

In the Bookstores



Bad Pharma: How drug companies mislead doctors and harm patients

by Ben Goldacre

Fourth Estate, 2012.

ISBN: 978-0-00-735074-2 (paperback).

13.99 GBP. 448 Pages.

Bad Pharma

Bad Pharma is the latest book by the well-known anti-quackery campaigner Ben Goldacre, and attempts to explain to us that medicine is broken. Despite the title, he criticises not only the pharmaceutical industry, but also regulators, doctors, academic clinical researchers, ethics committees, and various other players in the world of clinical research. His take home message (I don't think a spoiler alert is really needed here!) is that we simply can't trust the evidence that we see about the efficacy and safety of drugs in common use.

The book is divided into six chapters, which cover different aspects of the pharmaceutical industry. Chapter 1 is entitled 'Missing data', and describes at considerable length the important problem of publication bias. The take home message from this chapter is that we cannot assess the evidence for a particular drug if not all the trials on it are published, and, worse still, those that are not published tend to be different from the ones that are. Chapter 2 is a brief and well put-together description of the drug development process. Chapter 3, 'Bad regulators', does what it says on the tin, and explains the many ways in which Goldacre believes that drug regulation isn't working. Chapter 4 talks about the design of individual clinical studies and how they can be flawed. Chapter 5 describes how pragmatic randomised trials could be (but very rarely are) incorporated into routine clinical practice. This seems a little out of place, as it is not really about 'bad pharma' at all, but is interesting nonetheless. Chapter 6, the longest chapter of all at over 100 pages, talks about marketing in the pharmaceutical industry.

Goldacre has a well-earned reputation as a fearless debunker of dodgy scientific claims. His previous book, *Bad Science*, mercilessly took to pieces the dubious tricks played by various pedlars of pseudoscience. He regularly writes articles both on

his own blog and for the popular media in which he rigorously dissects questionable claims, pointing to the flaws in the scientific and statistical methods used by those who make them.

So if you are familiar with Goldacre's reputation, then you would expect that this book would be backed up with similarly rigorous scientific arguments. However, you would be disappointed.

Goldacre tells us at several places in the book (quite correctly) about the importance of using systematic reviews and being careful not to cherry-pick examples that back up a specific point, and promises to cite systematic reviews to make his points. Sadly, the reality of the way he presents his evidence does not live up to those fine promises. He certainly presents the results of some systematic reviews, but he is far from consistent in doing this. At one place he presents a single study, which is not a systematic review, but describes it as a systematic review anyway. In many places he does exactly what he warns against and cherry-picks unrepresentative cases to make a point. He sometimes ignores evidence that contradicts his message. The overall impression is that he decided from the start that he was going to tell as powerful a story as possible that the whole system of drug research is flawed, rather than attempting to follow the evidence in a scholarly manner.

It would, however, be a mistake to dismiss this book as being based on poor scholarship and therefore unworthy of our attention. Despite the shortcomings in his use of evidence, Goldacre does make some important points whose validity is not in doubt.

One such point is that much of the evidence on how well drugs work is not available to patients and prescribers: the problem of publication bias that he describes in the first chapter. Many attempts have been made to fix this problem, and most big pharma companies now commit to publishing all their trials, although Goldacre describes these efforts (without presenting evidence) as 'fake fixes'. Nonetheless, it would be overly optimistic to assume that every study that takes place is published, and until we can be sure that it is, then we all need to try harder to ensure more complete publication. Goldacre also makes the very good point that even if incomplete publication has now been fixed, there is still a mountain of studies that were

done in the past and are still not published, even though their results are still relevant to today's medical practice. So we should not consider the problem solved until it has been solved retrospectively as well.

Goldacre's criticisms of the secrecy that surrounds the regulatory process are also very well made. He points out that it is unjustifiable that regulators have access to huge amounts of data on the drugs they approve, but do not publish them. It is hard to argue with this. I personally cannot think of any valid reason why regulators do not routinely make submission dossiers available via their websites, and we could all have far more confidence in the regulatory process, as well as know far more about the drugs that we use, if they did.

Medical writers will find some parts of the book frankly offensive. Goldacre seems to use the terms 'medical writing' and 'ghostwriting' interchangeably, completely ignoring the considerable efforts that EMWA and other medical writing organisations have made to combat ghostwriting in the medical literature. He describes professional medical writing thus: 'They [pharmaceutical companies] pay professional writers to produce academic papers, following their own commercial specifications, and then get academics to put their names to them.' This is a caricature of the work of the medical writer based on a few examples of bad practice mostly dating from the 1990s, and EMWA members will be acutely aware that this bears little resemblance to the way medical writing is practised in real life today, even though Goldacre describes ghostwriting papers for academics who have no input into them as 'bread-and-butter activities' of medical writing. If you are offended by this mischaracterisation of the medical writing profession, then I am not surprised. It is telling that Goldacre does not provide any evidence to back up this claim, other than to quote some old individual cases where some companies did not play by the rules in the past. This is cherry-picking of the worst kind: there

is no evidence whatever that those kinds of abuses were common even back in the 1990s when most of them occurred, let alone today. It would be like making the claim that most doctors are serial killers, and backing it up with reference to Harold Shipman.

Of course, if you did claim that most doctors were serial killers, no-one would believe you, because most people are very familiar with who doctors are and what they do, and know that most of them are conscientious and caring individuals. Sadly, however, medical writing is not such a well-known profession, and it is probably true that many people who read the book will not be familiar with what medical writers do, and so will simply believe Goldacre's flagrant mischaracterisation of our profession.

At 448 pages, *Bad Pharma* is a long book. It is probably longer than it needs to be: Goldacre's fondness for using anecdotes about specific cases to make his point adds more to the emotive qualities of the book than it does to the scientific data presented.

EMWA members will probably not learn much from this book that is new to them. There are some good explanations of how drug development works, but this will already be familiar territory. The book does, however, provide much food for thought. Although Goldacre goes beyond the evidence and overstates his case in places, he does, as I mentioned earlier, still make some valid points. If any EMWA members who read this book are prompted to give some more thought to how they can help to ensure that the trials they work on are always published, then it will have fulfilled a useful function.

Reviewed by Adam Jacobs
Dianthus Medical Limited
ajacobs@dianthus.co.uk
<http://dianthus.co.uk>
<http://twitter.com/dianthusmed>

Note from Editor: EMWA has published guidelines on the role of medical writers in developing peer-reviewed publications and has reiterated these in the position statement on ghostwriting found on Page 3 of this issue.

Greg Morley also discusses *Bad Pharma* in the Regulatory Writing column on page 61.



Writing for Peer Reviewed Journals Strategies for getting published
by Pat Thomson and Barbara Kamler:
Routledge, 2012.
ISBN-13: 978-0-415-80931-3.
22.99 GBP. 190 pages.

A guide aimed at junior social science researchers which contains some information applicable to other disciplines and of use to other types of writers

The blurb on the back cover of *Writing for Peer Reviewed Journals* asserts that it ‘assists anyone concerned about getting published’ and ‘uses a wide range of multi-disciplinary examples’. This information could at best be described as somewhat misleading: it is clearly aimed at junior researchers, for whom there is a lot of (quite useful) information on converting the PhD thesis into journal articles, and even structuring the thesis with such articles in mind. Moreover, it is squarely focussed on the social sciences. The book’s authors, Pat Thomson and Barbara Kamler, both work in education and while they refer to conventions in other disciplines, most of their examples are taken from their own field. Nonetheless, they do provide some information that will be useful to medical writers.

In the book’s introduction, Thomson and Kamler clearly set out their goal: to focus on scholarship rather than writing development; to offer a pedagogical and ‘theorised approach rather than a set of tips and tricks.’ In its first chapter proper (*The Writer*), they argue cogently that the moulding of a scholarly identity is acutely influenced by what one writes and how one writes it. While of little practical benefit, this philosophical discourse is rather interesting.

The book’s remaining eight chapters variously deal with fundamental and practical facets of writing. The authors provide a brief summary for each chapter in the introduction to allow readers to skip straight to a particular chapter if they so wish. By referring back to previous chapters in which key concepts are introduced and defined, they almost (but don’t quite) make it possible to read individual chapters in isolation.

Chapter 2 (*The Reader*) emphasises the importance of writing with a specific reader in mind; *What’s the Contribution?* and *So what? Who cares?* largely focus on writing abstracts in a way that makes clear the nature and importance of one’s work; *Beginning work* and *Refining the argument* deal with writing

and revising/editing articles; and *Engaging with reviewers and editors* does exactly what you would imagine it does.

The eighth chapter, *Writing with others*, is excellent (albeit it is targeted to junior researchers). It introduces three different types of collaborative writing and, with the aid of comments from successful writing partnerships, explains how to make writing collaborations work. Importantly, it notes that it is not possible to write with everyone, but fails to acknowledge that you don’t always get to choose whom you write with!

The book’s last chapter (*Living hand to mouse*) concludes with some smashing advice about peer reviewing, including sets of questions the reviewer should ask him/herself when reading a manuscript and rules to follow when writing the review. As the authors note, how to be a good peer reviewer is a neglected topic. *Have a look at this manuscript* was the only instruction I and no doubt many others got when starting out.

This advice on peer reviewing is complemented by tips on responding to reviews: don’t ruin your article by accepting wholesale all the reviewers’ comments; be authoritative; and don’t fawn. I once edited a set of point-by-point responses to reviewers’ comments in which the author thanked each reviewer for each and every comment. Twice!

Thomson and Kamler claim an ‘international approach’ and an ‘accessible style’. While they describe the increasing requirement to publish in English as ‘contentious and sometimes extraordinarily difficult,’ they do not employ the simplest English imaginable. I am grateful to them for adding several new words to my vocabulary; less patient readers may be less appreciative. The book’s ‘international approach’ is in fact limited to (i) a couple of lines on the writing difficulties of individuals whose mother tongue has different cultural conventions than those of English and (ii) problems non-native English speakers have interpreting nuanced comments from peer reviewers (e.g. ‘I would suggest...’ = ‘You should...’). These are interesting topics that warrant more detailed analysis.

For experienced writers and researchers the points of real interest may be limited to a few pages here and there. Key passages deal with avoiding signing off with an empty, lazily written conclusion and ways of improving abstracts (illustrated with real examples). Other topics such as choosing which journal to submit to and reasons for rejection are covered in more detail in recent articles in *TWS/Medical Writing*.^{1,2} Whether to write the abstract first

or last is another important subject Thomson and Kamler cover. They advocate an abstract-first approach to writing. That is, decide what you want your article to say before you start writing it (don't just write all your results down and try to weave them into a story). Others, however, disagree.³

The value of writing retreats and writing groups, where writers can receive constructive criticism on their efforts, is emphasised. This seems smart. I don't know what has happened in the three years since I abandoned research, but I lacked and could have used a forum for getting feedback on my early writing efforts.

The authors should be credited for drawing the reader's attention to a number of helpful online resources. These include Manchester University's Academic Phrasebank (www.phrasebank.manchester.ac.uk), a set of phrases that can be useful in academic writing, and Authorder (www.authorder.com), a tool for determining author sequence.

Writers of scientific papers will have to disregard some of the advice, e.g. to avoid the IMRAD (Introduction, Methods, Results, And Discussion) structure. Nor should they worry unduly about another problem the authors identify: the 'incapacity ... to *literally* insert [oneself] on the page'! Easier to accept is their advice to anticipate potential objections from readers when formulating your argument. The assertion that writers should

reference previous papers published in the journal to which they are submitting may be astute, but it must clearly not be done in a contrived way.

A big minus for me is Thomson and Kamler's obsession with attaching fancy names to concepts without clearly explaining what they mean. Despite reference after reference to 'text work/identity work' (one of the authors' central concepts), I couldn't tell you what it is. Still, the authors do, in spite of their idiosyncratic lexicon, manage to imbue their writing with wit and empathy, although their default perspective of writing as scary and horrible will presumably not strike a chord with most EMWA members.

Reviewed by Stephen Gilliver
Science Editor, Center for Primary
Health Care Research
Malmö, Sweden
stephen.gilliver@med.lu.se

References

1. Leventhal P. How do I select a target journal for a manuscript? *TWS* 2011;20(4):267-9.
2. Leventhal PS. What are the most common reasons for a manuscript to be rejected (and how can they be avoided)? *Medical Writing* 2012;21(1):66-8.
3. Writing an Abstract. Writing Centre, the University of Adelaide. Available from www.adelaide.edu.au/writingcentre/learning_guides/learningGuide_writingAnAbstract.pdf [Accessed 2012 December 3].