# A Two-Headed Coin: Review of *Bad Pharma* by Ben Goldacre

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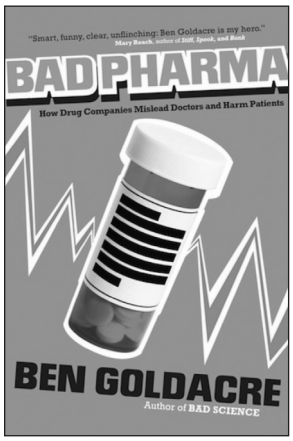


**Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients**
Ben Goldacre
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How often do we appreciate the flesh-and-blood reality of concepts learned in class? Consider publication bias: the *Users' Guides to the Medical Literature* states it's "when the publication of research depends on the direction of the study results and whether they are statistically significant."[1] Though precise, this bland definition belies the severity of a problem that pervades medicine. Flattering results are more likely to get published and this has appalling effects on patients, as British physician and epidemiologist Ben Goldacre shows in *Bad Pharma*.[2]

Specifically, half of all clinical trials go unpublished.[2] Positive findings – those that favour the drug under study – are twice as likely to be published as negative ones.[2] And pharmaceutical-industry-sponsored clinical trials are four times more likely to report a positive result, compared to independently-funded trials.[2-4] Publication bias, therefore, skews the relative benefits and harms of drugs on the market. It pollutes the well of knowledge from which doctors draw their decisions and, for patients, this leads to unnecessary suffering, even death.

In *Bad Pharma*, Goldacre collates research documenting the malignancy of publication bias in medicine, and to underscore the flesh-and-blood consequences of such research, he weaves in anecdotes and news stories. In this way, Goldacre manages a book that is not only well researched and referenced, but passionate and accessible.

Some examples stem from his experience as a psychiatrist. When Goldacre prescribed the antidepressant reboxetine to a patient, he did so after consulting the literature, which was overwhelmingly in favour of the drug. But both he and his patient were misled. A group of researchers would go on to assemble all the data on reboxetine – from both published sources (e.g., academic journals) and unpublished ones (e.g., documents from manufacturers and regulators).[5] Their findings: of the seven trials comparing reboxetine against placebo, only one had a positive result – the only trial published for the eyes of doctors and researchers. The other six trials – those showing reboxetine was no better than a sugar pill – were not published.

And the story gets worse: the results of yet more trials were also buried, which showed that reboxetine was less effective and generated more side effects than other available antidepressants. This is but one drug in a book rife with examples of misconduct.

The issue of missing data is only chapter one. *Bad Pharma* also documents many other problems associated with the practices of Big Pharma, ranging from trials that are outsourced to the developing world, with questionable ethical practices; to subversively influencing doctors' prescribing habits with marketing. Yet, despite the title of the book, Goldacre's ire is not fixated solely on the pharmaceutical industry. He explains the roles of, and criticizes, all parties whose (in)actions contribute to these problems: ethics committees, regulators, journal editors, academics, doctors, and patient advocacy groups. Regarding journal editors, for instance, he discusses "fake fixes" – changes in regulations and practices, announced with fanfare, that have been ignored or bypassed. One example is the promise made by the International Committee of Medical Journal Editors (ICMJE) in 2004: they declared they would not publish any clinical trials after 2005 unless they had been properly registered. [6] When a group of researchers in 2008 combed through the top ten general medical journals in the world – all of whom are members of the ICMJE – they checked the editors against their word:[2]

> *Out of 323 trials published during 2008 in these high-impact academic journals, only half were adequately registered (before the trial, with the main outcome measure properly specified), and trial registration was entirely lacking for over a quarter.[7] The ICMJE editors had simply failed to keep their word.*

This is but a small sample of the topics and examples discussed by Goldacre in *Bad Pharma*. Importantly, while Goldacre uses anecdotes, he avoids cherry-picking results by relying on systematic reviews. Given the number of topics, he wisely summarizes his key points, and also offers suggestions for improvements after every section – thereby making the book accessible to the lay reader. The solutions he recommends will require a coordinated effort – not to mention a fundamental cultural change in medicine. However, some progress has been made with the AllTrials campaign (AllTrials.net), a petition launched in January 2013 to ensure all clinical trials are registered, and their results published. The initiative has thus far garnered support from many organizations, notably

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GlaxoSmithKline,[8] and over 100 patient advocacy groups.[9]

Study after study, this book is sure to incite indignation. Yet overall, Goldacre presents a balanced, measured critique of how we regulate, market, and prescribe drugs. He systematically impresses upon the reader the importance and complexity of these problems. His emphasis on the issue of publication bias and recent "fake fixes" distinguish *Bad Pharma* from related books of the past decade, which focused on dubious marketing strategies, questionable research practices, medicalization, and/or ghostwriting, among other issues.[10-13] And neither is Goldacre ungrateful for the virtues of Big Pharma; he duly recognizes the immense costs that companies bear with innovation, and outlines his optimistic outlook toward industry at the outset of the book.

As is customary when teaching statistical concepts, Goldacre explains publication bias with a coin: "If I toss a coin a hundred times, for example, but only tell you about the results when it lands heads-up, I can convince you that this is a two-headed coin."[2] If half of all clinical trials go unpublished in modern-day medicine, doctors are being bamboozled: to believe that the coin bears heads on both faces.

## References

1. Guyatt G, Rennie D, Meade M, Cook D. Users' Guides to the Medical Literature. 2nd ed. Toronto: McGraw-Hill Professional; 2008. 860 p.
2. Goldacre B. Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients. Toronto: Signal; 2013. 448 p.
3. Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. JAMA. 2003; 289(4):454-65.
4. Lexchin J, Bero LA, Djulbegovic B, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. BMJ. 2003; 326(7400):1167–70.
5. Eyding D, Lelgemann M, Grouven U, Härter M, Kromp M, Kaiser T, Kerekes MF, Gerken M, Wieseler B. Reboxetine for acute treatment of major depression: systematic review and meta-analysis of published and unpublished placebo and selective serotonin reuptake inhibitor controlled trials. BMJ. 2010; 341:c4737.
6. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, Kotzin S, Laine C, Marusic A, Overbeke AJ, Schroeder TV, Sox HC, Van Der Weyden MB; International Committee of Medical Journal Editors. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. Lancet. 2004; 364(9438):911-2.
7. Mathieu S, Boutron I, Moher D, Altman DG, Ravaud P. Comparison of registered and published primary outcomes in randomized controlled trials. JAMA. 2009; 302(9):977-84.
8. GSK announces support for AllTrials campaign for clinical data transparency [Press Release]. London: GlaxoSmithKline; 2013 Feb 5 [cited 2013 May 5]. Available from: http://www.gsk.com/media/press-releases/2013/GSK-announces-support-forAll-Trials-campaign-for-clinical-data-transparency.html.
9. AllTrials campaign launched in US [Press Release]. Hanover: Geisel School of Medicine; 2013 May 1 [cited 2013 May 5]. Available from: http://geiselmed.dartmouth.edu/news/2013/05/01_trials/.
10. Horowitz AV, Wakefield JC. The Loss of Sadness: How Psychiatry Transformed Normal Sorrow into Depressive Disorder. New York: Oxford University Press; 2007. 312 p.
11. Cassels A, Moynihan R. Selling Sickness: How the World's Biggest Pharmaceutical Companies are Turning Us All Into Patients. Vancouver: Greystone Books; 2006. 272 p.
12. Angell M. The Truth About the Drug Companies: How They Deceive Us and What to Do About It. New York: Random House; 2004. 352 p.
13. Kassirer JP. On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health. New York: Oxford University Press; 2005. 272 p.