively.

*Id.* at 24.

223. *Id.* at 23.

224. *Id.* at 24.

225. *Id.*

226. *Id.* at 24-25.

homicidal when thrown into intolerable states of anguish by prescription of these drugs. . . . Further, we know that depressed patients given SSRI drugs are more likely to harm themselves than are those who are given tricyclic antidepressants. . . . Already anxious, his mind speeding, and sleepless, when given an SSRI in 1998, he [the decedent] quickly became violent and killed his family and himself. . . . In this case I can identify only one factor which triggered the murders and subsequent suicide--Paxil. . . . Though we lack details of what exactly Mr. Schell's mental state was on that fatal night, it is clear to me that it was Paxil that drove him out of control.<sup>227</sup>

Judge Beaman noted that while there are significant differences in the chemical structures, chemical properties, and ability to inhibit the reuptake of serotonin of the various SSRIs, SSRIs are often classified together and collectively referred to as "the SSRIs" by the scientific and medical communities because of their similar ability to block serotonin reuptake:

SSRIs are widely referred to in the scientific community as SSRIs precisely because they share this physiological property and the functional effects of this property [the inhibition of the reuptake of serotonin] in common. These drugs in fact share a wide range of functional effects in common. The list of side-effects for all of the drugs in the class overlaps heavily. . . . The general designation of these drugs as SSRIs . . . refers to a common understanding that broadly speaking the drugs are similar - there may be differences but there is broad overlap.<sup>228</sup>

In 1994 there were approximately 160 active Prozac cases involving suicide or acts of violence committed by persons who were taking Prozac.<sup>229</sup> The first Prozac suit in the nation to reach a courtroom was precipitated in September, 1989, when Joseph Wesbecker, who had started taking Prozac a month earlier, armed himself with an AK-47 and walked into the Louisville printing plant where he had worked,

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227. *Id.* at 4. The judge also cited "the Donovan study," which provides significant support for the causations opinions and methodology employed by the expert witnesses employed by the plaintiffs. Stuart Donovan et al., *Deliberate Self-Harm and Antidepressant Drugs Investigation*, 177 BRIT. J. PSYCHIATRY 551, 554 (Dec. 2000).

228. *Tobin v. Smith Kline Beecham Pharmaceuticals*, No. 00-CV-0025-Bea (D. Wyo. Filed May 8, 2001), available at <http://www.justiceseekers.com/files/NLPP00000/042.PDF>.

229. Richard Zitin & Carol M. Langford, *Hide and Secrets: The depressing tale of a clandestine Prozac settlement*, 156 N.J. L.J., 24-25 (1999).

killed eight people, wounded twelve more, and committed suicide.<sup>230</sup> Survivors of the shooting victims brought a wrongful death and products liability case known as *Fentress v. Eli Lilly*,<sup>231</sup> and at trial sought to introduce evidence that Lilly had pled guilty in 1985 to twenty-five criminal counts for failing to report adverse reactions, including four deaths, to the FDA in connection with another Lilly product, an anti-inflammatory drug called Oraflex, which had been taken off the market in 1982 as too dangerous.<sup>232</sup> It was plaintiffs' intention in the *Fentress* case to show that Lilly had done the same thing with Prozac.<sup>233</sup> When the judge indicated that he would allow that evidence to go before the jury, there was a "flurry of activity" in which counsel for the plaintiffs and counsel for Lilly made a secret verbal agreement to settle the case; but it was agreed that plaintiffs' attorney would immediately rest his case without introducing the damaging Oraflex evidence. The jury returned a verdict in favor of the defense.<sup>234</sup> Lilly's defense attorney said in a press conference:

We have proven in a court of law, just as we have to more than 70 scientific and regulatory bodies all over the world, that Prozac is safe and effective. Our hearts go out to the victims of the terrible tragedy. . . . But the members of the jury, after hearing the scientific and medical facts . . . came to the only logical conclusion - that Prozac had nothing to do with Joseph Wesbecker's actions.<sup>235</sup>

As revealed later by an investigation by the Kentucky State Attorney General, Lilly secretly agreed to pay the plaintiffs, win or lose.<sup>236</sup> In addition, Lilly agreed that all of the plaintiffs' lead counsel's other Prozac cases would be settled, and half of his expenses would be paid by Lilly.<sup>237</sup>

In 1998 it was disclosed that about a dozen cases involving Prozac disappeared from the court record, with the implication that the cases had been "resolved."<sup>238</sup> "The history of Prozac litigation reads like a

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230. *Id.*

231. *Fentress v. Eli Lilly & Co.*, No. 90-CI-06033 (Cir. Ct., Jefferson County, Ky. Jan. 25, 1995) (judgment dismissing case with prejudice).

232. Zitin & Langford, *supra* note 229.

233. *Id.*

234. *Id.*

235. Michael Jonathan Grinfeld, *Protecting Prozac*, CAL. LAW., Nov. 1998, at 36, 38.

236. *Id.*

237. *Id.*

238. *Id.* at 36.

mystery thriller, filled with allegations of backroom deals, hidden agendas, and unethical behavior. Although many of the details have circulated among trial lawyers, new revelations continue to percolate."<sup>239</sup>

A recent case involves a thirteen-year-old boy, Matthew Miller, whose parents sued Pfizer claiming he had committed suicide because he took Zoloft, manufactured by Pfizer, for the treatment of depression. The case, *Mark Miller and Cheryl Miller v. Pfizer Inc.*,<sup>240</sup> held that forensics testimony would be excluded on the issues of (1) general causation (whether Zoloft causes suicide); (2) specific causation (whether Zoloft caused Matthew Miller's suicide); and (3) the adequacy of Pfizer's Zoloft warnings to physicians.<sup>241</sup> The basis of the court's ruling was that the proffered testimony pertained to statistical calculations that "did not represent a generally accepted methodology for testing the hypothesis that Zoloft causes suicide, and therefore general causation was not established."<sup>242</sup>

In recent years Eli Lilly has offered to indemnify doctors who prescribe Prozac and are sued for malpractice arising from prescribing the drug, in addition to helping prosecutors thwart attempts of defendants to interpose the "Prozac defense" in criminal cases.<sup>243</sup> Lilly's indemnification to doctors includes "the cost of defending any litigation as well as any judgments that should arise from lawsuits challenging the use of Prozac."<sup>244</sup> By indemnifying physicians, Lilly has foreclosed the possibility of claiming intervening negligence on the part of doctors that could exonerate the company from liability, particularly since the company has given constant assurances about Prozac's safety to doctors.<sup>245</sup>

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239. *Id.* at 38.

240. *See Miller v. Pfizer Inc.*, No. 99-2326 (D. Kan. Feb. 7, 2002).

241. *Id.*

242. *Id.*

243. *See Jonathan M. Moses, Lilly Order to Turn Over Prozac Studies*, WALL ST. J., Jan. 17, 1992, at B1.

244. Daniel Wise, *Eli Lilly to Pay Legal Expenses, Awards to Doctors in Prozac Suits*, N.Y. L.J., June 6, 1991, at 1.

245. *See Jane Light, Moves to Stem Decline in Prozac Sales*, REUTERS, June 4, 1991 (financial report); *See also Daniel Wise, Eli Lilly to Pay Legal Expenses, Awards to Doctors in Prozac Suits*, N.Y.L.J., June 6, 1991, at 1.

VIII. IMPROPER INDUCEMENTS, GHOST WRITING IN SCIENCE JOURNALS, FINANCIAL TIES, AND OTHER UNETHICAL PRACTICES THAT ERODE PUBLIC FAITH IN THE PHARMACEUTICAL INDUSTRY

Recently, the United States government has warned pharmaceutical companies that they must not offer any financial incentives to doctors, pharmacists, or other health care professionals to prescribe or recommend particular drugs, or to switch patients from one medicine to another.<sup>246</sup> The new standards, the first of their kind, were issued by the inspector general of the Department of Health and Human Services, as guidance to the medical industry. The purpose of this directive is to deter the widespread practice of drug companies inviting physicians to dinner meetings at expensive restaurants, where they are also paid \$500 to \$1500 or more to listen to research studies, often paid for by the pharmaceutical company, and to hear sales pitches regarding new drugs. The new standards do not have the force of law, but pharmaceutical firms that flout them are more likely to be investigated and prosecuted for violations of federal fraud and kickback statutes.<sup>247</sup>

Many practices commonly used in the marketing and sale of prescription drugs are thought to run afoul of federal fraud and abuse laws.<sup>248</sup> Other practices of pharmaceutical companies discouraged by the new directive include treating doctors to free Broadway plays, weekend trips, and paying generous stipends for attending “educational conferences” at which their drugs are promoted. Pharmacies have often received payments for putting a company’s products on lists of recommended drugs, known as formularies. Pharmaceutical companies have routinely rewarded doctors and drugstores for switching patients from one medication to another, or from generic drugs to brand-name medicines.

During the public comment period to the government’s proposed regulations, the drug industry, health maintenance organizations, and doctors have flooded the Department of Health and Human

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246. Robert Pear, *U.S. Warning To Drug Makers Over Payments*, N.Y. TIMES, Oct. 1, 2002, at A1.

247. *Id.* Presently, the Food and Drug Administration is reviewing its own regulations to determine whether it should relax limits on behind-the-scenes marketing of pharmaceuticals. See Melody Petersen, *Madison Ave. Has Growing Role In the Business of Drug Research*, N.Y. TIMES, Nov. 22, 2002, at C4.

248. Pear, *supra* note 246.

Resources with letters criticizing the proposal.<sup>249</sup> They contend that the proposal constitutes a federal “code of conduct” that would require radical changes that would be profoundly disruptive to the pharmaceutical industry. At the same time, pharmaceutical companies acknowledge that they routinely make payments to insurance companies to increase the use of certain drugs or add them to recommended lists, so as to expand their market share, and that they reward doctors and pharmacies for switching patients from one drug to another.<sup>250</sup>

The drug industry relies substantially more on behind-the-scenes promotion than on direct advertising. In 2001, just \$2.8 billion of the \$11.8 billion spent by the drug industry on marketing was aimed at consumers, with the remainder going for “educational conferences,” dinner meetings, and other behind-the-scenes promotions, according to Verispan, a health-care information firm.<sup>251</sup>

A separate and equally, if not more troubling, concern is the growing role of advertising agencies in the business of conducting clinical trials of pharmaceuticals.<sup>252</sup> In the early 1990s, about seventy-five percent of the drug industry’s clinical research budget went to universities, according to a study by CenterWatch, a firm that tracks clinical trials.<sup>253</sup> In 2000, by contrast, thirty-four percent went to academic institutions, with the rest budgeted to investigators working under the auspices of private research firms that are partly owned by advertising agencies or by firms under the direction of pharmaceutical companies.<sup>254</sup> Some advertising companies ghost-write articles for medical journals with the aim of showing that certain drugs have the qualities patients most desire and to manipulate doctors’ prescribing protocols.<sup>255</sup>

Only a few years ago, drug research and education were the province of universities. But with pharmaceutical companies counting on instant blockbuster sales of their new drugs, executives found the university system too slow. And ad agencies - having built a multibillion-dollar business selling drugs to consumers - pushed deeper and deeper into the process.<sup>256</sup>

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249. *See id.*

250. *See id.*

251. *See Petersen, supra* note 247.

252. *Id.*

253. *Id.*

254. *Id.*

255. *Id.*

256. *Id.*

The involvement of advertising agencies now introduces a whole new bias into clinical trials “so that the American public and the physicians in the United States are not going to know, really, the true facts about [new] drugs.”<sup>257</sup> Because of aggressive marketing in the pursuit of huge sales shortly after a drug enters the marketplace, millions of patients may take a drug before all of its side effects are known. That is apparently what happened with the bandwagon attraction to Prozac, before the public learned about the extensive and serious side effects such as aggressiveness, suicidal ideation, and so forth, as discussed above.

A further ethical concern is that in 1998 it was reported that eleven percent of the articles published in the nation’s top medical journals, including *The Journal of the American Medical Association*, were ghost-written.<sup>258</sup> One strategy is to ghost-write research and medical education pieces as a way of promoting drugs before they have completed the clinical trials and been approved by the FDA in order to create markets for new drugs long before they gain FDA approval.<sup>259</sup> In addition, these advertising agencies strive to persuade physicians to prescribe drugs for conditions that they are not approved to treat.<sup>260</sup> “Doctors are led to prescribe drugs that may not be necessarily worth the money, may not be better than a generic that’s already on the market and that their patients don’t need. It’s clearly contributing to the rising costs of prescription drugs and health care.”<sup>261</sup>

Apart from the ghost-writing issue, there is a separate ethical problem involving financial ties of contributors to scientific journals with regard to products or companies that could benefit from the articles they write. In some instances, studies that appear in peer-reviewed journals are financed by drug companies, creating what appears to be a straightforward conflict of interest. Hidden financial conflicts have forced the publisher of some of the world’s most influential scientific journals to modify their editorial policies. *Nature*

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257. See Petersen, *supra* note 247.

258. *Id.* In a lawsuit against the drug company, Wyeth, it was disclosed that the company had hired ghostwriters to help promote the diet drug fen-phen after it became evident that the drug causes a potentially fatal heart-valve deficiency. Federal and state investigations of Warner-Lambert’s marketing of Neurontin, an epileptic drug, disclosed ghostwriting of journal pieces to market more than a dozen unapproved uses. *Id.*

259. *Id.*

260. *Id.*

261. *Id.* (quoting Arnold S. Relman, M.D., professor emeritus at Harvard Medical School and a former editor of *The New England Journal of Medicine*).



Publishing Group, part of the Macmillan Publisher, recently announced that it would henceforth require its authors to disclose any financial ties to the products they evaluate.<sup>262</sup> This new policy has been implemented at the journal *Nature* and its sister publications.<sup>263</sup> This change arose in response to widespread criticism of an article in *Nature Neuroscience* in November 2002 which addressed treatments for depression. The author, Dr. Charles B. Nemeroff, chairman of the department of psychiatry and behavioral sciences at the Emory School of Medicine in Atlanta, praised some of the products in which he had significant financial stakes in three of the therapies he mentioned favorably.<sup>264</sup> It makes ethical sense to require authors of original research articles to disclose their financial conflicts because industry financing carries with it the inherent potential to influence and shape commercial bias. The editors of *Nature Neuroscience* stated that when scientists “offer their professional expertise without disclosing potential financial benefits to themselves, it threatens to undermine public trust, not simply in a particular paper or journal, but in the integrity of the scientific enterprise as a whole.”<sup>265</sup> Up until now, the journals required only the authors of articles describing original research to disclose any financial ties. Other medical journals that have not yet adopted expansive disclosure rules, or those that have no policy at all, should proceed to establish appropriate new policies that are in keeping with the higher ethical standards suggested by the editors of *Nature Neuroscience*.

In addition, there are alarming allegations that five of the ten voting members on the FDA’s Psychopharmacology Advisory Committee (PDAC) that approved Prozac for marketing to the public had financial ties with the pharmaceutical industry; one of them had done extensive research on Prozac and received a check from Lilly within a few days of the vote in which Prozac was approved.<sup>266</sup>

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262. Melody Petersen, *Science Journals Tighten Rules For Disclosure of Financial Ties*, N.Y. TIMES, Sept. 27, 2003, at A10.

263. *See id.*

264. *Id.*

265. *Id.*

266. *See Cole Complaint, supra* note 31, at ¶31.

## IX. THE FURTHER PROBLEM OF "COSMETIC PHARMACOLOGY"

One final ethical concern involves the emergence of the field of "cosmetic pharmacology." With the introduction of Prozac in 1987, the question of using psychiatric drugs to alter personality in useful, attractive ways has lost any futuristic tone that it might have once had. Despite the fact that Prozac has only been approved for use in clinically depressed patients, bulimia, and obsessive-compulsive disorder,<sup>267</sup> "folks are using it for just about everything but hangnails."<sup>268</sup> Ethical issues become particularly acute when the patient is one who, all things considered, is "normal." It has been widely noted that numerous people take Prozac who have never suffered from depression, because it gives them an "edge" in the corporate world, with such enhancements as assertiveness, vivacity, mental acuity, and a "dash of hedonism."<sup>269</sup> The ethics of what we might call cosmetic pharmacology extends to the use not only of Prozac and other SSRIs for conditions that are not mental disorders, but to Ritalin, which is used to enhance concentration; beta blockers to alleviate stage fright; and anticonvulsants for stress.<sup>270</sup>

The principal ethical concern here is the propriety of prescribing drugs for normal patients that can alter their very conception of self. One of the consequences of the "cosmetic" use of such drugs is that more and more people might be convinced or in a way compelled to jump on the bandwagon so as to maintain parity in competition. If a rival in one's firm seems to be enjoying a certain mental acuity and assertiveness hitherto dormant and now bolstered by Prozac or similar drugs, one might feel at a disadvantage unless one joins suit. A similar pressure developed in the early 1980s, prior to drug testing for steroids in professional athletics. As one football player commented on the use of steroids in his sport: "Every team was looking for an edge."<sup>271</sup> There was "an *inherent coerciveness* present in these situations: when some choose to do what gives them a competitive edge, others will be pressed to do likewise, or resign themselves to either accepting a

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267. Cebuliak, *supra* note 110, at 612.

268. Geoffrey Cowley, *The Culture of Prozac*, NEWSWEEK, Feb. 7, 1994, at 41.

269. Cebuliak, *supra* note 110, at 620.

270. *Id.* at 619.

271. T. H. Murray, *Drugs, Sports and Ethics*, in FEELING GOOD AND DOING BETTER: ETHICS AND NONTHERAPEUTIC DRUG USE 115 (Thomas H. Murray et al. eds., 1984).

competitive disadvantage, or leaving the endeavour entirely.”<sup>272</sup> It is not difficult to see how this same inherent coerciveness might well involve an employee who feels pressure to be as aggressive and confident as others in the workplace or marketplace.

The very concept of “normal” could well be ratcheted up, and perhaps that has already happened, based on evolving cultural norms associated with mood enhancing drugs. “Prozac highlights our culture’s preference for certain personality types . . . by allowing people to move toward a cultural ideal - the flexible, contented, energetic, pleasure driven consumer.”<sup>273</sup> If more and more people clamor for enhancements in order to feel a certain way, they may come to regard certain states of aggressiveness or imperviousness to disappointment as “normal,” which could turn psychiatry on its head.

Perhaps cosmetic pharmacology is the inevitable wave of the future. As the ranks in the business world are filled with new breeds of personality, the playing field likely would ratchet up quite dramatically, and the popularity of various personality traits might increase as well. One can imagine a pharmacological battle of sorts, with consumers pushing for stronger “free enterprise” personality traits. If a large number of people opt to select for “cosmetic pharmacology” there could be an overabundance of these similar personalities. If so, we would live in a strange new world in which everyone could or would be a highly aggressive individual with the same personality traits.

When science enters a new domain, it becomes necessary for the language of rights to likewise undergo a paradigm shift, or else explain its theory consistent with technological advance, and I believe philosophers are doing so. Technology is a tool for expanding human potential, to permit greater freedom, not the limiting of freedom.<sup>274</sup> I suggest that we examine the ethical concern over “cosmetic pharmacology” from the following standpoints:

#### *A. The Impact on Individuality and Human Dignity*

John Stuart Mill said that because of the need for self-expression that follows upon the capacity for thought and reflection, human beings simply cannot be made happier by external constraints on our

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272. *Id.* at 116 (emphasis in original).

273. PETER D. KRAMER, LISTENING TO PROZAC: A PSYCHIATRIST EXPLORES ANTIDEPRESSANT DRUGS AND THE REMAKING OF SELF 270-272 (1993).

274. *Changing Your Genes*, THE ECONOMIST, Apr. 25, 1992 at ll, l2.

development and spontaneity, however benevolent these external constraints might be.<sup>275</sup> If people's personalities have been determined by pharmacological aids they may encounter a loss of a normal sense of individuality and self, or the freedom to create their own identity. Some people might feel "inauthentic"-that there is no real "self" for them to be because their personality has been fixed or altered by a drug. One consequence of a pharmacological society is, as Carl R. Rogers said, "depersonalizing them, controlling them by means so carefully selected that they will perhaps never be aware of their loss of personhood."<sup>276</sup> If people can select personality traits, this could lead to a market model which would put a price on all human characteristics, thereby commodifying human beings.

### B. *The Problem of Free Will*

It is a fundamental notion of liberty that human beings make their own decisions about their lives. This theory is expressed in the Constitution,<sup>277</sup> and it is a principle found in Locke's proposition that everyone has the "equal right . . . to his natural freedom, without being subjected to the will or authority of any other man."<sup>278</sup> This underscores the importance of liberty in our capacity for self-expression.<sup>279</sup> If patients are in effect programmed to develop a personality set, this could undermine the conception of free will. What is to be said of the status of free will if people are in effect programmed to behave in a particular way? If people's personality traits are causally determined, we may need to re-examine traditional notions of free will.

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275. See John Stuart Mill, *On Liberty*, in THE UTILITARIANS 483-84 (Doubleday Books 1973).

276. Quote of Carl R. Rogers, former president of the American Psychological Association, in *What is Psychiatry doing at this very moment in the year 2002?*, available at <http://www.prozactruth.com/index> (last visited Feb. 8, 2004).

277. See David A.J. Richards, *The Individual, The Family, and the Constitution: A Jurisprudential Perspective*, 55 N.Y.U. L. Rev. 1, 6, 8 (1980).

278. JOHN LOCKE, SECOND TREATISE ON GOVERNMENT § 54, at 31 (C.B. Macpherson, ed. 1980) (1690).

279. See Mill, *supra* note 275, at 484.

### *C. The Problem of Fairness*

A system of “cosmetic pharmacology” could promote various types of personality advantages. Would this be unfair to people who had worked their way towards these goals rather than popping a pill? On the other hand, some people, because of pharmacological advantages, might not develop virtues such as perseverance, determination, aggressiveness, and so on - and may be disadvantaged in the areas of life where these skills come into play.

### *D. The Problem of Equal Distribution*

As many people start using “cosmetic pharmacology” to produce better personality traits and other behavioral advantages, people who are not able to afford its use could become severely disadvantaged. This could pose significant problems in our otherwise egalitarian social structure, with a group of privileged individuals on Prozac pitted against those who cannot afford it. People would no longer believe that they have just as good an opportunity to succeed as the next person. The enhanced would tend to monopolize desirable occupations and fill high status social roles. The disadvantaged would no longer be able to count on traditional methods of social advancement, such as hard work or perseverance, to improve the quality of their lives. By giving an unfair advantage to enhanced individuals, we would undermine the principle of social equality, and the idea in the Declaration of Independence that “all men are created equal” would seem to be simply false.

If health insurance coverage of today’s technology is any indication, “cosmetic enhancement” will not be covered by most insurance policies. Cosmetic surgery, in vitro fertilization, fitness centers, performance enhancing drugs, and other technological advantages in life are paid for by the individuals involved. Thus, “cosmetic pharmacology” can exacerbate social and economic inequalities unless these drugs are made available to everyone at an affordable cost.

The use of Prozac and other psychiatric drugs to treat clinical depression and other mental disorders is a medical breakthrough of great value to many who suffer from serious mental illness. But its use to bring about socially desirable personality changes poses disturbing ethical implications.

## CONCLUSION

Bruno Bettelheim, in his study “The Uses of Enchantment,” said that a struggle against severe difficulties in life is unavoidable, that it is an intrinsic part of human existence.<sup>280</sup> In other words, life is difficult. There are certain evolutionary and practical utilities to such “negative” emotions as sadness, depression, grief, and shame. Sadness over something in one’s midst pushes one to look at, appreciate, and understand interpersonal causal connections; if sadness is caused by the loss of a loved one, one’s bond is seen as something that matters; if there is no sadness over the loss of a loved one, there would be little survival motivation to stick with a mate, partner, or other loved one. Many other examples might be elicited as to the worth of “unwanted” emotions. One commentator notes that in American society it is seen as abnormal to express grief beyond one year after the death of a loved one, while in rural Greece, formalized grief customarily extends for five years.<sup>281</sup> Unlike Americans, those in rural Greece have a high level of affect tolerance, which refers to the ability to endure what one feels.<sup>282</sup>

Psychiatry no longer seems to encompass such things as awareness, attention, intention, imagination, and concentration, or to develop techniques to aid patients in strengthening their use and control of these faculties. Psychiatry seems to have obliterated its mission to aid patients in investigating the actual *source* of the problems they experience with their own mind. Psychiatrists increasingly seem to back away from engaging in the endeavor of empowering or strengthening the capabilities of patients, and instead opt for psychiatric drugs.

Many patients who have taken antidepressants or other psychiatric drugs have found that the medications, while helpful, have not solved their problems in forming intimate relationships, in avoiding destructive behavior patterns, or in overcoming other pervasive personality problems. In an era of managed care, in an era when time is often a bigger issue than money, in an era when mental health professionals are perceived as “arrogant,” “elitist,” “uninvolved,”

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280. BRUNO BETTELHEIM, *THE USES OF ENCHANTMENT: THE MEANING AND IMPORTANCE OF FAIRY TALES* (1976).

281. Cebuliak, *supra* note 110, at 621 n.83.

282. *Id.* at 400.

“cultish,” and “insular,”<sup>283</sup> psychiatry has been transformed into an institution with a split personality of its own. The function of psychiatry seems to have moved far away from aiding the patient to investigate the nature and potential of one’s inner and invisible mental activity. Has America become a nation where painful emotions are classified as a mental illness that can only be treated with pharmaceuticals? Such a philosophy casts aside traditional notions of self and puts the very idea of self into disarray. For such users, where is the true self to be found? Ought psychiatry to be in the business of muting all negative emotions? Does Prozac really transform a person’s life into a happy one in the full sense intended by philosophers such as Aristotle?

Aristotle emphasized the importance of self-perfection, self-mastery, and human excellences in connection with human flourishing. One may have the feeling of happiness without really being happy in a full-blown, authentic, objective sense. A person may be induced into a sense of happiness by self-deception, but if external facts, such as the activities in one’s life, are not constitutive of human excellences, the feeling of happiness will be counterfeit, inauthentic, and something that can be easily disappear. Whether a person is or is not happy depends on whether the person is living a life of virtue, of human excellences, and that is something we can evaluate from an objective standpoint. Thus, from Aristotle’s perspective, feeling good is not necessarily equated with being happy so that it would be contrary to a good life to medicate away life’s ordinary feelings that emerge from the little disappointments and setbacks that we experience, feelings that often enough propel us to look inward, to know ourselves better, and to become more authentic human beings as a result of such contemplation.

Psychotherapy, brain physiology, and philosophy have become increasingly interlinked. Psychoanalytic treatment attempts to unlock the sexual and aggressive conflicts presumed to underlie the frightful nature of the unwanted thoughts and action. A point now widely accepted by most psychoanalysts is that psychotherapy rarely works for obsessive compulsive disorder, which encumbers “patients with unwanted thoughts, often violent or sexual, that play in the mind like a broken record,” nor with other serious mental disorders such as psychopathy and paraphilias.<sup>284</sup> Furthermore, psychotherapy alone is ineffective with psychoses such as schizophrenia, where there is strong

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283. Erica Goode, *Even in the Age of Prozac, Some Still Prefer the Couch*, N.Y. TIMES, Jan. 28, 2003, at D1.

284. Friedman, *supra* note 16, at D5.

evidence of structural, as well as functional, brain abnormalities. In cases where the brain is severely damaged or abnormal, talk therapy cannot cure the patient or modify the patient's behavior.

Clearly patients who do best on SSRIs are those who receive psychotherapy along with the medication.<sup>285</sup> Prozac seems to be appropriate in the treatment of various mental disorders, but only in conjunction with supervised psychotherapy. The majority of people taking Prozac are not getting any psychotherapy and obtain the prescription from their family doctors.<sup>286</sup> Thus, the root causes of the depression, anxiety, or other symptoms are in effect ignored, suppressed, and not authentically dealt with.

If psychiatric drugs are routinely administered as a substitute for analysis of a patient's underlying pain, and especially if such drugs are used purely for cosmetic purposes or for the purpose of merely enhancing a patient's performance or behavior, then there are serious ethical concerns. Pharmacology misses the point that caring for a patient ought to be done in a human, interpersonal basis, rather than through the sterile and impersonal mode of medication. Many people think that psychotherapy is preferable to pharmacotherapy because it is more "natural" and because it strives to get to the root of the patient's problem. They are convinced that self-understanding will bring relief, whether the problem is anxiety, depression, or obsessive compulsive disorder. I believe that any well-being achieved without the hard work of psychotherapy runs the risk of being artificial and inauthentic. I believe it is important to examine the source of one's happiness, what constitutes it, since happiness can be authentic only if it corresponds with external reality as compared to inauthentic, drug-induced means.

To some extent the medicalization of psychiatric patients has been motivated by economic concerns, since states no longer are willing to allocate significant resources to mental hospitals, and privatizing the care of many of these patients is impossible because psychiatrists cannot make money off of this kind of business. In addition, the impact of managed care and the growing popularity of shorter forms of psychotherapy, and the unprecedented targeted advertising campaign for antidepressants, coupled with the even more costly behind-the-scenes marketing of drugs to physicians, reflect the marked shift towards psychiatric pharmacology.<sup>287</sup> The future of psychiatry can be

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285. See Fine, *supra* note 144, at 27.

286. L. O'Connell, *Prozac: Worrisome and Wonderful*, EDMONTON J., Feb. 17, 1994, at C13.

287. Goode, *supra* note 3.



seriously jeopardized by a culture of pharmacology and medical insurers pushing for immediate results and who are unwilling to cover complete treatments consisting of a combination of drug and talk therapy. Psychiatrists themselves may be pressured to give up the couch because fewer and fewer people may believe that it is worth their time and money when new and better drugs are available to eradicate all their emotional problems.

The ethical treatment of psychiatric patients is of international concern. The *Declaration of Hawaii*, which was enacted at the General Assembly of the World Psychiatric Association in 1997, states in its preamble: "Since the psychiatrist is a member of society as well as a practitioner of medicine, he or she must consider the ethical implications specific to psychiatry as well as the ethical demands of all physicians and the societal responsibility of every man and woman."<sup>288</sup> This statement emphasizes the ethical need for psychiatrists to look to the political and societal consequences when Prozac or other mood enhancers are used to transform the personalities of "normal" individuals. In this regard, section seven of the *Declaration* states: "The psychiatrist must on no account utilize the tools of his profession, once the absence of psychiatric illness has been established."<sup>289</sup> Under this protocol, in all cases Prozac is inappropriate when prescribed to those who are diagnostically classified as "normal."

On the other hand, in a society that places a high value on individual freedom, it is hard to find any legitimate basis for restricting the use of cosmetic pharmacology. Roscoe Pound suggested that law should reflect the "received ideals" of the "time and place."<sup>290</sup> If people believe that in our time and place the "received ideals" of our culture endorses and approves of cosmetic pharmacology, lively debates on the issue would likely seem to persist. In terms of the ramifications on quality of life, psychiatric pharmacology can make life easier for many people. Psychiatric pharmacology can provide people with settled states of tranquility and a feeling of well-being and certain manifested personality traits that people generally agree are important for success in the business and social world. If antisocial behavior can be eliminated by taking a pill, what interest could society possibly have in restricting such pharmacology? At the same time, it may be disquieting to think that the evolution of mankind would end up being reduced to a marketplace agenda in which consumers clamor for more and better pharmacological enhancements to expand their personality

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288. APPENDIX: CODE OF ETHICS 517, 524 (S. Bloch & P Chodoff eds.).

289. *Id.* at 525.

290. See ROSCOE POUND, LAW AND MORALS 113 (1924).

potential rather than to seek and celebrate each one's unique and autonomous path towards self-knowledge.

As Plato says in his *Gorgias*, routine cooking is distinguished from medicine. Cookery operates in an entirely untheoretical way, while medicine involves investigation of the nature of the person whom it treats and the causes of the symptoms, and can give an account of these things:

[I]n my opinion cookery differed from medicine in being, not an art, but a routine, pointing out that the other, that is, medicine, has investigated the nature of the subject it treats and the cause of its actions and can give a rational account of each of them, whereas its counterpart, which is exclusively devoted to cultivating pleasure, approaches it in a thoroughly unscientific way, without once having investigated the nature of pleasure or its cause; and without any pretense whatever to reason and practically no effort to classify, it preserves by mere experience and routine a memory of what usually happens, thereby securing its pleasures.<sup>291</sup>

A thought experiment suggested by the philosopher Robert Nozick appears appropriate here. Imagine being plugged into a theoretical "pleasure machine" that provides you with a "virtual reality" experience of fulfilling your ambitions, dreams, and aspirations or whatever you desire for happiness. You might feel happy, but these experiences would be no more than dreams playing out in a virtual reality theatre of brain waves and would not manifest in the real world.

Would you want to live your life that way? My view on this is that it would seem odd if pleasures or the feeling of happiness are not connected to real life experiences, for as a species we value real experiences. A good life seems to be one that engages and makes use of rational capacities. Someone looking at me hooked up to the machine would see something analogous to someone in a persistent vegetative state - to the objective observer I am a pitiful creature whose quality of life is bleak, whose well-being is nil. I will simply be experiencing a succession of pleasurable dreams and adventures, all the while being oblivious to the reality of my hibernation.

Life, after all, consists of much more than feeling good. In life pleasure is associated with the attainment of real goals. A happy life is one that entails the normal engagement of plans, risks, failures - an inclusive notion of well-being that contemplates a pluralism of things

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291. PLATO, THE COLLECTED DIALOGUES, GORGIAS 501A (Edith Hamilton & Huntington Cairns trans., Princeton Univ. Press 1989).

that are of value - not only feeling good, but living a moral life, having an active sense of agency, really having freedom.

As mentioned above, Aristotle takes it that an assessment of whether one is or is not happy is an objective matter, based on evidence that the inner and outer state of affairs in our lives, both our psychological attitude and the doings of our lives, correspond. The external facts about our lives must be objectively good in order for happiness to be authentic, rather than be predicated by being hooked up to a pleasure machine. We can have a tranquil state of mind whether or not we are doing well in life, simply by a taking an ample amount of the right kind of drug to generate a burst of the brain chemical, dopamine, or to have hypnosis, and so on. The pleasure machine emphasizes pleasure as an end in itself to the preclusion or exclusion of all other ends. There is a certain loss of honor, of dignity, in engaging in such a scheme. How can we say the person in the pleasure machine *has* well-being or is happy? There may be a chimera-like *state* of well-being, but little reflection is needed to see that the person's state of happiness is flawed because it lacks objective criteria.