THE DEVELOPMENT OF A MEDICINE

In all experimental knowledge there are three phases : An observation is made, a comparison is established and a judgment rendered.

C. Bernard (1865)

Stages in the discovery and development of a typical drug (courtesy ICI and the *Financial Times*).

THE DEVELOPMENT OF A MEDICINE

R. B. Smith

M
STOCKTON
PRESS

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To Stephanie, Edward, Alexander and William

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Foreword

Medicines, and the drugs they contain, are taken for granted by most people. We have been born and bred in a generation whose medicine cabinets contain 'something for every occasion' — analgesics for pain, antacids for indigestion, laxatives for constipation, contraceptives, and, all too often, antidepressants, tranquillisers and sleeping pills. So conditioned have we become to thinking that 'there is a pill for every problem' that many of us forget the equally important truism 'every pill has its problem and its price'.

The price of a drug is not only the enormous cost of its development, assessment and marketing, but also the sum of adverse effects which it may inflict, and which have to be accepted by the few if its beneficial effects are to be enjoyed by the many. We cannot be reminded too often of this risk-benefit ratio which every therapeutically active medicine possesses, and in this book Dr Smith spells out the situation clearly and concisely, based on his long experience in drug development.

An understanding of the processes that lead to the discovery of new medicines and the balanced assessment of their therapeutic roles may lead to a better appreciation of their true value and a more responsible approach to their use. This is essential if the true potential of drug treatment is to be realised in the conquest of disease.

Paul Turner
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Preface

This book has been in gestation for almost five years. During this time I have been made aware repeatedly of the fact that, although many people do have a genuine interest in how their medicines come into being, relatively few have an overall view on how this development of a medicine is achieved. Therefore the major purpose of this book is to provide a general 'broad-brush' impression of the many components of drug development. It aims to draw together and associate the various disciplines which interrelate and interact to make the end result — a safe and effective medicine for human use — a reality.

Goring-on-Thames, 1985

R.B.S.

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I am extremely grateful for the forbearance, patience and accuracy of Sarah Tobitt and Carol Miller who typed the manuscript through its various drafts and revisions.