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Academic Stalking and Brand Fascism

David Healy

Academic Stalking: A Case History

From the early 1990s, using the example of how companies had marketed antidepressants, in particular the then new selected serotonin reuptake inhibiting (SSRI) antidepressants, I had authored a series of articles that illustrated the marketing power of pharmaceutical companies.¹ This strand of thinking led to the publication in 1997 of a history of the antidepressants.² This book was favourably reviewed both by those supportive of pharmacotherapy and those against it, as well as by reviewers from the pharmaceutical industry. Company reviewers appear to have been pleased that industry involvement in the creation of the field was acknowledged instead of being overlooked, as typically happens in traditional histories of medicine that feature a series of “great” individuals or academic institutions and downplay the business side of science and medicine.

I had also from 1991 onwards written a number of articles and made a number of presentations on the issue of antidepressant-induced suicidality, especially as this linked to the SSRI antidepressants and in particular to Prozac³. In books written for general readers from 1993, I included the observation that antidepressants could cause problems of this type.⁴ In response, Lilly, the makers of Prozac, invited me to consult for the company, and otherwise invited me to meetings and were “friendly.”⁵

The reception for another article, appearing in 2000, that combined these two themes was quite different. This article appeared in the *Hastings Center Report*, one of the leading bioethics journals in the field, whose Spring issue in 2000 was entitled “Prozac, Alienation and the Self.” This issue contained five articles on Prozac.⁶ Two of these articles suggested that as Prozac was so wonderfully effective it would be a mistake to restrict its use simply to people who are depressed and that it should be available more widely to anyone who responded to it. Two

¹ D. Healy, “The Psychopharmacological Era: Notes toward a history.” *J Psychopharmacology* 4 (1990): 152–67; D. Healy, “The Marketing of 5HT: Anxiety or depression,” *British J Psychiatry* 158 (1991): 737–42.

² D. Healy, *The Antidepressant Era* (Cambridge, MA: Harvard University Press, 1997).

³ W. Creaney, I. Murray, D. Healy, “Antidepressant Induced Suicidal Ideation,” *Human Psychopharmacology* 6 (1991): 329–32; D. Healy, “The Fluoxetine and Suicide Controversy,” *CNS Drugs* 1 (1994): 223–31; D. Healy, M. Savage, “Reserpine Exhumed,” *British J Psychiatry* 172 (1998): 376–8; D. Healy, C. Langmaak, M. Savage, “Suicide in the Course of the Treatment of Depression,” *J Psychopharmacology* 13 (1999): 94–99.

⁴ D. Healy, *Psychiatric Drugs Explained*, 5th ed. (Edinburgh: Churchill & Livingstone, 2008), originally published (London: Mosby Yearbooks, 1993).

⁵ D. Healy, *Let Them Eat Prozac* (Toronto: James Lorimer, 2003).

⁶ C. Elliott, introduction to *Prozac as a Way of Life*, ed. C. Elliott and T. Chambers (Duke University Press, 2004, Durham North Carolina). The original articles were P. Kramer, “The Valorization of Sadness: Alienation and melancholic temperament,” *Hastings Center Report* 30 (2000): 13–19; C. Elliott, “Pursued by Happiness and Beaten Senseless: Prozac and the American Dream,” *Hastings Center Report* 30 (2000): 7–12; D. DeGrazia, “Prozac, Enhancement and Self-creation,” *Hastings Center Report* 30 (2000): 34–40; J.C. Edwards, “Passion, Activity and ‘The Care of the Self,’” *Hastings Center Report* 30 (2000): 31–33; D. Healy, “Good Science or Good Business?” *Hastings Center Report* 30 (2000): 19–22.

further articles argued that even though Prozac was very effective, its use should be restricted to people who are depressed. The fifth article, by me, argued that Prozac was not particularly effective and that impressions of its efficacy stemmed in great part from the fact that negative trials went unreported, that data on the hazards of the drug were concealed, and that in part this state of affairs was linked to the fact that articles on Prozac and on other psychotropic drugs were increasingly ghost written.

Following the publication of this issue, Eli Lilly, who at the time were the biggest single funder of the Hastings Center, withdrew their support, because the Center had “published articles that Lilly felt contained information that was biased and scientifically unfounded and that may have led to significant misinformation to readers, patients and the community”.⁷

In July that year, at the British Association for Psychopharmacology’s (BAP) annual meeting in Cambridge, I presented data on a healthy volunteer study conducted in which two volunteers who had been blindly randomized to Zoloft (sertraline), one of the Prozac group of SSRI drugs, had become suicidal.⁸ Professor Charles Nemeroff from Emory University was the guest lecturer at the meeting. Quite extraordinarily in the course of his lecture, he indicated there was research at the meeting which he felt did not have a place at an academic meeting. It appeared clear that he was referring to my work and it seemed likely that when the study was presented in poster format later that day he would be present.

He appeared at the poster, and in the course of a brief encounter he made it clear to me that he had been approached to get involved in legal action against me. He also made it clear that he thought presenting research of this kind was unlikely to be helpful to my career, as pharmaceutical companies roll over people who are awkward to them.

Finally, at the end of November 2000, the University of Toronto and the Centre for Addiction and Mental Health hosted a meeting to celebrate the 75th anniversary of the university department and the 150th anniversary of the mental health services in Ontario. I was one of the guest speakers at the meeting. At the time I was scheduled to move to the University of Toronto, having been interviewed for and offered a post as Professor of Psychiatry earlier that year. The distinguished collection of speakers for the meeting included Dr. Nemeroff. The audience was invited to evaluate both the content and presentation of talks afterwards. My talk was rated the highest on the combined scores.

During the course of that day, I gather Dr. Nemeroff made it clear to members of the university that it would be a mistake to hire Healy. Later that evening I had the first intimations that my appointment was in jeopardy. The following morning, as I understand it, Dr. Nemeroff told colleagues at meetings in New York that Healy had lost his job. A week later I had an email confirming that my contract with the university was terminated.

Stalked

I contested the termination. The story broke in April 2001.⁹ and the media approached me for my side of the issues. They also approached the university, who declined to comment but directed reporters to a Dr. James Coyne, then at the University of Pennsylvania, indicating that Dr. Coyne would be able to comment on Healy.

I had never heard of Dr. Coyne. His remarks appear to have been intemperate, and none of the outlets that covered the story featured his views. This led him to write letters, the first of

⁷ Cited in C. Elliott (2004), introduction to *Prozac as a Way of Life*, ed. C. Elliott and T. Chambers (Duke University Press, 2004, Durham North Carolina).

⁸ D. Healy, “Antidepressant induced suicidality,” *Primary Care Psychiatry* 6 (2000): 23-28.

⁹ A. McLroy, “Prozac Critic sees U of T job revoked,” *Globe and Mail*, April 14, 2001.

which was published in the University of Toronto *Bulletin*, in which he indicated the only odd feature of what has come to be known as the Healy affair was that the university had seen fit to consider hiring Healy in the first instance, as he had little research to his name and his healthy volunteer study was poor from a methodological point of view and likely unethical.¹⁰ Dr. Coyne sent a number of comparable contributions to locations, including Web sites, where they could be posted without oversight.

Who was James Coyne? I later found that he had consulted for a number of pharmaceutical companies, including Lilly, and also that he had links with Chamberlain Communications, a New York-based PR agency working for Lilly. He was a psychologist who had previously been employed in Ann Arbor, working on depression.

From 2000 onwards, Dr. Coyne made regular and colourful contributions to a Society for Scientific Clinical Psychology (SSCP) listserv berating me and my research and anyone who offered me support on the issue of whether antidepressants could trigger suicidality.¹¹ This was not a listserv on which I was a participant. I only became aware of the contents some years later.

In a posting on 9/11/01, before other news broke that day, referring to Healy he stated: “He had not only BEEN an expert witness when he published that article, he was ACTIVELY a witness in an unresolved civil suit in which it was crucial that he be able to cite data for his otherwise unsubstantiated position that SSRI's make people suicidal. Releasing the paper to accomplish that was both timely and sleazy, and all the more so because he did not disclose his relevant financial interests in the study having a particular outcome. His testimony and soliciting of law suits was quite germane to any effort to make sense of his bizarre report and I doubt many readers understood the connection. . . . Incidentally, when it is convenient, Healy accepts considerable money from drug companies, more than most people I know.”

Many of the claims made by Dr. Coyne in his postings and correspondence regarding the Healy affair contained claims and assertions about me that were only otherwise being made to my knowledge in briefings to the media by Lilly, Pfizer and GlaxoSmithKline (GSK).

The types of materials aired by Dr. Coyne found an echo in a posting by Pfizer on the US FDA's Web site in July 2004. This posting was linked to a drugs advisory committee meeting to consider the issue of suicidality on antidepressants given to pediatric patients. An earlier meeting in February 2004 had indicated there appeared to be a problem—antidepressants made minors suicidal. The FDA had deferred handling the issue further for a period of half a year on the basis that the agency needed to analyze the data further. Prior to the second hearing in September 2004, interested parties were allowed to make postings on the FDA's Web site and Pfizer did so.

The Pfizer letter was a fifty-page billet-doux extolling the character and science of David Healy in terms such as the following:¹²

Dr. Healy has distorted and mischaracterized the evidence. . . many erroneous statements, unsupported contentions and data distortions. . . .

Dr. Healy has been hired by lawyers representing civil-litigation plaintiffs and criminal defendants to criticize SSRIs in at least 8 cases. Although he is a psychiatrist and reader at the University of North Wales, he is primarily known

¹⁰ J. Coyne, “Healy's study ‘odd,’” *Bulletin* (University of Toronto), July 23, 2001: 8.

¹¹ [Http://www.healyprozac.com/AcademicStalking/default.htm](http://www.healyprozac.com/AcademicStalking/default.htm).

¹² S. Ryder, letter to Robert J Temple, Director, Office of Drug Evaluations, July 26, 2004, <http://www.FDA.gov/ohms/dockets/ac/04/briefing/2004-406561-31-pfizer-letter.pdf>, 24-25. (Accessed September 21, 2007).

for his work as a medical historian. He has little scientific experience in conducting and interpreting the results of controlled clinical research. . . .

Before becoming a litigation expert witness testifying against SSRI manufacturers, Dr. Healy published views opposite to those he now espouses on the question of whether SSRIs induce suicide.

This material contains a number of claims that appear to me actionably false, but taking an action against a pharmaceutical company seemed counter-productive in that any legal effort would likely distract my attention from other important work, and it seemed to me quite likely that Pfizer and other companies had this possibility in mind. FDA denied me a right of reply, but I have since published a reply.¹³

Aside from postings on the SSCP listserv, Dr. Coyne's stalking took more concrete form in 2005. I was aware from postings on the listserv that he was writing or proposing to write an article on the Healy affair. When an article on the "Martyrdom of David Healy" finally appeared in the *American Journal of Bioethics*, it was only published online. There was no hard copy.¹⁴ The journal refused a right of reply. The article is in many respects curiously unfocused, but from its title onwards it conveys the impression that Healy has a lot to answer for.

This article led the Collegium Internationale Neuro-Psychopharmacologicum (CINP), the leading international psychopharmacological association, of which I am a member, to institute an investigation. Curiously this investigation and apparently a number of other investigations of the Healy affair have been able to proceed without consulting me at any point.

The Coyne article set up a debate, scheduled for Columbia University in October 2005, supposed to feature Dr. Coyne and myself. I turned up, but Dr. Coyne did not. Subsequently, Dr. Coyne posted on the SSCP listserv a series of comments on Healy and Healy's positions, which I presumed were the kinds of things that he would have said in the debate. These comments and my replies have been posted on the Alliance for Human Research Protection and healyprozac.com Web sites.¹⁵

The most ominous development in relation to the Coyne article came in March 2006 when I had a letter from the General Medical Council (GMC) in the UK, the body responsible for the registration of doctors. Investigation by the GMC can lead to a doctor being struck off. The letter from the GMC started "Dear Healy, . . ."

Letters like this from the GMC must also include the letter of complaint. The GMC is headed by Sir Graeme M. Catto. Ordinarily letters to Dr. Catto would be addressed "Dear Sir Graeme," but this letter of complaint was addressed "Dear Graeme, . . ." It was from someone I would have considered a relatively close professional colleague, Professor David Nutt, the Professor of Psychiatry and previously the Dean of Medicine at Bristol University. This letter referred Dr. Catto and the GMC to the Coyne article, which "raises serious concerns about the scientific and ethical conduct of Dr. Healy. . . . Is this something the GMC should be concerned about?"¹⁶

Complaints to the GMC often take years to run their course. Individuals being complained about find the process highly stressful. In this instance, the correspondence

¹³ D. Healy, "Contra Pfizer," *Ethical Human Psychology & Psychiatry* 7 (2005): 181-195.

¹⁴ J. Coyne, "Lessons in Conflict of Interest: The construction of the martyrdom of David Healy and the dilemma of bioethics" *American J of Bioethics* 5 (2005): W3-W14.

¹⁵ <http://www.ahrp.org/cms/content/view/18/87/> and <http://www.healyprozac.com/AcademicStalking/default.htm>.

¹⁶ All correspondence on <http://www.healyprozac.com/AcademicStalking/default.htm>.

surrounding the complaint was fast and furious. It has been laid out in its entirety on healyprozac.com. Using freedom of information provisions, I was able to establish that Dr. Nutt and colleagues had apparently drafted several letters to the GMC to complain about me, but it would seem had lacked a clear focus for a complaint until the appearance of Coyne article.

Dr. Nutt's closest collaborator in the exercise of drafting a letter to the GMC appears to have been Dr. Guy Goodwin, the Professor of Psychiatry at Oxford, another colleague I would have regarded as relatively close. In 2000, I had given a lecture in Oxford at Dr. Goodwin's invitation on the history of the antidepressants and issues to do with suicidality on these drugs.

In 2003 in the course of legal work, I had visited Pfizer in New York to look for documents the company might have on rates at which children in the clinical trials of their antidepressant, Zoloft, had become suicidal. Almost all of the documents related to pediatric suicidality were apparently missing from the archives when I was there, but a vast number of pages remained. There had therefore to be considerable odds against finding any single loose page amongst this material. But a loose page came to hand that appeared to be notes of a telephone call that had been made by an employee of Pfizer to Dr. Goodwin following the lecture on antidepressants and suicidality I had given in Oxford.

These notes may have been taken entirely without Dr. Goodwin's awareness. He appears to have been asked to give an account of what I had said in my lecture, and may also have been asked for, or volunteered, further information on issues to do with me that might be of interest. It seems likely to me that someone gets approached in this way after all my lectures, and that something similar probably happens when anyone critiques the pharmaceutical industry.

Presented with the evidence of serial complaints by Drs. Nutt and Goodwin and apparent plotting on this issue, together with information on Dr. Coyne's background and links and his failure to engage on the issues, and the co-incidental emergence of a letter from GlaxoSmithKline that conceded their antidepressant, Paxil, was linked to a two-fold increase in the risk of suicidality, the GMC chose to draw their investigation to a close some months later. Their letter informing me of this contains a phrase to be cherished: "The paper by James Coyne represents an alternative view and perspective, which is encouraged in the arena of academia and research."

Handling Academics

This case history needs to be read in a context that includes the role of PR agencies such as Chamberlain Communications, with whom Dr. Coyne had links. When a new drug is launched or when an old drug needs to be defended, public relations companies like this have a brief to handle some of the problems in the field that the new drug might face, including perceived critics.

The kind of "handling" involved can be seen in the example of what happened to another clinician who questioned the received wisdom on Prozac, Joseph Glenmullen. In 2000 Dr. Glenmullen published *Prozac Backlash*, a book that details hazards linked to treatment with the SSRI antidepressants Prozac, Paxil, and Zoloft. On its launch Chamberlain Communications in New York, and other communications agencies working for Lilly, such as Rasky Baerlein in Boston, sent reviews of the book by eminent figures in US psychiatry including John Greist, Tony Rothschild, David Dunner, Graham Emslie, and Harvey Rubin to media outlets such as *Newsday* in New York and the *Boston Globe*. These reviews from some of the more eminent figures in American psychopharmacology broadly state that *Prozac Backlash* was an unfortunate book that emphasized the hazards of treatment without detailing the benefits. The reviewers

feared that such a book would put people off seeking treatment and that the failure to seek treatment might lead to their suicide.

The reviews sent to *Newsday* arrived with a covering letter from Robert Schwadron of Chamberlain Communications, who asked *Newsday* to take these reviews into account. Schwadron went on to indicate that he could arrange for *Newsday* to have interviews with people from Lilly and with “independent researchers” to balance the views in *Prozac Backlash*.¹⁷

This system of controlling the message does not necessarily require people to change their views in return for money from a pharmaceutical company. The companies’ power lies in their ability to select the views that suit their interests and to ensure a wide distribution of these views, rather than in their abilities to buy off opinion leaders, although the latter almost certainly also happens.

Even before I had lost my job in Toronto, both Dr. Glenmullen and I had become problems for Chamberlain to handle, in my case likely owing to the fact that as of 1999 I had become an expert witness in legal cases against all three major SSRIs. It is possible that at least three different PR agencies working for the respective companies had Healy briefs.

Around that time, I became aware from colleagues as far away as Japan that American academics linked to pharmaceutical companies—who had never met me, heard me talk, or engaged with me on any of the issues I had raised—were spreading the word that Healy was trouble and likely to be in trouble and anyone linked to him risked being damaged by association.

A subsequent freedom of information request to Lilly UK threw up 109 items. The contents of items 103 and part of 104 are reproduced here:¹⁸

103: Healy long term strategy.

Thank you for the message outlining your strategy to counteract Dr. David Healy’s claims re: Prozac and violence.

Send a letter to Healy designed to get him to stop discussing a study that he has never done.

Have a third party expert in the audience at BAP to ask Healy questions when he presents.

Just last Thursday Healy was quoted in a Cincinnati paper saying Prozac causes violence and suicide . . . X has asked that we go back to legal and determine if we can sue Healy under UK law.

104: Huge turn out. . . . Good talk. Lesson no sponsor if Healy present in future.

I have been informed by several colleagues in pharmaceutical companies that they had been told they could not have me as a speaker at meetings they organized. Efforts were made at meetings where I was scheduled to speak, such as the International Society for Pharmacoepidemiology, to have me disinvited right up to the last minute. Funds already committed by pharmaceutical companies to meetings were withdrawn in a manner that appeared linked to positions I was taking. None of this is unusual; others such as Adrienne Fugh-Berman have reported similar experiences.¹⁹

I also learned through emails that a number of what were described as national (American) meetings had supposedly been held to discuss the Healy issues, and speakers or other materials at these meetings had made it clear to participants that those who supported Healy were

¹⁷ All reviews and the covering letter are available from the author.

¹⁸ Further documents can be found on <http://www.healyprozac.com/AcademicStalking/default.htm>.

¹⁹ A. Fugh-Berman, “Doctors Must Not Be Lapdogs to Drug Firms,” *BMJ* 333 (2006): 1027.

simply not aware of the facts. These meetings were held without any input from me and even without my awareness.

Despite having good links to most major psychopharmacology forums, it proved almost impossible to get the issues of antidepressant-induced suicidality onto the agenda of any meetings. On the rare occasions when debates were set up, such as at an Irish psychiatric meeting in 2003, my opponents and the chair were briefed by pharmaceutical companies with material that overlapped heavily with Coyne and Pfizer material.

Finally, in the midst of my difficulties with the GMC in 2006, I had another difficulty. The Internal Revenue Service (IRS) in the United States made it clear they thought I owed them over \$30,000 for the years 2001 and 2002. This covered tax they regarded as unpaid, the interest on unpaid tax, and fines for non-payment. It seemed quite likely that something similar would unfold for 2003, 2004, and 2005, and indeed for subsequent years.

Britain and America have a tax treaty which allows an individual to pay tax in one jurisdiction only. Aware of possible developments of this sort, I had ensured that all of my accounts had been professionally handled from 1997 onwards, and that all tax had been paid. Within the UK, I had been subject to several reviews in the years from 2000 onwards, to the surprise of my accountant. My accountant was, however, unable to help me with the American tax authorities. I had to seek help from an American accountant. (The IRS ultimately concluded they owed me money, but I continue to have to file tax returns in both the US and UK.)

In 2004, at the time of the hearings on the risks of suicidality in pediatric populations linked to antidepressant intake, the FDA's associate commissioner for external relations was Peter Pitts, whose challenge it apparently was "to clearly define FDA's brand image."²⁰ Pitts later went on to be a prominent figure in the Centre for Medicine in the Public Interest (CMPI). This proclaims itself as "a non-partisan, non-profit educational charity, whose Mission is to discuss, debate and demonstrate how exponential and accelerating technological progress coupled with smart public policy will enhance and advance 21st Century health care by predicting, preventing, diagnosing, and treating diseases with greater speed, more precision and less cost."

CMPI runs a Web site, <http://www.drugwonks.com/>. As the Internet has become a source of information on the development and the hazards of drugs and on health in general, pharmaceutical companies have learned how to ensure that pharma-friendly sites come up early on Internet searches and hostile sites do not. Drugwonks.com comes up early in searches for information on antidepressant hazards. A prominent figure posting here is Peter Pitts, who writes about critics of pharmaceutical companies, such as David Healy.

Given the huge body of evidence that the decline in the use of antidepressants has fueled an increase in suicides, the fearmongers now blame the use of anti-psychotics. That includes David Healy, the well-paid expert witness for trial attorneys now suing the likes of Eli Lilly who make anti-psychotics. Can we say conflict of interest? Where will Healy, David Graham and the rest go to wash the blood off their hands²¹

Mr Pitts is also a vice-president for Manning, Selvage and Lee. MS&L "is ranked among the world's top healthcare communications practices. We specialize in health policy, direct to consumer, health policy, medical education, third party alliances and strategic communications around key pharmaceutical benchmarks including medical meetings, advisory committee

²⁰ From profile of Peter Pitts on Drugwonks.com.

²¹ From Drugwonks.com. Posting on September 6th 2007.

meetings, product approvals and launches.”²² Its clients include Eli Lilly, Pfizer and GlaxoSmithKline.

Conversely, other sites such as <http://furiousseasons.com/>, or clipsync.blogspot.com which may feature material on the hazards of psychotropic agents, are regularly trawled by legal offices, PR agencies and other groups linked to pharmaceutical companies for, among other things, references to the views of or work of David Healy.

All of the experiences above find echoes in the accounts of what happened to Nancy Olivieri,²³ Aubrey Blumsohn,²⁴ and John Buse,²⁵ among others. Marketing departments arrange for critics of current products to be marginalized or silenced in a manner that fits well with fascist traditions of the 1930s, 1940s, and 1950s. Anyone who criticizes a brand is likely to have “friends” planted in the audience to monitor what they say and if need be challenge it; is likely to have their utterances or writings scrutinized for possible legal actions; is likely to find “friends” and colleagues have been mined for information; is likely to find “friends” complain them to whatever body monitors their registration as a physician; is likely to have all their emails and telephone calls monitored, and is at distinct risk of losing their job.

Censoring Academia

The current academic scene involves a number of other factors and forces. There is more involved than just individual stalkers operating in a climate facilitated by PR agencies. Whatever the fate of individual academics in the past, science in general has been viewed as relatively unaffected by passing commercial concerns, but the SSRI, osteoporosis, and other stories noted above involve a distortion of the science base. And it is this distortion, and the ability of companies to get the majority of academics to buy into distorted versions of the facts, that isolates academics from the herd and makes them vulnerable to being stalked.

For most academics it is probably close to inconceivable that scientific journals and meetings might be censored. Those a little wiser to the ways of the world might concede there is a certain amount of interference in areas that bear on commercial sensitivities but nothing that could conceivably be called censorship. Readers are likely to think the difficulties surrounding the Hasting Center Report mentioned above, must simply have been an aberration, one that likely backfired on the company that withdrew its funding.

The alternate explanation, namely that the way Lilly treated the Hastings Center has come close to being the norm for the way companies treat academic journals and meetings, would need to be substantiated. With this in mind, consider the following 11 cases.

1. In 1999, having agreed to testify medico-legally in a case involving homicide and suicide on Prozac, I became aware of documents shedding light on the propensity of Prozac to trigger suicidality and of company efforts to avoid warning of the risk. The documents were in the public domain but few were aware of their existence. My immediate thought was to write an article outlining the material for the *British Medical Journal (BMJ)*.

When the question of Prozac-induced suicide was first raised in 1990 and the first legal actions had been filed against the company, the *BMJ* carried an article with a company-only

²² From <http://www.mslpr.com/>, Accessed January 15, 2008.

²³ J. Thompson, P. Baird, and J. Downie, *The Olivieri Report* (Toronto: James Lorimer, 2001).

²⁴ A. Blumsohn, <http://scientific-misconduct.blogspot.com/> (2006); A. Blumsohn, “Authorship, Ghost-science, Access to Data and Control of the Pharmaceutical Scientific Literature: Who stands behind the word” *Professional Ethics Report* (American Association for the Advancement of Science) XIX, no. 3 (2006), <http://www.aaas.org/spp/sfml/per/per46.pdf>.

²⁵ [Http://finance.senate.gov/press/Bpress/2007press/prb111507a.pdf](http://finance.senate.gov/press/Bpress/2007press/prb111507a.pdf).

authorship line that, despite demonstrating a 1.9-fold increased risk of a suicidal act on Prozac compared to placebo, was widely spun as evidence that there was no risk from the treatment.²⁶ This article drew an intriguing response from a professor of psychiatry who had a history of difficulties with the pharmaceutical industry: “The *BMJ* is a journal of distinction and, dare I say it, perhaps also of some innocence. At a time when in the United States the manufacturer of fluoxetine is facing litigation, the corporate defense attorneys will be pleased by the journal having published a piece authored wholly by the manufacturer’s employees.”²⁷

The initial *BMJ* response to my submission was encouraging. The editor suggested reframing the article for the education and debate section of the journal. A revised article was sent to a reviewer, who was apparently not told that it was an education and debate article about company behaviour and not an evidence-based assessment of the case for Prozac-induced suicidality. The reviewer suggested the article had not established the case for treatment-induced problems—which it had never attempted to do. The editor rejected the piece on this basis. Mystified at the mismatching messages, I appealed but in vain, with the editor in a phone call stating that no matter what revisions I made nothing would be published.²⁸

This article was published unaltered in the *International Journal of Risk and Safety in Medicine*, whose editor, Graham Dukes, commented that “It seems to me your approach is original and fair. . . . I had not seen the issues of litigation, regulation and patents juxtaposed in this way before. . . . I agree entirely from my own experience with many of your comments; there are some striking examples of companies tenaciously hanging onto a profitable and patented drug despite the evidence that it is doing more harm than good. Their motives are a mixture of opportunism and genuine belief that the product is being wrongly accused. I also agree with your remarks about the failure of the present overall research approach to elicit a reliable picture of adverse effects and the sometimes unrealistic defenses put up by industry when their products are the subject of injury litigation.” The article was given guest editorial status to emphasize its message.²⁹

2. A year later, having conducted a blind and randomized trial in healthy volunteers, in which two volunteers had become suicidal on an SSRI, I again contacted the *BMJ* about a submission but was told there was no point submitting the article. This was the research that so exercised Drs. Coyne and Nemeroff. My assessment of the situation suggested seeking publication instead in a journal whose editors had previously worked within the pharmaceutical industry, on the basis that this background would make them less rather than more nervous about offending industry. The paper was reviewed and rapidly published.³⁰

3. Subsequently, I submitted a data-driven article to the *British Journal of Psychiatry* on ghost writing, whose key finding was a majority of articles that deal with pharmaceutical products in our leading journals are likely to be ghost written. This journal usually has two peer reviewers. In this case a clearly nervous journal used at least five reviewers and had the revised

²⁶ C.M. Beasley, B.E. Dornseif, J.C. Bosomworth, M.E. Saylor, A.H. Rampey, J.H. Heiligenstein, V.I. Thompson, D.J. Murphy, and D.N. Massica, “Fluoxetine and Suicide: A meta-analysis of controlled trials of treatment for depression,” *BMJ* 303 (1991): 685–92.

²⁷ I. Oswald, Letter, *BMJ* 303, (1991): 1058.

²⁸ All correspondence is available on <http://www.healyprozac.com>.

²⁹ D. Healy, Guest Editorial, “A Failure to Warn,” *Int J Risk Safety in Medicine* 12 (1999): 151-56.

³⁰ D. Healy, “Antidepressant Induced Suicidality,” *Primary Care Psychiatry* 6 (2000): 23-28.

article re-reviewed. The article was subsequently referred to the legal department of the journal and the copy editors for the journal spent a great deal of time working on the final version.³¹

4, 5, 6, & 7. Around this time a much smaller journal, *Contemporary Psychology*, requested a review of Joseph Glenmullen's *Prozac Backlash*. My review outlined the key points made by the book, without endorsing the position of the author. It added that I was in possession of five highly critical reviews of the book by distinguished American psychiatrists, with accompanying documentation from public relations agencies working for Lilly providing these reviews to media outlets and encouraging them not to feature the book. I sent the review and the accompanying documents to the editors. The review was initially accepted but failed to appear. On enquiring I was told that the journal could not find a balancing reviewer and so they could not carry my review. The response made little sense.

When the issue of antidepressant-induced suicidality in pediatric populations emerged, *Open Minds* and *Young Mind* requested pieces on the issue. Both journals declined to publish on what I was told was legal advice. They made it clear the decision was entirely based on the assessment that they did not have the resources to handle any difficulties they might run into with pharmaceutical companies as a result of publishing the articles, and to invite such problems could put them out of business.

In 2005 the *Times Higher Education Supplement (THES)* featured a series of articles on Aubrey Blumsohn who had "blown the whistle" on Sheffield University and Proctor and Gamble over company concealment of data on the response to therapy with risedronate, a treatment for osteoporosis (See Blumsohn's chapter in this book). A series of letters were submitted to *THES* commenting on aspects of the case. Mine sought to make clear that Blumsohn's case was not unique. *THES* amendments to the letter stripped its meaning. I suggested their revisions made the letter pointless, to which they responded: "We have also had to run these letters past our lawyers as this is, as you are aware, a very sensitive issue, and there are certain legal amendments we had to make." They did not publish any letter from me.

8. In 2004 *Evidence Based Mental Health* approached me to provide a 300-word commentary on a *Journal of the American Medical Association (JAMA)* article on antidepressants and suicide by Herschel Jick and colleagues.³² This article, which appeared in the midst of controversy as to whether newer antidepressants might trigger suicidality in minors, appeared to exonerate these antidepressants of any risk. Following its publication the FDA requested Dr. Jick to make available a further analysis that the published data obviously called for but which the manuscript did not include. This analysis suggested the newer antidepressants were riskier than older ones. My commentary used this new data from Dr. Jick as a comment on their methods.³³

This seemed to be an unusual development for the journal. Frontline staff invoked the senior editors. Despite my contention that the best way forward surely was to have new evidence made available, perhaps with an accompanying comment by any other party of their choosing, the journal decided instead to abandon any comment on Dr. Jick's article. In follow-up correspondence I noted:

³¹ D. Healy, and D. Cattell, "The Interface Between Authorship, Industry and Science in the Domain of Therapeutics," *British J Psychiatry* 182 (2003): 22-27.

³² H. Jick, J.A. Kaye, and S.S. Jick, "Antidepressants and the Risk of Suicidal Behaviours," *JAMA* 292 (2004): 338-43.

³³ This data is also available on <http://www.fda.gov/ohrms/dockets/ac/04/transcripts/2004-4065T2.pdf>, 154.

I think looking at the confidence intervals in the originally published version, it was pretty clear that a reanalysis of the figures would throw up problems for anyone who was committed to the view that SSRIs pose no problems. And that's just what a reanalysis did.

JAMA has also published another article on the Treatment of Adolescent Depression (TADS) where again the abstract and headline and content are at variance with the data from the study, which by strict criteria is a failed Prozac study. But JAMA have turned down pretty well all correspondence on the Jick article or the TADS, while running lengthy commentaries praising these same articles, both of which have also attracted front page New York Times and Boston Globe coverage. At the same time I and colleagues have sent a meta-analysis of all 677 [published] SSRI trials to JAMA, who have turned it down on the basis of a point that could be handled by a simple rewording. Make what you will of this. (Email D.H. to S. Vincent of *Evidence Based Mental Health*, October 29, 2004).

In the view of my colleague authors and I, the *JAMA* reviews had not pointed to any substantive problem with our article and indeed the *BMJ* later accepted the same article essentially unchanged. It has been among the top three cited articles in the *BMJ* in recent years.³⁴

9. In 2005, *BMJ* had a new editor, and I submitted an article on how the data on suicide and antidepressants had been manipulated. The peer reviews were longer than the original paper. After I'd answered all queries from both a first and second round of peer reviews, the paper was accepted. In the middle of correcting the proofs, I received an email from the editor: "Thank you very much for all your hard work on this article. I'm afraid we've run into a legal wall with our libel lawyer reluctant for us to publish your piece. . . . I remain supportive of publication but obviously can't do this against legal advice."

Eventually, possibly because of my persistence, a year and a half later the article was published.³⁵ The wording had been minimally altered to emphasize the failings of the regulatory authorities for the corrupted data in the public domain and to de-emphasise any company failings.

10: Study 329 was the key study of GlaxoSmithKline's SSRI antidepressant, paroxetine, in depressed children. Faced with the results from this trial, company documents show GSK had concluded in 1998 that the drug didn't work, that the data could not be presented publicly, or even shown to the regulator. Nevertheless the "positive" aspects of the data would be selected for publication.³⁶

In 2001 an article reporting the results of Study 329, apparently authored by some of the most distinguished psychopharmacologists in America claiming paroxetine was safe and effective for children, appeared in the *Journal of the American Academy of Child and Adolescent Psychiatry (JAACAP)*, the journal with the highest impact factor in child psychiatry.³⁷ In fact the paper was primarily authored by a medical writer, Sally Laden.³⁸ The selected data and claims

³⁴ D. Fergusson, S. Doucette, K. Cranley-Glass, S. Shapiro, D. Healy, P. Hebert, and B. Hutton, "The Association between Suicide Attempts and SSRIs: A systematic review of 677 randomized controlled trials representing 85,470 participants. *BMJ* 330 (2005): 396-99.

³⁵ D. Healy. "Did Regulators Fail over Selective Serotonin Reuptake Inhibitors?" *BMJ* 333 (2006): 92-95.

³⁶ See <http://www.healthskepticism.org/presentations/2007/Study329.ppt>.

³⁷ M.D. Keller, N.D. Ryan, M. Strober, et al. Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A randomized, controlled trial," *J Am Acad Child Adolesc Psychiatry* 40 (2001): 762-72.

³⁸ Earlier versions of this paper and correspondence between the company and medical writer, as well as letters to the journal, are available from DH.

presented in this paper were presented at a series of meetings by the “authors,” and sales of this drug, whose use in children was unlicensed, soared.

This is not the only case of its type. As of 2004, when concerns about antidepressants given to children blew up, from material available to me it appears that 100 percent of the published literature was primarily authored by medical writers or pharmaceutical company personnel. The ghost writing of these articles was, however, only a minor issue. The real problem is that there was a comprehensive divide between what the articles universally claimed, namely that the drugs were safe and effective, and what the raw data later showed. This is the greatest known divide in all of medicine between what the published literature and the actual trial data show, but the processes that gave rise to this divide can be reasonably assumed to apply as well to all other areas of therapeutics.

Asked baldly on BBC’s investigative *Panorama* program whether she would retract Study 329 or regretted its publication now that it had been shown to be ghost written and misleading, the editor of *JAACAP* said No. More generally the editors of our leading medical journals have attempted to clean up the mess posed by ghost writing and lack of access to the underlying data from company studies by asking for authorship declarations and conflict of interest statements, rather than seeking to require companies to make raw data available.

11. In 2007 I was approached by *Index on Censorship*

“for a piece outlining evidence that pharmaceutical companies are not transparent and that medical journals allow this to happen. The implications of this for doctors and the general public would also have to be spelt out. You put it very succinctly when we spoke—pharmaceutical companies get to publish articles in major journals under the banner of science but they don't conform to the norms of science. The fact that there's this curious “gentleman's agreement” which means that pharmaceutical companies don't have to produce their data should also of course be mentioned. . . . I think to an outsider who has certain expectations of science (that data is widely available and that access to data is fundamental in terms of any credibility) it's a baffling and shocking state of affairs”. The resulting article covered the evolution of ghost writing, and the lack of access to clinical trial data, focusing on Study 329. An iterative process began that finally got to the lawyers:

“Our lawyer's just taken a look at your piece—and I do need to ask you for more chapter and verse on some points.

I realise this is taking up more of your time than you bargained for and do apologise—lawyers must make you weary by now—but am sure you'll understand that it's necessary.”

The process ended with:

“The documents made interesting reading—and certainly answered the concerns—along with the cuts. But I've still got worries about running the piece. . . . I regret how things have turned out very much. I've appreciated all your help in finding documents and in cooperating with all my requests. As I've said before—it's a hugely important subject and we should be covering it.”

Index on Censorship self-censored.

12. The difficulties with publication of a critique of 329 do not seem to be solely due to its author. Following the emergence of evidence that SmithKline Beecham (later Glaxo SmithKline (GSK)) had viewed 329 as a failed study but nevertheless considered selecting the

good bits for publication, the *Lancet* published an editorial, “Depressing Research.”³⁹ Subsequently, the journal published a letter from A. Benbow of GlaxoSmithKline claiming the company were transparent on all issues to do with clinical trials. Leemon McHenry and Jon Jureidini wrote to the *Lancet* taking issue with Benbow’s claims in a letter, clearly stating that as an expert in a legal case involving Study 329, Jureidini had a conflict of interest. The *Lancet* agreed to publish their letter, but sent it first to GlaxoSmithKline, who replied that it would not seem appropriate to publish the letter given Dr. Jureidini’s role as an expert witness involving these issues, implying that seeking publication in the *Lancet* was a tactic designed to achieve a legal advantage. On this basis the *Lancet* declined to publish McHenry and Jureidini’s letter, even though the original Benbow letter could as readily be construed in this fashion, as New York State had taken a fraud action against GlaxoSmithKline for their lack of transparency in 329 and related studies, which the company later settled.⁴⁰

McHenry, Jureidini and Peter Mansfield wrote a further paper on Study 329, “Clinical Trials and Drug Promotion: Selective Reporting in Study 329.” The *BMJ* editor wrote to them saying she had heard of their paper and wanted to fast track its publication. Six months later, after revisions, the *BMJ* indicated their lawyers still had concerns and they would not publish.

In contrast to these difficulties in getting articles published, the process of publishing ghost-written articles in major journals appears to be straightforward. In a 2006 *JAMA* editorial, Catherine de Angelis tackled the issue of why leading journals could not ban further articles from those linked to tainted articles saying that “Levelling sanctions against an author who fails to disclose financial interests by banning publication of his or her articles for some time period would only encourage that author to send his or her articles to another journal; it cleans our house by messing others. So what about all editors, or at least a group, such as the ICMJE (International Committee of Medical Journal Editors), agreeing to share the information and jointly to ban the offending authors? Those who suggest this approach have not considered the risk of an antitrust suit.”⁴¹

This statement appears to concede that “scientific” journals cannot insist that contributors adhere to the norms of science by, for instance, being able to make publicly available the data on which their claims are based. This being the case, to avoid misleading a wider public, it might be better if publication outlets unwilling to commit to the norms of science were redesignated as periodicals rather than journals.

Company power can be seen in the sequence above. Such pressure tactics are another means to ensure that views not favourable to company interests get closed down. There must be many other instances of journals self-censoring but where the authors have no idea why they have been rejected or no way of proving their suspicions. The effects on academic discourse can only be profound.

The process affects the most prestigious journals in the field—as does the ghost writing, which now affects the most prestigious journals in the field primarily. Where once ghost writing happened in obscure journals, the bulk of articles linked to pharmaceuticals appearing in *JAMA*, the *New England Journal of Medicine*, and the *Lancet* are now likely to be ghost written. The agencies responsible for writing these articles trawl the offices of academic journals to find out which journals might be interested in material on a particular issue in order to speed the

³⁹ Editorial, “Depressing Research,” *Lancet* 363 (2004): 1335.

⁴⁰ D. Healy, “Our Censored Journals,” in ed. A.R. Singh and S.A. Singh, *Medicine, Mental Health, Science, Religion, and Well-being, MSM*, 6, (Jan–Dec 2008) 244-256

⁴¹ C. De Angelis, “The Influence of Money on Medical Science,” *JAMA* 296 (2006): 996-98.

publication of their product. Such articles will not be impeded on their way by any considerations about incurring a legal action.

On the one hand, companies appear to be able to block the publication of material inimical to their interests, even when this stems from clinicians or others doing what they are legally supposed to be doing—namely reporting on treatment hazards—while on the other hand our journals are ever more full of material that does not conform to the basic norms of science, namely to make available the data on which claims are based.

Systematic action on behalf of companies or related public relations agencies to damp down the effects of publications that do not suit their interests, added to the increasing willingness of journals to effectively self-censor out of fear of the legal consequences of publishing material that is not in the interests of the pharmaceutical companies, puts in place the conditions to recreate a climate not unlike that in Germany in the 1930s and the Soviet Union in the 1950s.

I grew up in Ireland in the 1950s and 1960s, a period when Catholic censorship meant that work by Joyce, Beckett, Kiely, Broderick, McGahern, O'Brien, Dunne, Moore and many others were banned in Ireland because they tackled sexual issues.⁴² But it is a moot point as to whether that censorship was any more draconian than the current censorship. Having prided ourselves on finally overcoming Catholic, Nazi, McCarthyite or Soviet censorship, we perhaps think this could never happen again. We fail to see what is happening and to call it what it is. One symbol of the shifting forces is the contrasting experiences of John Cornwell, who wrote books on the risks linked to Prozac⁴³ and on the inaction of the Vatican vis-à-vis the extermination of Jews in the Second World War.⁴⁴ Where once incurring Vatican wrath, as the second book did, might have been a cause for concern, but is no longer as Cornwell found, incurring the strong displeasure of Lilly, as the first book did, led to warnings of legal action against Cornwell in multiple jurisdictions.⁴⁵

Brand Fascism⁴⁶

Since the 1950s, a wealth of new drugs has come into medicine. The 1950s also saw the emergence of randomized controlled trials (RCTs), and many thought these methods would help curb the excesses of the pharmaceutical industry. Finally the new drugs were made available as prescription-only from doctors, who it was thought were less likely to be influenced by industry than non-professionals and better able to understand research and its implications.

However, while in the 1950s these new treatments saved lives that would otherwise have been lost and extended the compass of human freedom, forty years later we have moved instead into a world in which pharmaceutical products appear to be contributing to reductions in life expectancy, a degradation of the scientific and academic base of medicine, and the emergence of a medico-pharmaceutical complex that is making the discovery of agents for illnesses that need to be vanquished less likely, while at the same time pathologizing a range of life's vicissitudes and variations.

Key to all this has been the emergence of the marketing departments of pharmaceutical corporations as one of the most potent cultural forces in our world today. They have been able to suck into their ambit the academics who were supposed to act as a counterweight to industry, as

⁴² J. Carlson, ed., *Banned in Ireland: Censorship and the Irish writer* (London: Routledge, 1990).

⁴³ J. Cornwell, *The Power to Harm: Mind, medicine and murder on trial* (London: Penguin, 1996).

⁴⁴ J. Cornwell, *Hitler's Pope: The Secret History of Pius X11* (London: Penguin, 1999).

⁴⁵ J. Cornwell, personal communication.

⁴⁶ The term *brand fascism* was coined by Kal Applbaum, author of *The Marketing Era*. See note 55.

well as the apparatus that was supposed to regulate companies, and have in addition transformed those in the media, who distrust every politician whose lips move, into the willing bearers of the good tidings of salvation through pharmaceuticals. Their operations also engineer a situation in which most academics view the efforts of clinicians to fulfil their legal duty to draw attention to the hazards of prescription-only agents as an attack on clinical medicine. As a result, the most distressing attacks on clinical academics typically come from other academics.

The Levers of Power

The new marketing has availed of the use of brands, a weakening of patent laws, an industrialization of the clinical trial process, the willingness of physicians to be sold diseases, and their inability to manage uncertainty. But above all it has been aided by physician ignorance of marketing.

While brands such as Nike and Reebok are household names, pharmaceutical brands are the oldest and most profitable brands. The industry turned to branding in the late nineteenth century with astonishing success, as evidenced by Aspirin and Heroin, which a century later still have greater recognition than their generic compounds. With the SSRIs, there has been a much greater investment in these brands than in any other branded products from non-pharmaceutical domains.

Companies brand more than the names of drugs. They can conjure into existence notions such as mood stabilizers, a term that did not exist before the mid-1990s but which is now among the most commonly heard terms within psychopharmacology. Diseases like manic-depressive illness can be rebranded as bipolar disorder, as part of a transformation aimed at persuading clinicians and others that a disorder that until recently was thought to occur at a rate of approximately ten new cases per million per year, affects 5 percent of North Americans—16.5 million people.⁴⁷

Two developments in the patent systems in the US and elsewhere made an increased focus on brands possible. First, where these patent systems once aimed at rewarding substantial novelty that clearly contributed to public utility, the US system in particular has moved toward rewarding even novelty with diminishing regard for evidence of benefit. Thus Abbott gained a patent on semisodium valproate for mania and created Depakote, even though the off-patent sodium valproate had already been demonstrated to be useful for mania since the 1960s.⁴⁸ Lilly was able to get a patent on olanzapine and create Zyprexa for schizophrenia and mood stabilization on the basis that it was less likely to produce lipid elevations in dogs compared to a never marketed compound, when in fact this drug raises lipids in humans more than almost any other drug in medicine.⁴⁹ This relaxation in the application of patent laws in the US to the point where compounds with no novelty and no utility can now be patented may be linked to a calculated attempt to seduce pharmaceutical companies to the United States.

Second, in the 1960s, older laws enabling companies to take out process patents were phased out in favour of patents on products, so that only one company could have a fluoxetine. This has enabled companies to embark on the creation of brand blockbusters such as Prozac, Depakote and Zyprexa. As a consequence, companies have a much greater incentive than ever before to aggressively defend their compounds and conceal their hazards.

⁴⁷ D. Healy, *Mania: A short history of bipolar disorder* (Baltimore: Johns Hopkins University Press, 2008.)

⁴⁸ United States Patent 4,988,731. Date of Patent Jan 29, 1991; United States Patent 5,212,326. Date of Patent May 18, 1993.

⁴⁹ United States Patent 5,229,382. Date of Patent May 22, 1992. European patent, EP0,454,436, filed on April 24, 1991.

Thus talking about early difficulties Lilly had with reports of suicidality on Prozac, one of their then senior scientific officers, Leigh Thompson, put the issues like this: “I am concerned about reports I get re UK attitude toward Prozac safety. Leber (FDA) suggested a few minutes ago we use CSM database to compare Prozac aggression and suicidal ideation with other antidepressants in UK. Although he is a fan of Prozac and believes a lot of this is garbage, he is clearly a political creature and will have to respond to pressures. I hope Patrick realizes that Lilly can go down the tubes if we lose Prozac and just one event in the UK can cost us that.”⁵⁰

More recently company marketing documents linked to Zyprexa make the stakes clear: “The company is betting the farm on Zyprexa... the ability of Eli Lilly to remain independent and to emerge as the fastest growing pharma company of the decade depends solely on our ability to achieve world class commercialization of Zyprexa.”⁵¹

World class commercialization has been achieved by, among other things, the following developments. First, companies gained control of clinical trials in the 1980s, when clinical research organizations (CROs) took over from academic physicians as the organizers of trials. As of 2000, CROs ran more than two-thirds of clinical trials undertaken by industry, worth \$30 billion. Privatized research of this sort is profoundly different from previous clinical research. CROs have transformed human subjects research, restructured controls of disclosure and confidentiality, managed intellectual property in an entirely new way by for instance sequestering RCT data in a way that did not happen when a federation of academic centres conducted trials.

CROs provide a privatized institutional review board system (ethics review) that grants ethical approval to company studies, when university centres might not. CROs have made it possible to move trials on drugs for Western markets into Asia or Africa, in a way that university departments could not have done. Whether this move has been prompted by concerns to avoid regulatory oversight or cost considerations is less clear. Even in trials done in Western settings, it is now clear that CRO-run psychotropic trials have included bogus patients.

Second, as mentioned above, companies now control the production of the scientific literature. In the case of drugs on patent, a significant proportion of the trials undertaken that do not return the right result now remain unpublished, while a majority of those published are in all probability ghost written and bear an ambiguous relationship with their underlying data.

Third, a further problem for scientific developments lies in the very methods put in place to control the industry. Strapped into a supposed clinical trial straitjacket, pharmaceutical companies found the new methods meant that barely beating placebo would get a licence for all mood disorders or all psychoses or for other conditions. Where once clinical trials had been a method to debunk the claims of treatments that didn't work or didn't work reliably, they have since become the fuel for the therapeutic bandwagons of treatments that are not particularly effective—such as Prozac or Zyprexa.

Trials in which drugs barely beat placebo on rating scale measures are read as evidence that drugs “work,” when philosophically it would be more accurate to state that in fact these trials offer evidence that it is simply not possible to say the drug does nothing, but that most of whatever benefit there is stems from non-specific factors. The emergence of trial results of this kind should, almost by definition, have marked the point at which scientific investigation of the drugs began, not the point at which independent scrutiny of the drugs in fact finished. This

⁵⁰ Memo from Leigh Thompson, February 7, 1990. Exhibit 98 in *Forsyth vs. Eli Lilly*, cited in Healy, *Let Them Eat Prozac*, chapter 11.

⁵¹ Zyprexa Multidistrict Litigation 1596, Bates page ZY201548772, July 25, 2001.

should be the point where we ask if we can identify the small number of patients who benefit specifically and move on to develop other approaches for those who don't.

But having received marketing authorization on the basis of rating scale evidence that the drugs “work” rather than on outcomes such as saved lives or return to work, there is no incentive for companies to find treatments that have big effects on particular syndromes. If the drugs “work,” surely it would be unethical for clinicians not to use them for all cases of depression or schizophrenia!

Fourth, clinical practice is increasingly constrained within guidelines issued by a variety of academic or semi-regulatory bodies. Faced with escalating costs and public bewilderment at variations in medical practice, the managers of medical services have turned increasingly to guidelines. Companies have been aware of this for some time and, through their control of the clinical trial and publication processes, they now effectively control the guidelines governing large swaths of medical practice. Although regulators have refused to endorse claims that newer agents, from the antipsychotics and antidepressants through to the antihypertensives are superior to older agents, even those guidelines drawn up by apparently independent academics invariably endorse newer over older agents, making them among the most powerful marketing tools that pharmaceutical companies have.⁵²

Of course, guidelines state that they are not law, but any commentary on whether one must adhere to them makes it clear that any deviations without justification dramatically increase the medico-legal risks of practice. The element of coercion may soon increase with payments being linked to guideline adherence. It is not too fanciful to see in this process a silencing of formerly independent physician voices by an *una duce, una voce* process.

Control of the scientific literature and the clinical trial process has enabled drug companies to monger diseases.⁵³ Disorders such as social phobia, panic disorder, and depression have been sold in the expectation that sales would follow. Epidemiological research that establishes how many people might potentially meet criteria for particular conditions provides some of the most valuable data for this disease mongering.

This selling of disorders has gone hand in hand with a marketing of risk and fear. Early hints of depression must be detected and treated in order to reduce the risks of suicide, alcoholism, divorce, and career failure, and treatment must continue to reduce the risk of relapse. Where treatment of a disease might mandate treating one person per hundred, with treatment stopping once the condition responds, treatment of those at risk of a disease or its consequences mandates the treatment of one in ten, and has no natural stopping point.⁵⁴

But there is more to disease mongering than this. Company marketing is less and less about spreading recognition of established disorders and increasingly about pathologizing vicissitudes. A licence for Viagra, for instance, became a means for companies to question young men with normal sex lives as to whether things couldn't be better. Any of life's vicissitudes are now grist for the marketing mill, and companies with a licence do not balk at changing our understanding of what it means to be human, if it captures a niche for the product. There are no academics drawing this to wider attention, perhaps because physicians in general fail to understand where disease mongering comes from.

⁵² D. Healy, *Trussed in Evidence? Ambiguities at the Interface of Clinical Evidence and Clinical Practice* *Transcultural Psychiatry* 2009, 46, 16-37.

⁵³ R. Moynihan and A. Cassels, *Selling Sickness* (New York: Nation Books, 2005).

⁵⁴ I. Heath, “Combating Disease Mongering: Daunting but nonetheless essential,” *PLoS Medicine* 3 (2006): e146.

The Role of Academics in the New Fascism

At the heart of these developments is the failure of academics to understand modern marketing. Despite regular surveys from marketing companies about the properties of a desirable antidepressant or antipsychotic, and despite the participation of clinical academics in opinion leader (focus) groups, clinicians confuse marketing with the trinkets, free lunches, lecture fees, and trips to conferences sponsored by company sales departments. They fail to see that they are the source of the knowledge that goes into creating brands and fail to see their role in virally transmitting new brands.⁵⁵ The actual differences between modern antidepressants and modern antipsychotics are minimal; the perceived differences come almost entirely from sophisticated consumer research aimed at understanding what physicians might swallow.

In this process, academics have three roles. First, as repositories of knowledge their role is to help companies understand what the average clinician might perceive as a development. Second as opinion leaders they help deliver the company message to non-academic clinicians. Third, they lend their names to ornament the authorship lines of journal articles and programs of academic meetings reporting the results of the most recent company studies.

These academic meetings have come to resemble political rallies, where the faithful assemble to hear about the evils to be vanquished and the new methods to do so. It has been some time since a trace of uncertainty entered into any of our major meetings, even though we are living through a profound medical crisis in that the health of our patients is worsening and beyond medicine there is debate about the corruption of our science.⁵⁶ Yet the adverse effects of drugs are only aired if it suits the marketing interests of one of the competing companies. Meanwhile companies have commandeered most of our platforms and journal space to present their products under the banner of science, while flouting the basic norms of science—to make data publicly available.

Marketing of this sort does a great deal to create the Healy, Olivieri, Blumsohn, Nissen, and Buse stories. Because the marketing copy for drugs is derived from the most cherished notions of academics and clinicians, rather than support colleagues grappling with the pharmaceutical industry, clinicians perceive anyone who raises hazards of treatment as attacking clinical care and the welfare of patients rather than attacking the pharmaceutical industry, and these academics and clinicians react accordingly, even if they have little or no connection to pharmaceutical companies.

What the Olivieri, Blumsohn, and Healy stories suggest is that academia and health care have been infected with an academic immune-deficiency virus (AIV). The defence reactions that might have been expected from prestigious journals and professional bodies in response to the virus seem to be paralyzed. Quite the contrary, the virus seems to have been able to subvert normal defenses to its own purposes. These defences have reacted almost as though it was their programmed duty to shield a few fragile companies from the malignant attentions of a pharmacovigilante.

But just as everything was crumbling behind the rhetoric of Stalinism, so also there is good evidence that outcomes within both mental and physical health are deteriorating. Within psychiatry, rates of hospital admission are rising and life expectancy for patients with serious

⁵⁵ K. Applbaum, *The Marketing Era*. (New York: Routledge, 2004).

⁵⁶ M. Angell, *The Truth about the Drug Companies. How they deceive us and what to do about it* (New York: Random House, 2005); J. Kassirer, *On the Take. How medicine's complicity with big business can endanger your health*. (New York: Oxford University Press, 2005).

mental illness is declining⁵⁷. What we are seeing within mental health is not what happens when treatments work; it is not what happened to the dementia paralytica (tertiary syphilis) services after the discovery of penicillin.

It is difficult to see our professional organizations of clinicians, scientists, and academics being able to take stock of the current situation and engage with the new corporate campus. Our major journals and academic meetings have lost brand value.

Another way forward lies in the recognition that drugs are not made in company laboratories—chemicals are. In order for a drug to come into being, two things have to happen. First, healthy volunteers and later patients in clinical trials agree to take these chemicals to see what happens. Willingness to participate in these studies was borne out of the global calamity of World War, when conditions of scarcity mandated the development of the first controlled trials. We participated on the basis that taking risks might injure us but would benefit a community that included our friends, relatives, and children. We did so for free. At first this worked and extended the compass of human freedom from the epidemics and other scourges to which our ancestors had been subject for millennia.

But now this data freely given is sequestered by corporations who market selected parts of it back to us under the banner of science. This business model has made these corporations the most profitable on the planet, while increasingly jeopardizing the health and wellbeing of our friends, relatives, and children.

Second, companies take the inner aspirations and fears of both patients and clinicians to transform a chemical into a drug and also to mould a strategy designed to get patients to consume drugs more faithfully than they would if they were living in a totalitarian regime and ordered to consume them. This is what branding and patenting is about. It yields the biggest profit margins in history, significant amounts of which go to ensure a continuing hold on academic minds, and through academics the public mind.

There are both ethical and scientific grounds to object. It is not clear that companies own the data of clinical trials other than by force majeure. Whether they do or not, it is time for clinicians to consider whether it is ethical to enter their patients into such “exercises.” The consent form should at the very least contain an explicit statement that the company may sequester any data from the trial, rendering it unavailable for scientific use. We should see whether patients would accept involvement in trials on that basis.

The scientific grounds to object lie in the fact that current academic practices breach the norms of science by not making data available. If we are to be scientific we must object. This can only be good for both health care and companies in that a medicine of the sort we now have will inevitably be sterile and is only capable of rescue by the serendipitous discovery of new agents. We were supposed to have left the era of discovering drugs by blind chance behind some decades ago.

⁵⁷ D. Healy, “The New Engineers of Human Souls and Academia,” *Epidemiologia e Psichiatria Sociale* 16 (2007): 205-11.

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