Deadly medicines and organised crime

How big pharma has corrupted healthcare



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OVERALL RATING Excellent

STRENGTHS Comprehensive, with worldwide examples across many categories of drugs. It describes the history well, and is current

WEAKNESSES Not always correctly referenced. Some arguments are simply the author's personal views. Book could have benefited from a better editor **AUDIENCE** Physicians and interested members of the public

The thesis of this book attracts attention: medicines are produced by organized crime syndicates. Peter Gøtzsche shows that the official definition of organized crime closely matches the activities of the largest drug companies. He lists each of them and shows that they have all been repeatedly convicted of marketing harmful—often fatal—drugs; substantial fraud; price manipulation; and concealment of evidence. The billions of dollars in fines levied against them for these offences pale in comparison to the profits they continue to make, so these convictions are merely the cost of doing business. It is not clear that convictions in the United States have had any effect in Canada or elsewhere in the world.

Gøtzsche began his career as a drug representative who became a marketing manager. He then went to medical school and become an internist and clinical researcher. He is now the director of the Nordic Cochrane Centre in Copenhagen, Denmark. In his progress he has created controversies by questioning accepted wisdom.1,2

He agrees that there are indeed many valuable drugs, but emphasizes that those are not his target. Such drugs need little promotion, as they sell themselves. His concern is with the rest: the "me, too" drugs that provide no benefit and those that are actively harmful. His book describes substantial flaws in the way that medical evidence is produced, and how it has become worse over the past 20 years as a result of more commercially oriented drug approval policies implemented with the intent of reducing delay in marketing. These changes have occurred primarily in the United States, but are echoed in the rest of the world. The consequence has been less critical review, less oversight, and

less protection of the public, as Gøtzsche demonstrates with a host of examples. Perhaps the best example is oseltamivir, which has minimal (if any) value, many side effects, and on balance appears to have no place in the formulary at all. Yet Roche persuaded governments to stockpile it to halt the 2009 H1N1 influenza epidemic.

How companies manipulate data and increase drug costs

The drug and medical device companies organize trials in the best populations and comparison groups to demonstrate their point; they control the data, do the analyses in-house, and employ professional writers to write the papers. They then select outcomes that suit their marketing needs and demonstrate the greatest differences, rather than the most important outcomes for patients. Too often, academics are then paid to be listed as authors when they had little input and cannot vouch for the data. Trials with negative results are buried and not published. Physicians who are concerned about marketing hype, and who therefore seek a balanced and valid view of the evidence, are fooled, as all the available data are biased. As Gøtzsche says, "The 'best' drugs may simply be those with the most shamelessly biased data."

The book is structured in chapters that describe his own involvement; outline the business models of pharmaceutical, test, and device companies; and show how clinical trials are designed to emphasize benefits and minimize flaws and harms, so that patients (and clinicians) who participate are deluded into helping with marketing, rather than contributing to the common good. He asserts that most patients taking drugs do not benefit from them.

Gøtzsche critiques the myth promoted by "Big Pharma" that we need to continue paying exorbitant prices for branded drugs to ensure that innovation continues. Drugs are expensive not because of development costs, which are largely borne by publicly funded research, but because of the marketing machine, political lobbying, and excess profit taking. He provides numerous examples from off-label marketing of gabapentin, cyclooxygenase-2 inhibitors, more expensive insulin and other diabetes medications, weight-loss treatments, proton pump inhibitors, and psychiatric medications. He shows how psychiatry has changed from unscientific psychoanalytic approaches to unscientific drug pushing ("biological psychiatry") while ignoring side effects and difficulty withdrawing from drugs. This general system failure calls for a revolution in the whole process, including the need for all data to be open, as espoused by the Cochrane movement, and the AllTrials initiative in Europe. We doctors and our organizations, including those responsible for continuing professional development, must wean ourselves from biased funding, such as "unrestricted educational grants" that are really marketing schemes, as the pharmaceutical industry will not pay for programs that do not advance their causes. So-called patient organizations are usually marketing fronts: organizations that demand public funding for new and expensive drugs seldom request reductions in those exorbitant prices.

Weak points

The barrage of evidence is overwhelming. The book is extensively referenced, but not always correctly, as I found when checking, and some arguments are simply the author's personal views. Gøtzsche could have benefited from a better editor to give each chapter a clear message and summary, reduce duplication, check references, and improve the writing style.

Why read this book?

Several other books provide similar analyses, including 2 by past editors of the New England Journal of Medicine^{3,4} and 1 from an editor of the BMJ.5 Some other books go into depth about specific fields such as cancer^{6,7} and psychiatry,8 or describing the process of overdiagnosis.9 Some are written for the layperson^{6,7,9,10} and others for physicians. So why should you read this one?

The book is comprehensive, with worldwide examples across many categories of drugs of how the pharmaceutical industry operates. It describes the history of the pharmaceutical industry well, and is current, with references from 2013. The comprehensive attack on the largest drug companies is scathing, and it provokes physicians to be more cautious about prescribing. But most important, it shows us that evidence-based medicine and guidelines have been hijacked, as the evidence base has been systematically distorted. 11,12 Consequently, we must rethink which evidence and which recommendations we should use to help our patients. A helpful start is the Public Citizen approach of not using any new drug until it is 7 years old.13

—James Dickinson MBBS CCFP PhD

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