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How Medicines are Born – the Imperfect Science of Drugs

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Medicines dominate modern life. The process of how medicines are discovered, how they are tested, certified as safe for use in humans and monitored for adverse effects are often not known by the lay public. This book by two Italian scientists has been translated into English and is written in an easy to read and understand style. We enjoyed the frank foreword by the authors. The book delves deep into the history of modern medicines. There are detailed descriptions of the discovery and use of penicillin, insulin, ACE inhibitors, aspirin, low-dose aspirin, streptokinase, and cisplatin. Drug discovery previously was often by chance and the book describes the first drug discovered according to a plan, imatinib. The second chapter deals with 'Hunting for drugs'. Receptors are among the most important targets of drug action and advances in genetics and molecular biology are providing us with an ever deepening understanding of diseases which is being used to develop appropriate treatments. The authors describe 'biologicals' in some detail. Biologicals are becoming increasingly dominant in modern day therapy. Erythropoietin is the best known biological. The authors revisit the statement by Paracelsus about all drugs being poisons and only the dose determining whether a substance is a drug or a poison. They describe in a simple manner different routes of drug administration.

Laboratory studies are the focus of chapter 3. The authors argue why even in the modern era of cell lines and molecular targets, animals still remain essential to evaluate a drug. Animal models are being created for most diseases. The authors end this chapter by describing how the results of animal studies are used to decide on whether to go ahead with clinical trials in humans. Many regard the experiments of James Lind on sailors with scurvy to be the first clinical trial. Recruitment of study participants, informed consent and randomization, having a control group and doing a blinded study as the three pillars of a clinical trial are explained. The four phases of a clinical study are described in a simple and engaging manner.

Clinical trials and drug action is governed by probabilities and not by certainties. With simple examples the authors discuss complex concepts like power of a study, false positive, false negative results, and correlation. The next chapter deals with approval or rejection of a new drug. The drug approval process is examined in detail. Generic medicines are widely used and are much cheaper than patented drugs. Biosimilars are also briefly discussed. Chapter 7 starts with the discovery of the COX-2 isoenzyme and the story of the drug, rofecoxib. Throughout the book the authors highlight the fact that any drug directed against microorganisms will eventually fail due to microbial

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resistance resulting from genetic and other changes in the microbes. Off-label prescribing and disease mongering are also explored.

Chapter 8 examines predicting the drugs of the future. Nanovehicles for drugs, pharmacogenomics, new indications for old drugs, bioinformatics, drugs which repair are among the topics covered. Chapter 9 examines the pre-anesthetic era in some detail. Complementary medicines, vitamin and food supplements are described as pills which are not drugs. The authors provide a list of books and websites and articles for further reading. Among enduring myths especially among laypersons are natural remedies are harmless and do not have adverse effects, drug experimentation using animals is not needed, biologicals are better than chemically synthesized drugs, new drugs are better than older ones, and generic drugs are worse than branded ones. The authors try to address each of this using scientific evidence.

The book ends with an interesting section titled 'Did you know that...?' Pharmacovigilance plays an important role in medicine safety and is addressed throughout the book. This book is a good read for all individuals interested in knowing more about medicines, their creation, testing, approval and rational use. The authors have to be commended for tackling a complex topic in a simple and engaging manner.

About the book:

Lisa Voza, Maurizio D' Incalci, Andreas Gescher (translator).

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