Book Review Essay

Review by **Tom Cotton**, psychotherapist and schizophrenia researcher

SYNOPSIS

In this article, psychiatrist and science journalist, Ben Goldacre's critique of the pharmaceutical industry, *Bad Pharma*, is reviewed and contextualised with other recent publications in this area. This review article focuses in particular on psychopharmaceutical medicine, and its relationship to psychiatric diagnosis, increasingly medicalised notions of mental suffering, and the cultural and economic forces that relate to its treatment. While Goldacre occupies a critical position towards the industry's powerful influence over these areas, his position also seems to rest on some modernist and objective scientific interpretations of mental health, which, it is argued, are incomplete tools for understanding human experience.

Bad Pharma

By: Ben Goldacre, Fourth Estate, London, 2012, xvii + 448pp, price £13.99

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Following on from his *Bad Science* column for the *Guardian* newspaper, and his best-selling book of the same name, psychiatrist and self-confessed science nerd Ben Goldacre turns his attention to what he terms the 'dark arts' of the pharmaceutical industry. Clearly relishing his role as a crusader, he paints this powerful $600 billion sector – the world's most profitable along with oil and banking – as ripe for a crusade. This is not new territory, however. Jacky Law's 2006 book, *Big Pharma,* follows a similar format, while, amongst others, Irvin Kirsch's *The Emperor's New Drugs* (2009) and Robert Whitaker's *Anatomy of an Epidemic* (2010) – texts I will come back to – focus more particularly on the psychopharmaceutical sector. Readers of this journal may find Goldacre sparse in this area – even when taking his focus on the industry as whole into account – and the ethical, social, political and moral dilemmas that abound in the relationship between psychiatric diagnosis and the market for psychopharmaceutical products feel correspondingly underexplored.

Goldacre has an infectious enthusiasm for the methods of objective science, and is a compelling, often witty guide to a world that he has researched meticulously. In the book's 448 pages he uses an in-depth knowledge of scientific trials, papers and journals to document and deconstruct the pharmaceutical industry's systematic abuse of objective science, the vast profits derived from this, and the harm caused to patients. Make no mistake, it is a shocking, tawdry, and deeply depressing story that unfolds.

Over the book's six chapters, Goldacre scrutinises the phases of research, testing, regulation and marketing that a drug goes through before it ends up in your medicine cabinet. Each chapter then summarises his argument, and offers bullet points to summarise what action he believes should be taken. In Chapter 1, Goldacre explores the scandal of missing drug trial data, where pharmaceutical companies can choose which outcomes they wish to publish. This means creating a statistical fiction akin to claiming you can

roll a six every ten throws by not disclosing the multiple attempts where you failed to support your claim. On this flawed-by-omission evidence, new drugs pass through regulation, are recommended by advisory committees such as the National Institute for Clinical Excellence (NICE), promoted to doctors and prescribed to patients. This practice is commonplace, and formed the deeply flawed evidence base of, for example, the widespread prescription of the antidepressant reboxetine for ADHD, despite being 'no better than a sugar pill' at relieving depression, but which 'does more harm than good' because of dangerous side effects (p. 7).

The chapter goes on to detail the tricks that enable data to be hidden from weak or pharmaceutical industry-biased regulators, the lack of independent academics conducting trials, whose complicity is assured by threats of withdrawing research grants, or who are silenced by gagging orders. The remainder of the chapter is devoted to ineffectual regulators – the FDA in America, and the EMA which regulates Europe. For example, the FDA's $10,000 per day fine for trials that fail to register with them before commencement – a much-heralded attempt to clean up the industry – has yet to be levied despite an estimated one in five trials since the 2007 legislation failing to comply. Another notable scandal is weak policing of 'off-label' prescribing – medications marketed for a symptom or patient population for which the drug was not explicitly tested. Glaxo Smith Klein, for example, marketed the antidepressant paroxetine for children, at the same time as repeatedly blocking calls from regulators for missing data which showed that 'the drug was not only ineffective, but actively dangerous' (p. 61).

Chapter 2 looks at how drugs make the journey from lab to pill, and centres on another important ethical dimension – how data are actually obtained. 'First in human trials' in America, for example, often recruit participants without healthcare insurance who are incentivised with the promise of free treatment. The chapter goes on to explore the problems of outsourcing trials abroad where they can be conducted for a fraction of the cost. In China, for example, only 11 per cent of trials obtained ethical approval, and 18 per cent discussed informed consent with patients. Here you can see both the potential for appalling treatment of participants, and flawed data with even harder-to-trace evidence.

Goldacre expands further on 'bad regulation' in Chapter 3, and we are introduced to the industry euphemism 'regulatory capture', in which personal, financial and emotional ties with regulators are actively sought by pharmaceutical companies to influence regulation. It would be naïve to think that an industry this size doesn't spend serious money attempting to influence regulators – what industry doesn't – but as Goldacre points out, with fatal conflict of interests at stake, weak regulation in this area is a disaster. Regulators are described as being not just toothless, but their loyalties are often questioned as well. There are an alarming number of senior regulators (the EMA is singled out for particular scorn), for instance, who have financial interests in pharmaceutical companies, as well as patient groups who are funded by the industry to sit on regulatory boards and present a supposedly neutral viewpoint. All such links have repeatedly been shown to influence decision-making.

Since Reagan and Thatcher-era market deregulations, these increasingly muddied conflicts between public and corporate interests have led to consistent failures to regulate bad practice – from the withholding of unfavourable data that would reveal the inefficacy of a drug, to manipulating data in other ways to get the results you want. 'Outcome switching', 'sub-group analyses', and unfair comparison tests on ideal patients that will perform better than with 'real world' patients, are just a few of the games (detailed in Chapter 4) that can be played, if you want 'to get away with as much as you can, rather than to conduct fair tests of the treatments we use' (p. 223). If, at the end of the trial, you still haven't been able to get a positive result, 'you can exaggerate it in the way that you present the numbers', or 'you can just spin harder' (p. 216).

Throughout the book, Goldacre illustrates bad practice with detailed case studies like the tamiflu vaccine, which has cost governments around the world billions, despite lacking evidence of its efficacy, and refusals from its manufacturers (Roche) to hand over trial data to independent researchers for scrutiny. Indeed, much of these activities have only come to light because of the dogged work of independent researchers, or criminal charges leading to data and internal documents being seized. Indicating the scale of the problem, Goldacre reveals that 66 per cent of all fraud committed in America involves the pharmaceutical industry, and that the largest corporate fine in American history was levied against Glaxo Smith Klein last year, to the tune of $3.2 billion. They are not alone. The next largest fine in American history was paid by Eli Lilly in 2009, who 'trained their sales force

to disregard the law' over their off-label promotion of the antipsychotic drug olanzapine, in order to – according to an internal memo – make it the 'number one antipsychotic in history' (p. 295). According to Law's book, with $4.8 billion in sales, olanzapine fulfilled this promise by 2003, and was the third highest earning drug of that year. Despite assurances by the industry that it has cleaned itself up, Glaxo Smith Klein were back in the news in April this year for allegedly paying rivals to slow down production of cheaper generic versions of the SSRI antidepressant seroxat, in order to keep its price high, at considerable cost to the British National Health Service.

As well as the antidepressants paroxetine and reboxetine (mentioned above) and duloxetine (which, in an enthusiastic drive to create a new market, was prescribed for incontinence and saw an increase in suicides), a small number of other psychopharmaceutical drugs are mentioned in the book, including the antipsychotic rispiredone. However, for an area of pharmacology that is held in such contention – not just the over-prescription of these drugs, but their very validity in some quarters – there could be more detail here. In this respect, Kirsch's book, which explores flawed antidepressant trials, offers a more comprehensive read, while Whitaker's book questions the cultural, financial and political forces that feed into the 'epidemic' of diagnoses such as schizophrenia. It is also worth mentioning here the work of Richard Bentall and John Read, who have methodically debunked the science supporting psychopharmaceutical drugs, such as the claim that overactive dopamine systems cause psychosis and therefore need to be chemically suppressed.

Chapter 5, 'Bigger, Simpler Trials', appears to be an extension of the previous chapter in the form of an elaborated bullet point 'how to change things' summary. Where Goldacre excels is in his exposé of how drugs are marketed (Chapter 6) – perhaps the most chilling chapter of the book. Collectively, the industry spends $60 billion on marketing alone – twice the amount spent on research and development – and explains why it can afford to employ between three and six sales reps for every doctor, in order to influence how they prescribe. Aside from everyday misrepresentation – independent researchers found, for example, that an alarming number of medical journal print campaigns presented drugs in a way that was not even backed up by the clinical trials they had *chosen* to make public – it is the covert forms of marketing that are the most sinister. These include Hollywood 'A-list' actors paid to drop in references to drugs in chat shows (which are not governed by advertising standards), academics being paid to put their names to work they had nothing to do with, supposed real-life patient stories being planted in the press by PR firms, creating phony medical journals to promote products, funding charities to endorse drugs with an 'independent' view, amongst many other ploys. Most shocking of all is the rapid creep into education. Medical books were found to be funded by pharmaceutical companies to profile their drugs as the correct intervention, and on a wider scale, Continuing Medical Educational forums for doctors, which are largely funded by the pharmaceutical industry and dress up promotion – often for the semi-legal off-label use of drugs – as education. Goldacre estimates that for every $1 spent on 'teaching', the industry can expect $2 back in new prescription revenue.

It is the grey areas between education and promotion, and how market forces have insidiously shaped the way we understand mental distress, that I find personally the most disturbing. Having spent the last five years researching experiences of schizophrenia, as well as working as a psychotherapist with that client group, I have explored the contradictions in the diagnosis in detail, and how the consistent underplaying of traumatic life events in favour of biological interpretations of psychosis help to brand schizophrenia as a disease that we can only hope to manage with medication. Read and Bentall's (2012) landmark article in the *British Journal of Psychiatry* questions this assumption, and argues that there is now significant evidence to show a strong link between childhood trauma and adult onset of psychosis. Citing a range of studies carried out since 2004, the authors also highlight the link between severity of trauma and psychosis. For example, people who had been abused as children were nine times more likely than non-abused people to experience 'pathology-level psychosis'.

Transposing the reframing of psychosis away from faulty biology toward personal experience and meaning can have a profound effect on treatment. For example, of the participants in the Open-Dialogue Therapy approach in Finland over the last 20 years, only 30 per cent took medication, yet the overall recovery outcomes were far better than the UK's medical model approach. Harrow et al.'s (2012) 20-year study looking at relapse after coming off long-term antipsychotic

medication suggests why this might be the case. The mainstream biological view is that psychosis is caused by an endogenously overactive dopamine system, and antipsychotic medication manages this by suppressing it. This has led to frequent claims from the pharmaceutical industry that antipsychotic medication is to schizophrenia what insulin is to diabetes. However, what Harrow et al. found was the exact reverse. Relapse seems to be caused by the brain adjusting to an artificially supressed dopamine system, and once it returns to a pre-medicated balance (after between 6 to 10 months), symptoms associated with relapse declined. Those who remained undedicated had better long-term recovery outcomes than those who didn't.

To what extent have pharmaceutical PR departments been responsible for this chemical imbalance management message? If that sounds far-fetched, Goldacre reveals that the 'hugely contradictory... serotonin hypothesis' (p. 256) for depression has been carefully 'fostered and maintained' (p. 257) by the industry as a marketing tool, despite lacking credible evidence. As Goldacre points out, even if the science were credible, it is directly contradicted by the antidepressant tianaptine, which claims to be effective by *stripping* the brain of serotonin – the exact reverse of the existing theory on which millions of SSRI (Serotonin Reuptake Inhibitor) prescriptions have been given. Yet, despite these serious contradictions, a 2008 study investigating press reporting of the hypothesis as *fact* found that not one journalist responsible was able to account for the clinical origins of their source information.

However, herein lies, for me, a shortcoming of the book. While Goldacre summarises that the mythology surrounding chemical imbalances ensures that 'normal variants of human experience are pathologised, so they can be treated with pills' (p. 258), he never really explores the wider implications of this. What, for instance, does it say for the validity of the 'depression' or 'schizophrenia' diagnoses, which have become intrinsically bound with the theory of chemical imbalances? If, as is suggested, such myths and scientific contradictions are used as evidence daily in consulting rooms, and indeed lie at the heart of Western mainstream mental health treatment, there should be cause for considerable alarm.

Goldacre briefly touches on the worrying relationship between diagnosis and product placement, where 'our models of personhood, and what is normal, are being quietly engineered by a $600 billion industry' (p. 266), and gives the vivid example the Female Sexual Dysfunction diagnosis, which was based on data generated in order to create a new market for drugs like Viagra. However, he stops short of ground that has been well-trodden recently by authors such as Richard Bentall, Ian Parker, Mary Boyle, Alison Bass and Peter Breggin. See, for example, DSM's (the Diagnostic and Statistical Manual of Mental Disorders) proliferation of psychiatric diagnoses, since its first volume (from 20 to 700 in 50 years), and how the well documented links between its publishers (the American Psychiatric Association) and the pharmaceutical industry create powerful incentives to medicalise 'normal' human experience. Contrary to this proliferation, Lacanian psychoanalyst Darian Leader, for example, states that the same 700 could be collapsed down to just three meaningful diagnoses. Such a radical reduction in the market for new product is unlikely to receive the blessing of shareholders in any sector, let alone one that delivers such staggering profits year on year. Moreover, Goldacre doesn't question the complex subjectivity of a diagnosis like 'depression', or 'schizophrenia', or the often inappropriate objective measures that are used to research them, or evidence their treatment. This may be one reason why the placebo effect – where placebo pills regularly outperform trial drugs – often seems, to Goldacre, an inconvenient yardstick, rather than an astonishing facet of the mind to influence recovery. Kirsch's book, on the other hand, explores this phenomenon in detail – as well as its often harmful counterpart, the 'nocebo' effect.

All this suggests that Goldacre believes that if carried out correctly, drugs trialled to treat *a priori* diagnostic constructs such as 'depression' and 'schizophrenia' would be appropriate, ethical and effective. However, there is an epistemological problem with this assumption. As Heidegger makes us aware, an objective science of 'things' is an inadequate framework for making sense of human experience – an intrinsically subjective realm in which these diagnostic constructs are deeply embedded. It is with these assumptions that we have seen what critical psychiatrist Pat Bracken calls the 'medicalisation of misery' – both within psychiatry *and* psychology – which rests on the belief that life experience can be carved up into abstracted diagnoses, where 'symptoms' are attributable to faulty mechanisms, and treated with correspondingly abstracted methods. In psychologically, or chemically, suppressing 'symptoms' that we locate in the 'faulty' individual, we

wilfully neglect the interpersonal dynamics that manifest in misery. In this sense, do we *have* 'depression' or 'schizophrenia' like a bad knee, or is it a logical response to complex, confusing or traumatising life experiences?

Whitaker's book, amongst others, highlights the deeply concerning real-world implications of this medicalisation. Since 1990, the number of children on disability benefits with psychiatric diagnoses has risen by an incredible 35-fold, an 'epidemic' that Whitaker argues is being fuelled – not managed – by psychiatric drugs. By way of providing an equitable control measure, in the same period children on benefits with non-psychiatric diagnoses declined. As House and Loewenthal point out in their book *Against and For CBT* (2008), psychology has eagerly taken part in this medicalisation, especially where manualised, psychologically abstracted medical models of talking therapy impose modernist notions of wellness on patients, instead of helping them to make sense of their experience and promote healing from the inside. In encouraging patients to not think about their distress, it is argued that the resultant alienation from self runs the risk of compounding misery, not relieving it. Goldacre draws a parallel between greed in the banking sector and corrupt pharmaceutical industry practices; however, the latter's ability to generate staggering profits is so intrinsically linked with the faith we invest in a pill, its collapse seems unlikely. Given Law's estimate that 'the combined profits of the ten pharmaceutical companies in the 2002 Fortune 500 ($39.9 billion) were more than the profits for all the other 490 listed businesses put together ($33.7 billion), what is far more likely is a continued infiltration deeper into our perception of mental illness and its treatment.

Recent developments do not bode well. The outsourcing of trials that used to be conducted by (not always) independent academics to private companies operating in third world countries with even more lax regulation will not help transparency of evidence or charges of unethical practice. Closer to home, the UK Department of Health's invitation to the Association of British Pharmaceutical Industries (ABPI) to become more involved in identifying 'undiagnosed patients' and 'improving patient adherence to medicines and treatment pathway design' (ABPI's quotations) is recognised by Goldacre as 'very dangerous' (p. 356). This seems like a free licence to deepen this medicalisation with the blessing of the state.

Where Law's book *Big Pharma* has the advantage of exploring the wider social implications of the issues discussed, and develops the scandal surrounding SSRI antidepressants into a chapter of its own, Goldacre excels in the level of detail with which he examines the 'dark arts' of the industry. However, while *Bad Pharma* is a substantial achievement and an important book, in the area of mental health the distinction between 'bad pharma' and 'good pharma' is more complex than the book portrays. Goldacre's zeal for activism is genuinely refreshing. He has a real gift for communicating complex science to a wider readership, and it would be intriguing to see how he might tackle these crucial issues.

Tom Cotton is a UKCP-registered psychotherapist and film-maker with a special interest in schizophrenia and the implications of modern and postmodern discourses for its treatment. His 2010 Wellcome Trust funded documentary, *There is a Fault in Reality*, explored first-person experiences of schizophrenia, which is also the subject of his current doctoral research. Tom studied Fine Art Film at Central St Martins, and gained an MSc in Psychotherapy and Counselling from Roehampton University in 2008. He managed a residential therapeutic community for psychosis between 2010 and 2012.

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