

Book Review

Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients

By Ben Goldacre. 364 pages. London: Fourth Estate, 2012. ISBN 978-0007350742.

For a new medicine or vaccine to make a meaningful contribution to the prevention and/or treatment of disease, it has to clear a number of hurdles: consistent evidence of efficacy, in the population to be treated; safety, insofar as the benefit of the medicine should justify the risk of possible adverse events; and quality, demonstrated by laboratory studies. All this, it is generally assumed, derives from studies conducted ethically, objectively and honestly by clinical and pharmaceutical scientists.

In more than 100 countries, these requirements for medicines are overseen by the national drug regulatory authority (in South Africa this is the Medicines Control Council), collectively consisting of experts thoroughly versed in clinical and pharmaceutical medicine. They serve the public health, applying the highest standards. They are believed to be incorruptible and uninfluenced in their decision taking by industry or government. The public takes it on trust that clinical trials are conducted by experienced clinicians and that they are reviewed and overseen by ethics committees, likewise independent and of high standing. Doctors, it is accepted, prescribe medicines in the best interests of their patients, based on the evidence available. It's a big ask, and a huge trust conferred on the health professions and the medical scientific community.

Things are not so simple, maintains Ben Goldacre in his latest book *Bad Pharma*.

Some 25% of the massive global turnover of the pharmaceutical industry goes to advertising and promotion, which translates *inter alia* to incentives to doctors in the form of gifts, promotional meetings and conferences, overseas travel expenses (including spouses and partners), sponsored hospital grand rounds and other clinical meetings, even holidays. Companies draft study protocols and trial results for lead investigators to sign off, and negative non-supporting results get buried and not published. Under such circumstances doctors are no better than ordinary consumers. Goldacre provides examples to show that the industry, profession, ethics committees, medical journals and regulatory authorities are lacking in vigilance in the design, conduct, analysis and interpretation of clinical studies. This puts a challenge to industry and to the profession that is necessary and must be answered.

Bad Pharma is a brutal attack on the pharmaceutical industry and, by extension, the medical profession who are innocent (and sometimes not so innocent) bystanders. Goldacre is on a mission, and his book is overwrought. The facts, cases and argument are based largely on experience in the UK, Europe and North America. Whether matters are the same, better or worse in the remainder of the world, especially in less affluent countries, does not come up for consideration. It is a significant and careless omission. The dedicated work of ethics committees and national regulatory authorities is overlooked. Does Goldacre know of the generous, free and expert advice and assistance in drug and vaccine development and safety given by the industry to the World Health Organization, and to other not-for-profit international

organisations that deal with neglected diseases? If he does, it is remiss of him not to acknowledge it. If he does not, he has been unbalanced in his critique. The solutions proposed by Goldacre are wide ranging and reasonable, but lacking in imagination and inspiration. At the heart of it, the ethos of the profession must change, through consensus, education and example.

On one particular, and crucial, issue Goldacre is correct and spot on. That is the culture of secrecy, shared by the industry, regulatory authorities and by extension the professions. It is a throwback to the 1960s, when the foundation principles of most national regulatory authorities were drafted. Ostensibly to protect the intellectual property of the industry and to encourage full disclosure, it has not worked out that way, with the result that secrecy interferes with exchange of essential information and decision taking. It impacts on safety, too. Secrecy obstructs proper exchange between regulatory authorities, and between the authorities, the professions and the public, and it compromises public trust.

In summary, Goldacre raises necessary issues that require attention and redress. However, his book falls short of being a complete and fair-minded exposé according to standards that he himself would advocate. At times it deteriorates into little more than a rant. In large measure, that is due to its failure to consider the global situation in his limited, one-sided and parochial investigation.

The reviewer declares that he has no conflict of interest.

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