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Edited by Michael A. Santoro and Thomas M. Gorrie
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Ethics and the Pharmaceutical Industry

Despite the pharmaceutical industry's notable contributions to human progress, including the development of "miracle" drugs for treating cancer, AIDS, and heart disease, there is a growing tension between the industry and the public. Government officials, physicians, and social critics have questioned whether the multibillion-dollar industry is fulfilling its social responsibilities. This doubt has been fueled by the national debate over drug pricing and affordable healthcare, and internationally by the battles against epidemic diseases, such as AIDS, in the developing world. Debates are raging over how the industry can and should be expected to act. The contributions in this book by leading figures in industry, government, NGOs, the medical community, and academia discuss and propose solutions to the ethical dilemmas of drug industry behavior. They examine such aspects as drug pricing and marketing, the role of intellectual property rights and patent protection, and the moral and economic requisites of research and clinical trials.

Michael A. Santoro is Associate Professor with tenure at Rutgers Business School, where he teaches courses on business ethics, multinational corporations and global social issues, labor and human rights, international law, and ethical issues in the pharmaceutical industry. He has lectured and published widely on these topics. Professor Santoro is the author of *Profits and Principles: Global Capitalism and Human Rights in China* (2000). He holds a Ph.D. in Public Policy from Harvard University, a J.D. from the New York University School of Law, and an A.B. from Oberlin College. He was also a Fulbright Fellow at the University of Hong Kong.

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Preface

The chapters in this book are written by authors with diverse experiences and perspectives. They come from government and industry, from advocacy organizations and academia, as well as from the scientific and medical communities. It is a notable sign of the force and maturity of globalization that most of the contributors, regardless of their nationality or backgrounds, quite naturally address these issues by considering different international perspectives. Although not every voice and every relevant issue appears in these pages, we believe we have made an unprecedented effort to gather a highly diverse and talented group of authors to address a broad spectrum of the issues that dominate the relationship between the pharmaceutical industry and society in a global context.

The diversity of viewpoints among the contributors is mirrored in the differing perspectives of the editors. Together, since the year 2000, we have taught a class at Rutgers Business School on the ethical and regulatory issues facing the pharmaceutical industry. Sometimes much to the unintended amusement of our students, and we hope occasionally to their enlightenment, we have sharply, though collegially, disagreed on many matters affecting the pharmaceutical industry. Our disagreements are perhaps rooted in two fundamentally different perspectives. First, Dr. Gorrie believes that healthcare is a commodity purchased by the individual or society, the provision of which is made through that most social of institutions, insurance. Government's role is to ensure that the economically disadvantaged have access to healthcare. By contrast, Prof. Santoro believes that healthcare is a fundamental human right that circumscribes the exercise of intellectual property

rights, particularly in the case of life-saving drugs for diseases such as HIV/AIDS.

Second, although we both believe in the power of the free market to drive innovation and progress in healthcare, Prof. Santoro believes that stronger government regulation of the pharmaceutical industry is desirable and inevitable because he believes that the dictates of the market too often drive pharmaceutical companies to maximize their profits in a manner that fails to deploy social resources optimally to provide the best healthcare for citizens. Dr. Gorrie, by contrast, believes that marketplace forces can more effectively address issues in the system than can the controlling hand of government.

Our differing perspectives are, in part, based upon our different experiences – Dr. Gorrie has spent his career at Johnson & Johnson in a number of roles, most recently as the Corporate Vice President of Government Affairs; Prof. Santoro has devoted his academic career to bringing accountability to multinational corporations for global social issues such as human rights and the environment.

Our differences, philosophical and otherwise, are real and significant; however, we both believe that choice is the lynchpin of effective healthcare and that all people should have access to affordable products and services that will save, enhance, improve, and prolong their lives, a mandate that certainly extends to people suffering from global pandemics. Most importantly, we both believe that knowledge best emerges from dialogue and listening to diverse viewpoints. This book offers multiple perspectives about the highly charged ideological issues the industry faces today. Written by leading experts in their respective fields, the essays comprising this book are not biased toward one particular point of view (either pro-business or anti-corporate). We both highly value the opportunity to engage in public discourse about business and ethics, and, in particular, to talk about the complex ethical issues inherent in medicine and healthcare. We believe that reasoned discussion will open channels of communication, lead to better understanding, and ultimately result in progressive change.

Another area of agreement between the editors is that future healthcare innovations and solutions will arise from long-term partnerships. Too much of the debate thus far has focused on confrontation (e.g., advocates vs. industry). Although such conflicts are inevitable given the diversity of the material interests involved, in order for

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sustainable solutions to be achieved in the twenty-first century, we believe that parties on opposite ends of the debate must come together as global citizens, take responsibility, and be accountable for delivering results. There is work to be done. The public and private sectors, the advocacy organizations and academia, the medical and scientific communities, all need to work together on the development of technologies that add quality, value, and cost efficiency to healthcare systems. By doing so, we will provide citizens with the highest quality of healthcare and the continued hope that new technologies can bring a better future. It is to that end that we have brought together the extraordinary authors in this volume, and we hope that the debate and dialogue that follow will help point the way to a future when all people can enjoy the fruits of the global pharmaceutical industry.

Michael A. Santoro and Thomas M. Gorrie

Acknowledgments

We gratefully acknowledge the many and crucial contributions by our Book Project Director, Mary Child. The task of coordinating the submission and review of the various chapters in this book was a daunting one that Mary performed with professionalism and extraordinary equanimity. In the process, Mary became a partner in our work, offering many valuable suggestions in shaping the book.

Scott Parris, our editor at Cambridge University Press, was a strong and steady supporter of the idea of this book. He set the highest standards of quality and integrity and gently pushed us to make good on our promise of engaging diverse and outstanding authors to address a wide array of issues.

We are grateful to our students over the years at Rutgers Business School. They cheerfully endured the process by which we worked out many of our ideas and challenged us in an intelligent and knowledgeable manner. In addition, we were fortunate at various stages of this project to have a number of outstanding research assistants, including most notably the following: Caren Speizer, Mari Boggiano, Melanie Milhorat, Brian Moran, Jennifer Flynn-Uptegrove, Greg Adams, and Sharzad Moosavi. We are also grateful to Polly Chen for proofreading.

Reflecting the highest standards and aspirations of academic publishing, three anonymous reviewers carefully read the manuscript and offered many insightful and constructive criticisms and suggestions about the book as a whole and on particular chapters.

We especially want to thank the many outstanding authors who contributed chapters to this volume. They are an extraordinarily diverse group with one common denominator: each was far too busy to

contribute a chapter. Nevertheless, they all came through in the end. We believe that ultimately all of the authors were driven by the same factor that motivated us to finish this book – the hope that by assembling such a talented and diverse group of thinkers some measure of insight and progress might be achieved in the goal of bringing the fruits of the pharmaceutical industry to the broadest possible spectrum of the world's citizens.

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Tom Gorrie gratefully acknowledges the contributions of Patricia Molino and Michael Miller. He gives special thanks to Pat Gruber for her ongoing assistance. He also thanks his wife, Meg, for her support, friendship, and love, and his sons, Alex and Rob, for their daily enrichment of his life. Finally, he wants to remember his daughter, Kate, who will always be an inspiration.

Foreword

It is a privilege to help set the scene for the deliberations in this book on ethics and its applications to the pharmaceutical industry and healthcare in the twenty-first century. In Classical Greek, the word “ethics” means the “beliefs of the people” – the study of what is right and good in human conduct and the justification of such claims. Applied to the complex and multifaceted world of healthcare, it is a formidable task to try and uncover the fundamental principles involved in “right and good conduct.” Without a doubt, this task is not simply about setting up a list of rights and wrongs. Rather, it is a discussion, a process that helps to tease out the real issues and find ethical solutions to complex practical problems.

Herein lies the greatest success of this book. It brings together outstanding leaders and thinkers from all segments of global healthcare to engage in ethical debate. They are all highly knowledgeable and experienced and from their different perspectives they mold together a unique view on some of the burning questions of our time. These include the ethics of clinical research, the empowering of patients by providing access to quality information, and the critically important issues of equity and access to care, especially in the field of HIV/AIDS. You will notice that the contributing authors brilliantly succeed in sensitizing the conscience of the reader and the different stakeholders involved in the healthcare leadership. As we all know, a sensitized conscience is a prerequisite for sound ethical decision making.

Another highlight of the book is its focus on partnerships. For too long, decisions with major implications for global health have been made in a compartmentalized fashion. Often there is a very troubling

divide in the thinking of public- and private-sector leaders, regulators and providers, and most important of all, the patients involved in the healthcare system and those working in it. Not only does this cause inefficiencies and high costs, but it can lead to ethically bad behavior. This divide can be overcome by constructive and synergistic partnerships, and fortunately this book, in itself, represents such a partnership. All of the authors believe in the value of promoting good ethics in healthcare. Surely this type of attitude and collaboration will help us address the global health issues we face.

Last, a word on the centrality of the patient in any discussion on the ethics of healthcare. Most professional healthcare associations acknowledge in their foundational policies that ethically, the health of the individual patient should be the first consideration in any decision on care. This book will definitely contribute greatly to this ideal. It calls for more effective communication and standards of health information and sets the informed, respected, and cared-for patient as the goal of all our collective efforts. Bravo!

My sincere wish is that after reading the book, you and your organization will have a greater understanding of the ethical complexities of healthcare in the twenty-first century. More importantly, I hope that you and your organization will be encouraged to participate in the ethics debate and the partnerships necessary to put patients first and make healthcare work. We owe it to them and to humanity.

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Association (WMA)
*The WMA is the global representative body for
physicians worldwide.*