

# Research in Pharmacy and Health Sciences

## Book Review

### Book review: *Deadly medicines and organized crime*

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Clinical trials have attracted negative attention recently. The degree of control of the pharmaceutical industry over the design, conduct and analysis of clinical trials has been criticized. Healthcare professionals increasingly rely on data obtained from clinical trials and from meta-analysis and systematic reviews. The process of publishing clinical trials and framing clinical practice guidelines is being increasingly influenced by the pharmaceutical industry.

Dr Gotzsche, a medical doctor had worked in the 1970s in the pharmaceutical industry. He is an outspoken critic of the industry and its powerful influence on drug regulatory agencies and politicians. Studies show the pharmaceutical industry has consistently been one of the most profitable industries on earth with the resource to finance and influence political campaigns. Dr Gotzsche's recently published book titled 'Deadly medicines and organized crime: How big pharma has corrupted healthcare' examines the pervasive influence of the pharmaceutical industry in detail. The book has forewords by Richard Smith, former Editor-in-Chief of the BMJ and Drummond Rennie, Deputy Editor of JAMA.

The author towards the beginning of the book describes his days working for the pharmaceutical industry in Denmark. His account about his grandfather who was a general practitioner in Denmark and his approach to pharmaceutical promotion and continuing education makes for interesting reading. The story of clioquinol marketed to combat amebic dysentery and its use later expanded to other forms of dysentery makes for disturbing reading. The drug was neurotoxic and was implicated in an epidemic of subacute myelo-optic neuropathy (SMON) in Japan. In the fourth chapter of his book the author explains how very few patients may be obtaining benefit from the drugs they take. There are a number of 'me-too' drugs on the market which are cheaper to develop than an originator molecule and with a proper marketing campaign can bring equivalent or greater profits to the industry. The author explains the pervasive influence of the industry on the clinical trial process and how this leads to the promotion and use of drugs with doubtful efficacy.

In the fifth chapter Dr Gotzsche explains how clinical trials are a broken social contract with patients. Many individuals volunteer to participate in clinical trials based on altruistic motives. In developing countries like India the regulations and safeguards are less stringent and people may volunteer to participate in return for monetary gains due to poverty. Throughout the book, the author provides countless

examples of how the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) two of the world's most powerful drug regulators are influenced by the industry. Being aware of other articles, videos and documentaries about promotion much of what has been mentioned in the book did not come as a surprise. Access to clinical trial data is another major theme which recurs throughout the book.

The author states that during recent decades the drug industry has been transformed for the worse. One possible reason could be the dominance of marketing people and managers over 'professionals' in the higher echelons of the industry. Conflicts of interest in many medical journals which publish clinical trials and scientific research has again been well documented. Industry advertising is a major revenue source for journals and this dependence and influence can have a serious impact on their objectivity as demonstrated by the author through case studies and examples.

Companies have an increasing number of doctors on their payroll and doctors are becoming an important element of the marketing arm of companies. 'Off label' uses of medicines is becoming a major source of profit and the author provides examples of these uses with accompanying documentation. Academic thought leaders are useful as 'key opinion leaders' to companies and are in a strategic position to influence other doctors. Pharmaceutical promotion is especially pervasive in the case of drugs for which there is a large market and the chance of high profits. Drugs for many chronic diseases affecting the developed world are a good example. Companies may try to market more expensive congeners of medicines already present in the market. Dr Gotzsche describes how drug regulation in many nations is becoming less effective. The author mentions how regulators seldom do their own research and testing but rely on the documentation submitted by the industry. He questions whether car inspectors would be satisfied with the documentation a person has generated about his/her car rather than actually inspecting the car. He provides examples of political influence and interference with drug regulators and how the expedited review process funded by money obtained from the drug's sponsor can compromise drug safety.

Chapter 12 deals with various off-label uses of an epilepsy drug, gabapentin. There have been scientific and other articles dealing with the various uses of this drug and the author mentions how it has been marketed as an epilepsy

drug for everything. The case of COX-2 inhibitors also makes for poignant reading. The author describes how companies were aware of the increased risk of cardiovascular events associated with these drugs but continued to market these until finally forced to withdraw the same. Chapter 15 focuses on how switching patients needing long-term therapy (like for many of the chronic diseases) from cheaper to more expensive medicines has huge potential for profit. The example of insulin preparations, omeprazole congeners, and of minor changes or modifications in drug dose or mode of delivery to extend patents have been mentioned. Psychiatric disorders offer a very lucrative opportunity for aggressive marketing and 'pushing drugs'. The diagnostic criteria of these diseases are often not objective and new diseases can be 'created' relatively easily. The author provides examples of how the prevalence of mental disorders has 'increased' in the US and other industrialized nations following the development and aggressive marketing of medicines for psychiatric disorders.

The chapter on intimidation, threats and violence and how the industry deals with whistleblowers makes for disturbing reading. Towards the end of the book the author busts common myths touted by the industry. Among these are drugs are expensive because of high development costs, if we do not use expensive drugs then innovation will dry out, savings are greater than costs for expensive drugs, breakthroughs result from industry funded research, drug companies compete in a free market, drug trials are done to improve the treatment of patients, we need many drugs of the same type because patients vary in their response, generic medicines are not dependable among others.

The author concludes by examining the effects of huge industry profits and high medicine prices on the health systems of countries. Even in rich countries the high cost of medicines and medical devices is having a huge impact on health economics. The US spends over 15% of its budget on health and this is expected to increase to 20% in a few years. Even with such a high spending the country has not been successful in ensuring access to health services and medicines to all its citizens.

The book has been written in an engaging style with frequent references to the scientific and other literature. We are sure lay readers will be able to understand most of the ideas and arguments in the book. The book can provide ideas for vigorous debate on this important topic. All those interested in promoting rational use of medicines will find this provocative book of interest.

**About the book:** *Deadly medicines and organized crime*. Gotzsche PC. Radcliffe Publishing, 2013. 310 pages.

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