JCPCP / Papers / Volume 15, Number 4 / Leo

National Public Radio on Prozac: A case study of how the media presents the risks and

benefits of antidrepressants

Abstract

On March 26, 2008 National Public Radio's 'The Infinite Mind' challenged the FDA's recent black box warning about antidepressants. This essay examines the evidence presented on the show.

Citation

Leo, J. (2015). 'National Public Radio on Prozac: A case study of how the media presents the risks and benefits of antidepressants', *The Journal of Critical Psychology, Counselling and Psychotherapy*, 15 (4), pp. 236-251.

Full-Text

National Public Radio on Prozac: A case study of how the media presents the risks and benefits of antidrepressants

Jonathan Leo

SUMMARY: On March 26, 2008 National Public Radio's 'The Infinite Mind' challenged the FDA's recent black box warning about the antidepressants. This essay examines the evidence presented on the show.

KEY WORDS: Antidepressants, NPR, suicide, SSRI, FDA, depression

In this era of blockbuster psychiatric medications, most successful medications have gone through a predictable, algorithmic rise and fall. When a new medication first comes to market, it is usually on the basis of short-term trials (i.e., six weeks) demonstrating only that there is a statistically significant difference between medication and inactive placebo (Cohen, 2005). Nonetheless, it is usually introduced to an enthusiastic reception, including peer-reviewed articles in the scientific literature (Glenmullen, 2000; Whitaker, 2010), glowing portrayals in the general media, and copious direct-to-consumer advertisements (Lacasse, 2005), all of which declare impressive efficacy, targeted mechanisms of action, and negligible adverse effects. These well-co-ordinated marketing campaigns also include statements from prominent academic psychiatrists, known as Key Opinion Leaders (KOLs), who explain the benefits of the new medication (Moynihan, 2008). Unfortunately, because the media often fail to report on the financial conflicts of interest involved, the public is usually unaware that they are viewing a multimedia advertising campaign, not an objective dissemination of information.

Jonathan Leo, PhD is a professor of neuroanatomy at Lincoln Memorial University in Harrogate, Tennessee. For further questions he can be reached at jonathan.leo@Imunet.edu

These tactics and others targeting both consumers and prescribers (see Brody, 2007; Spurling et al., 2010) appear to work very well. Many psychiatric drugs have gone on to become blockbuster best-sellers (more than \$1 billion in sales) shortly after coming on the market, despite little evidence of a true therapeutic advance (Cohen, 2011; Moncrieff, 2009).

In most cases the initial enthusiasm and subsequent commercial success of a given medication is eventually tempered by both time and increased numbers of consumers (Glenmullen, 2000). Millions of people begin to take the medication outside of the specialized, short-term environment of randomized controlled trials (Greenberg, 2011; Jacobs & Cohen, 2010), and these patients take the medication for much longer than the original six-week trial period. Adverse effects inevitably emerge that were not captured in the industry-funded and authored clinical trials (Diav-Citrin et al., 2008; Healy, 2012; Serretti & Chiesa, 2009). Eventually, though, such medications are more thoroughly evaluated through research funded by governmental entities such as the National Institutes of Health or Veteran's Administration. The results of such studies are often sobering, come to markedly different findings from those in studies generated by the pharmaceutical industry, and call into question the cost-effectiveness and efficacy of recently introduced medications (Lieberman et al., 2005). Critical analyses (Cohen, 2002; Rosenheck, 2005), re-analyses of available data (Kirsch et al, 2008; Tsai et al., 2011), and academic and journalistic investigations of conflicts of interest (e.g. Healy, 2003; Leo, Lacasse & Cimino, 2011) further damage the pharmaceutical industry-driven image of the medication. As a more realistic picture emerges, questions of longterm benefits are raised (Hughes & Cohen, 2009; Kirk, Cohen & Gomory, 2013), product liability lawsuits start to appear, government investigations begin, and in some contexts prescriptions taper off. This pattern has occurred so frequently that it is nearly a cliché.

When fluoxetine and the other SSRIs were first introduced in the late 1980s and early 1990s, they were marketed as more effective and safer than the older antidepressants, but 20 years later, the process described above has run its course. The rose-coloured glasses have come off, and both the scientific literature and the popular press are now more sceptical. Critical content is easily available on the internet, including both research analyses and consumer accounts (Hughes & Cohen, 2011; Lacasse & Leo, 2005). Following a series of critiques in the peer-reviewed literature, the misleading and pseudoscientific Serotonin Theory of Depression, used to market SSRIs to the public, was publicly disavowed by leading psychiatric authorities (Lacasse & Leo, 2006). Articles questioning the efficacy of antidepressants now appear periodically in the mainstream media; a recent article in *Newsweek* comprehensively covered the academic debate over the placebo effect, reporting that more and more researchers are concluding

that 'antidepressants are basically expensive Tic-Tacs' (Begley, 2010). Finally, a series of popular press books have critiqued the efficacy of antidepressants and the marketing messages used to sell them (Glenmullen, 2000). To summarize, in the past decade criticisms of antidepressants have become mainstream, and critical analyses are now readily available in most bookstores, not to mention the internet.

National Public Radio's The Infinite Mind

National Public Radio (NPR) is considered one of the more unbiased media outlets in the United States. From 1998 to 2008, NPR's most honored and listened to health programme was *The Infinite Mind*. During its award-winning run, the series had two prominent psychiatrists at the helm. The first host, Peter Kramer, authored *Listening to Prozac* (1993), perhaps the emblematic book of the 'Prozac Revolution'. He was followed by Frederick Goodwin, former Director of the National Institutes of Mental Health (NIMH). Both hosts are well known for their strong belief in the biological theory of mental disorders and their support for and use of psychiatric medications.

On 26 March 2008, with Goodwin serving as host, the title of *The Infinite Mind* was 'Prozac Nation: Revisited'. The theme of the show was to challenge the FDA's recent black box warning about a potential link between the antidepressants and suicide (FDA, 2004a), but the host and guests also openly disagreed with the recent wave of scientific studies showing that the true efficacy of the SSRIs is quite limited. The expert guests that day were Andrew Leuchter, Director of the Laboratory of Brain, Behavior and Pharmacology at the University of California at Los Angeles (UCLA); Peter Pitts, described as a former FDA official, and Nada Stotland, President of the American Psychiatric Association (APA) (Goodwin, 2008).¹

Shortly after the show aired a media-frenzy erupted over allegations of numerous undeclared financial conflicts. Besides the fact that *The Infinite Mind* is partially funded by Eli Lilly, manufacturer of Prozac, Cymbalta and Zyprexa, there was also concern regarding the guests, particularly Dr Pitts who, although described as a former FDA official, had served as a paid consultant to the pharmaceutical industry, a conflict of interest that was not disclosed. In addition, Fred Goodwin's financial relationships with the pharmaceutical companies were also raised. In an article in *Slate* titled 'Stealth Marketers: Are doctors shilling for the drug companies on public radio?', Shannon Brownlee and Jeanne Lenzer referred to the episode as 'a show that may stand in a class by itself for concealing bias' (Brownlee & Lenzer, 2008). It is important to point out that financial conflicts don't automatically equate to factual errors, and that a presentation by someone with a financial conflict could be entirely correct. Yet it is also true that often when

a KOL speaks about the benefits of a medication the audience is not informed that the KOL is getting paid by the company, which has led to a heightened scepticism among the general public.

There were numerous discussions, blogs, and articles about *The Infinite Mind* after Prozac Revisited aired, such as the hidden conflicts of interest, the main stream media's ability to compete with specialized bloggers, and whether the guests had made the producers aware of their conflicts. However these are not the concerns of the following analysis. Putting aside any arguments about whether there were financial conflicts involved with the show, there were serious problems with the content of the show. In some cases, facts were presented that are incongruent with the peer-reviewed scientific literature; in others, crucially important information for listeners who wanted to make an informed decision was omitted. The most important question is: Were the listeners of *Prozac Nation: Revisited* given a fair and balanced presentation of the issues surrounding the use of antidepressants in children?

The FDA's Black Box Warning

When the FDA examines data from clinical trials, their job is to weigh the benefits versus the adverse effects. Every drug has adverse effects, but hopefully the benefits outweigh them. In the case of the SSRIs, in both the case reports and the controlled clinical trials it has come to light that there appears to be a signal that the SSRIs are associated with increased suicidality. When one combines the possibility of increased suicidality along with limited efficacy, many people question whether the developing brains of children and adolescents should be exposed to these medications.

In October of 2004, after a review of all the pertinent data and a public hearing, the FDA took the most drastic step possible by placing a black box warning on the SSRIs. The warning noted that these drugs may increase the risk of suicidal thinking and behavior in some children and adolescents and, in a recommendation that is hard to argue with, the FDA encouraged close monitoring of patients, especially during the first four weeks of treatment.

Goodwin's first interview is with Andrew Leuchter, and in very strong words they both critique the FDA black box warning. For both Goodwin and Leuchter, the overriding problem with the FDA's reasoning is that no one took their own life while in the trials. Goodwin sees no evidence at all to justify the FDA warning and states (44:27), 'In fact, the FDA database there was zero – no suicide at all in any of the antidepressant trials – 35,000 patients.' Leuchter does raise the issue of the problematic case studies regarding suicidality and states (1:17): 'There were no suicides – that people thought about it more but they didn't act on it.' Throughout the show the host and guests confusingly go back and forth between the paediatric and adult studies regarding suicidality. In Leuchter's statement regarding suicides, he should have qualified it by saying that there were no suicides in the *paediatric* studies, as there were suicides in the *adult* studies (as Leuchter's statement stands now, it is potentially misleading to anyone unfamiliar with the psychiatric literature).

Goodwin's statement that there were no suicides in the adult trials is contradicted by numerous studies. An often cited 2003 article puts the number of suicides in SSRI trials at 77, with 0.59% of SSRI trial participants taking their own life (Khan et al, 2003). Rates vary, depending on which group of studies one examines, and one could argue, as the companies have, that it is the disease and not the medications that is at fault, but there have certainly been suicides in FDA trials. For instance, according to the 1991 Paxil Safety Review, there were five completed suicides in the Paxil group (Healy, 2004).

There is no doubt that, at least according to the FDA and GlaxoSmithKline (GSK), some adults in the trials took their own life. The ongoing debate in the medical literature is not about whether there were any suicides or not but about the classification of these deaths. For instance, Dr Joseph Glenmullen points out that in one of the clinical trials for Paxil there were five suicides in the Paxil group compared with two in the placebo group, but some of the suicides were inappropriately listed under 'placebo' when in fact they did not occur during the actual trial but before and after the trials (Schor, 2008). The problem for the FDA is that, while there were no suicides in the paediatric studies, there were suicides in the adult trials and, when one takes into account that some of the children in the clinical trials did have suicidal ideation, there is cause for concern. Without mentioning any of this, Goodwin states (2:38): 'There is no credible scientific evidence linking antidepressants to violence or suicide.'

This seems to be a somewhat off-hand statement about a significantly large body of data and, again, is at odds with the FDA. Certainly the FDA believes that their decision to place a black box warning on the SSRIs was based on an analysis of the scientific evidence. Even GSK acknowledges the risk of suicidality in certain populations (2008). It would have been more effective if Goodwin had first mentioned the scientific evidence, pointed out the problems with the data, discussed both sides of the debate and then mentioned why he thinks the FDA has come to the wrong conclusion.

For instance, consider David Healy's 2003 paper showing that, in all of the studies performed by the companies and submitted to the FDA, the researchers started with a group of depressed patients and divided them in half. One group was given an antidepressant and the other group was given a placebo and, according to the data, there were more suicides and suicidal events in the medication group compared with the placebo group. Since both groups were diagnosed with

depression to begin with, it suggests that the problem is the drug and not the depression. Furthermore, this is not an isolated finding; it is the case for almost every single antidepressant studied – in adults, no less (Healy, 2003).

As another example, in 2002 Arif Khan and colleagues published a metaanalysis in the *Journal of Affective Disorders* that analyzed the FDA's data on suicides in adults suffering from anxiety disorders (Khan, 2002). Out of 12,914 patients taking an SSRI, there were 11 deaths by suicides; in the other 3,875 patients there were no suicides.

Suicide rates: up or down?

Later in the show, Goodwin interviews Peter Pitts, who once worked for the FDA. At the time of the interview his employer was a PR firm representing Eli Lilly, GSK and Pfizer. Much of the discussion between Pitts and Goodwin centers on a recent paper published in the fall of 2007 claiming that the black box warning has led to a drop in antidepressant use and subsequent increase in the suicide rate.

The study they are referring to was authored by Robert Gibbons and John Mann, and was published in the American Journal of Psychiatry, and partially funded by Pfizer, the manufacturer of Zoloft (Gibbons et al, 2007). The study looked at two variables in different age groups: SSRI prescription rates and suicide rates. By placing graphs of the two variables side by side the authors believe the data suggest that a drop-off in the prescribing rate, which was supposedly caused by the unnecessary black box warning, has led to an increased suicide rate. In Pitts' words: '... the result was that a lot of doctors stopped prescribing the medications because they are afraid of liability. And a lot of parents stopped giving their children medicines that had been prescribed. And not surprisingly one or two years later very large studies came out to show that in fact teen suicidality had shown an increase – so there was really a direct correlation...' And Goodwin agrees with him (44:45): 'And in fact what happened, as you said, in the year or two after that the CDC confirmed that the actual rate of deaths by suicide went up 17% that paralleled precisely the 17% drop in prescriptions for these drugs, apparently in reaction to this label.

The host's interpretation of this study is closely aligned with the initial media reports about the study, but this initial analysis had a short life in the media. Several days following its publication a debate ensued (Berenson & Carey, 2007). According to some critics, a major problem with the paper's conclusions was that the increased suicide rate occurred in 2003, one year before the decrease in prescription rates and well before the warning label was issued. As their data shows, there was an increase in suicides in 2004. However the black box warning was not issued until October of 2004. As several commentators pointed out, claiming that a warning issued in October 2004 raised suicide rates for all of 2004 simply doesn't

make sense. Furthermore, when the data for 2005 were examined (the first full calendar year following the warning), suicide rates actually fell slightly (Clinical Psychiatry, 2007).

But most problematic is that much of this information about the study's controversy was available to Goodwin and his guests. In September of 2007 (six months before *Prozac Revisited* aired) *The New York Times* published an article entitled 'Experts Question Study of Youth Suicide Rates'. This cited concerns from other experts (Berenson & Carey, 2008) and even quoted the study's lead author Robert Gibbons saying that the data from the United States that he and his colleagues analyzed did not support a causal link between prescription rates and suicide in 2004. *The Boston Globe* published an article titled 'It's Premature to Blame the FDA for Suicide Rise,' highlighting the problems with the study (Allen, 2007). And this eventually was followed up by a *Globe* Op-Ed piece entitled: 'Suicide Rates as a Public Relations Tool' (Bass, 2007). When Drs Pitts and Goodwin claim a causal connection between the black box warning and increased suicide, these claims are very controversial, and the listeners that day did not hear both sides of the debate.

The efficacy of the SSRIs

Both Goodwin and Leuchter disagree with the published results from the latest meta-analysis, which examined the clinical trials designed to get the antidepressants approved by the FDA. In Leuchter's words (17:27): 'Yeah, once every few years somebody puts out one of those articles that looks at a bunch of studies and says antidepressants don't work. My take is the same as yours: that those studies really are a gross misinterpretation of the scientific literature.'

Presumably Leuchter is referring to the studies by Irving Kirsch, who found that in the company-sponsored trials SSRIs barely beat placebo, with the difference being statistically different but not clinically significant. It is common for pharmaceutical companies to only publish those studies that find that their products are effective and to withhold the negative studies, thereby making it difficult to reach accurate conclusions from the published data. Kirsch and his colleagues have used the Freedom of Information Act to gain access to the unpublished trials and have then pooled all the clinical trial data – both published and unpublished – and analyzed it as a single data set (Kirsch et al, 2008).

All of Kirsch's studies have shown that in company-sponsored trials the antidepressants have only performed marginally better than placebo – a performance, or lack thereof, that, were it not for Kirsch, most people would probably be unaware of. For most of the antidepressants studied there is only a two-point difference on the Hamilton depression rating scale between the drug and the placebo groups. Other psychiatric researchers have found similar results (Barbui, Furukawa & Cipriani, 2008).

In contrast with most critics of the clinical trial process, who claim that the companies plan their studies to give their drug the best possible chance of coming out ahead, Goodwin and Leuchter have a somewhat unique view on the process. With regard to the clinical trial process Leuchter says that the bar is low: 'All you have to prove is that people get somewhat better. So the studies are designed very conservatively just to show that the medication has an effect.' If the companies had been unsure of their medication's efficacy, presumably they would have been more careful with the experimental design.

But others have different views about the clinical trial process. Consider the experimental design for one of the two studies used to get Prozac approved for children. Like many clinical trials of antidepressants, there was a placebo runin phase, and children who responded robustly to placebo were removed from the study (Emslie et al, 2002). But this study also employed a unique aspect that most clinical trials do not use. The study had a run-in phase to pre-select for drug responders. Before the trial technically started, all the Prozac-treated children in this study were given 10mg for the first week and children who did not respond, or who had negative responses, could then be dropped from the study (p.1206). At the start of the second week the dose was increased to 20mg. The subsequent statistical analysis only used children who had had at least one week of treatment with 20mg (p.1208). Thus, before the study even started there were mechanisms in place to maximize any difference between the drug and placebo groups – the placebo group was pre-selected for non-responders, while the drug group was pre-selected for responders.

Yet, even with this advantage, on the primary outcome measure 65 per cent of the children on Prozac had a beneficial response compared with 53 per cent of the placebo patients – a result that was not statistically significant. It was only by looking at secondary measures that clinical significance was found: on the patientand parent-rated scales there was no advantage to Prozac, but on one of the clinician-rated scales there was a slight advantage. In other words, if the opinions of the children and their parents were considered, Prozac did not work, but on the rating scales given by the researchers funded by the makers of Prozac, Prozac had a small advantage. Although Russell Katz of the FDA wrote in 2001, 'One could argue that this post hoc choice of primary outcome is inappropriate,' in the end the FDA accepted the post hoc change and approved Prozac for children in January 2003 (Center for Drug Evaluation and Research, 2002; Vedantam, 2004).

It was the only antidepressant that the FDA ever approved for use in childhood depression. If the bar had been set any higher, and it was not set high, then Prozac would never have been approved for children. As it was, Prozac barely made it. To many, this sounds more like a trial that was designed to give Prozac every

advantage possible, and not like a clinical trial done by researchers who were so confident in Prozac's efficacy that they simply wanted to conduct a quick study to get it approved.

Leuchter also mentions the STAR*D study, which he co-authored. In his words, 'If you take a look at the better studies, like the STAR*D study, which is the largest study of depression ever done in this country... done at 14 sites around the country. I was the director for the Los Angeles center... [w]hat we showed was that these medications unquestionably improve depressive symptoms, decrease anxiety, get people back to work, improve their function, improve their social relations, decrease disabilities' (Walden, et al., 2007).

STAR*D study was a major multi-site study sponsored by NIMH. If a patient in STAR*D did not improve on one antidepressant they were switched to another one. However, there is a major problem with using STAR*D to justify the use of the SSRIs: *it was not a placebo controlled trial*. The researchers did not compare antidepressant treatment with psychotherapy, placebo, exercise, self-help, stress reduction, or no treatment at all, which would have yielded useful data on how SSRIs work in comparison with other approaches. Since they did not, they simply cannot use their data to argue that SSRIs are efficacious. Many of the patients did get better, but researchers did not design their experiment to isolate the efficacy of SSRIs. Also, since *The Infinite Mind* aired, the conclusions published from STAR*D have been subjected to scrutiny and scepticism. Although Leuchter claims that STAR*D established the efficacy of antidepressants, this is hard to reconcile with other statements in the literature, such as, 'The proportion that responded or remitted and stayed well for a year was estimated to be a disappointing 15%' (Nierenberg et al, 2008: 433, as cited in Cohen, 2011).

Leuchter's claims about efficacy and his reference to Kirsch's conclusions being 'a gross misinterpretation of the scientific literature' need to be strongly questioned. It is a fairly well-accepted fact that the SSRIs hold only a minor advantage over placebo. Consider that one long-term comparative study found that patients who were prescribed Zoloft had worse long-term outcomes than those who simply exercised (Babyak et al, 2000). A discussion of SSRI efficacy grounded in science would seemingly need to address data such as these. As it was, *The Infinite Mind* did not have a guest with a more critical view who could have pointed out the limitations of the STAR*D study.

But it is really a non-existent argument because, even within mainstream psychiatry it is now well acknowledged that the difference between placebo and antidepressant drug effect is minimal. The current state of the SSRI debate amongst Prozac's proponents is as follows: At one end of the spectrum, some clinical trial researchers and medication proponents say that for every ten people taking an antidepressant the drug helps one person. At the other end of the spectrum there are those who argue that it helps three people. The debate comes down to the significance of these low efficacy numbers. Or, put another way: Are SSRIs effective for 10 per cent or 33 per cent of the patients that receive them?

Even the pharmaceutical companies acknowledge that the difference between drug and placebo is minimal. A 2001 advertisement for Wellbutrin had a graph showing that the difference in efficacy between Wellbutrin and placebo is only 10 per cent (Leo & Lacasse, 2012). This does not come from a critic; it is on the manufacture's website. *The Infinite Mind* hosts are not just disagreeing with Kirsch, they are disagreeing with the majority view of mainstream psychiatry and the pharmaceutical companies.

American Psychiatric Association

In the second part of the interview, Goodwin interviews Dr Nada Stotland, the President of the American Psychiatric Association (APA). The interview consists mostly of Stotland repeatedly stating that the press is biased. She does not discuss evidence or research findings to support her claims. However at one point (35: 45) she strongly disagrees with the FDA and declares: 'There was no good reason for the black box warning.' Keep in mind that Stotland's disagreement is not with some unknown blogger or the Church of Scientology; she is disagreeing with the FDA. In reference to the use of antidepressants in children, at the 2004 FDA hearing, the committee member agreed with the FDA's conclusion that 'the data in aggregate indicate an increased risk of suicidality in pediatric patients' (Temple, 2004). Again, there is nothing wrong with the fact that the President of the APA believes this, but couldn't the opposite view also have been presented?

For a moment, put yourself in the shoes of a patient who has just been prescribed an SSRI and whose doctor has carefully explained the black box warning. What would this patient think to hear the President of the American Psychiatric Association declare on NPR that there was no good reason for the black box warning? In other words, just ignore the warning label. If the patient went back to their prescribing doctor and asked for an explanation of why the APA and the FDA are at odds, what would the doctor say?

Research into the use of antidepressants in children

While Prozac, Paxil and Zoloft were all used to treat depression in children, only Prozac was ever approved by the FDA. Clinicians who prescribed the other SSRIs were using it off-label. Some professionals believe that the studies involving the three most common SSRIs – Prozac, Paxil and Zoloft – serve as excellent examples of how, at every step of the way, the benefits were overestimated and the risks underestimated. According to Healy, 'There is probably no other area of medicine in which the academic literature is so at odds with the raw data' (2004: 10). Is this body of research really something worthy of wholeheartedly defending – to the point of showing complete disdain for anyone who points out its problems?

In 2012, several years after *The Infinite Mind* aired, GSK was fined \$3 billion by the Department of Justice (DOJ). The fine involved several medications, such as Avandia, Wellbutrin, Advair and Paxil. Regarding Paxil, the DOJ's complaint mainly focused on Study 329, which examined the use of Paxil for paediatric depression. While the DOJ treats GSK as the sole author of Study 329, only two of the named authors were actually GSK employees. All of the other named authors were affiliated with universities. In their complaint about Paxil and the role of Study 329 the DOJ did not mince words:

The United States argues that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy.

They also note that: 'GSK published an article that misstated Paxil's efficacy and safety for children and adolescents.' Clearly it would be unfair to fault *The Infinite Mind* for headlines that came after the show was aired. But if one looks beyond the headlines there is a problem for the show, because virtually all the documents the DOJ looked at were available and in the public record before *The Infinite Mind* aired (DOJ, 2012).

As soon as Study 329 was published in 2001, people started to point out its problems. John Jureidini wrote a letter to the editor, and then followed up with several peer-reviewed papers about Study 329. In 2004 Whittington and colleagues published a paper showing that, once the unpublished literature is included in the risk-benefit analysis of these drugs, the benefits do not outweigh the risks (Whittington et al, 2004). In 2008 Alison Bass, a health reporter for the *Boston Globe*, extensively documented problems with the study in her book *Side Effects*. For example, she pointed out that the study miscoded several suicidal teenagers as noncompliant when they were really suffering from suicidal ideation. And in 2004 the editors of *The Lancet*, one of the most elite medical journals in the world, referred to the paediatric studies of antidepressants as 'confusion, manipulation, and institutional failure' (Editors, 2004). Unlike the characterization made on the show that the critics of the trials were unscientific, it is important to point out that the guiding principle for all the voices pointing out the problems with the SSRI clinical was the 'science'.

Medical publishing process

A major hurdle to making an educated decision about a potential link between the SSRIs and suicide is the current nature of the medical publishing process. Some of the information that would aid interested parties has not even been published; some of it has only seen the light of day because of court proceedings, and some of it is only available to regulators and not the general public. The goal in this paper has not been to provide a definitive answer to the question of whether or not the SSRIs are linked to suicidality. Rather it is about the presentation of the issue by a supposedly unbiased major media outlet and whether or not that outlet presented a full and open discussion about the topic. No doubt in all the data presented here there are controversies and substantial room for debate regarding these issues; but the listeners of *The Infinite Mind* were not given a fair flavor of that debate. At the very least, since the host and guests disagreed with the FDA and accused it of being misguided and unscientific, it would have made sense to have at least included a representative from the FDA on the show to state their case.

One of the strengths of NPR is that on most topics the audience is exposed to a variety of perspectives. Usually there are individuals with extremely different points of view (ideology, political affiliation etc) discussing the different ways of looking at an issue. This is what NPR is known for and why it is a preferred source of news for so many people – it ostensibly serves the public interest rather than corporate interests. But on *The Infinite Mind* that day, throughout the entire show, there was hardly any criticism directed at the pharmaceutical industry. This is despite the fact that there is ongoing concern about research fraud in SSRI trials (specifically regarding the miscoding of suicidality, resulting in a lower suicide rate; that ghost-written articles have downplayed signs of suicidal behavior in children and adolescents prescribed antidepressants; and that pharmaceutical companies are withholding data that might have shed light on these exact issues). Whether coincidental or not, the views expressed on *The Infinite Mind* were almost universally congruent with the interests of pharmaceutical companies that manufacture antidepressants.

In a sense the question of suicidality served as a distraction for *The Infinite Mind* as it kept them from discussing all the other issues that have recently come out regarding these antidepressants. *The Infinite Mind* could have informed their listeners of the following: that there is evidence of selective reporting of the clinical trials; that much of the scientific literature on the SSRIs has been ghostwritten; that non-medication approaches have been shown to work; that there is little direct evidence in support of the chemical imbalance theory, and that there is significant controversy around STAR*D. All of these issues had made the news headlines before the show aired.

NPR and *The Infinite Mind* eventually acknowledged that there were problems with the undeclared conflicts (Shepard, 2008), but I am not aware of any acknowledgement about the problems with the show's content. NPR could produce another show on the same topic and invite the same guests, but could also include professionals such as David Cohen, Robert Whitaker, Irving Kirsch, John Jureidini, Peter Mansfield, David Healy, or even an FDA spokesperson, all who would take a more critical view of the issues. And instead of a show that just made assertions about who is right or wrong, the issues could be mapped out for the audience, as NPR routinely does with political topics.

Endnote

1. On the website of *The Infinite Mind* it is possible to purchase recordings of many past shows. The show analyzed here is not available for sale. I have transcribed the entire show. Educators who would like a copy of the transcript should contact me. A comparison of the transcript with the content in this article and the overall critical literature would make an interesting critical thinking exercise.

References

Allen, S. (2007). It's premature to blame FDA for suicide rise. The Boston Globe, 17 September.

- Antonuccio, D. (2009). Treating depressed children with antidepressants: more harm than benefit? *Journal of Clinical Psychology in Medical Settings*, 15.
- Babyak, M., Blumenthal, J.A., Herman, S., et al. (2000). Exercise treatment for major depression: maintenance of therapeutic benefit at 10 months. *Psychosomatic Medicine*, 62: 633–638.
- Bass, A. (2007). Suicide rates as public relations tool. The Boston Globe, 24 September.
- Bass, A. (2008). *Side Effects: a prosecutor, a whistleblower and a bestselling antidepressant on trial.* Chapel Hill, NX: Algonquin Books.
- Barbui, C., Furukawa, T.A. & Cipriani, A. (2008). Effectiveness of paroxetine in the treatment of acute major depression in adults: a systematic re-examination of published and unpublished data from randomized trials. CMAJ : Canadian Medical Association Journal, 178(3), 296–305. doi:10.1503/cmaj.070693
- Begley, S. (2010). Why antidepressants are no better than placebos. *Newsweek online at thedailybeast.com*. Retrieved January 21, 2012, from http://www.thedailybeast.com/ newsweek/2010/01/28/the-depressing-news-about-antidepressants.html
- Berenson, A. & Carey, B. (2007). Experts question study on youth suicide rates. *The New York Times*, 14 September.
- Brody, H. (2007). *Hooked: Ethics, the medical profession and the pharmaceutical industry.* Lanham, MD: Rowman and Littlefield.
- Brownlee, S. & Lenzer, J. (2008). Stealth marketers: Are doctors shilling for drug companies on public radio? *Slate.com*. 9 May. http://www.slate.com/id/2190775/

- Center for Drug Evaluation and Research (2002). Application number 18-936/SE5-064, Administrative documents for fluoxetine. Available:http://www.fda.gov/cder/foi/ nda/2003/18936S064_Prozac%20Pulvules_admindocs.pdf.
- Cohen, D. (2002). Research on the drug treatment of schizophrenia: A critical appraisal and implications for social work education. *Journal of Social Work Education*, 38(2), 217–239.
- Cohen, D. (2005). Clinical Psychopharmacology Trials: 'Gold Standard' or 'Fool's Gold'. In S.A. Kirk (Ed.) *Mental disorders in the social environment* (pp. 347–367). New York: Columbia University.
- Cohen, D. (2011). Psychopharmacology and clinical social work practice. In J.R. Brandell (Ed.) *Theory and practice in clinical social work* (2nd ed) (pp. 763–810). New York: Sage.
- Clinical Psychiatry (2007). Less SSRIs, more suicide apparently not. 14 September. Retrieved from http://clinpsyc.blogspot.com/2007/09/less-ssris-more-suicide-apparently-not.html
- Department of Justice (2012). Settlement agreement with GlaxoSmithKline. http://www. justice.gov/sites/default/files/opa/legacy/2012/07/02/plea-ex-b.pdf
- Diav-Citrin, O., Shechtman, S., Weinbaum, D., Wajnberg, R., Avgil, M., Di Gianantonio, E., Clementi, M., et al. (2008). Paroxetine and fluoxetine in pregnancy: a prospective, multicentre, controlled, observational study. *British Journal of Clinical Pharmacology*, *66*(5), 695–705. doi:10.1111/j.1365-2125.2008.03261.x
- Editors (2004). Depressing research. *The Lancet* 363: 1335. Available at: http://pdf.thelancet. com/pdfdownload?uid=llan.363.9418.editorial_and_review.29416.1&x=x.pdf.
- Emslie, G., Heiligenstein, J.H., Wagner, K.D., Hoog, S.L., Ernst, D.E., Brown, E., Nilsson, M., & Jacobson, J.G. (2002). Fluoxetine for acute treatment of depression in children and adolescents: a placebo-controlled, randomized clinical trial. *Journal of the American Academy of Child Adolescent Psychiatry* 20, 1205–1215.
- Gibbons, R.D., Brown, C.H., Hur, K., Marcus, S.M. et al (2007). Early evidence of the effects of regulators' suicidality warning on SSRI prescriptions and suicide in children and adolescents. *American Journal of Psychiatry* 164, 1356-1363.
- Glenmullen, J. (2000). *Prozac Backlash: Overcoming the dangers of Prozac, Zoloft, Paxil and other antidepressants with safe, effective alternatives.* New York: Simon & Schuster.
- Goodwin, F. (host). (2008). Prozac Revisited [Radio Broadcast]. In, B. Lichtenstein (Producer). The Infinite Mind, 26 March. Washington, D.C.: National Public Radio.
- Greenberg, G. (2011). *Manufacturing Depression: The Secret history of a modern disease*. New York: Simon & Schuster.
- Healy, D. (2003). Interface between authorship, industry and science in the domain of therapeutics. *British Journal of Psychiatry*, 183(1), 22–27. doi:10.1192/bjp.183.1.22
- Healy, D. (2004). Let Them Eat Prozac: The unhealthy relationship between the pharmaceutical industry and depression. New York: New York University Press.
- Healy, D. (2005). Contra Pfizer. Ethical Human Psychology and Psychiatry, 7(3), 181–195.
- Healy, D. (2012). *Pharmageddon*. Jackson, TN: University of California Press.
- Hughes, S. & Cohen, D. (2009). A systematic review of long-term studies of drug treated and non-drug treated depression. *Journal of Affective Disorders*, 118(1–3), 9–18. doi:10.1016/j. jad.2009.01.027

- Hughes, S. & Cohen, D. (2011). Can online consumers contribute to drug knowledge? a mixedmethods comparison of consumer-generated and professionally controlled psychotropic medication information on the internet. *Journal of Medical Internet Research*, 13(3), e53. doi:10.2196/jmir.1716
- Jacobs, D. H. & Cohen, D. (2010). Afterword: The make-believe world of antidepressant randomized controlled trials. *Journal of Mind and Behavior*, 31(1–2), 23–36.
- Jureidini, J., & Tonkin, A. (2003). Letter to the Editor. *Journal of the American Academy of Child and Adolescent Psychiatry*, 42(5), 514–515.
- Khan, A., Leventhal, R., Khan, S. & Brown, W.A. (2002). Suicide risk in patients with anxiety disorders: a meta-analysis. *Journal of Affective Disorders*, 68, 183–190.
- Khan, A., Khan, S., Kolts, R. & Brown, W.A. (2003). Suicide rates in clinical trials of SSRIs, other antidepressants, and placebo: analysis of FDA reports. *American Journal of Psychiatry*, *160*(4), 790–792.
- Kirk, S.A., Cohen, D. & Gomory, T. (2013). *Mad Science*. New Brunswick, NJ: Transaction Publishers.
- Kirsch, I., Deacon, B.J., Huedo-Medina, T.B., Scoboria, A., Moore, T.J. & Johnson, B.T. (2008). Initial severity and antidepressant benefits: a meta-analysis of data submitted to the Food and Drug Administration. *PLoS Med*, *5*(2), e45. doi:10.1371/journal.pmed.0050045
- Kramer, P. (1993). Listening to Prozac. Harmondsworth: Penguin Books.
- Lacasse, J. R. (2005). Consumer advertising of psychiatric medications biases the public against nonpharmacological treatment. *Ethical Human Psychology and Psychiatry*, 7(3), 175–179.
- Lacasse, J. R. & Leo, J. (2005). Serotonin and depression: a disconnect between the advertisements and the scientific literature. *PLoS Medicine*, 2(12), e392. doi:10.1371/ journal.pmed.0020392
- Lacasse, J. R. & Leo, J. (2006). Questionable advertising of psychotropic medications and disease mongering. *PLoS Medicine*, *3*(7), e321. doi:10.1371/journal.pmed.0030321
- Leo, J., Lacasse, J. R. & Cimino, A. N. (2011). Why does academic medicine allow ghostwriting? a prescription for reform. *Society*. doi:10.1007/S12115-011-9455-2
- Leo, J. & Lacasse, J.R. (2012). A pharmaceutical company that agrees with Irving Kirsch? Wellbutrin advertised as 10% more effective than placebo. MadInAmerica.com. http:// www.madinamerica.com/2012/02/a-pharmaceutical-company-that-agrees-withirving-kirsch-wellbutrin-advertised-as-10-more-effective-than-placebo/
- Lacasse, J.R. & Leo, J. (2015). Antidepressants and the chemical imbalance theory of depression: A reflection and update on the discourse. *The Behavior Therapist*, 38(7), 206–213.
- Lieberman, J.A., Stroup, T.S., McEvoy, J.P., Swartz, M.S., Rosenheck, R.A., Perkins, D.O., Keefe, R. S. E. et al. (2005). Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. *The New England Journal of Medicine*, 353(12), 1209–1223. doi:10.1056/ NEJM0a051688
- Moncrieff, J. (2009). *The Myth of the Chemical Cure: A critique of psychiatric drug treatment*. Basingstoke: Palgrave Macmillan.

- Moynihan, R. (2008). Key Opinion Leaders: Independent experts or drug representatives in disguise? *British Medical Journal* 336(7658):1402–1403. doi:10.1136/bmj.39575.675787.651.
- Nierenberg, A.A., Ostacher, M.J., Huffman, J.C., Ametrano, R.M., Fava, M. & Perlis, R.H. (2008). A brief review of antidepressant efficacy, effectiveness, indications, and usage for major depressive disorder. *Journal of Occupational and Environmental Medicine*, *50*(4), 428–436.
- Pigott, H. et al. (2010). Efficacy and effectiveness of antidepressants: current status of research. *Psychotherapy &d Psychosomatics*, 79(5), 267–279. http://content.karger.com/ ProdukteDB/produkte.asp?Doi=318293
- Rosenheck, R. (2005). The growth of psychopharmacology in the 1990s: evidence-based practice or irrational exuberance. *International Journal of Law and Psychiatry*, 28(5), 467–483. doi:10.1016/j.ijlp.2005.08.005
- Schor, E. (2008). GSK faces US scrutiny over Paxil Suicide link. The Guardian, 12 June.
- Serretti, A. & Chiesa, A. (2009). Treatment-emergent sexual dysfunction related to antidepressants: a meta-analysis. *Journal of Clinical Psychopharmacology*, 29(3), 259–266. doi:10.1097/JCP.ob013e3181a5233f
- Shepard, A. (2008). Is 'The Infinite Mind' an NPR show? 12 may. Available at: http://www.npr. org/sections/ombudsman/2008/05/is_the_infinite_mind_an_npr_sh.html
- Spurling, G.K., Mansfield, P.R., Montgomery, B.D., Lexchin, J., Doust, J., Othman, N. & Vitry, A.I. (2010). Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: a systematic review. *PLoS Medicine*, 7(10), e1000352. doi:10.1371/journal.pmed.1000352.too9
- Temple, R. (2004). Antidepressant drug use in pediatric populations: statement of Robert Temple, Director, Office of Medical Policy. Congressional testimony. 23 September. Available at: http://www.fda.gov/NewsEvents/Testimony/ucm113265.htm
- Tsai, A.C., Rosenlicht, N.Z., Jureidini, J.N., Parry, P.I., Spielmans, G.I. & Healy, D. (2011). Aripiprazole in the maintenance treatment of bipolar disorder: a critical review of the evidence and its dissemination into the scientific literature. *PLoS Medicine*, 8(5), e1000434. doi:10.1371/journal.pmed.1000434.too1
- Vedantam, S. (2004). Antidepressant use in children soars despite efficacy doubts. *The Washington Post*, 18 April.
- Warden, D., Rush, J. Tivedi, M.H., Fava, M. & Wisniewski, S.R. (2007). The STAR*D Project Results: A comprehensive review of findings. *Current Psychiatry Reports*, 9, 449–459.
- Whitaker, R. (2010) Anatomy of an Epidemic: Magic bullets, psychiatric drugs, and the astonishing rise of mental illness in America. New York: Crown Publishing.
- Whittington, C.J., Kendall, T., Fonagy, P., Cottrell, D., Cotgrove, A. & Boddington, E. (2004). Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data. *The Lancet*, 363, 1341–1345.