Preface

Organizations, whether they be societies, foundations or commercial corporations, are as a rule brought into existence to put into motion the hopes and ideals of those who create and lead them. At the same time, they justify and finance their existence primarily by providing some form of service to society. To a very large extent, therefore, society has come to rely upon their existence and to encourage their development. That applies to the pharmaceutical industry as it does to others.

On the other hand, the community must remain watchful. Whatever the motives for their creation, these bodies over the years grow, change, merge and alter course; an institution that has served society well at one stage may later fail to do so. Just as in the case of individual citizens, society therefore needs to create rules of behaviour, laid down in the form of laws and regulations, orders and codes, and to ensure compliance with them. In many an instance those rules will closely parallel the standards that a right-minded corporation believes must govern its own acts. In some other matters, however, the community will find it necessary to impose further constraints on a company or an entire industry where a conflict has emerged between certain interests of the body in question and those of society as a whole.

Where medicines are concerned, the community has a very particular interest in ensuring that there is an acceptable balance between the reasonable desire of a producer to seek a fair reward for its efforts and the extent to which its products are capable of fulfilling the hopes and expectations of those who make use of them. Many medicines are life-saving; many more relieve suffering, speed recovery from illness or protect the individual from infection. Just as patients have a right to expect that their doctors, surgeons or pharmacists will at all times act in the best interests of those who rely on them, so too are they surely entitled to believe that those who develop and make medicines will be doing their best to serve the individuals who take them. No doctor is infallible and no medicine is universally effective; in either case, however, it is reasonable to expect a modicum of honest effort, truth and support.
Although views on medicines are diverse, and in some respects fluid or controversial, no one will challenge the major role that they can play in health care, as they have done for centuries. Controversy with respect to medicines has related primarily to the increasingly dominant (and sometimes questionable) role played by commercial interests in their preparation, promotion and sale. By the seventeenth century in Europe and North America a thriving trade in the production and supply of medicines had come into being; two centuries later, major industrial firms were emerging to provide packaged pharmaceuticals. Among the makers of medicines there have been scientific pioneers of the first order, but alongside them one has repeatedly encountered mere charlatans and heartless profiteers. The patient in a sickbed and even the doctor in a consulting room may be poorly placed to distinguish the good from the bad; but progressively the law has come to their aid, setting standards for medicines and taking measures to ensure that these are respected. It is an ongoing story, but one in which there is a constant hope of betterment, particularly as notions of commercial ethics have become better defined, though not always respected.

In the course of the twentieth century, with the emergence of massive industrial corporations in this sector as in others, society has become ever more aware of the manner in which corporate power may be abused and may pose risks for the society that these corporations profess to serve. In 1984 John Braithwaite published Corporate Crime in the Pharmaceutical Industry. Based both on knowledge that at that time was becoming more generally available and upon his examination of the phenomenon in the United States, Australia, Guatemala and Mexico, that book recognized and defined many forms of malpractice that are still all too evident in the sector today. The fact that these challenges to society have within the last generation become more severe, more widespread and sometimes more subtle provides one sound reason for the present volume. It is however also a fact that within that period the entire concept of corporate crime as a social phenomenon has become much more clearly defined. For such reasons this book sets out to complement John Braithwaite’s study of a generation ago; it provides a detailed view of the problem as it exists today.

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now, in the early years of the twenty-first century: appropriately, it culminates in an analysis by John himself of the current scene and his view of the future.

This study is by no means a witch-hunt directed against the pharmaceutical industry. It acknowledges this industry’s positive achievements, but it takes a frank look at its less creditable side. Corporations both large and small have repeatedly let down their team, soiled their own reputations and betrayed the trust that society has placed in them. Attempts to correct such failings have too often been limited to fine words; gross wrongdoing has sometimes been denied outright; penalties, where there has been a need for them, have rarely been sufficient to provide a real deterrent.

Many of the acts and omissions discussed here are criminal offences in some countries, only infractions of civil law in other countries, and in yet other countries are merely matters that some regard as unethical and that therefore demand ethical self-regulation. A purpose of Part III of the book is to suggest a policy on which kinds of unethical conduct should be criminalized. We argue for an important place for criminal enforcement, but one where the criminal law shows humility and deference at times to other legal, regulatory and self-regulatory strategies. Those events which have resulted in identifiable harm will call for adequate compensation through the machinery of civil courts or tribunals. Above all, however, there is a pressing need to identify much more effective tools than have hitherto existed to persuade industry to remain on a socially acceptable course. Society has been patient too long, and far too much unnecessary injury has been suffered. It is surely time to reach out a friendly but firm hand to the pharmaceutical industry and proceed resolutely to action.

During the 1960s and 70s constructive criticism of what was happening began to emerge from various quarters; the names of Charles Medawar, Ellen ’t Hoen, Andy Chetley, Sidney Wolfe and Andrew Herxheimer deserve particular mention. Within the World Health Organization, Halfdan Mahler and Ernst Lauridsen developed a clear global basis for policy. From Australia, David Henry, Ken Harvey and Peter Mansfield provided bold leadership on various fronts. We must also acknowledge our debt to others who over the years have inspired us by their example, while some have contributed directly to our present analysis. We would mention in particular the research on the pharmaceutical industry by Fred Abbott, Marcia Angell, Peter Drahos, Philippe Guerin, Ane Haaland, David Healy, Joel Lexchen, Donald Light, Mark Mildred, Philippa Saunders, Dan Sigelman and Barbara Swartz, as well as the late Milton Silverman.
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In approaching our subject we have chosen to present in Part I a single account of personal experiences that may help to explain our approach to truth and justice in this field; Graham Dukes has seen the industry from within but also from the standpoint of the regulator and policy maker, and in his Essay he describes the manner in which over the years his view of the world of medicines evolved.

In Part II, Graham Dukes leads the authors in considering pharmaceutical rights and wrongs as they have developed, particularly over the last half-century. We examine in turn each of the main facets of the pharmaceutical industry’s role in society – research, manufacturing, information, distribution and pricing – as well as some questionable aspects of this industry’s relationship to society.

Finally, in Part III, John Braithwaite leads the team in looking towards the challenges of the near and more distant future and the opportunities for reform. Past successes and failures in dealing with what is commonly termed “big pharma” provide some guidance as to future policies; above all, however, there is now a need for new thinking and fresh approaches. The foundations for a radically new course have already been laid by researchers in the social sciences. Concepts of responsive regulation, the complementary role of supports and sanctions and the mobilization of private initiatives to bolster enforcement are now well-defined and within our grasp. These are no castles in the air but the fruits of concrete innovation and empirical research.

In building this book, Graham Dukes and John Braithwaite have been generously supported by the critical and informed voice of James Moloney, a public health specialist who during the course of writing this book acquired practical experience in developing and developed economies. James started out with the team as a research assistant. His contribution became so central and pervasive that he became a co-author. James’ co-authors are grateful for his scholarship, his personal character and integrity and his unwavering commitment to the project.

Finally, the three of us would like to thank our families and institutions for their support, especially Dr Elisabet Helsing, the University of Oslo, the Australian National University and the Australian Research Council; Kylie McKenna and especially Kate Macfarlane for her capable and dedicated administrative, editorial and research support. We also thank our extremely patient and helpful colleagues at Edward Elgar.

Graham Dukes
John Braithwaite
James Moloney