

## LIFE AS A BLONDE: THE USE OF PROZAC IN THE '90s

COLLEEN CEBULIAK\*

*With the rapid rise in the use of such anti-depressant drugs as Prozac comes a host of legal and ethical issues for psychiatrists prescribing the drugs. This article examines the implications of prescribing mood-altering drugs from the standpoint of professional ethics and the law. The author discusses the side-effects of Prozac and the current trend towards "cosmetic psychopharmacology" — the use of the drug to alter or enhance the personalities of patients who are technically healthy but looking for an "edge" or mood-improver.*

*The article explores the controversy surrounding the claim that Prozac patients experience suicidal and violent thoughts as a result of the drug; the author goes on to discuss the issue of the psychiatrist's potential liability when something goes wrong and when the drug has been prescribed to a patient who is well. Following is a summary of current civil and criminal litigation surrounding the Prozac controversy.*

*The author concludes that in most cases, the legal and ethical implications of prescribing Prozac to the "normal" patient should prohibit psychiatrists from doing so; however, the reality is that the prescription of Prozac to patients who are not clinically depressed is already widespread. Thus, the author concludes that the psychiatric community must encourage public debate and education.*

*L'utilisation de plus en plus répandue des antidépresseurs de type Prozac soulève un certain nombre de questions juridiques et éthiques pour les psychiatres qui prescrivent des psychotropes. L'article examine les implications d'une telle pratique sur le plan de l'éthique professionnelle et du droit. L'auteure parle des effets secondaires du Prozac et de la tendance actuelle vers une «psychopharmacologie cosmétique» — soit le recours aux médicaments en vue de modifier ou de rehausser la personnalité d'une clientèle par ailleurs en bonne santé mais recherchant un certain «avantage» ou tonus psychologique.*

*L'article explore l'accusation controversée selon laquelle le Prozac pourrait provoquer des pensées suicidaires ou violentes; l'auteure discute ensuite de la responsabilité éventuelle du psychiatre en cas de problème ou quand le médicament est prescrit à une clientèle en bonne santé. Il présente ensuite un sommaire du contentieux des affaires civiles et criminelles entourant la controverse Prozac.*

*L'auteure conclut que dans la plupart des cas, vu les implications juridiques et éthiques d'un tel geste, les psychiatres devraient s'abstenir de traiter la clientèle «normale» par le Prozac — la prescription du médicament à cette fin étant par ailleurs déjà très répandue. L'auteure exhorte la communauté des psychiatres à encourager le débat public et l'éducation.*

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\* Articling student at the firm of Milner Fenerty. This article won first prize in the general category of the 1995 William Morrow essay contest.

## I. INTRODUCTION

Since you only live once, why not do it as a blonde? Why not as a peppy blonde? Now that questions of personality and social stance have entered the arena of medication, we as a society will have to decide how comfortable we are with using chemicals to modify personality in useful, attractive ways. We may mask the issue by defining less and less severe mood states as pathology, in effect saying, "If it responds to an antidepressant, it's depression." Already, it seems to me, psychiatric diagnosis had been subject to a sort of "diagnostic bracket creep" — the expansion of categories to match the scope of relevant medications.<sup>1</sup>

With the approval and release of the antidepressant Prozac (known in the medical literature as fluoxetine hydrochloride) in 1987 in the United States and in Canada the following year,<sup>2</sup> musings on the issues surrounding drugs that can alter personality have lost any futuristic tone they might have once had. The advent of drugs that have the capacity to "improve" a patient's personality with few common serious side effects has left psychiatrists struggling with a myriad of ethical questions, which perhaps become even more pointed when the patient requesting the medication is, by psychiatric standards, normal. Despite the fact that Prozac has only been approved to date for use in clinically depressed patients in the United States,<sup>3</sup> and for clinical depression and bulimia in Canada,<sup>4</sup> "folks are using it for just about everything but hangnails."<sup>5</sup> This article will address the ethical and legal implications for the psychiatrist prescribing mood-improving or altering drugs to patients who are normal by psychiatric diagnostic standards. Emphasis will be on the current problems and controversy surrounding the prescription of Prozac. As an introduction to these issues, a detailed examination of the history, uses and controversy surrounding Prozac is in order.

## II. DESCRIBING PROZAC

### A. WHAT IS PROZAC?

Prozac is chemically unrelated to any antidepressant which was on the market when it was introduced.<sup>6</sup> Prozac acts by blocking or inhibiting the central nervous system's uptake of serotonin.<sup>7</sup> Although labelled for use in depression and bulimia, Prozac has proven, through both studies and anecdotal evidence, to be effective in the treatment of many other disorders, including: body dysmorphic disorder,<sup>8</sup> trichotillomania,<sup>9</sup>

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<sup>1</sup> P.D. Kramer, *Listening to Prozac: A Psychiatrist Explores Antidepressant Drugs and the Remaking of Self* (Toronto: Viking, 1993) at 15.

<sup>2</sup> Canadian Press, "CPE-Prozac" (16 July 1991) *Lifestyles*, Edmonton 11.36 EDT.

<sup>3</sup> S. Begley, "One Pill Makes You Larger, And One Pill Makes You Small...." *Newsweek* (7 February 1994) 37 at 37.

<sup>4</sup> Canadian Press, "National General News: Science-Shorts" (18 September 1992) *Toronto* 17.28 EDT.

<sup>5</sup> G. Cowley, "The Culture of Prozac" *Newsweek* (7 February 1994) 41 at 41.

<sup>6</sup> *Drug Facts and Comparisons*, 1994 ed. (St. Louis: Facts and Comparisons, a Wolters Kluwer Company, 1994) at 1344.

<sup>7</sup> *Ibid.*

<sup>8</sup> K.A. Phillips *et al.*, "Body Dysmorphic Disorder: 30 Cases of Imagined Ugliness" (1993) 150 *Am. J. Psych.* 302.

writer's block,<sup>10</sup> alcoholism,<sup>11</sup> pathologic jealousy,<sup>12</sup> attention deficit hyperactivity disorder,<sup>13</sup> panic disorder,<sup>14</sup> premenstrual tension,<sup>15</sup> chronic pain,<sup>16</sup> dementia,<sup>17</sup> gambling,<sup>18</sup> fear of public speaking<sup>19</sup> and many forms of obsessive-compulsive disorder.<sup>20</sup> As a result of the ability of this one drug to treat what have always been considered to be separate disorders, the psychiatric community is beginning to reevaluate the basic categorization of psychiatric disease.<sup>21</sup> As well, because Prozac has seemingly made "better than well"<sup>22</sup> persons whose problems seemingly relate directly to a history of abuse or to a dysfunctional family, psychiatrists have begun to wonder about the neurological changes caused by such situations.<sup>23</sup>

Currently, approximately 10 million people worldwide have taken Prozac.<sup>24</sup> Eli Lilly and Company, the corporation which introduced Prozac, made approximately \$1.2 billion from the sales of the drug last year.<sup>25</sup> It must be noted, however, that Prozac is a relatively expensive drug, which costs approximately twenty times more than the generic variety of antidepressant,<sup>26</sup> at about \$1.95 per 20 mg capsule.<sup>27</sup>

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- <sup>9</sup> R.M. Winchel *et al.*, "Clinical Characteristics of Trichotillomania and its Response to Fluoxetine" (1992) 53:9 *J. of Clinical Psych.* 304. *Contra* J. Kerbeshian & L. Bud, "Familial Trichotillomania" (1991) May 148 *Am. J. Psych.* 684, which states that fluoxetine merely improves mood without affecting hair pulling behaviours.
- <sup>10</sup> J. Cummings & G.W. Small, "Dealing With Writer's Block in an Older Man: Depression, Parkinson's Disease or Both?" (1991) 42:1 *Hospital and Community Psych.* 19.
- <sup>11</sup> T.K. Li *et al.*, "Alcoholism: Is it a Model for the Study Of Disorders of Mood and Consummatory Behaviour?" (1987) 499 *Annals of N.Y. Academy Sci.* 239.
- <sup>12</sup> R.D. Lane, "Successful Fluoxetine Treatment of Pathological Jealousy" (1990) 51:8 *J. Clinical Psych.* 345.
- <sup>13</sup> D.G. Gammon & T.E. Brown, "Fluoxetine and Methylphenidate in Combination for Treatment of Attention Deficit Disorder and Comorbid Depressive Disorder" (1993) 3:1 *J. Child & Adol. Psychopharmacology* 1.
- <sup>14</sup> W.F. Boyer, "Potential Indicators for the Selective Serotonin Reuptake Inhibitors" (1992) 6 (Suppl. 5) *Int. Clinical Psychopharmacology* 5.
- <sup>15</sup> *Ibid.*
- <sup>16</sup> *Ibid.*
- <sup>17</sup> *Ibid.*
- <sup>18</sup> *Supra* note 5.
- <sup>19</sup> *Ibid.*
- <sup>20</sup> *Supra* note 14.
- <sup>21</sup> *Supra* note 1 at 42.
- <sup>22</sup> *Ibid.* at x.
- <sup>23</sup> *Ibid.*
- <sup>24</sup> L. O'Connell, "Prozac: Worrisome and Wonderful" *The [Edmonton] Journal* (17 February 1994) C13.
- <sup>25</sup> *Supra* note 5 at 41.
- <sup>26</sup> G. Cowley, "The Promise of Prozac" *Newsweek* (26 March 1990) 39 at 39.
- <sup>27</sup> *Supra* note 6.

## B. WHAT ARE THE SIDE EFFECTS OF PROZAC?

### 1. Violent Behaviour and Suicidal Thoughts

Prozac, like all pharmaceuticals, has side effects. The most famous alleged side effects are violent behaviour and suicidal ideation. Prozac has been blamed for everything from the suicides of Del Shannon<sup>28</sup> and Abby Hoffman,<sup>29</sup> to the murderous rampage of Joseph Wesbecker, who killed eight co-workers with an AK-47.<sup>30</sup> The claim that Prozac is associated with suicidal ideation is most commonly cited in conjunction with a 1990 paper from the American Journal of Psychiatry, entitled "Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment."<sup>31</sup> The article detailed six case studies wherein the patients developed intense suicidal preoccupation within two to seven weeks of being prescribed Prozac. No patient admitted to being actively suicidal before being prescribed the drug. One aspect of the patients' behaviour which the physicians found particularly disturbing was the violent nature of the suicidal thoughts. Patients were fantasizing about violent new ways of killing themselves, including gas explosions, car crashes and guns. The article's authors found that in their own experience suicidal preoccupation occurred in approximately 1.3 percent to 7.5 percent of patients on Prozac, with 95 percent confidence limits.<sup>32</sup> Despite the furore that this article created, there is some doubt that the statistical observations of the authors are scientifically valid.

In 1991, a United States Food and Drug Administration (FDA) committee held public meetings to investigate the allegations regarding Prozac.<sup>33</sup> The committee recommended, based on the evidence before it, that there be no change to product warnings. As FDA member Dr. Paul Leber pointed out, depressed persons are more likely to be suicidal and thus it is difficult to know whether the thoughts are caused by the depression or the drugs.<sup>34</sup> As well, there are other problems with the Teicher study. The sample size was small, and four of the six case studies involved patients who were also taking other drugs.<sup>35</sup> The results obtained in other studies have since refuted the Teicher study's statistics.<sup>36</sup>

However, the controversy and the filing of new lawsuits have continued. One reason for the continuing controversy in the face of what is at best anecdotal evidence is the

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<sup>28</sup> J. Schwartz & B. Cohn, "A Prozac Backlash" *Newsweek* (1 April 1991) 64 at 65.

<sup>29</sup> N. Blodgett, "Eli Lilly Drug Targeted" (November 1990) 76 ABA J. 24 at 29.

<sup>30</sup> *Ibid.* at 24.

<sup>31</sup> M.H. Teicher, C. Glod & J.O. Cole, "Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment" (1990) 147 Am. J. Psych. 207 [hereinafter the "Teicher study"].

<sup>32</sup> *Ibid.* at 210.

<sup>33</sup> "FDA Holds Public Discussion of Prozac Side Effects" (November 1991) *Trial* 93 at 93.

<sup>34</sup> *Ibid.*

<sup>35</sup> *Supra* note 31 at 207.

<sup>36</sup> See e.g. E.A. Ashleigh & F.A. Fesler, "Fluoxetine and Suicidal Preoccupation" (1992) 149 Am. J. Psych. 1750; C. Beasley *et al.*, "Fluoxetine and Suicide: A Meta-Analysis of Controlled Trials of Treatment for Depression" (1991) 303 Brit. Med. J. 685; and Fava & Rosenbaum, "Suicidality and Fluoxetine: Is There a Relationship?" (1991) 52 J. Clinical Psych. 108, all of which posit that there is no relationship between Prozac and suicidal ideation.

media attention paid to the phenomenon. Several letters have been written to psychiatry journals by doctors documenting cases of patients who attributed their anxiety and fears of suicide to Prozac only *after* seeing reports in the media.<sup>37</sup> Thus, despite the attention that Prozac has received for allegedly producing suicidal and violent behaviours, there is no definitive evidence that Prozac produces these side effects in any greater quantities than any other antidepressant. Despite the lack of hard evidence linking Prozac to violence, the prescribing psychiatrist must always be cognizant of the fact embodied in the comment of the chair of the FDA committee, Dr. Daniel Casey: "There may be some as yet unassessed possibility that antidepressants are associated with self-injurious behaviour."<sup>38</sup>

## 2. Other Side Effects

For the psychiatrist contemplating giving Prozac to a patient who is not severely depressed, the spectre of other side effects should also loom large. However, communication of the side effects of Prozac to the patient seems to be sadly lacking. At the FDA committee meetings on the possible relabelling of Prozac, "many of the witnesses said their physicians told them Prozac has no side effects, when in fact it can have a range of effects...."<sup>39</sup>

First, there is the problem of the lack of research regarding various types of patients. For example, safety and efficacy of the drug have not been proven for children.<sup>40</sup> In the elderly, only single doses in healthy subjects have been proven not to differ significantly in effect from that in younger subjects. Not enough evidence exists to state that chronic use would follow the same path.<sup>41</sup> There are also no adequate studies in pregnant women.<sup>42</sup> A Canadian study did show an abnormally high rate of miscarriages in women who took the drug. However, the miscarriage rate of 14.8 percent was also found in women taking other antidepressants, leading to the speculation that the unusual rate was the result of an underlying psychiatric condition, and not the antidepressant.<sup>43</sup>

The side effects themselves, while on average less troubling to patients than the side effects from other antidepressants, are still serious. In the original Eli Lilly marketing trials, 15 percent of patients discontinued treatment because of "an adverse event."<sup>44</sup> The most common of these related to the central nervous system in the form of

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<sup>37</sup> See e.g. C. Ioannou, "Media Coverage Versus Fluoxetine as the Cause of Suicidal Ideation" (1992) 149 Am. J. Psych. 572; J.A. Selzer, "Fluoxetine, Suicidal Ideation and Aggressive Behaviour" (1992) 149 Am. J. Psych. 708.

<sup>38</sup> Associated Press, "Prozac-Suicide" (21 September 1991) Foreign General News, Washington 04.35 EST.

<sup>39</sup> *Ibid.*

<sup>40</sup> *Supra* note 6 at 1345.

<sup>41</sup> *Ibid.*

<sup>42</sup> *Ibid.*

<sup>43</sup> Reuter, "Prozac-Pregnancy" (4 May 1993) Foreign General News, Chicago 16.02 EST.

<sup>44</sup> *Supra* note 6 at 1347.

nervousness, anxiety and/or insomnia.<sup>45</sup> Other side effects which occur at a frequency of more than 10 percent in the patient population include: headaches (20.3 percent), drowsiness (11.6 percent), nausea (21.1 percent), and diarrhea (12.3 percent).<sup>46</sup> The discomfort produced by these relatively common side effects must be weighed and considered by the prescribing physician and the patient, as must the discomfort of those symptoms that are more rare, such as amnesia, paranoid reaction, psychosis and coma.<sup>47</sup>

### C. A PHYSICIAN'S RESPONSIBILITIES AND LIABILITIES

At base, however, the prescribing physician should always keep in mind what is unknown about Prozac as well as what is known. Prozac is not thought to be addictive,<sup>48</sup> but other drugs such as Valium and nicotine were also considered to be non-addictive in their preliminary use.<sup>49</sup> As well, there is little research directed at examining what effect Prozac will have on the toxicity associated with long term use — Prozac accumulates in brain tissues in concentrations that are several times higher than those in plasma.<sup>50</sup> As clinical trails are conducted on young, healthy persons, the verdict should be considered to be out for many years as to whether Prozac is as *relatively* non-toxic as it appears to be, as well as what the profile of side effects is in the *general population*.

Any doctor who undertakes to prescribe Prozac, whether he or she is a psychiatrist at a mental hospital or a family physician, must remember the standard of disclosure required by the Supreme Court of Canada in *Reibl v. Hughes*.<sup>51</sup> Any reasonable practitioner ought to be aware of the side effects which have been discussed to this point. The test for the disclosure of those risks, as enunciated by Laskin C.J.C., looks at those risks which the defendant objectively should have known that a reasonable person in the plaintiff patient's position would have wanted to be disclosed.<sup>52</sup> In order to avoid liability if there is some adverse reaction to Prozac, the doctor in question would be best advised to spend a great deal of time discussing the possible risk factors. This need becomes especially acute when Prozac is being prescribed for an elective use, because of the element of causation.<sup>53</sup> Thus, by prescribing Prozac to patients who are "normal" by diagnostic standards, doctors are leaving themselves more vulnerable to legal liability.

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<sup>45</sup> *Ibid.*

<sup>46</sup> *Ibid.*

<sup>47</sup> *Ibid.*

<sup>48</sup> *Ibid.* at 1346.

<sup>49</sup> *Supra* note 3 at 37.

<sup>50</sup> P.F. Renshaw *et al.*, "Accumulation of Fluoxetine and Norfluoxetine in Human Brain During Therapeutic Administration" (1992) 149 *Am. J. Psych.* 1592 at 1594. (1980), 114 D.L.R. (3d) 1 (S.C.C.).

<sup>51</sup>

<sup>52</sup> G. Robertson, "Informed Consent Ten Years Later: The Impact of *Reibl v. Hughes*" (1991) 70 *Can. Bar Rev.* 423 at 429 contains an excellent explanation of the test.

<sup>53</sup> *Ibid.* at 435.

Other areas of legal liability also exist in relation to the way in which Prozac is commonly prescribed. As will be discussed in more detail later, Prozac is often prescribed by a family physician, with few of the appropriate evaluations and tests conducted. Thus, there are at least two other potential categories of liability which may commonly arise. One deals with the failure to test for and determine whether there are factors or existing conditions which indicate that Prozac should not be used.<sup>54</sup> The literature on Prozac states that clinical experience with concomitant illness is limited, making such a failure even more problematic.<sup>55</sup> A second and closely related area of possible liability (which is more common with the family physician than the psychiatrist) is the failure to follow up or adequately monitor the patient.<sup>56</sup> Prozac is inherently easier to prescribe than other antidepressants due to its lower level of toxicity. Since regular blood monitoring is not mandated, follow-up by a family physician may be less detailed than follow-up by a psychiatrist who still sees the patient on a regular basis. Thus, even without considering the moral hazard inherent in prescribing Prozac for unlabelled uses, there are reasons for a prescribing physician to hesitate. Physicians may also be involved in actions against the drug manufacturer through the medium of the "learned intermediary" rule, wherein the manufacturer's duty to warn functions indirectly through the physician.<sup>57</sup> A discussion of the present state of the litigation against Eli Lilly, as well as a description of the criminal "Prozac defence," follows.

#### D. CIVIL AND CRIMINAL LITIGATION

By 1991 in the United States, seventy-five civil suits had been filed against Eli Lilly in relation to Prozac. In twenty criminal cases, the drug had been used as part of an insanity defense.<sup>58</sup> The civil suits against Eli Lilly have blamed Prozac for everything from violent acts and homicide to the various known side effects.<sup>59</sup> In criminal cases, the defendants face the problem that most, if not all, had a pre-existing psychological condition. Thus, proving that Prozac caused their behaviour is difficult.<sup>60</sup> In the civil suits against Eli Lilly, the plaintiffs must prove recklessness or negligence on the part of the company. This argument is equally difficult to make out, in light of the extensive testing of the drug which was undertaken prior to FDA approval.<sup>61</sup> Each case has

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<sup>54</sup> J. Rinas & S. Clyne-Jackson, *Professional Conduct and Legal Concerns in Mental Health Practice* (Norwalk: Appleton & Lange, 1988) at 204.

<sup>55</sup> *Supra* note 6 at 1346.

<sup>56</sup> *Supra* note 54 at 204.

<sup>57</sup> *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986), 25 D.L.R. (4th) 658; P. Peppin, "Drug/Vaccine Risks: Patient Decision-Making and Harm Reduction in the Pharmaceutical Company Duty to Warn Action" (1991) 70 Can. Bar Rev. 473 at 474.

<sup>58</sup> Reuter, "Prozac" (23 May 1991) Foreign General News, Washington 08.26 EDT.

<sup>59</sup> J. Lewis, "Prozac: Dark Side of a Wonder Drug" *Trial* (August 1990) at 62.

<sup>60</sup> J. Schwartz & B. Cohn, "'The Drug Did It': A Tough Sell in Court" *Newsweek* (1 April 1991) 66 at 66.

<sup>61</sup> Prozac was discovered by Dr. David Wong in 1972. Eli Lilly conducted clinical trials for ten years, involving over 11,000 participants. Finally, the FDA carried out four years of its own extensive analysis before approval. This does not, of course, mean that no civil suit can find a flaw in this process, or that the drug labelling is 100 percent accurate, but it does make a successful suit more difficult to achieve. (History of Prozac taken from M.M. Katz, "Prozac: Another Drug

therefore faced an uphill battle, and none of the civil trials or the criminal defenses has succeeded to date. Despite this lack of success, by 1991 there was a United States-wide forty member practice group devoted to Prozac litigation.<sup>62</sup>

## 1. Canadian Civil Suits

In Canada, reference to only two filed civil suits can be found. The first, filed in 1991 by a Vancouver lawyer, Gustav Kroll, claims that the lawyer "suffered from hallucinations, paranoia, memory blackouts and skin rashes from Prozac."<sup>63</sup> The second statement of claim against Eli Lilly Canada Inc. was filed in 1992 by an Edmonton physical education teacher, Clinton Coultman.<sup>64</sup> Coultman claims that a seizure he had while boarding an Edmonton Transit bus was brought on by Prozac, and that as a consequence he injured his back, neck and shoulders. He has been unable to work since the incident. Neither case has a reported outcome. All of the symptoms reported by both plaintiffs are listed in the Prozac product literature.

## 2. The "Prozac Defence" in Canadian Criminal Cases

In Canada, there are few reported criminal cases in which the defendants have tried to use the "Prozac defence." There are some cases where the defendant pleaded guilty, but claimed that Prozac should be considered a mitigating factor in sentencing. Perhaps the most famous Canadian case of this sort is that of Jason Laberge, who pleaded guilty to charges of break-in and mischief relating to the deaths of six flamingos at the Stanley Park Zoo.<sup>65</sup> In sentencing Laberge, Scherling Prov. J. made no mention of Laberge's lawyer's contention that Prozac led to the incident.<sup>66</sup>

However, there is at least one other case wherein the defendant pleaded innocent and attempted to use, at least in some measure, a form of the "Prozac defence." Stephen Kirincich was convicted of two charges of theft in connection with the theft of some

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Wrongfully Attacked-What Can Be Done To Stop the Legal System From Driving Good Drugs Off the Market, While Protecting State and Federal Interests" (1992) 25 Akron L. Rev. 635 at 647-48.

<sup>62</sup> Advertisement, "Prozac" *Trial* (November 1991) at S20.

<sup>63</sup> Canadian Press, "Prozac" (19 December 1991) National General News, Vancouver 23.35 EST.

<sup>64</sup> Canadian Press, "Teacher-Prozac-Lawsuit" (7 November 1992) National General News, Edmonton 16.12 EST.

<sup>65</sup> Canadian Press, "Crime-Flamingos" (27 April 1992) National General News, Vancouver 18.04 EDT.

<sup>66</sup> See also *R. v. Normington*, [1993] O.J. No.1977 (QL) (Ont. C.J.) where Bernard Normington pleaded guilty to the manslaughter death of his half-brother Clive Normington. Bernard Normington had taken a "handful of Prozac" after ingesting a substantial amount of alcohol, as well as marijuana. Kent J. made no specific comments on the undetermined amount of Prozac that the accused ingested, however, his main concern in sentencing was that: "The court is required to denounce the combining of the ingredients that led to this tragedy." Mr. Normington received a sentence of three and one half years, at the middle of the penitentiary range.



coins from a soft drink vending machine at the school where he taught.<sup>67</sup> At trial, Kirincich's psychiatrist testified that the "disinhibiting and agitating influences of Fluoxetine [sic] Prozac"<sup>68</sup> gave rise to a reasonable doubt that Kirincich had the requisite *mens rea* at the time in question. The appeal court gave several reasons why it agreed with the trial judge's assessment that the evidence should be given little weight. One reason is perhaps of some significance in predicting the success of the "Prozac defence" in Canadian criminal cases. The appeal court, citing *R. v. Wilband*,<sup>69</sup> stated that the opinion of a psychiatrist is only as good as the basis in fact upon which it rests.<sup>70</sup> Therefore, because the psychiatrist had to rely on the hearsay of the accused (who did not testify) to state that the Prozac had in fact been ingested, the psychiatrist's evidence could be given less weight in the judge's reasons.<sup>71</sup> Thus, for this reason, as well as those reasons previously mentioned, it is likely that the "Prozac defence" will find as little success in Canada as it has in a large number of cases in the United States.

### III. ETHICS AND THE PRESCRIPTION OF PROZAC

#### A. BEYOND PROZAC

The ethical implications surrounding the issue of whether Prozac should be prescribed to those who do not suffer from severe depression or bulimia also apply to a host of other present and future drugs, all of which may be lumped under the heading of "cosmetic psychopharmacology." As one author stated: "It's gone beyond Prozac."<sup>72</sup> Disregard for the moment the probable future existence of drugs specifically targeted to alter various personality traits. There are currently other drugs in existence, besides Prozac's sister drugs — Zoloft and Paxil — which are used in ways that generate many of the same ethical questions as does Prozac. For example, Ritalin is used to improve concentration; beta blockers to combat stage fright; and anticonvulsants for stress.<sup>73</sup> Thus, in any discussion of the ethics of prescribing Prozac to persons without psychiatric disorders, one must always be conscious of the parallels with other existing and future personality enhancers.

There are several issues which psychiatrists should look at before they prescribe any of these drugs, yet many do not and "are still convinced that their professional mandate is simply that of healing a form of illness and that their therapeutic activities do not and should not have political consequences."<sup>74</sup> The drugs which fall under the roster of cosmetic psychopharmacology are perhaps the most political drugs available to date,

<sup>67</sup> *R. v. Kirincich*, [1994] N.S.J. No.11 (QL) (N.S.C.A.). The Nova Scotia Court of Appeal dismissed the appeal on the basis that the trial judge properly gave little weight to the psychiatrist's opinion evidence, on the effect that Prozac had on the appellant, because of the other evidence before the court.

<sup>68</sup> *Ibid.* at para. 18.

<sup>69</sup> *R. v. Wilband*, [1967] S.C.R. 14 at 21.

<sup>70</sup> *Supra* note 67 at para 26.

<sup>71</sup> *Ibid.*

<sup>72</sup> *Supra* note 3 at 37.

<sup>73</sup> *Ibid.* at 40.

<sup>74</sup> S. Bloch & P. Chodoff, eds., *Psychiatric Ethics* (Toronto: Oxford University Press, 1991) at 2.

as they can change our very definition of "self." Discussion of some of the ethical questions of interest to psychiatrists and society in general regarding these drugs, again with special emphasis on Prozac, follows. Some of the discussion is future-oriented; that is, some of the anecdotal personality transformations attributed to Prozac may not yet be satisfactorily proven. However, the alleged personality enhancements are likely to be goals of the next generation of cosmetic psychopharmaceuticals, and thus of interest in spite of the lack of strict scientific proof.

## B. ETHICAL PROBLEMS AND PROZAC

### 1. "Be All That You Can Be" — Or Else!

"She has never suffered from depression, and she's not one to pop pills for fun. So why would a successful, 43-year-old public-relations executive take Prozac? Helen Baker ... takes it to give herself an edge."<sup>75</sup> Prozac's main effects: assertiveness; vivacity; mental acuity; and a dash of hedonism seem tailor-made for today's corporate world.<sup>76</sup> In a recessionary economy, the pull towards taking a drug which will make your personality fit more snugly into the corporate mould is obvious. However, at what point does this desire to "Be All That You Can Be" take on a menacing coercive tone? Will there come a time that "company drug test" will take on a whole new meaning as companies test their employees to ensure that they are taking the drugs which have been prescribed?

An apt analogy is to athletes and steroids, especially in the early 1980s when drug testing was less sophisticated. The words of one football player commenting on the use of steroids in his sport are an echo of Helen Baker's: "Every team was looking for an edge."<sup>77</sup> Thomas H. Murray, writing about drugs and sports, explains the pressure to take drugs among those wary of their hazards — the "free choice" under pressure — in this way: "There is, then, 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 competitive disadvantage, or leaving the endeavour entirely."<sup>78</sup> An extrapolation is easily made from the athlete determined to succeed, to the employee (or employer for that matter) who is feeling pressure to be as aggressive and confident as his or her colleagues in a constricting job market.

### 2. Will the Definition of "Normal" Change?

"[T]here has been a contrary trend in recent years to broaden the definition of mental health. This has led to the risk of inappropriate medicalization, with associated abuse

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<sup>75</sup> *Supra* note 5 at 41.

<sup>76</sup> D. Gates, "The Case of Dr. Strangedrug" *Newsweek* (11 June 1993) 71 at 71.

<sup>77</sup> T. M. Murray, "Drugs, Sports and Ethics" in T.H. Murray, W. Gaylin & R. Macklin, eds., *Feeling Good and Doing Better: Ethics and Nontherapeutic Drug Use* (Clifton: Humana Press, 1984) 107 at 115.

<sup>78</sup> *Ibid.* at 116 [emphasis in original].

of drug treatment so as to achieve societal control."<sup>79</sup> What would "normal," at base a cultural definition, become if society had a series of mood brighteners at its collective fingertips? "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>80</sup> Despite this observation, Peter Kramer also posits that a society on Prozac may be one in which people are able to conform more perfectly. Alternately, he says, it may create a society in which people suddenly have the confidence to "be disruptive of the status quo."<sup>81</sup> What Kramer does not discuss is whether the disruption of the *status quo* would be for different reasons or achieve different results if the instigators were on Prozac. Given that he cites some of the effects of Prozac to include diminished rejection-sensitivity and vulnerability, as well as hedonistic behaviour, it is possible to imagine a society in which the disruptors of the *status quo* are motivated only by self-interest and not by any sense of connection to a larger group of humanity.

In reference to their personal lives, people may be motivated by a heightened sense of self-confidence to make positive changes in their lives. However, the feeling of well-being that Prozac provides could also have the opposite effect, by allowing people to ignore the source of their previous discontent. Surprisingly, studies have shown that depressed persons are actually more in touch with reality than those who are not depressed.<sup>82</sup> People who are "normal" are the ones with the distorted view of reality. So while Prozac allows depressed persons to distance themselves from reality in a "normal" fashion, a non-depressed person who takes Prozac is distancing himself or herself further from reality than is typical. As the number of persons on Prozac continues to grow, this factor could change the nature of what we collectively describe as "reality."

Society must also decide whether there is some utility in emotions such as sadness, grief and shame. In his essay, "Mood Brighteners, Affect Tolerance and the Blues," Richard Schwartz illustrates the cultural component inherent in determining what is considered to be normal in the expression of human emotion. He compares American society, where the "inappropriate" expression of grief one year after the death of a loved one is considered a case for medication, with that of rural Greece, where formalized grief is expected to continue for five years.<sup>83</sup> Schwartz posits that societies such as rural Greece have a high level of affect tolerance, which he defines as the ability to be able to stand what you feel.<sup>84</sup> This is the antithesis of either a mood brightener (which provides distortions that comfort), or depression (which leaves a person unable to function with their feelings).<sup>85</sup> Perhaps it is this capacity for Prozac to help people meet and thus reinforce cultural expectations regarding emotion which

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<sup>79</sup> P. Brown, "Ethical Aspects of Drug Treatment" in S. Bloch & P. Chodoff, eds., *supra*, note 74, 167 at 171.

<sup>80</sup> *Supra* note 1 at 270-271.

<sup>81</sup> *Ibid.* at 272.

<sup>82</sup> *Ibid.* at 253.

<sup>83</sup> R.S. Schwartz, "Mood Brighteners, Affect Tolerance and the Blues" (1991) 54 *Psych.* 397 at 401.

<sup>84</sup> *Ibid.* at 400.

<sup>85</sup> *Ibid.*

is the most disturbing aspect of the drug's possible uses: "Perhaps feeling better is not synonymous with feeling happy."<sup>86</sup> No one expects the clinically depressed to live with their mood, but is ridding our lives of the feelings produced by the little disappointments and sadnesses, those feelings which make us introspective and human, a socially desirable goal?

### 3. What Is the Future of Psychiatry?

#### a. Who is Prescribing Prozac and Under What Circumstances?

"But the majority of patients taking Prozac are not getting therapy ... They're getting prescriptions from their family doctors and forgoing counselling."<sup>87</sup> Many patients are receiving Prozac from their family doctors and not receiving any psychotherapy whatsoever. This section does not deal specifically with the ethical problems in prescribing Prozac to persons who are not depressed, but instead questions whether Prozac is being prescribed to all patients in a safe and effective manner. Prozac does not have to be as closely monitored (using blood tests) as other anti-depressants. Other antidepressants have toxic side effects which increase in severity with dosage, and are often taken in overdoses by patients who want to commit suicide. In contrast, Prozac is almost impossible to use as a vehicle for suicide, and is easily administered in initial doses of 20 to 40 mg.<sup>88</sup> This ease of use has produced a medical community whose "temptation is to prescribe first and ask questions later."<sup>89</sup> Often Prozac is prescribed without a complete physical and psychological exam, which is highly unusual for other antidepressants because of their toxicity. This means other causes for the depression are sometimes missed, such as cancer, hypothyroidism or AIDS.<sup>90</sup> Instead, the scenario that most patients experience is one similar to the one expressed by "Valarie": " 'I went to my family doctor,' she explained. 'I said, "My whole family is taking it; I think I need it." He asked me a lot of questions about the symptoms of depression, and he said that he liked the drug and had taken it himself.'"<sup>91</sup> A 1993 survey showed that less than half of family practitioners dealing with depressed patients spent more than three minutes with the patient before prescribing treatment.<sup>92</sup>

#### b. The Future of Talk Therapy

How does the way in which Prozac is prescribed affect the role of the psychiatrist? If the psychiatric profession involves little more than dealing with brain disorders that have a biological basis, then the enthusiastic prescription of Prozac by a family doctor involves little more than a turf war between the specialist and non-specialist. However, if one considers psychiatry to involve an interaction between drug and talk therapy, then perhaps the psychiatric community should be concerned by the advent of Prozac

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<sup>86</sup> *Ibid.*

<sup>87</sup> *Supra* note 24.

<sup>88</sup> *Supra* note 26 at 40.

<sup>89</sup> *Ibid.*

<sup>90</sup> *Ibid.*

<sup>91</sup> *Supra* note 24.

<sup>92</sup> *Supra* note 5 at 32.

*et al.* Medical insurers want to see immediate results and may be unwilling to cover complete treatments (a combination of drug and talk therapy), which take more time and cost more money.<sup>93</sup> Also, practitioners of the art of psychiatry have often felt that their chosen area of practice was looked down upon as not really being part of the medical scientific canon. Using drugs to achieve their result, just like everyone else, may be a way of fitting in. In any case, in view of the future growth of cosmetic psychopharmacology, psychiatrists may be pressured to give up the couch because fewer people can pay for it or want it. If psychiatrists believe in the value of talk therapy, in the future they may have to convince patients that it is worth their time and money when the drug they were given last week seems to have solved all of their problems.

#### 4. Should Physicians Be Prescribing Prozac as an Optimizing Drug?

##### a. The Medical Model

To this point, we have seen that physicians should be cautious in the prescribing of Prozac to the "normal" patient for a variety of reasons, including the potential legal liability and the political and social implications such prescriptions would involve. In the past, the general guidelines expressed by what has been dubbed the "medical model" have helped physicians make a differentiation between what would be considered legitimate and illegitimate uses of a given drug. The guidelines can be stated as follows:

1. Drugs are an acceptable substance for the curing of the disease and relieving pain.
2. Following from this principle, drugs are acceptable if their purpose is to bring a person's physiological or behavioral function up to medically determined levels of normalcy, *i.e.*, as long as you are reestablishing a normal level no moral issues seem to be involved.
3. Drugs are not considered acceptable, however, if they are serving purely recreational purposes, or if they seem to move beyond replacement into enhancement or improving performance or behavior.<sup>94</sup>

If one were to use this model, Prozac is considered to be a legitimate drug when it is prescribed to those who are suffering from some sort of mental disorder, but an illegitimate one when it is prescribed to those who are diagnostically classed as "normal." If this model was the be-all and end-all as the source of guidance in decision-making for the practitioner, the ethical determination would be straightforward. However, this model is not free from bias, and thus there is a problem using it as the objective basis for any decision. The model covers only those substances which are under the control of the medical establishment, thus the dividing line on whether or not a substance is a "drug" — and therefore within the model — is not merely a question

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<sup>93</sup> D. Gelman, "Drugs vs. the Couch" *Newsweek* (26 March 1990) 42 at 43.

<sup>94</sup> W. Gaylin, "Feeling Good and Doing Better: An Introduction" in Murray, Gaylin & Macklin, eds., *supra* note 77 at 3.

of its function. Note that if caffeine, alcohol or nicotine were considered to be "drugs" in this context, they would fall under the category of illegitimate ones. Thus, illegitimacy does not always preclude use. Another problem with the model is the lack of a definition of "normalcy." As has already been seen, "normal" is a slippery concept, capable of shifting to meet changing cultural expectations or to assuage the conscience of those prescribing drugs. Finally, the blanket opposition to optimizing drugs is too simplistic and ignores the different objectives and effects which could be achieved by dissimilar optimizing drugs. Thus, the medical practitioner must look elsewhere for guidance in deciding whether to prescribe Prozac on demand.

#### b. The Codes of Ethics

There are a variety of codes which are applicable to the practice of medicine in Canada.<sup>95</sup> Specifically in the area of psychiatry, in October 1978 the Board of Directors of the Canadian Psychiatric Association approved the *Canadian Medical Association Code of Ethics Annotated for Psychiatrists*.<sup>96</sup> The section which is most pertinent to the Prozac question is section 8 under the heading "A. Responsibilities to the Patient":

[A psychiatrist] [w]ill recommend only those diagnostic procedures which he believes necessary to assist him in the care of the patient, and *therapy which he believes necessary for the well-being of the patient*. He will recognize his responsibility in advising the patient of his findings and recommendations.<sup>97</sup>

There is no comment in the annotation on this particular section, but clearly the psychiatrist is only to prescribe a drug if he or she believe that the drug is "necessary" for the patient. Each psychiatrist will have to decide if Prozac is indeed "necessary" for the well-being of the patient in front of him or her. This may be problematic if the patient in question does not suffer from any illness or disease.

Further, one may want to look to the *Declaration of Hawaii*, which was created at the General Assembly of the World Psychiatric Association in 1977. The *Declaration* has been endorsed by the Board of Directors of the Canadian Psychiatric Association. The preamble to the *Declaration* states: "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

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<sup>95</sup> This article will concentrate mainly on the codes specifically prepared for psychiatrists, but there are many others which may have some applicability to other practitioners faced with the decision of whether or not to prescribe (or recommend that someone else prescribe) Prozac. These include: the *Canadian Code of Ethics for Psychologists*, the *Code of Ethics and Standards of Professional Conduct* of the Canadian Association of Psychoanalytic Psychotherapists for Children, the *Code of Ethics* of the Canadian Pharmaceutical Association, Inc., and the *Code of Marketing Practices* of the Pharmaceutical Manufacturers Association of Canada (PMAC).

<sup>96</sup> F. Baylis & J. Downie, eds., *Codes of Ethics: Ethics Codes, Standards, and Guidelines For Professionals Working in a Health Care Setting in Canada* (Toronto: Department of Bioethics, The Hospital for Sick Children, 1994) at 72.

<sup>97</sup> *Ibid.* at 74 [emphasis added].

responsibility of every man and woman."<sup>98</sup> This statement confirms the need for the psychiatrist to look at the political and societal consequences when Prozac is used to transform the personalities of "normal" individuals. Of specific consequence to this type of use is section 7 of the *Declaration*, which reads, in part: "The psychiatrist must on no account utilize the tools of his profession, once the absence of psychiatric illness has been established."<sup>99</sup> From this then, the psychiatrist would either have to define Prozac as not being a tool of his or her profession — a difficult argument to make — or would have to find a psychiatric illness where one does not exist in order to prescribe Prozac to a patient who is well.

#### IV. CONCLUSION

"[With the perfection of mood brighteners], we begin to transform not just how we are responding but who we are. I have seen too much of the suffering that depression brings to argue against travelling further down that path. But I wonder where it will take us."<sup>100</sup> Prozac has provided many millions of people with relief from the symptoms of their psychiatric illnesses. If its use in society ended there, there would be few disturbing ethical implications. However, due to the use of Prozac to bring about socially desirable personality changes, we are instead left to question the very nature of self. What is the true nature of self; the personality before or after the medication? Ought we to mute all negative emotions? Does Prozac really make us "better"? Add to these troubling questions the uncertain side and long term effects of the drug in the general population, and psychiatrists are left tossing on a murky ethical sea without a rudder. Seemingly, the codes of ethics counsel against such use of a psychopharmaceutical, but these codes were drafted when Prozac was a matter of science fiction, not scientific fact. The psychiatrist is instead forced to examine each case individually, weighing questions of patient autonomy, risk and societal interests. In most cases, the balance would favour not prescribing Prozac to the normal patient. However, this suggestion may have been rendered merely academic by events; the genie is out of the bottle. Thus, the best course for the psychiatric community to take at this point is to encourage public debate on the ethical questions relating to Prozac and its unlabelled use, as well as public education about its possible health risks. Psychiatrists and other physicians cannot predict the specific path that this drug will take us down, but perhaps informed public debate can highlight some of the forks in that path.

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<sup>98</sup> "Appendix: Codes of Ethics" in Bloch & Chodoff, eds., *supra* note 74, 517 at 524.

<sup>99</sup> *Ibid.* at 525.

<sup>100</sup> *Supra* note 84 at 402.