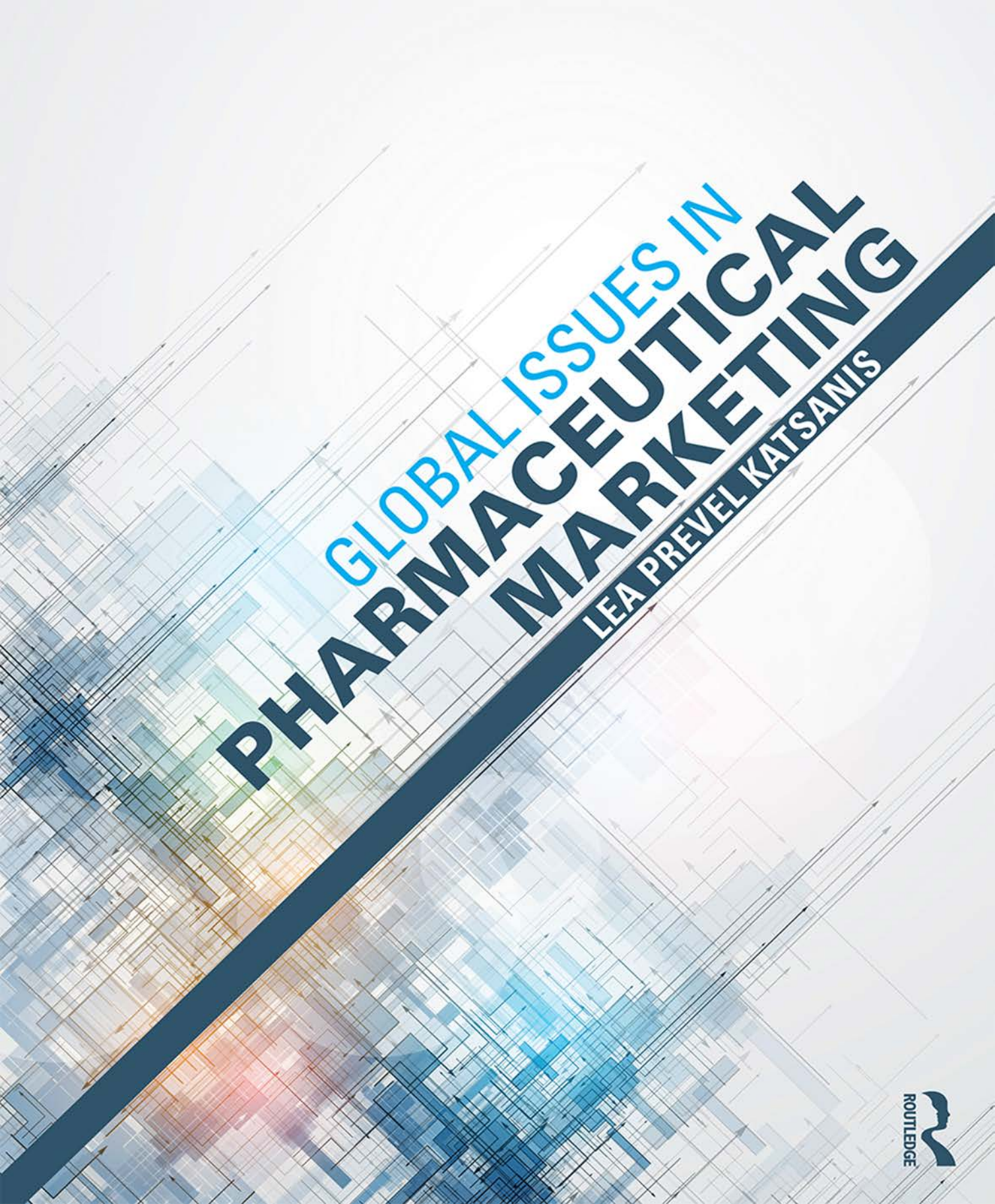
GLOBAL ISSUES IN
PHARMACEUTICAL
MARKETING
LEA PREVEL KATSANIS
ROUTLEDGE

Global Issues in Pharmaceutical Marketing

Global Issues in Pharmaceutical Marketing presents a balanced, research-based perspective combined with a practical outlook on the current issues faced by the ethical, biotech, and generic segments of the pharmaceutical industry. It integrates an analytical approach with a global view to examine such issues as market access, digital marketing, emerging markets, branding, and more. The book covers not only the North American and Western European markets, but also focuses on non-Western markets, such as Latin America and Asia. Each chapter is written as an individual essay about a given issue, and where relevant, original cases are provided to illustrate how these issues are currently managed by the global industry.

This book offers a thoughtful and thorough description of the industry's current situation and integrates the latest scholarly and industry research from different disciplines in one place for convenient reference. It may be used in the following ways:

- Stimulate class discussions and inspire new streams of research for academics and graduate students;
- Introduce the industry to those interested in a career in the pharmaceutical industry to the sector, orient new industry hires, or provide experienced practitioners with current research that will enhance their knowledge;
- Provide an understanding of the industry for those in the healthcare sector, such as physicians, pharmacists, as well as medical and pharmacy students; and
- Present recent and relevant research for those in government, public or private payers, and public policy environments to facilitate their decision making.

This book will prove to be a useful resource and an important source of information for academics and their students, professionals, and policymakers around the world.

Lea Prevel Katsanis is a Professor in the Department of Marketing at the John Molson School of Business, Concordia University, Canada. Prior to her academic career, she worked in the U.S., international, and subsidiary operations of three global pharmaceutical companies. She has published numerous articles in outlets such as the *International Journal of Pharmaceutical and Healthcare Marketing*, *Health Marketing Quarterly*, *Journal of Product and Brand Management*, *Journal of Consumer Marketing*, and *International Marketing Review*.

This page intentionally left blank

Global Issues in Pharmaceutical Marketing

Lea Prevel Katsanis

Routledge
Taylor & Francis Group
NEW YORK AND LONDON

First published 2016
by Routledge
711 Third Avenue, New York, NY 10017

and by Routledge
2 Park Square, Milton Park, Abingdon, Oxon OX14 4RN

Routledge is an imprint of the Taylor & Francis Group, an informa business

Library of Congress Cataloging-in-Publication Data
Katsanis, Lea Prevel.
Global issues in pharmaceutical marketing / by Lea Prevel Katsanis, Ph.D.
pages cm
Includes bibliographical references and index.
1. Drugs—Marketing. 2. Pharmaceutical industry. I. Title.
HD9666.5.K38 2015
615.1068′8—dc22
2014048861

ISBN: 978-0-415-89531-6
ISBN: 978-0-415-89532-3
ISBN: 978-0-203-11911-2

Typeset in Times New Roman
by Apex CoVantage, LLC

In memory of my father, James Prevel (1932–1988)—he was with me in spirit as I wrote every page.

This page intentionally left blank

Contents

	Preface	ix
	Acknowledgments	xi
1	Pharmaceutical Industry Structure and its Effect on Marketing Performance and Product Innovation	1
2	The Environmental Forces that Influence Industry Stakeholders and Shape their Interactions	15
3	Global Health Care Systems and Market Access: Variations on a Theme	31
4	The Structure of the Global Marketing Organization and its Effect on Market Performance	49
5	Global Pharmaceutical Branding: Moving from Blockbuster to Niche Strategies	64
6	Traditional Industry Communication to Physicians: Promotional and Informational Elements	80
7	Digital Communication to Physicians: Closed Loop and Multichannel Marketing	93
8	Direct to Consumer Advertising: Broadcast and Print Media	103
9	Consumer Digital Communication Channels: eDTCA 1.0, 2.0, and mHealth	116
10	Industry Self-Regulation: Finding the Balance	128
11	Emerging Markets and OTC Markets: Future Opportunities and Current Challenges	137
12	The Industry's Declining Reputation: A Prescription for Change	154
	Index	169

This page intentionally left blank

Preface

The objective of this book is to provide a balanced and research-based view of key marketing issues facing the pharmaceutical industry. Most of my career has been spent either working in the industry or researching its practices, and by writing this book I wanted to make some contribution to understanding how it operates. Its genesis began when I started to teach an MBA course on Pharmaceutical Marketing in 2006 and realized that the books available were either out of date or focused exclusively on the US market. This is certainly understandable, as the US market is one of the largest in the world and where much pharmaceutical marketing originates. However, as a professor based outside the US, I believed that a different perspective might be useful to those seeking to learn more about this important industry, particularly in light of its recent growth and development outside the US. I also observed that much of what was written in the public domain took one of two extreme perspectives: either pro-industry or anti-industry, with little in-between. A research-based view may be helpful in providing a more nuanced and deeper understanding of the industry.

I developed a series of presentations based on 30 years of my work and research about the industry, the research of others, and commentary from industry analysts and journalists, on what were considered to be its most important issues. These lectures were updated annually and then expanded into 12 complete essays, with each focused on one specific issue and they form the contents of this book. There is a significant body of research available about the industry, but it is scattered across different disciplines and in multiple outlets: scholarly publications, industry research studies, and articles by serious journalists and analysts. This book is designed to amalgamate all this information in one place, and I hope it will serve a useful purpose in this regard. In some chapters, I provide recent case studies where relevant to illustrate the way the industry handles a particular situation.

The book is structured as a series of independent essays rather than a thematically continuous stream. It is not a 'how to' book—there are already several available on the market and I did not want to add another to the list. Rather, it is designed as a source of the available research specifically focused on the pharmaceutical industry, and it may be used in several different ways: 1) by professors who teach at the graduate level who are looking for a book that can be used by Master's students but also in doctoral seminars; 2) by scholars seeking to identify streams of research; 3) by practitioners who are either entering the industry and need to learn about it or by seasoned professionals who would like a different perspective on the problems they face; 4) by health care professionals such as physicians and pharmacists who wish to understand what lies behind the marketing activities they experience in their practices; and 5) by government policy makers and private payers who wish to understand how pharmaceutical marketing works and what considerations govern the decisions made by industry marketers.

I have tried to make the book as readable as possible while maintaining scholarly rigor. The original sources are always used when available; however, some specialized industry publications were either not in print or only available at great cost, so I relied on the secondary source in these specific cases. In addition, emphasis is placed on the research findings rather than my personal perspective. I want the research to stand on its own so the reader may form his or her own opinions about the industry based on this body of collective wisdom. Some chapters may be longer or shorter than others—this is a reflection of the amount of research available or the novelty of a particular topic. Generally speaking, no research study, or book, for that matter, is intended to be the final word on any subject. It is, rather, suggestive of a possible outcome or direction of the research in some cases, or in others, the beginning of a new research focus. This should lead to both stimulating discussions and future research about these topics. One can always rely on change to keep things interesting.

I am only too aware that I have either covered too much or too little on certain issues, and I may have inadvertently left out some important research. Ultimately, I had to make some difficult choices about what to include and when to stop researching; otherwise, I would still be writing this book and you would not be reading it! I welcome your feedback for the inclusion of new or different issues for future editions.

Acknowledgments

No author writes a book without considerable help and support, and I was very fortunate in this regard. I would first like to thank Routledge and in particular John Szilagyi, Sharon Golan, Jabari LeGendre, Emily Boyd, Emily Davies, Emma Capel and Scott Sewell. John was my first editor and provided great encouragement with my decision to write this book and in preparing the proposal. Sharon, my current editor, inspired me when I simply could not envision the monumental task ahead (and we shared a wonderful lunch at Cipriani's in New York that I will always remember). Jabari's steady guidance and enthusiasm helped to organize the manuscript in the final stretch to submission. Emma created a spectacular cover design. Emily Boyd was most diligent in the copyediting of the book, and Emily Davies skillfully guided the book to its final publication. Scott managed a successful book launch and marketing campaign. I also wish to thank the 15 reviewers who sent valuable comments about the original book proposal: I have incorporated many of your suggestions in the final manuscript.

To my former MSc students Erica Leonard, Tara Kayhani, Rachel Banton, and Ph.D. candidate Chun Zhang, for helping to sort hundreds of documents and with general research assistance. To Thai-Son Nguyen Quang at Ernst & Young and Enza Cignarella at Novartis Canada, my great appreciation to both of you for reading selected chapters and providing important feedback.

To Concordia University, for their continued support and the sabbatical leave necessary to complete this book. I am very lucky to have spent the last 23 years of my career (and counting) at this great university. To my colleagues Professor Christopher Ross and Professor Bryan Barbieri, for their generous assistance with my Department Chair summer duties for one month so I could complete the book proposal. To my Pharmaceutical Marketing MBA and MSc students for their shared interest and enthusiasm for this subject; in many ways, you inspired this book.

To Dr. Mickey Smith, F.A.P. Distinguished Professor Emeritus of Pharmacy Administration at the University of Mississippi, and the founder of the pharmaceutical marketing field, for publishing some of my first articles and his interest in my research. To Professor Emeritus Jack Duffy and Assistant Professor David Roach at the Rowe School of Business, Dalhousie University, for their valued friendship and support of my work. To the Canadian law firms Heenan Blaikie, Osler Hoskin and Harcourt, Goodmans, and Aitken-Klee, for the privilege of working with them on legal matters as a pharmaceutical marketing expert. Their insightful questions about the industry led me to re-examine the foundations of my discipline, and this exercise contributed to my thinking for this book.

Last but not least, my love and deepest appreciation to my family for their never-ending support during this period of what can only be described as enormous disruption: my husband Constantine, my son Alexander, my mother Sandra, my brother Christopher, my aunt Clara and my uncle Phillip. To my dearest friends Lucille Fletcher and Lynda Maddox, who always listened to me when I needed a sympathetic ear. To anyone I may have forgotten to mention, please accept my apologies and sincere thanks.

The greatest danger in times of turbulence is not the turbulence – it is to act with yesterday's logic.

Peter Drucker

This page intentionally left blank

1 Pharmaceutical Industry Structure and its Effect on Marketing Performance and Product Innovation

The pharmaceutical industry is in a state of constant flux, with at least one or two mergers or acquisitions (M&As) reported on a regular basis in the business press. M&As take place for the express purpose of buying research pipelines, trimming costs and personnel, and entering or exiting new therapeutic or business categories. According to *The Economist* (2009), the health care industry has experienced the highest levels in merger activity and consolidation other than the technology industry. As a consequence of this consolidation, as well as other changes to the industry environment, there has been a gradual and continuous realignment in the traditional roles of the ethical pharmaceutical, generic, and biopharmaceutical sectors in the market: for example, generic firms are developing innovative drugs and ethical pharmaceutical companies are acquiring generic firms.

What is important to consider is how this evolution of the industry combined with consolidation and continuous change may affect innovation and marketing performance. Further, the adoption of business strategies should be examined that may have some short-term effects for financial institutions and shareholders, but may not be in the best long-term interests of the pharmaceutical companies themselves, physicians, or patients. There are public policy implications to be considered, as M&As combined with resulting R&D (research & development) cost reductions may have negative long-term effects on product innovation and market performance.

Pharmaceutical Industry Structure

For many years, it was fairly simple to outline the structure of the pharmaceutical industry. Companies could be classified into three easily identifiable and separate segments in the industry: 1) 'Big Pharma,' or ethical pharmaceutical companies, which consists of firms that classify themselves as research based—such as Merck, Pfizer, and GlaxoSmithKline (GSK-); 2) biotechnology companies, which focus on research to develop biologic drugs, and consist of both large firms such as Amgen, Biogen, and Genzyme, as well as many smaller start-up firms seeking to enter the industry; and 3) generic firms, which produce the bioequivalent products from the ethical companies when their patents expire, and which consist of firms such as Teva and Mylan.

Today, it is not quite as simple to divide the industry in this way—both M&A activities and licensing arrangements have blurred these traditional lines. For example, Danzon (2006) states that: "The biotechnology revolution has transformed the nature of drug discovery and the structure of the industry. Increasingly, new drugs originate in small firms, which often out-license their products to more experienced firms for later-stage development, regulatory review and commercialization" (Danzon, 2006). Biotechnology firms

often seek out larger partners, either in the research-based pharmaceutical sector or amongst their own. Many companies now have biotechnology divisions through M&As.

Further, many Big Pharma companies such as Novartis have specialized generic divisions (Sandoz); others such as Daiichi Sankyo acquired India's Ranbaxy in 2009. These firms no longer view the generic companies as predators, but as part of a longer-term strategy to keep their own brands in-house rather than losing them to competitors. In addition, generic firms such as Teva are adopting research and licensing strategies to produce new chemical entities (e.g. dalbavancin for the treatment of MRSA infection) as well as drug delivery system development strategies in order to ensure their own sustainability—because as patented and blockbuster drugs disappear, so do the potential products for generic firms to copy. Finally, there are emerging global players from India, China, and Russia in an industry once dominated by the US. Mittra (2007) stated quite accurately that "the notion of a homogeneous big pharma sector may no longer be a useful conceptual tool" (p. 298).

Therefore, one can no longer view the industry in such a limited and categorical way, but now needs to examine the interdependencies among the different business models and what this means to the future of the industry. A brief discussion of the role of the ethical, generic, and biotechnology sectors will be presented to shed some light on these changes.

Big Pharma: The Ethical Pharmaceutical Sector

In terms of dollar value, the ethical pharmaceutical sector is the largest of the three sectors and includes industry leaders such as Pfizer, Merck, GSK, and Novartis. This sector accounts for approximately US$650 billion and is forecasted to reach US$1 trillion by 2020 with a projected CAGR (compound annual growth rate) of approximately 4 to 5 percent; it is the largest sector and represents approximately 80 percent of total industry sales (Evaluate Pharma, 2014). Table 1.1 provides a list of the largest firms in this sector with their dollar revenue.

The focus of this sector is on small molecule compounds for frequently occurring and chronic diseases such as hypertension, hypercholesterolemia, and arthritis as well as acute infectious diseases. It is characterized by its concentration on R&D activities (US$141 billion in 2013) (Evaluate Pharma, 2014). It is also well known for its emphasis on marketing directed primarily to physicians with some consumer focus in the US and select countries worldwide: the sector's global marketing budget reached US$14 billion in 2013,

Table 1.1 Leading Global Ethical Pharmaceutical Companies

Company	*Sales ($US billions)*
Novartis	46.0
Pfizer	45.0
Roche	39.1
Sanofi	37.7
Merck	37.5
GlaxoSmithKline	33.1
Johnson & Johnson	26.5
AstraZeneca	24.5
Eli Lilly	20.1

Source: Adapted from Evaluate Pharma, 2014

excluding drug samples (Mack, 2014). Key issues facing this sector include the recent patent cliff, challenges due to pricing regulation worldwide, and steadily declining reputation.

The Biotechnology Sector

Silverman (2013) reported that biotechnology products accounted for 71 percent of the top selling pharmaceutical products in 2012 compared to only 7 percent in 2001, and doubled in share from 8 percent in 2002 to 17 percent in 2012, with worldwide growth in that year of 353 percent—reaching $163 billion. He also points out that approximately 40 percent of all biotech products are now being developed by the Big Pharma sector. A biopharmaceutical product, also called a biologic, is one that is developed from any biological source (human, animal, or a micro-organism), and some examples include gene therapy, hormones (such as insulin), and vaccines (such as hepatitis B), among others. According to Ernst & Young (2013), the industry consists of what they call 'a handful' of industry leaders such as Amgen, Biogen-Idec, and Gilead with revenues greater than $500 million, followed by hundreds of small firms with revenues significantly below that level. Table 1.2 provides a list of the major biotechnology firms.

Schweizer (2005) suggests that these products are a significant change from existing technology (small chemicals) in the pharmaceutical industry with a new scientific base: they are likely to make R&D more stable; may reduce development costs and time to market; and finally, allow marketers to better segment patient populations on the basis of their genomics.

The biotech sector possesses certain features that distinguish it from the other sectors in the industry. For example, there is greater technological uncertainty; there are potential problems with patient side effects that may either prevent market entry or reduce the potential market; there is a potentially unstable product life cycle; there is the possibility of obsolescence due to the rapidity of technological advancement; there is a dependence on protection of patent rights; and finally, the biotech sector is estimating the potential market for their products (Rajamäki, 2008). Vanderbyl and Kobelak (2007) suggest that early stage companies depend on funding from governments and other sources, with later stage companies focused on the development of internal development issues such as retaining and educating their employees.

Table 1.2 Leading Global Biotechnology Companies

Company	*Market Cap ($US billions)*
Gilead Science	139.0
Novo Nordisk	125.0
Amgen	92.5
Biogen Idec	69.0
Celgene	69.0
Shire	49.6
Alexion Pharmaceuticals	33.1
Regeneron Pharmaceuticals	30.7
CSL	30.3
Vertex Pharmaceuticals	22.6

Source: Adapted from GEN, 2014

Biotech firms have traditionally relied on strategic alliances with established pharmaceutical companies in order to manufacture and market their products. Glick (2008) reported that this has led to more firms having the ability to be successful in the market. Some factors that lead to success in these strategic alliances include the early initiation of joint projects; having a product with a large number of indications; solid patent protection for the product; and having projects initiated after clinical trials were completed (Hoang & Rothaermel, 2005).

What is the future for this sector? Presentations made at the Bio 2013 conference suggest that the small and nimble firms are seeking academic–commercial relationships for new product development, but venture capital growth has been flat for the last five years (Ernst & Young, 2013). A bigger problem these firms will experience is reimbursement with third-party payers; they will need to prove that their drugs are in fact better than existing therapies, regardless of how innovative the technology may be (Ernst & Young, 2013). Finally, the threat of biosimilars (copies of biologics also known as 'follow-ons') will prove a significant threat as the first of these drugs is due to come off patent: for example, drug approval applications have already been filed by Sandoz for these medications. There is also some debate as to whether or not they will be allowed to keep the same INN (international non-proprietary name), as governmental agencies are in favor and medical societies and the biotech industry are opposed (Silverman, 2014).

The Generic Sector

The generic sector is an important one in the industry as it provides medications at significantly lower prices compared to brand name drugs once a patent on the chemical or biological entity has expired. The size of this sector has grown from $50 billion in 2004 to over $80 billion today (Harding, 2010). It is well understood that dollar sales do not reflect the importance of this sector, as generic drugs are steadily increasing as a percentage of total unit drug sales worldwide. This is a result of the recent patent cliff and the pressure by governments to lower health care costs by requiring mandatory substitution of generics where such 'gold standard' drugs are available for the treatment of chronic conditions such as arthritis and hypertension. Firms in this sector include Israel's Teva, the US's Mylan, Switzerland's Actavis, and Japan's Daiichi Sankyo. Table 1.3 provides a list of these firms (Statista, 2014). Indian firms have a strong global presence in the generic

Table 1.3 Leading Global Generic Companies

Company	*Sales ($US billions)*
Teva Pharmaceuticals	9.2
Sandoz (Novartis)	8.2
Activis	6.3
Mylan	5.9
Aspen Pharmaceuticals	2.7
Sun Pharmaceuticals	2.7
Hospira	2.4
Daiichi Sankyo	2.2
Lupin	1.7
STADA Arzneimittel	1.6

Source: Adapted from Statista, 2014

industry, led by local manufacturers Sun Pharmaceuticals and Ranbaxy. Some ethical pharmaceutical firms have specialized generic divisions, such as Novartis' Sandoz.

The traditional business model for generic firms is different from other firms and they face issues specific to their sector. In most cases, generic firms must wait until a patent expires (or challenge the patent in court prior to its expiry) in order to have products available to market. According to Epperly (2013), the patents of 120 drugs expired in 2013, representing a significant opportunity for the sector. Generic firms concentrate their marketing efforts on third-party payers and pharmacists, as physicians are not appropriate targets for these efforts although the latter are influenced and in some cases required by insurers and governments to prescribe generics when appropriate. Sheppard (2010) identified numerous obstacles facing the sector which include: potential delays in governmental pricing approvals and reimbursement; problems with patent challenges; lack of incentive by physicians to prescribe; reliance on pharmacists to substitute a specific generic brand; patients who do not always request generic drugs; lower margins for distributors and a need to offer significant discounts; and preference for brand name drugs for higher profit margins.

An additional problem facing generic firms is the competition they face within their own sector. Dey and Shinghal (2012) suggest that while pricing regulation favors generic firms, at the same time, it creates the potential for price caps and the prospect of shrinking profit margins, particularly for smaller firms. This problem has led to what is known as the creation of 'super generics' or 'hybrids': generic firms that are developing new chemical or biosimilar compounds through drug delivery, manufacturing, or reformulation as a way to gain competitive advantage (Barei et al., 2013). In addition, biosimilars represent a significant future for this sector, and the first court challenge to this took place in September 2014 regarding the drug Enbrel (Amgen's drug for arthritis) (Greene, 2014).

The Rationale for Mergers and Acquisitions

There are multiple and well-known reasons for M&A activity with the most commonly cited as follows: the expiration of blockbusters (patent cliff) and the subsequent genericization of these brands; the enhancement of R&D activity in the wake of downsizing by acquiring companies with complementary or new products that can command higher prices; pressure to reduce costs from investors, governments, and third-party payers; the need to increase market share in specific product categories; the need to gain new market entry opportunities; generation of increased revenue and profit; and to achieve economies of scale.

Despite the concern over the current patent cliff, these patent cliffs and subsequent merger activity are not new phenomena. Kipp and Leiding (2008) point out that a similar phenomenon occurred in 2005 when 53 of the top 100 products lost their patent protection; they also note that between 2005 and 2007, 1,737 M&As were completed with a total value of US$213 billion, likely driven by the patent expirations. Saboo (2014) reported that from 2008 to 2013 there were 1,076 M&As completed with a total value of $513 billion; these were likely also driven by patent expiration but included deals for biotechs, specialty drug companies, and generics. The total number of M&As is down by 38 percent, but the value of these deals is up by approximately 140 percent. Although there is some suggestion by many industry analysts that in the future pharmaceutical firms may prefer collaborative relationships, the pending or completed large deals at present, as well as the current industry environment, do not support this claim. Additionally, at the time of the writing of this book, new forms of acquisition emerged called asset swaps, carve-outs and spin-offs. However, the future of these swaps remains to be seen.

The Effects of M&As on Product Innovation

There is a wealth of research on the topic of R&D innovation and M&A activity in the pharmaceutical industry. From a marketing perspective, this research is important, as product innovation is the lifeblood of a research-based industry such as pharmaceuticals. It is also critical for marketers, since a research-based industry requires novel products to replace outdated therapies or brands that are no longer patented. Further, the types of products that will be available to market will influence both the size and activities of marketing departments worldwide, both at the global and local levels.

Horizontal mergers are the most common type of merger in the pharmaceutical industry, and these are associated with a decline in innovation after the merger: levels of innovation were the same as if no merger had occurred (Park & Sonenshine, 2012). One reason given for this finding is that a firm may not feel obligated to spend money on R&D because there is less competition in the marketplace.

In addition, Comanor and Scherer (2013) argue that "parallel paths" (p. 107) are the key to successful R&D and subsequent product innovation. Their concept of parallel paths states that "[T]echnological progress is best achieved in a field like pharmaceuticals when there is widespread dispersion of R&D initiatives both across companies and within them through the exploration of multiple technical paths" (p. 107). They conclude from their study that when a large merger takes place, "the number of independent sources of technological initiative is reduced, perhaps appreciably" (p. 111). In other words, the lack of parallel paths slows the rate of R&D product innovation. They further relate this to the common phenomenon of the reliance of biotechnology firms on large pharmaceutical companies to provide funding for their R&D—because if there are fewer large firms, it means fewer firms available to take on the responsibility for developing innovative new biotechnology drugs: "New drugs may be lost" (p. 107). The yet unproven potential of asset swaps may be one way to avoid this from happening, as the large company remains intact, but simply shifts assets from one firm to the other.

As mentioned earlier, a firm may engage in M&A activity because it is attempting to fill its pipeline with another firm's products. Higgins and Rodriguez (2006) developed what they called a "desperation index" to determine the propensity to engage in M&A behavior driven by lack of new product development. Their index is based on two components: progress in the firm's new product pipeline and the state of the current portfolio. Their results suggest that firms with relatively healthy research pipelines and new product potential were less likely to engage in acquisition activity, while firms with relatively unhealthy pipelines were more likely to engage in acquisition activity. They also note that firms "with greater R & D intensity have a greater propensity to undertake R & D outsourcing acquisitions" (p. 370). Their findings suggest that in the short term, firms are able to move to a less desperate level and short-term stabilization of their condition. This notion of desperation is also referenced in Mittra's (2007) work on the behavior of large firms in the pharmaceutical industry. An industry insider is quoted as follows:

> All the sensible mergers have happened. If you get any more it will be from desperation. These companies have got to a size where if you make them any bigger it won't work. I think it's marginal whether they're working now, because they're so big.
>
> (Former Research Scientist-INT7/
> Company A (Mittra, 2007, p. 288))

In another study of 383 pharmaceutical firms that supports these findings, Danzon et al. (2007) concluded that mergers for large firms "are frequently the response to expected excess capacity that is triggered by patent

expirations and gaps in the product pipeline which render marketing resources unproductive" and there is "no evidence that mergers create positive long term value" (p. 325). In other words, using M&A activity to cut costs and achieve economies of scale does not succeed in the long term and does not assist in the marketing of their products.

Given the current 2014 M&A situation, Ornaghi's (2009) findings provide some insight. He examined 27 pharmaceutical M&As and found that "research inputs declined in the same year and in all subsequent years following the mergers." He further found that the number of patents following a merger would decrease for merging firms. He concluded that "merged companies have on average, worse performances than the group of non-merging firms" (p. 70) and "contradict the idea that mergers can deliver relevant economics of scope and knowledge synergies" (p. 77). This predicted pattern of cuts to R&D expenditure is evident at the present time. LaMattina (2011) argues that R&D integration and cost cutting is done behind the scenes—and therefore, is not obvious when examining M&A activity on the surface. He cites the fact that since 1988, only 11 companies remain from an original 42 in the industry, and posits that the fewer companies that exist, the less opportunity for success in finding new and successful drugs. His comments are supportive of the need for parallel paths in research to generate product innovation.

The Effects of M&As on Market Performance and Marketing Strategy

As is expected, the effects of M&A activities in the marketing area will not be significantly different from those experienced in the R&D sector of the global organization. There is excess capacity as both marketing and sales staffs are made redundant (Danzon et al., 2005). In the US, Basta (2014) reported that sales forces were reduced in size from approximately 110,000 in the mid-2000s to a current count of 60,000. However, he also points out that many of these salespeople may be deployed in the communication of outcomes research and real world evidence (this topic is covered in Chapter 4 on the Marketing Organization). In addition, there are new and highly technical products for which personal communication will be essential and for which salespeople will be needed. With respect to the internal marketing organization, it is posited that their activities will be centralized at the global level and branding messages will be communicated downward to the local affiliates to minimize promotional costs (Kipp & Leiding, 2008). This centralization will be made easier and more efficient through the use of the Internet and closed loop marketing, with the resulting ease of changing marketing messages online to tailor them to local markets.

A larger issue is the way in which marketing performance is affected by M&As. Homburg and Bucerius (2005) examined the marketing integration process post-M&A to determine its effect on market performance. The variables in their study included the speed of integration, magnitude of cost savings, and market related performance after the merger or acquisition; firm and market levels as moderator variables. Their results suggest that while there was a positive effect of integration on financial performance vis-à-vis cost savings, these effects were reversed due to both the negative market related consequences of integration and high levels of customer uncertainty. They conclude that overall cost savings as a result of M&A activities are realized at the expense of a firm's market position. It may be noted here that integration effects are not new when considering the effects of M&As on marketing activities. Datta (1991) reported that the "acquisition of firms with a different management style can result in conflicts, difficulties in achieving operational synergies, market share shrinkages and poor performance" (p. 291).

Using a qualitative case approach, Srivastava (2012) examined two recent deals—Daiichi–Ranbaxy and Pfizer–Wyeth (one a Japanese/Indian combination, and the other an exclusively American combination)—to

determine whether or not the companies were able to calculate an appropriate value for their brands. The results suggest that there was a large variance between the two parties for both deals in the valuation of brand equity: he concluded that the primary driver for the merger activity was emotional rather than factual. In other words, there are some decisions made as part of a merger or acquisition that affect marketing activities that are not made in a rational fashion.

The Effects of M&As on Physicians and Consumers

Little has been written about the effects of M&A activities on physicians, which is somewhat puzzling given their importance to the success of new prescription drugs in the market. It is interesting to note that this audience is "unexplored" when M&A activities take place (Kipp & Leiding, 2008, p. 215). Their findings from German physicians suggest that the primary way physicians find out about M&A is through the sales representative—this occurs after the fact from the new replacement representative. Only 50 percent of physicians were informed prior to the M&A and another 50 percent were not personally contacted by the outgoing sales representative. It is suggested that M&A activity may cause disruption and distress to physicians.

While no specific empirical research could be found on the impact of M&As on consumers, there are issues that can be inferred from the above discussion. Industry consolidation generally results in reduced competition, higher prices (despite managed care), less consumer choice, and loss of employment opportunities. Reduced levels of innovation may result in fewer new compounds developed to help patients with chronic diseases as well as acute infectious disease. For example, the current superbug crisis and lack of new and effective antibiotic therapy are key problems for the general population as research is directed toward niche markets with novel therapies that may be more profitable. Some drugs that have important uses are no longer manufactured and there are shortages of others that are no longer profitable to make as a result of the consolidation in the generic sector of the industry (Chabner, 2011). LaMattina (2011) provides a list of 17 drugs no longer manufactured by merged companies and notes their importance in the treatment of serious conditions such as cancer and heart disease. The long-term effects of recent merger activity on society at large are yet to be seen.

The Effects of M&As on Financial Returns

There are several studies that address whether or not pharmaceutical M&A generates returns for investors and suggest that the effects are not positive in the long term. While this particular stream of research differentiates between mergers and acquisitions, the results, nonetheless, are fairly consistent.

In their study on 160 pharmaceutical acquisitions, Higgins and Rodriguez (2006) determined that there were abnormal and significant financial returns realized for acquiring companies: these returns amounted to approximately 3.91 percent. However, in order to reap these rewards, firms needed to avoid the following: overbidding; selecting an incorrect target; and failing to properly integrate post-acquisition. Their findings are supported by Hassan et al. (2007) in their study of 259 mergers and 146 acquisitions. They concluded that acquisitions generate significant positive abnormal returns for the acquiring company in both the short and long term; however, no abnormal returns in the short or long term result from mergers, either for US/US mergers or US/foreign mergers. They noted that because mergers represented 64 percent of the sample, most M&A activity did not generate abnormal positive returns. Demirbag et al. (2007) confirmed these results in their comparison of pre- and post-M&A activity for three different mergers: they also noted that research

productivity declined after the mergers and lower returns were realized on investment post-M&A. As was observed in the research on the effects of M&As on marketing, the financial returns realized do not appear to justify the level of M&A activity in the industry.

One recent study by McKinsey & Company (Cha & Lorriman, 2014) suggests that there are economic benefits to what they call 'megamergers' that include shareholder value. However, this study used a sample of only 17 transactions during the same time period as previously mentioned studies which included hundreds of transactions. Consequently, the findings cannot be considered in the same light as the methodologically rigorous studies mentioned earlier that reach a very different conclusion.

Licensing and Strategic Alliances

Licensing is not a new strategy for pharmaceutical firms when they seek out new product opportunities. There are obvious benefits to this strategy, such as choosing specific compounds for development without incurring the cost and disruption of a merger. Mittra (2007) reported that "licensing has become a key growth strategy for the top 20 global pharmaceutical companies, with some companies embracing licensing as their core business development strategy" (p. 294). For example, he noted that five of the largest pharmaceutical firms licensed an average of 31 percent of their product candidates. Certain problems, however, do exist with licensing as an alternative and some firms prefer internally driven innovation, but they may lack the internal ability to develop these drugs (Mittra, 2007).

It is interesting to consider the effect of alliances on research and product innovation. Danzon et al. (2005) examined productivity in the pharmaceutical-biotechnology sector with a focus on experience and alliances in the R&D area. Based on data collected from 900 firms, the evidence suggests that products developed in an alliance are more likely to succeed at the Phase II and Phase III levels, particularly if at least one of the firms is a large one. The experience of the larger firm appears to be particularly valuable as the product nears the latter phases and is being readied for approval. This experience does not appear to matter at the Phase I level. The research suggests a continuing and important role for alliances in the industry.

Asset Swaps, Carve-Outs, and Spin-Offs

The year 2014 will be remembered as a milestone for the pharmaceutical industry with the adoption of the asset swap as an alternative to the large M&A. The objective of an asset swap is to avoid the pitfalls of mergers while building up certain businesses and divesting others; the potential benefits of this structure include the cutting out of capital markets and private equity firms while having increased options with fewer strings attached (Hirschler et al., 2014).

The first asset swap in the industry was completed by Novartis and GSK and is seen as a bellwether of things to come in the industry; however, one problem may be the valuation of the assets and their ultimate worth. Johnson (2014) quoted Sir Andrew Witty, CEO of GSK, stating that:

> the deal is likely one of the first in a new age of mergers in acquisitions . . . I believe if you really focus the transaction on just the things you really care about you can create tremendous value in that space.

GSK is seeking to strengthen core businesses, create value for shareholders, reduce costs, and strengthen its offerings to consumers and patients (GSK Press Release, 2014). Additional swaps reported in the media at the

time this book went to press include Novartis and Merck; Bayer and Merck; and AstraZeneca, which seeks a partner for a swap of its anti-infective and neuroscience businesses. Swaps may be a way to circumvent the scrutiny of public policy makers as they may be less disruptive than the larger scale traditional M&A; however, there is no current research to document this supposition.

Other alternatives to M&As that have been used in the pharmaceutical industry are carve-outs and spin-offs. A carve-out is a form of divestment in which the firm sells shares in one of its business units. This then allows the firm to benefit from an immediate inflow of cash while still maintaining some equity. A spin-off is a variation of the carve-out, in which the firm sells the business unit outright to another company. The business unit becomes a separate entity and existing investors receive shares in the new 'spin-off' company. The original company may or may not hold a stake in the firm. Some examples of these transactions in the US include the spin-off of Abbott's innovative drug unit into AbbVie and Pfizer's spin-off of its animal health division into Zoetis, as well as the sale of its nutrition business to Nestlé just nine months earlier (Reuters, 2013). Reuters (2013) also reports that European companies are more conservative in their approach to these arrangements because of their "broader global footprint relative to US rivals"—European firms have a greater presence in emerging markets and are more globally diversified than their US competitors.

M&As and Tax Inversions: Two Case Studies

Two controversial deals emerged early in 2014 that raised questions about the marketing and public policy implications of pharmaceutical mergers: Valeant's ongoing attempt to acquire Allergan, and the aborted (but not yet concluded) acquisition of AstraZeneca by Pfizer. It is important to examine why these deals attracted such great attention from public policy makers in the US and Europe as this may influence the future of big M&As.

Valeant/Allergan

One of the most hostile takeover attempts in many years is that of Valeant Pharmaceuticals, which teamed with Pershing Square Capital Management LP in pursuit of Allergan, a company with a rich menu of successful products and others in development with great potential. Valeant's business strategy is to acquire existing businesses with strong product portfolios and then to initiate R&D spending cuts as well as other cost cutting measures (Silcoff, 2013). This reduction in R&D expenditure allows for further acquisitions, with current revenues generated from existing products. Its corporate philosophy has been reported as the belief that R&D does not provide good returns to shareholders, while M&As provide benefits that include the purchase of firms with established products that do not attract the attention of larger pharmaceutical companies (Silcoff, 2013). Valeant acquired Biovail, a Canadian company, and then relocated the originally California-based Valeant to Canada in order to benefit from lower tax rates. This strategy is known as tax inversion, and Pfizer, a much larger pharmaceutical company, sought to use it in a similar way in its recent merger attempt with AstraZeneca (this is discussed later in this chapter).

Much has been reported in the business press about Valeant's low R&D expenditures—Rockoff and Mattioli (2014) stated that while Allergan spends approximately 16.5 percent of its revenue on research, Valeant only spends 2.7 percent. Valeant plans to cut $2.7 billion in R&D research at Allergan should the takeover be successful (Humer & Beasley, 2014). Industry experts and Wall Street financiers are of two minds—one view is that Valeant's tough stance on what they call unproductive R&D is good for business; another view

is that this strategy of seeking products without significant R&D is unsustainable due to the need for product innovation in the industry. For example, *Forbes*' Herper (2014) has stated that "Valeant Pharma's arguments about drug research are misleading and wrong."

Allergan instituted a poison pill to prevent the merger. In the meantime, seven members of the US Senate drafted a letter to the Federal Trade Commission and Department of Justice asking them to review the merger and "its potential negative impact on patients and an innovative pharmaceutical marketplace." They commented that the business model used by Valeant is potentially anti-competitive and may result in price increases to consumers. They are also concerned about tax inversion, as Allergan would be repatriated to Canada (US Senate Letter, June 25, 2014).

When this book went to press, Allergan was acquired for US$66 billion by Activis, a pharmaceutical company based in Ireland. While this acquisition also results in a tax inversion, no negative reactions were reported in the press about the arrangement. Industry media reported that Valeant would be focusing less on acquisitions and more on R&D activity for growth.

Pfizer/AstraZeneca

Another controversial acquisition attempt took place early in 2014 when Pfizer placed a bid for AstraZeneca. Carroll (2014) reported that AstraZeneca's pipeline was not the reason for the acquisition because AstraZeneca's R&D performance was somewhat lackluster; however, Pfizer CEO Read referred to their potential for research in oncology given its current work in cancer. According to industry experts, the real reasons for the merger were tax inversion and patent incentives, and this caused an outcry from both the US and UK governments (Carroll, 2014). As a direct result of the Pfizer bid, legislation to restrict inversion is "now on a more public radar" (Morphy, 2014). In May, 2014, 14 US Senators introduced The Stop Corporate Inversions Act in order to stop this practice in future acquisitions. Finally, the UK Labour Party threatened to block the deal if they won the upcoming general election and began talks with Brussels about making changes to the public interest test (Farrell, 2014).

While tax inversions are legal in the US and some analysts argue that it is in the best interests of the shareholders, it may not be in the best interests of the public as important tax revenues that fund research as well as other programs that benefit the public good are lost. The UK government was concerned about job losses and loss of a major research center in Cambridge. However, this story is not yet over—Pfizer may come back with another bid in three to six months and the deal may still be concluded. It can be argued that these types of arrangements will attract a great deal of attention in the future; and it may very well result in making it more difficult to conclude these transactions should legislation be introduced to prevent them in the US and other countries.

Implications and Conclusions

In the final analysis, the available research suggests that the traditional lines among the different sectors in the industry have become increasingly blurred with greater consolidation both within sectors and across sectors. Some possible implications to this consolidation are the following: reduced competition; overreliance on a single 'feeder' source of research that specializes in niche products (biotechnology firms) with smaller patient populations at the expense of product line development and research in other sectors with broader patient bases; and potentially higher prices to patients as the number of competitors in some sectors is reduced.

M&A activity as a means to shore up product pipelines and cut costs has a negative effect on product innovation in the short and long term. As mentioned earlier, there cannot be reliance on one sector of the industry (biotech) to generate new products with broad utility for the general population. Firms must continue research as it is the primary driving force in the industry moving forward.

There are significant and adverse market effects to M&A activity, as any cost savings realized by firms are negated by effects on overall market performance, which includes both loss of market share and market position. Unless speed of integration and customer focus are maintained, there are no significant benefits to marketing organizations from M&A activities. The fewer products in the marketing portfolio, the less visibility and impact a firm will have on the market with both physicians and patients.

There are negative effects felt by both physicians and consumers, key audiences for pharmaceutical firms in the aftermath of M&As: disruption in physician practices and the loss of important medications to the general public. While these effects may not be apparent at first glance, the loss of important therapies and the repercussions on physician practices must be taken into account given their importance to marketing and business strategies.

Asset swaps, carve-outs, and spin-offs present alternatives to the traditional M&A model that may be less disruptive and more productive for the industry. Research is needed to demonstrate the positive or negative effects of these transactions for the pharmaceutical industry. Licensing and joint venture arrangements appear to be the least disruptive, and have been used successfully in the industry for some time.

There are no abnormal returns reported for industry M&As either in the short or long term, and the question remains as to why, given the lack of evidence, pharmaceutical companies continue to pursue M&A at such a steady pace. The purported benefits in these arrangements as suggested by the commonly accepted wisdom appear to be taken at face value. These benefits may be true for other industries; yet, for the pharmaceutical industry, the empirical evidence seems to suggest otherwise.

References

Barei, F., Le Pen, C., & Simoens, S. (2013). The generic pharmaceutical industry: moving beyond incremental innovation towards re-innovation. *Generics and Biosimilars Initiative Journal*, *2*(1), 13–19. doi:10.5639/gabij.2013.0201.011

Basta, N. (2014). US pharma layoffs do not reflect the industry's health. Retrieved October 21, 2014, from www.pharmaceuticalcommerce.com/index.php?pg=latest_news&articleid=27236&keyword=pharma-layoffs-employment-BLS-Pfizer-Valeant&utm_content=bufferb4bbf&utm_medium=social&utm_source=twitter.com&utm

Carroll, J. (2014). Why would Pfizer want to buy AstraZeneca? It's not R&D. *FierceBiotech*. Retrieved October 21, 2014, from www.fiercebiotech.com/story/why-would-pfizer-want-buy-astrazeneca-its-not-rd/2014–04–29

Cha, M., & Lorriman, T. (2014). Why pharma megamergers work. McKinsey & Company Insights and Publications. Retrieved October 31, 2014, from www.mckinsey.com/insights/health_systems_and_services/why_pharma_megamergers_work

Chabner, B.A. (2011). Drug shortages: A critical challenge for the generic-drug market. *New England Journal of Medicine*, *365*(23), 2147–2149. doi:10.1056/NEJMp1112633

Comanor, W.S., & Scherer, F.M. (2013). Mergers and innovation in the pharmaceutical industry. *Journal of Health Economics*, *32*(1), 106–113. doi:10.1016/j.jhealeco.2012.09.006

Danzon, P.M. (2006). Economics of the pharmaceutical industry. Retrieved October 21, 2014, from www.nber.org/reporter/fall06/danzon.html

Danzon, P.M., Nicholson, S., & Pereira, N.S. (2005). Productivity in pharmaceutical–biotechnology R&D: the role of experience and alliances. *Journal of Health Economics*, *24*(2), 317–339. doi:10.1016/j.jhealeco.2004.09.006

Danzon, P.M., Epstein, A., & Nicholson, S. (2007). Mergers and acquisitions in the pharmaceutical and biotech industries. *Managerial and Decision Economics*, *28*(4–5), 307–328. doi:10.1002/mde.1343

Datta, D.K. (1991). Organizational fit and acquisition performance: effects of post-acquisition integration. *Strategic Management Journal*, *12*(4), 281–297. doi:10.1002/smj.4250120404

Demirbag, M., Ng, C.-K., & Tatoglu, E. (2007). Performance of mergers and acquisitions in the pharmaceutical industry: a comparative perspective. *Multinational Business Review*, *15*(2), 41–62. doi:10.1108/1525383X200700007

Dey, E., & Shinghal, M. (2012). Analysis: small generic drug firms need niches to survive looming price war. *Reuters*. Retrieved October 21, 2014, from www.reuters.com/article/2012/07/20/us-genericdrugs-specialization-idUSBRE86J0ZI20120720

Epperly, L. (2013). Generic drug manufacturers. Retrieved October 21, 2014, from http://tippie.uiowa.edu/henry/reports13/generics.pdf

Ernst & Young. (2013). Ernst and Young 2013 global biotech report. Retrieved October 21, 2014, from http://biotech.about.com/od/investinginbiotech/a/Ernst-And-Young-2013-Global-Biotech-Tech-Report.htm

Evaluate Pharma. (2014). World Preview 2014: Outlook to 2020. Retrieved October 21, 2014, from www.evaluategroup.com/public/reports/EvaluatePharma-World-Preview-2014.aspx

Farrell, S. (2014). Pfizer's battle to buy AstraZeneca – timeline. *The Guardian*. Retrieved October 21, 2014, from www.theguardian.com/business/2014/may/14/pfizer-takeover-approach-astrazeneca-timeline

GEN. (2014). Top 25 biotech companies of 2014. Retrieved October 24, 2014, from www.genengnews.com/insight-and-intelligence/top-25-biotech-companies-of-2014/77900218/

Glick, J.L. (2008). Biotechnology business models work: evidence from the pharmaceutical marketplace. *Journal of Commercial Biotechnology*, *14*(2), 106–117. doi:10.1057/palgrave.jcb.3050085

Greene, J. (2014). First biosimilar drugs challenge unfolds in federal circuit. Retrieved October 21, 2014, from www.nationallawjournal.com/id=1202669580142/First-Biosimilar-Drugs-Challenge-Unfolds-in-Federal-Circuit

GSK Press Release. (2014). GSK plc announces major three-part transaction with Novartis to drive sustainable sales growth, improve long-term earnings and deliver increasing returns to shareholders. Retrieved October 21, 2014, from www.gsk.com/media/press-releases/2014/gsk-announces-major-three-part-transaction-with-novartis.html

Harding, D. (2010). Gaining market share in the generic drug industry through acquisitions and partnerships. Retrieved October 21, 2014, from http://thomsonreuters.com/products/ip-science/04_013/newport-deals.pdf

Hassan, M., Patro, D.K., Tuckman, H., & Wang, X. (2007). Do mergers and acquisitions create shareholder wealth in the pharmaceutical industry? *International Journal of Pharmaceutical and Healthcare Marketing*, *1*(1), 58–78. doi:10.1108/17506120710740289

Herper, M. (2014). Valeant Pharma's arguments about drug research are misleading and wrong. *Forbes*. Retrieved October 21, 2014, from www.forbes.com/sites/matthewherper/2014/06/12/valeant-pharmas-arguments-about-drug-research-are-misleading-and-wrong/

Higgins, M.J., & Rodriguez, D. (2006). The outsourcing of R&D through acquisitions in the pharmaceutical industry. *Journal of Financial Economics*, *80*(2), 351–383.

Hirschler, B., Geller, M., & Davies, A. (2014). *Novartis-GSK asset swap offers template for pharma and beyond*. Retrieved October 21, 2014, from http://uk.reuters.com/article/2014/04/23/novartis-gsk-assetswaps-idUKL6N0NF3RT20140423

Hoang, H., & Rothaermel, F.T. (2005). The effect of general and partner-specific alliance experience on joint R&D project performance. *The Academy of Management Journal*, *48*(2), 332–345. doi:10.2307/20159659

Homburg, C., & Bucerius, M. (2005). A marketing perspective on mergers and acquisitions: how marketing integration affects postmerger performance. *Journal of Marketing*, *69*(1), 95–113.

Humer, C., & Beasley, D. (2014). Allergan readies defense as it fights Valeant for votes. Retrieved October 24, 2014, from http://uk.reuters.com/article/2014/07/01/uk-allergan-valeant-defense-idUKKBN0F656Y20140701

Johnson, M. (2014). GSK and Novartis agree on asset swap worth billions. Retrieved October 24, 2014, from www.pharmaceuticalonline.com/doc/gsk-and-novartis-agree-on-asset-swap-worth-billions-0001

Kipp, O., & Leiding, P. (2008). Effects of mergers & acquisitions on the day-to-day work lives of general practitioners. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *8*(3), 211–219. doi:10.1057/jmm.2008.8

LaMattina, J.L. (2011). The impact of mergers on pharmaceutical R&D. *Nature Reviews Drug Discovery*, *10*(8), 559–560. doi:10.1038/nrd3514

Mack, J. (2014). Pharma promotional spending in 2013. *Pharma Marketing News*, *13*(5). Retrieved October 21, 2014, from www.news.pharma-mkting.com/pmn1305-article01.htm

Mittra, J. (2007). Life science innovation and the restructuring of the pharmaceutical industry: merger, acquisition and strategic alliance behaviour of large firms. *Technology Analysis & Strategic Management*, *19*(3), 279–301. doi:10.1080/09537320701281540

Morphy, E. (2014). Pfizer ends AstraZeneca bid but the tax issues it raised live on. *Forbes*. Retrieved October 21, 2014, from www.forbes.com/sites/erikamorphy/2014/05/26/pfizer-abandons-astrazeneca-bid-but-its-tax-issues-live-on/

Ornaghi, C. (2009). Mergers and innovation in big pharma. *International Journal of Industrial Organization*, *27*(1), 70–79. doi:10.1016/j.ijindorg.2008.04.003

Park, W. G., & Sonenshine, R. (2012). Impact of horizontal mergers on research & development and patenting: evidence from merger challenges in the U.S. *Journal of Industry, Competition and Trade*, *12*(1), 143–167. doi:10.1007/s10842–011–0119–0

Rajamäki, H. (2008). Anticipating and managing the challenges of biotechnology marketing. *Journal of Commercial Biotechnology*, *14*(3), 225–231. doi:10.1057/jcb.2008.13

Reuters. (2013). Drugmakers weigh carve-outs as Abbott, Pfizer set pace. Retrieved November 4, 2014, from http://mobile.reuters.com/article/idUSL5N0BDCUM2013214?irpc=932

Rockoff, J. D., & Mattioli, D. (2014). Bid for Allergan puts Valeant's research and development cuts under scrutiny. Retrieved October 21, 2014, from http://online.wsj.com/articles/bid-for-allergan-puts-valeants-research-and-development-cuts-under-scrutiny-1402443053

Saboo, A. (2014). Pharma's top 10 M&A deals of 2013. *FiercePharma*. Retrieved October 21, 2014, from www.fiercepharma.com/special-reports/top-10-ma-deals-2013

Schweizer, L. (2005). Organizational integration of acquired biotechnology companies into pharmaceutical companies: the need for a hybrid approach. *The Academy of Management Journal*, *48*(6), 1051–1074. doi:10.2307/20159729

Sheppard, A. (2010). Generic medicines: essential contributors to the long term health of society. Retrieved October 21, 2014, from www.imshealth.com/imshealth/Global/Content/IMS%20Institute/Documents/Generics_Medicines.pdf

Silcoff, S. (2013). How Valeant became Canada's hottest stock. *The Globe and Mail*. Retrieved October 21, 2014, from www.theglobeandmail.com/report-on-business/rob-magazine/how-valeant-became-canadas-hottest-stock/article8889241/

Silverman, E. (2013). Biotech products are filling the pharma pipelines: study. Retrieved October 21, 2014, from http://pharmalot1.rssing.com/chan-14571441/all_p18.html#item360

Silverman, E. (2014). Physician groups side with big drug makers over biosimilar names. Retrieved October 21, 2014, from http://blogs.wsj.com/pharmalot/2014/08/15/physician-groups-side-with-big-drug-makers-over-biosimilar-names/

Srivastava, R. K. (2012). The role of brand equity on mergers and acquisition in the pharmaceutical industry: when do firms learn from their merger and acquisition experience? *Journal of Strategy and Management*, *5*(3), 266–283. doi:10.1108/17554251211247571

Statista. (2014). Top 10 generic drugs producing pharmaceutical companies by U.S. prescription market share in 2010. Retrieved October 24, 2014, from www.statista.com/statistics/205057/percent-of-generic-prescriptions-dispensed-by-corporation/

The Economist. (2009). The return of the deal. *The Economist*. Retrieved October 21, 2014, from www.economist.com/node/14409594

US Senate Letter. (June 25, 2014). US Senate letter. Retrieved October 24, 2014, from www.feinstein.senate.gov/public/index.cfm/files/serve/?File_id=8893d3eb-6042–48a7-a213–4c78d8095d1a

Vanderbyl, S., & Kobelak, S. (2007). Critical success factors for biotechnology industry in Canada. *Journal of Commercial Biotechnology*, *13*(2), 68–77. doi:10.1057/palgrave.jcb.3050042

2 The Environmental Forces that Influence Industry Stakeholders and Shape their Interactions

In order to understand the pharmaceutical industry and its marketing practices, it is important to be aware of the various groups of interest in the health care arena and the key environmental factors that influence them. Why health care generally and not just the pharmaceutical firm? Smith's (1991) discussion about pharmaceutical marketing and subsequent definition contains timeless elements and it has been adapted here:

> Pharmaceutical marketing emphasizes that any article, service, or idea needed to anticipate and remove gaps in patient care should be included in the discussion of pharmaceutical marketing. Pharmaceutical marketing is significantly broader than the marketing of pharmaceuticals, as the justification for the existence of pharmaceutical marketing is the patient.
>
> (Adapted from Smith, 1991, p. 9)

This discussion provides a brief overview of the key forces and participants in the industry for those who are new to it, and will possibly add some fresh insights for those who are either industry professionals or scholars seeking to expand their avenues of research. It is not intended to be an exhaustive analysis; rather, its purpose is to focus on stakeholders and their relationships as shaped by important environmental forces. Indeed, if one accepts the definition presented above, the patient is the raison d'être of pharmaceutical marketing. Despite this, other stakeholders, such as government and private payers, have become a critical focus for marketers because of their importance to pricing of and access to prescription pharmaceuticals. This chapter begins with a discussion of the external environment and then proceeds to an analysis of the interactions between patients, physicians, pharmacists, and payers as among the most important stakeholders.

External Environmental Forces

Economic Factors

One of the most important forces affecting the global industry is economic. This includes, but is not limited to, the general state of the economy, levels of employment, general price levels (as well as prices for prescription drugs), and pressure from the financial markets on the pharmaceutical industry.

The world economy in recent years has seen an overall drop in full-time employment and there has not been a full recovery since the 2008 recession (Buysse, 2010). This reduction in full-time workers results in lower disposable and discretionary income, and thus, less to spend on necessities such as health care and,

in particular, prescription drugs. It has been an often stated maxim that the health care industry is 'recession proof,' as demand for health care generally remains constant even in a weakened economy. However, certain economic pressures will affect the pharmaceutical industry: for example, both small start-up companies and biotech firms, as well as larger firms, which are trying to obtain credit in the financial markets are experiencing difficulties, given the fact that governments and insurance companies are balking at paying for expensive new medications (Behner et al., 2009). A recent WHO study examined of the effects of recession on the pharmaceutical sector (Buysse, 2010). The findings suggest that the fallout from the 2008 economic crisis is still being felt with the cutting of government health care budgets. Buysse (2010) reported that Europe experienced the greatest decline in pharmaceutical consumption, with the American region showing only small increases.

Technological Factors

Technology is increasing at a rapid rate and in many ways is the backbone of the pharmaceutical industry given its emphasis on research. As a result, the key stakeholders are affected by the following trends:

Increasing Use of Technology by Physicians and Patients

Mobile technology has changed the way many sales representatives deliver information to physicians, as well as how marketers develop marketing programs. The Internet, mobile apps, and social media have forever changed the way patients communicate with one another and in some cases with their health care providers as well, whether they are physicians or pharmacists (see Lee, 2013, for some links to specific information). Access to medical information (both good and bad) by patients through the available technology has also affected the power dynamics of the relationships between patients, their health providers, and policy makers. Technology has the potential, if used correctly, to assist patients in improving their health outcomes through accessibility of information; however, poor and inaccurate information that is widely available has the potential to do tremendous harm.

Big Data

Technology has also increased the ability of marketers and clinical researchers to analyze voluminous quantities of various data; this has implications for how drugs will be marketed and researched by pharmaceutical companies in the future. For example, outbreaks of influenza and epidemics of other diseases can now be predicted and tracked based on these data. It has been suggested that 67 percent of pharmaceutical companies are using Big Data in their marketing efforts (mmm-online.com, 2014).

Big Data in the pharmaceutical industry has been likened to a 'tsunami': it allows every patient's experience to provide a picture of their health, and when grouped with other related data, may provide insight into both diseases and entire populations of patients (Drummy, 2012). There are currently thousands of online patient groups with thousands of members, as well as health apps that record data that includes height, weight, and eating habits: it is speculated that this data could be used to evaluate a large patient population in order to reduce the variability among individuals (Zhang, 2014). Staton (2014) suggests that insurance and government payers want information that proves drug effectiveness and positive outcomes of drug treatment in specific populations; Big Data has been used to do this by Sanofi in Germany, as one example (mmm-online.com, 2014). Some firms are redeploying their sales representatives as outcomes monitors: these individuals track patients' progress on their therapies to ensure compliance and, subsequently, a satisfactory therapeutic outcome.

However, there are critics of Big Data that believe the conclusions drawn from the data may not provide the appropriate insight because its analysis focuses on macro rather than micro level trends (Hjelmsoe, 2014). Privacy issues with respect to access to personal data are also a concern raised by critics. Finally, Ross et al. (2013) opine that Big Data has been 'hyped' to the point that the industry believes it can deliver more than is possible, and that companies have not analyzed the data they already possess.

Changing Treatment Modalities and Medical Breakthroughs

The development of nanotechnology in human health in drugs, medical devices, and tools used in surgery is increasing (Boruff, 2012). *Time* magazine (Park, 2013) reported the top ten medical breakthroughs of 2014, which included early detection of Parkinson's, advances in Alzheimer's, fertility, hair growth, and the treatment of high cholesterol. LaMattina (2014) reported that even new antibiotics for diseases such as pneumonia, tuberculosis, and urinary tract infections are on the research agendas of small firms, but not to the same extent for the larger firms. He suggests that these investments may not be sufficient to generate the drugs needed to combat the superbugs of today.

Social and Demographic Factors

Among the most numerous trends affecting the industry, worldwide social and demographic shifts are also some of the most significant for both marketers and policy makers, and these are discussed below.

The Reality of the Aging Global Population

The United Nations Report on World Population Aging (United Nations, 2013) confirms that the world population is indeed aging (all the statistics included in this paragraph are taken from this report). In 2013, China had the largest population over the age of 80, with 23 million; followed by the US with 12 million; India with 10 million; and Japan with 9 million. Two-thirds of the older population live in developing countries and by 2047, the number of older persons in the world will exceed that of young persons. Older persons are primarily female, and this proportion is expected to increase.

> Ageing is also partly the result of the trend toward longer and generally healthier lives of individuals, but because chronic and degenerative diseases are more common at older ages, they result in an increased prevalence of non-communicable diseases at the population level.
>
> (United Nations, 2013, p. 1)

Further, most developed countries such as the US and Japan already have a significant aged population, so this phenomenon is no longer a trend but a reality.

World Population Distribution

The World Demographics Profile (CIA World Factbook, 2013) reports that the ten most populous countries are: China (1.3 billion); India (1.2 billion); the US (316 million); Indonesia (251.6 million); Brazil (201 million); Pakistan (193 million); Nigeria (174 million); Bangladesh (163 million); Russia (142 million); and

Japan (127 million). It is interesting to note that two of the most populous countries (China and India) are also those with a rapidly emerging middle class; these emerging markets have great potential for pharmaceutical therapies.

The Varied and Changing Incidence of Disease

According to the World Health Organization (WHO, 2014), the ten leading causes of death in the world are ischemic heart disease; stroke; COPD (chronic obstructive pulmonary disease); lower respiratory tract infections; upper respiratory tract infections; HIV/AIDS; diarrheal disease; diabetes mellitus; road injuries; and high blood pressure. It is interesting to note that in high income countries, seven in ten deaths occur in those over 70 years old, largely from chronic diseases including cardiovascular disease, dementia, cancer, or diabetes. In low income countries, however, 40 percent of deaths occur in children under the age of 15 with the most common diseases being lower respiratory infections, HIV/AIDS, diarrheal disease, malaria, and tuberculosis (all the statistics in this paragraph are cited from the WHO 2014 report).

The widely reported increase in antibiotic resistant pathogens (e.g. MRSA and tuberculosis) or 'superbugs' has also resulted in susceptibility of both young and old to communicable diseases, particularly in institutional settings such as schools, hospitals, and nursing homes, as well as those living in rural areas without potable water and proper sanitation.

Alternative Therapies for Treatment of Disease

The use of alternative medicine such as acupuncture and herbal therapy is increasing in Western cultures. A WHO (2002) statement reported that increasing numbers of patients are seeking out alternative medicine for both palliative care and prevention of disease. In the UK, patients spent US$230 million on alternative medicine; 75 percent of the French population has used alternative medicine at least one time; and 77 percent of Germany's pain clinics provide acupuncture (WHO, 2002). In Thailand, the use of herbal medicines is well accepted, and in fact, these are primarily purchased in drugstores (Thongruang, 2008). Agrawal (2002) reported that approximately 66 percent of the worldwide population seeks alternative health care, which includes self-medication. Some reasons for this reported use include the rise in incidence of chronic disease; patient involvement with health care decisions; dissatisfaction with conventional treatment as impersonal, costly, and causing undesirable side effects; need for personal control; and a patient's worldview on illness and health (Agrawal, 2002).

Global Mass Communication

It is well accepted that traditional media forms are already globalized; what is less well understood is the globalization of the Internet and social media. A seminal and longitudinal study (Hutton & Fosdick, 2011) suggests that social networking "has become a global movement" (p. 564). It is interesting to note that of the ten countries in the study, Russia has the highest usage of social media at 80 percent, with France showing the lowest use at 53 percent. The global average is 61 percent and the US falls short of this average at 58 percent. The BRIC (Brazil, Russia, India, and China) markets (emerging markets), on average, show approximately 74 percent social media usage, which is well above the global average. According to the authors, most social media behavior is passive (watching video clips online, visiting a company or brand website, or reading a

blog or weblog are among the top five). Most importantly, Hutton and Fosdick (2011) conclude that social networking is the primary method of staying in touch; however, company and brand websites are declining in importance possibly because of the use of social media marketing for branding; content sharing is moving to the realm of social networking; blogs on specialized topics are increasingly important; media meshing (consumers using two media with one as a mobile) is emerging as a result of blogging; the desire to be part of a movement drives membership in a brand community; and while there is movement away from brand-sponsored websites, it is reported that "60% of respondents who said they had joined an independent brand community also claimed that they subsequently were more likely to buy the brand" (p. 570).

O'Connor (2010) commented that "Thanks to Dr. Google and Nurse Yahoo, consumers know better than ever how to get what they want" (p. 150). According to Pew (2014), 72 percent of Web users say they looked online for health information in the last year and researched diseases, treatments, procedures, and looked for physicians. Manhattan Research (2012) reported that 44 percent of European online consumers utilized both social networking websites as well as 33 percent using health ratings and reviews, and these percentages varied by country. Spain and Italy have the highest percentage of "social health users" (Manhattan Research, 2012).

Physicians globally are using both Web 1.0 and Web 2.0 (Katsanis & Maddox, 2010), and BRIC physicians are more likely to use social media than those in Europe or the US (PM Live, 2012).

The Consumerization of Health Care and Patient Empowerment

This factor is directly related to the globalization of media and use of the Web and social media discussed earlier, as well as to DTCA (direct to consumer advertising) in the US (Lober & Flowers, 2011). It should be noted that due to this globalization, consumers around the world are also exposed to DTCA originating from the US. Further, patient empowerment has also taken the form of patient advocacy groups and involvement with disease oriented non-profit organizations such as cancer societies, heart and stroke foundations, as well as others that interact with health care professionals and the industry.

Political, Legal, and Regulatory Factors

These trends have a profound impact on pharmaceutical marketing as political influences in world governments determine the application of intellectual property agreements, pricing, and marketing regulations.

Protection of Intellectual Property

A critical factor affecting the industry and policy makers alike is the issue of patent protection. One of the most important and comprehensive multilateral agreements affecting stakeholders is the TRIPS Agreement of 1995 (Trade Related Aspects of Intellectual Property Rights) (World Trade Organization, WTO, 2014). The rules for patents include what is patentable and what is not, and the agreement provides for certain exclusions, such as "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" as well as "plant varieties." While it provides for 20-year patent protection, it also allows for compulsory licensing (see referenced WHO document on Essential Medicines and Health Products for details) and government use without authorization, provided that a good faith attempt has been made to obtain a voluntary license with an appropriate payment.

Political considerations are important in patent law as non-Western countries have either successfully challenged patents under this agreement (most notably India) or ignored it completely in the belief that it does not meet with their needs (Dávila, 2011). One early example was the refusal of the Indian government to recognize the validity of Bayer's Nexavar patent (Anand, 2010). More recently, India's Supreme Court rejected Novartis' patent for Gleevec (an oncology drug) in a lengthy court battle ongoing since 2006, when India's patent office rejected the patent (Krishna & Whalen, 2013).

At present, the industry is experiencing what is known as a patent cliff: it is the expiry of multiple patents for different firms at the same time. It is a cyclical problem faced by large pharmaceutical firms and negatively affects corporate earnings if the firm has not ensured a strong product pipeline. In 2013, patents expired that had a market value of $29 billion, led by Cymbalta and OxyContin (Saboo, 2012).

Some ethical pharmaceutical companies try to protect their patents by adding product extensions (such as once-a-day dosing or chiral switches) also known as product evergreening. Generic firms frequently challenge patents in court in the hopes that they will be able to market their version sooner than the official patent expiry date. These lawsuits numbered 230 in 2011, compared to only 81 in 2005; generic firms are not only targeting blockbuster drugs, but also older drugs with smaller revenue streams (Roane, 2011). One high profile patent challenge for Viagra was settled in the US, with Pfizer granting Teva a royalty bearing license for the drug (Yahoo Finance, 2013). However, Pfizer did not fare as well in Canada as its Supreme Court ruled that the firm had not adequately identified Viagra's active ingredient; Teva was allowed to market a generic version of the drug (Ljunggren, 2012).

Governmental Health Care Policy and Drug Reimbursement Policy

This factor is significant because it affects the way health care is paid for by governments and patients. There is a tightening of both health care budgets worldwide and a change in the way in which health care is provided. An ongoing example of a recent and divisive development in health care public policy surrounded the passage and implementation of the Affordable Health Care Act in the US. Government policies also include the regulation of pricing and reimbursement for drug payments by either a government payer and/or a third-party payer. The pharmaceutical industry refers to this as market access. Maynard and Bloor (2003) provide a thoughtful discussion about the difficulties in pharmaceutical industry regulation with respect to this topic.

There are formal regulations in most countries regarding drug approvals and drug labelling; other regulation may also include that which controls advertising (DTCA in the US and New Zealand) as well as promotion (off-label marketing, for example).

Parallel Imports/Grey Markets

The WHO defines parallel imports or grey market imports as:

> imports of a patented or trademarked product from a country where it is already marketed . . . parallel imports often take place when there is differential pricing of the same product – either brand name or generic drugs – in different markets . . . the TRIPS agreement explicitly states that this practice cannot be challenged under the WTO dispute settlement system and so is effectively a matter of national discretion.
> (WHO, 2000)

The WHO distinguishes between parallel imports and counterfeit products: it classifies parallel import drugs as "legitimately put on the market, not imitations of original products . . . parallel imports would be subject, in principle, to the same import and other regulations applicable to any imported medicine."

Parallel imports are of particular controversy in the US, where the pharmaceutical industry has lobbied heavily for their outright ban with little success, because activist groups such as the AARP support their use (Bandyopadhyay, 2010). Research from Germany, however, suggests that parallel imports reduce the prices for brand name drugs by approximately 11 percent, but have no effect on the prices for generic drugs. Consequently, it is not necessarily viewed as a negative phenomenon given the downward effects on drug pricing seen as beneficial in some markets (Duso et al., 2014; Brekke et al., 2014). In a global context, some industry analysts argue that if regulations on parallel imports were tightened, pharmaceutical companies might be more willing to provide low income countries with lower drug prices; however, others believe that low drug prices permitted by parallel imported drugs provide relief to already overwhelmed health care systems (Ganslandt & Maskus, 2004).

Counterfeit Drugs

Cockburn et al. (2005) define counterfeit drugs as "the production of substandard and fake drugs" (p. 0302) and according to the authors, their presence is growing at an increasing rate. The authors estimate that up to 15 percent of all drugs sold are fake and that in countries such as Africa and Asia, the incidence may be as high as 50 percent. *The Lancet* (2012) called counterfeit drugs "a growing global threat" (p. 685), and believe that their existence is underreported because governments are reluctant to frighten the public. Additionally, they suggest that counterfeiting will be confused with parallel importation and affect the distribution of low-cost drugs in poor regions. However, this issue needs to be addressed to ensure the safety of the world's drug supply.

The Industry's Stakeholders and their Interactions

Industry stakeholders include patients (and their families, friends, and caregivers), physicians, pharmacists, health insurance companies (managed care providers), governments (both universal care providers and regulators of drug approval), and the pharmaceutical firms themselves. Some of these stakeholders also traditionally serve as gatekeepers (these include insurance companies and governments for payer policies; regulators for drug review and approval; and physicians for distribution of prescriptions and delivery of procedures).

Patients remain the recipients of the care and the physicians the decision makers as to the appropriate treatment; however, the governmental health care systems and payers (including private payers) decide what treatments and drugs will be reimbursed. In some cases, these groups may override the health professional's decisions or patient's wishes. In addition, payers demand that firms document the efficacy of different therapies before they are willing to pay for them (this subject will be covered in depth later in the book). Companies must now interact with patients directly (beyond merely advertising to them) in a clinical setting to determine how drug therapies are working in order to collect the data required by the payers to attain reimbursement.

In some countries such as the US, pharmaceutical companies communicate directly with patients in an attempt to influence the gatekeepers. This includes the expectation that patients will pressure both governments and payers to approve therapies that may be expensive and for physicians to prescribe these therapies. Several chapters that appear later in this book will address these issues in an in-depth manner—the balance

of this chapter is focused on the differences in access to health care professionals and the interaction between patients, physicians, and pharmacists.

Patient Access to Health Care Professionals and their Interactions

Health care and drug consumption vary in different parts of the world. Primary health care may not mean the same thing to those living in the Western countries, where access to health care is highly developed and readily accessible, as it does to those living in non-Western countries, where many patients may never see a physician; seek advice exclusively from pharmacists; or use non-pharmaceutical products like herbs. Self-care is important in poorer countries as a way to reduce reliance on the health care system and obtain quick medical care for minor problems (Reinstein, 1996). Wertheimer (1996) points out that income levels determine health care access to some extent, as certain countries lack the basics in food and medication distribution: the size of and gap between having a lower and upper class also determine health care access, as well as the presence of a vigorous middle class, as they can afford to pay for medical services.

In addition, there are differences between urban and rural parts of a particular country with respect to health care delivery. In rural areas, health care may be provided by a nurse or semi-trained worker; or possibly, one outpost manned by one individual (Wertheimer, 1996). For example, Krishnaswamy and Kumar (2010) report that most of the population in India's rural areas visit private health care providers, where irrational prescribing occurs, as well as 'self' prescribing and the sale of scheduled drugs (i.e. opioids) without prescription. Interestingly, they also reported low levels of self-medication, possibly due to the lack of retail pharmacies in these locales.

Given these differences in health care availability and modalities, it is important to understand what patients experience when they become ill and how their direct interaction with physicians and pharmacists occurs within a health care system. The research presented here brings the patient's experience with these health care professionals into focus, as they are among the most important stakeholders. These interactions are complex—they take place in a time frame that includes the moment when a patient decides to seek advice from a health professional until the time they decide whether they are going to take the advice they receive.

Patient/health care provider interactions may be divided into three phases: patient self-assessment; patient consultation with physicians and pharmacists; and post-professional decision making. The discussion that follows is intended to be a general view and does not capture all the possible outcomes of the interactions, particularly as there may be different pathways for various diseases depending on their etiology and severity. In addition, the types of interactions outlined here are a reflection of health care in countries with strong health care systems and large middle class populations. Differences between countries and cultures will be discussed at varying points where research is available; however, research in this area is sparse for certain parts of the world. Given this qualification, the discussion attempts to systematically describe what happens to a patient from the time they experience symptoms to the time they make a decision about the action they will take about their potential health problem.

Patient Self-Assessment

A patient may develop a series of symptoms: these may be minor and something they have experienced before; or they may be unusual, persistent, severe, or of sudden onset. When this happens, the research suggests that US respondents will seek information from multiple sources: 70 percent from a health care

professional; 60 percent from friends and family; and 24 percent from those with a similar health condition (Pew, 2014). Keselman et al. (2008) reports that 35 percent of US patients who access the Web for medical information do not confirm their symptoms with an MD and may either self-medicate or ignore symptoms. Some patients may also try to remember if they have seen an advertisement and whether or not their symptoms matched those in the ad. A patient may take one of two possible paths: either to seek further advice from a professional (either a physician or pharmacist), or to take a wait and see approach.

In a non-Western culture where health care services are not readily available, many patients will simply live with their symptoms if they are not acute, and medical symptoms may be experienced in different ways across cultures. In a study of 15 centers in Asia, Africa, Europe, and the Americas, Gureje et al. (1998) examined the incidence and impact of persistent pain in a primary care setting. When they compared the 'average pain' index for subjects in each participating center to individual countries, the highest levels of pain were reported in Italy and Chile, with the lowest in Turkey and China. However, all cultures included in the study suffered from this condition under study. Gureje et al. (1997) examined somatization (the appearance of symptoms with no apparent cause) in different cultures across 14 countries. Their results suggested that while symptoms appeared much more frequently in South America and were associated with low education, the condition did not differ significantly across cultures.

If the patient attempts to schedule an appointment with a physician, they may be required to consult with a nurse practitioner first, or may get an appointment with the physician immediately, depending on the urgency of the matter. This may depend on the type of health care plan the patient has (whether with managed care or universal care system as the gatekeeper). Wait times for a consultation vary, and also depend on whether the physician is primary care or a specialist. In some countries, like Canada, an initial visit with a specialist is restricted until after a general practitioner (GP) has been consulted. In other countries, like Germany (InterNations, 2014), GPs have 'open door policies' or clinics during certain hours of the day to treat emergencies that do not belong in the hospital emergency room. In the public sector of the non-Western countries, there may be long waits, in contrast to the shorter waits for those in the private sector (Wertheimer, 1996).

Patients wait to see physicians because in many countries around the world, including the US, there is a current shortage of physicians, and it is projected to persist, particularly in the primary care setting. A 2006 WHO bulletin reported that 57 countries have an absolute shortage of 2.3 million physicians, nurses, and midwives; however, this shortage is not evenly distributed, with some regions of the world—particularly in the Africas, Eastern Mediterranean, and Western Pacific regions of the world—showing the most severe physician shortages. In the US, it is forecasted that there will be a shortage of approximately 130,000 by 2025 and this is equally distributed among GPs and specialists (AAMC, 2014).

Patient Consultation with Physicians

When physicians meet with their patient, he/she will generally take their history, proceed with a physical examination, and then make either a firm diagnosis or a diagnosis that must be confirmed with additional testing.

The time physicians typically spend with their patients varies by country—for example, the average American receives 18 minutes with their GP (Goodman, 2014); in the UK it is ten minutes, although physicians generally recommend a 30-minute appointment with the GP (Davies, 2013). In addition, men and women are treated differently during the time they spend with their doctors. A UK study by Briscoe (1987) found that on average, women consulted physicians twice as often as men and that women use the physician visit

to ask about multiple conditions. The social status of men (parenthood and marital status) determined the number of physician consultations. A more recent study (Tabenkin et al., 2004) reports that women had more physician time spent on physical examination, questioning, and counseling; while visits from men focused on procedures and behavior modification. Men received counseling on behavior modification for exercise, diet, and substance abuse more frequently than women.

During the visit, a prescription may or may not be given to the patient. The physician may consult a compendium or pharmaceutical company literature, prescribe based on habit or sample availability of a particular drug, or look for a low-cost generic. Mellor and Green (2002) modelled patient–physician interactions to identify what issues physicians and patients consider important when discussing the prescribing of a particular medication. Their results suggest that patients were more concerned about short- and long-term side effects, while physicians were more concerned about efficacy and dosing schedules (the methodology used in this study is an interesting one and worth a detailed examination by the reader).

The patients themselves may ask for a particular prescription based on advertising and "[p]hysicians fulfilled most requests for DTCA drugs" (Mintzes et al., 2003, p. 405). In the UK, over half of patients expect to receive an antibiotic during a visit for a cough or cold, and this may be accompanied by a discussion about the benefits and side effects of the medication as well as costs (Health Protection Agency, 2011). The physician may also be bound by a managed care or government formulary when prescribing and may consult it during the examination, or ask the patient if their medication is covered by a particular plan. In non-Western countries without proper infrastructure, drugs may not even be available or limited to those on hand at the clinic (Wertheimer, 1996).

Patient Interaction with Pharmacists

Alternatively, the patient may have decided to consult a pharmacist rather than visit the doctor. The patient may either purchase an OTC (over-the-counter) medication or decide against self-medication for a variety of reasons, including the cost of the medication (as most OTC medications are not covered by insurance or managed care plans) or the possibility that he/she needs to be seen by a physician.

The patient's actions will depend on the pharmacist's role in that part of the world. Generally, the pharmacist has moved far beyond the simple selling of medication in a retail environment. In some countries, they are the patient's first and only contact with the health care system. According to Reinstein (1996), pharmacists are "the first port of call and . . . apply their professional knowledge more frequently to counsel consumers about their medicines" (p. 36). A patient may ask the pharmacist for advice about familiar ailments and possible self-medication, and may also ask if a physician visit is necessary. The pharmacist will ask the patient about his/her symptoms as well as their onset and duration and other drugs the patient may be taking. (Hustad et al. (1979) provide a Canadian model for OTC self-medication that may be of interest to the reader.)

There are many different types of pharmacies worldwide: some are private practices, where the individual pharmacist controls his/her own pharmacy—for example, in Australia and New Zealand, pharmacies must still be owned by pharmacists. However, in the US, the UK, and elsewhere in Europe, chain and corporate pharmacies are common (Lutz et al., 2009).

There are differing points of view as to the role of the pharmacists in patient self-care when a patient decides to treat themselves. Self-medication and self-care are prevalent in regions such as Asia and South Asia. You et al. (2011) found that there is a low acceptance rate in Hong Kong with respect to pharmacist-led self-care management. Patients tend to rely on their own knowledge, and these patients are typically of high

socio-economic status. In South Asia, Balamurugan and Ganesh (2011) found that self-medication is commonly recommended by a pharmacist (57 percent of the time) because the access to and use of this medication requires little time and effort.

Post-Consultation Patient Decision Making

When the patient leaves the physician's office, they may take one of two steps whether or not they received a prescription: either going directly home or going to the pharmacy. If the patient goes directly home, they may elect to search the Web or use social media to research the particular prescription they just received, particularly with regard to side effects or the experiences of others with the drug; or they may speak to family and friends for information and reassurance. If they are satisfied with the information they find, they may return to their pharmacist to fill the prescription.

If the patient goes directly to the pharmacy after their physician appointment, they will present the prescription to the pharmacist. The pharmacist may ask questions about other drugs the patient may be taking, as well as other untreated medical conditions they suffer from but for which they are not receiving treatment. They confirm which drugs are reimbursed by the patient's managed care provider or government universal health provider. In some countries with universal health care coverage, the pharmacist either has the right or is mandated to substitute a generic drug for a brand name drug if one is available. In a system where patients have private payer coverage, there may be more options open to patients. The pharmacist will discuss the possible side effects (and in some instances, provide an instruction sheet for the patient). If the medication is for a chronic condition, the pharmacist may suggest a monitoring program (for blood sugar or blood pressure, for example).

Pharmacists provide different services depending on the health care system in which they work. Pharmacists in Canada and Denmark have an important role in the optimization of drug therapy and services such as monitoring blood sugar, cholesterol, and blood pressure (Mossialos et al., 2013). In the US, pharmacists are actively "counseling patients face to face and on the phone, contacting patients who don't refill prescriptions and checking for potential interactions between drugs prescribed by different doctors" (Landro, 2012, p. 1). In other countries, such as Pakistan, while the pharmacist's role is developing, they are not well recognized due to their limited interaction with the public and the focus on managing the business aspects of the pharmacy versus the counseling of patients (Azhar et al., 2009).

In fact, many pharmacists in different countries are seeking an expanded role, including the right to prescribe certain classes of drugs such as birth control (note that in a few countries, pharmacists already have the right to prescribe—see Mysak et al. (2010); Tonna et al. (2008); Emmerton et al. (2005); The Royal Pharmaceutical Society England (2013); Mil et al. (2004); and Hudson et al. (2007) for a detailed discussion of this movement).

The patient may now decide to fill the prescription or not fill the prescription if cost or plan coverage is an issue; and some may even seek out an online pharmacy. Patients sometimes use online pharmacies and while there are some legitimate organizations that sell drugs online, much of this activity is illicit and, consequently, there is concern about drug safety and the appropriate use of medication. The US Food and Drug Administration (FDA, 2012) reported that 23 percent of Americans have purchased prescription medication online and 21 percent bought from a company based outside the US. Gurau (2005) found that 34 percent of respondents in his UK study had already purchased prescription drugs online (see Cicero & Ellis (2012) and Fittler et al. (2013) for in-depth research about online pharmacies; and Su et al. (2013) for information about Chinese online pharmacies).

Patient/Payer Interaction

Patients may have some or no interactions with private or government payers, depending on the health care system. In the public system, it is a government agency that determines what drugs will be reimbursed and made available to patients. In a system with private payers, the patient may challenge the refusal to approve the payment for a particular drug. The role of payers and their pricing policies will be described in Chapter 3.

Patient Adherence

It is well understood in the health care community that many prescriptions remain unfilled and a fair number of patients discontinue their treatment. Of course, in some countries, prescriptions are never even received and the option to fill a prescription does not exist. Depending on the severity of their condition, patients may return to the physician, decide to tolerate their symptoms, or speak to the pharmacist about managing the side effects. One critical question facing physicians, pharmacists, and the pharmaceutical industry (particularly in Western countries) is how to manage what is known as patient adherence (beginning and continuing with drug therapy).

Rao (2012) suggests that 30 to 50 percent of prescriptions never get to the pharmacy and that adherence levels drop significantly after the patient fills their first prescription: "compliance rates for rheumatoid arthritis, multiple sclerosis or anxiety are 50% or less" (p. 237). Landro (2012) reported that only 25 to 30 percent of medications are taken properly, and only 15 to 20 percent are refilled as prescribed. Physicians and pharmacists, and to some extent managed health care plans through their reimbursement policies, may play an important role in whether or not patients follow through with drug therapy.

While there may be some benefits to patients in complying with medical advice, there are commercial benefits as well. From the medical perspective, Andersson et al. (2014) indicate that adherence programs improve clinical outcomes to some degree; however, the effect of this improvement is relatively small. From the commercial perspective, Rao (2012) states that "[p]erhaps the single most important driver of growth for a pharmaceutical brand is adherence . . . the revenue potential inherent in encouraging adherence is vast" (p. 236). However, some patients voluntarily elect not to continue with their drug therapy and do not wish to be pressured into taking a prescription drug, particularly if the therapy is indicated for symptom reduction and not a permanent resolution to their problem.

Implications and Conclusions

The state of the global economy has become critically important to the pharmaceutical industry, as the research suggests it is no longer 'recession proof' as once believed. This reality may exert downward pressure on drug prices, despite the recent introduction of premium priced drugs in certain therapeutic classes such as oncology.

Technology, particularly with respect to mobile devices and rapid communication, has provided access to copious quantities of information for consumers, pharmaceutical firms, and governments along with the ability to analyze it. The use of this technology and information by the industry still remains in its early stages, as all stakeholders are still grappling with both how to use the data as well as how to prioritize it for proper decision making.

The aging world, population shifts, and changing importance of different diseases should be of paramount interest to the industry in the development of its product pipelines. The emergence of strong middle classes

and the accompanying lifestyle changes that occur in countries such as India and China will result in the development of similar disease states that are common in the Western world, such as diabetes. Poorer countries, however, still suffer from infectious diseases that remain untreated by current medications.

Intellectual property remains a critical issue for the industry as it is becoming harder to enforce patent laws in countries such as India despite agreements such as TRIPS. As BRIC countries become increasingly important to the industry, pharmaceutical firms will need to find ways of managing their patents to meet the needs of the patient population in these markets as well as their own.

Price setting and control by health care systems in different countries will exert downward pressure on prices. The pharmaceutical industry may need to re-evaluate its traditional reliance on premium pricing for new, branded products and look toward a longer payback period to recoup its R&D costs. For example, parallel imports are not necessarily viewed as a problem in all markets, but rather, as a means for controlling drug prices. As health care budgets continue to shrink and populations increase in size, pricing regulation and market access will have an even greater influence on the future of the industry than at present. While consumers may be more involved in their own health care, it is still the payers in most countries which determine what drugs they receive. At present, they may be a more important stakeholder than the end consumer in certain ways because of their tremendous influence as gatekeepers.

Patient care and treatment varies by culture and the roles of key stakeholders such as physicians and pharmacists differ by market. Patients in non-Western countries have significantly different interactions with health care professionals than those living in Western cultures. Self-care has become increasingly important as has the role of pharmacists in delivering health care services. This trend is even more notable due to the worldwide shortage of physicians and the changing role of the pharmacist in many countries. Patient adherence is generally of concern to health care professionals in Western markets, while drug availability is of concern in others. Global marketers will need to consider these differences as they develop appropriate marketing programs.

References

AAMC. (2014). GME funding: how to fix the doctor shortage. Retrieved November 4, 2014 from www.aamc.org/newsroom/keyissues/physician_workforce/

Agrawal, D. P. (2002). Review: complementary and alternative medicine: an overview. Pal, S. K. 2002. *Current Science*, *82*(5), 518–524. Retrieved November 4, 2014, from www.infinityfoundation.com/mandala/t_rv/t_rv_agraw_pal_frameset.htm

Anand, G. (2010). Drug makers decry Indian patent law. *Wall Street Journal*. Retrieved from http://online.wsj.com/articles/SB10001424052748703455804575057621354459804

Andersson, M., Garfield, S., Eliasson, L., Jackson, C., & Raynor, T. (2014). Delivery of patient adherence support: a systematic review of the role of pharmacists and doctors. *Patient Intelligence*, 31. doi:10.2147/PI.S46647

Azhar, S., Hassali, M. A., Ibrahim, M. I. M., Ahmad, M., Masood, I., & Shafie, A. A. (2009). The role of pharmacists in developing countries: the current scenario in Pakistan. *Human Resources for Health*, *7*, 54. doi:10.1186/1478-4491-7-54

Balamurugan, E., & Ganesh, K. (2011). Prevalence and pattern of self medication use in coastal regions of South India. *British Journal of Medical Practitioners*, *4*(3), a428.

Bandyopadhyay, S. (2010). The internet and gray marketing. *International Business & Economics Research Journal*, *9*(6), 95–101.

Behner, P., Vallerien. S., Ehrhardt, M., & Danielle, R. (2009). Pharmaceutical companies in the economic storm: navigating from a position of strength. Retrieved November 4, 2014, from www.strategyand.pwc.com/global/home/what-we-think/reports-white-papers/article-display/pharmaceutical-companies-economic-storm-navigating

Boruff, K. (2012). How technology has transformed medicine. *Examiner.com*. Retrieved November 4, 2014, from www.examiner.com/article/how-technology-has-transformed-medicine

Brekke, K. R., Holmas, T. H., & Straume, O. R. (2014). *Price regulation and parallel imports of pharmaceuticals* (SSRN Scholarly Paper No. ID 2382589). Rochester, NY: Social Science Research Network. Retrieved from http://papers.ssrn.com/abstract=2382589

Briscoe, M. E. (1987). Why do people go to the doctor? Sex differences in the correlates of GP consultation. *Social Science & Medicine*, *25*(5), 507–513. doi:10.1016/0277-9536(87)90174-2

Buysse, I. M. (2010). Impact of the economic recession on the pharmaceutical sector. Retrieved November 4, 2014, from http://apps.who.int/medicinedocs/documents/s17419e/s17419e.pdf

CIA World Factbook. (2013). World demographics profile 2013. *Index Mundi*. Retrieved from www.indexmundi.com/world/demographics_profile.html

Cicero, T. J., & Ellis, M. S. (2012). Health outcomes in patients using no-prescription online pharmacies to purchase prescription drugs. *Journal of Medical Internet Research*, *14*(6), e174. doi:10.2196/jmir.2236

Cockburn, R., Newton, P. N., Agyarko, E. K., Akunyili, D., & White, N. J. (2005). The global threat of counterfeit drugs: why industry and governments must communicate the dangers. *PLoS Med*, *2*(4), e100. doi:10.1371/journal.pmed.0020100

Davies, M. (2013). Ten minute appointments are an "anachronism", doctors agree. *Pulse Today*. Retrieved November 4, 2014, from www.pulsetoday.co.uk/home/finance-and-practice-life-news/ten-minute-appointments-are-an-anachronism-doctors-agree/20003445.article

Dávila, A. L. (2011). Global pharmaceutical development and access: critical issues of ethics and equity. *MEDICC Review*, *13*(3), 16–22. doi:10.1590/S1555-79602011000300005

Drummy, B. (2012). What is Big Data and how do we use it? *PharmExec.com*. Retrieved November 4, 2014, from www.pharmexec.com/pharmexec/Noteworthy/What-is-Big-Data-and-How-Do-We-Use-It/ArticleStandard/Article/detail/781853

Duso, T., Herr, A., & Suppliet, M. (2014). The welfare impact of parallel imports: a structural approach applied to the German market for oral anti-diabetics. *Health Economics*, *23*(9), 1036–1057. doi:10.1002/hec.3068

Emmerton, L., Marriott, J., Bessell, T., Nissen, L., & Dean, L. (2005). Pharmacists and prescribing rights: review of international developments. *Journal of Pharmacy and Pharmaceutical Science*, *8*(2), 217–225.

FDA. (2012). Buying medicines online? Be wary, FDA says. *WebContent.* Retrieved November 4, 2014, from www.fda.gov/ForConsumers/ConsumerUpdates/ucm321121.htm

Fittler, A., Bősze, G., & Botz, L. (2013). Evaluating aspects of online medication safety in long-term follow-up of 136 internet pharmacies: illegal rogue online pharmacies flourish and are long-lived. *Journal of Medical Internet Research*, *15*(9), e199. doi:10.2196/jmir.2606

Ganslandt, M., & Maskus, K. E. (2004). Parallel imports and the pricing of pharmaceutical products: evidence from the European Union. *Journal of Health Economics*, *23*(5), 1035–1057. doi:10.1016/j.jhealeco.2004.03.005

Goodman, B. (2014). Use time with your doctor wisely. Retrieved November 4, 2014, from www.arthritistoday.org/arthritis-treatment/getting-medical-care/your-role-as-a-patient/doctors-appointment-challenge.php

Gurau, C. (2005). Pharmaceutical marketing on the internet: marketing techniques and customer profile. *Journal of Consumer Marketing*, *22*(7), 421–428. doi:10.1108/07363760510631165

Gureje, O., Simon, G. E., Ustun, T. B., & Goldberg, D. P. (1997). Somatization in cross-cultural perspective: a World Health Organization study in primary care. *The American Journal of Psychiatry*, *154*(7), 989–995.

Gureje, O., Von Korff, M., Simon, G. E., & Gater, R. (1998). Persistent pain and well-being: a World Health Organization study in primary care. *Journal of the American Medical Association*, *280*(2), 147–151. doi:10.1001/jama.280.2.147

Health Protection Agency. (2011). Over half of people expect antibiotics for cold symptoms. Retrieved November 7, 2014, from www.pharmaceutical-journal.com/news-and-analysis/news/over-half-of-people-expect-antibiotics-for-cold-symptoms/11089602.article

Hjelmsoe, M. (2014). Why bigger isn't always better when it comes to big data in healthcare. Retrieved November 4, 2014, from http://medcitynews.com/2014/02/bigger-isnt-always-better-comes-healthcare-industrys-use-big-data/

Hudson, S. A., McAnaw, J. J., & Johnson, B. J. (2007). The changing roles of pharmacists in society. *International e-Journal of Science, Medicine & Education*, *1*(1), 22–34.

Hustad, T. P., Courtney, A. E., & Heeler, R. M. (1979). An emerging model for purchase and consumption of non-prescription drugs. *Journal of Consumer Affairs*, *13*(1), 86–98. doi:10.1111/j.1745-6606.1979.tb00130.x

Hutton, G., & Fosdick, M. (2011). The globalization of social media: consumer relationships with brands evolve in the digital space. *Journal of Advertising Research*, *51*(4), 566–570.

InterNations. (2014). Going to see a doctor in Germany. Retrieved November 4, 2014, from www.internations.org//germany-expats/guide/15986-health-insurance/going-to-see-a-doctor-in-germany-15995

Katsanis, L. P., & Maddox, L. (2010). Social media (Web 2.0) to physicians: current methods and their future in the EU. *The American Academy of Advertising 2010 European Conference*. Milan, June 4–6, 2010.

Keselman, A., Logan, R., Smith, C. A., Leroy, G., & Zeng-Treitler, Q. (2008). Developing informatics tools and strategies for consumer-centered health communication. *Journal of the American Medical Informatics Association*, *15*(4), 473–483. doi:10.1197/jamia.M2744

Krishna, R., & Whalen, J. (2013). Novartis loses Glivec patent battle in India. *Wall Street Journal*. Retrieved November 4, 2014, from http://online.wsj.com/articles/SB10001424127887323296504578395672582230106

Krishnaswamy, K., & Kumar, B. D. (2010). *Drug consumption pattern in urban and rural areas of India and their health implications*. Retrieved from www.healthpolicy.cn/rdfx/jbywzd/gjjy2/yd/yjwx/201002/P020100227570971897892.pdf

LaMattina, J. (2014). If big pharma ignores antibacterial R&D, where will we get the drugs to treat Superbugs? *Forbes*. Retrieved November 4, 2014, from www.forbes.com/sites/johnlamattina/2014/07/11/if-big-pharma-ignores-antibacterial-rd-where-will-we-get-the-drugs-to-treat-superbugs/

Landro, L. (2012). The pharmacist is in and nudging you to take your pills. *Wall Street Journal*. Retrieved November 4, 2014, from http://online.wsj.com/news/articles/SB10001424052702304765304577483033614613256

Lee, E. (2013). 5 ways technology is transforming health care. *Forbes*. Retrieved November 4, 2014, from www.forbes.com/sites/bmoharrisbank/2013/01/24/5-ways-technology-is-transforming-health-care/

Ljunggren, D. (2012). Canada's Supreme Court strips Viagra patent from Pfizer. *Reuters*. Ottawa. Retrieved from www.reuters.com/article/2012/11/08/us-viagra-idUSBRE8A70XG20121108

Lober, W. B., & Flowers, J. L. (2011). Consumer empowerment in health care amid the internet and social media. *Seminars in Oncology Nursing*, *27*(3), 169–182. doi:10.1016/j.soncn.2011.04.002

Lutz, E. M., Rovers, J., Mattingly, J., & Reed, B. N. (2009). Pharmacy practice around the world. *Journal of the American Pharmacists Association*, *49*(1), 4–10. doi:10.1331/JAPhA.2009.09500

Manhattan Research. (2012). New study shows 72 percent of European online consumers are social health users. Retrieved November 4, 2014, from http://manhattanresearch.com/News-and-Events/Press-Releases/european-social-health-users

Maynard, A., & Bloor, K. (2003). Dilemmas in regulation of the market for pharmaceuticals. *Health Affairs*, *22*(3), 31–41. doi:10.1377/hlthaff.22.3.31

Mellor, P., & Green, S. (2002). A novel approach to modelling the prescribing decision, integrating physician and patient influences. *International Journal of Market Research*, *Fourth Quarter*, 44, 449–491. Retrieved November 4, 2014, from www.highbeam.com/doc/1G1–94158838.html

Mil, J. W. F. van, Schulz, M., & Tromp, T. F. J. D. (2004). Pharmaceutical care, European developments in concepts, implementation, teaching, and research: a review. *Pharmacy World and Science*, *26*(6), 303–311. doi:10.1007/s11096-004-2849-0

Mintzes, B., Barer, M. L., Kravitz, R. L., Bassett, K., Lexchin, J., Kazanjian, A., & Marion, S. A. (2003). How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *Canadian Medical Association Journal*, *169*(5), 405–412.

mmm-online.com. (2014). Patient access: the latest insights, innovations and intel on the state of patient access. Retrieved November 4, 2014, from http://forms.mmm-online.com/patient-access-ebook/

Mossialos, E., Naci, H., & Courtin, E. (2013). Towards an expanded role for community pharmacists? *Health and Social Care*. Retrieved November 4, 2014, from http://blogs.lse.ac.uk/healthandsocialcare/2013/07/25/towards-an-expanded-role-for-community-pharmacists/

Mysak, T. M., Rodrigue, C., & Xu, J. (2010). Care providers' satisfaction with restructured clinical pharmacy services in a tertiary care teaching hospital. *The Canadian Journal of Hospital Pharmacy*, *63*(2), 105–112.

O'Connor, L. (2010). What pharma needs to know about M-Health. *PharmaExec.com*. Retrieved November 4, 2014, from www.pharmexec.com/pharmexec/author/authorDetail.jsp?id=38821

Park, A. (2013). Top 10 medical breakthroughs. *Time*. Retrieved November 4, 2014, from http://healthland.time.com/2013/12/04/health-and-society/slide/top-10-medical-breakthroughs/

Pew. (2014). Health fact sheet. Retrieved November 4, 2014, from www.pewinternet.org/fact-sheets/health-fact-sheet/

PM Live. (2012). Doctors in BRIC countries more likely to use social media than those in Europe. Retrieved November 5, 2014, from www.pmlive.com/blogs/digital_intelligence/archive/2012/jun_2012/doctors_emerging_markets_europe_usa_japan_social_media_use

Rao, S.K. (2012). Generating growth through patient-centered commercial strategies. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *12*(4), 229–239. doi:10.1177/1745790412450170

Reinstein, J.A. (1996). Marketing medicines for self-medication. *Journal of Pharmaceutical Marketing & Management*, *10*(2–3), 31–38. doi:10.3109/J058v10n02_04

Roane, K.R. (2011). Generics' new legal attack: big pharma's aging patents, *Fortune*. Retrieved November 4, 2014, from http://archive.fortune.com/2011/03/11/news/companies/big_pharma_lawsuits.fortune/index.htm

Ross, J., Beath, C., & Quaadgras, A. (2013). You may not need Big Data after all. Retrieved November 4, 2014, from http://hbr.org/2013/12/you-may-not-need-big-data-after-all/ar/1

Saboo, A. (2012). Top 15 drug patent losses for 2013. Retrieved November 5, 2014, from www.fiercepharma.com/special-reports/top-15-patent-expirations-2013

Smith, M.C. (1991). *Pharmaceutical Marketing: Strategy and Cases*. New York: Informa Healthcare.

Staton, T. (2014). Big data's double-edged sword: better drug marketing, bigger SG&A cost cuts. Retrieved November 4, 2014, from www.fiercepharma.com/story/big-datas-double-edged-sword-better-drug-marketing-bigger-sga-cost-cuts/2014–03–12

Su, L., Li, T., Hu, Y., & Chen, J. (2013). Factor analysis on marketing mix of online pharmacies – based on the online pharmacies in China. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *13*(2), 93–101. doi:10.1177/1745790413488778

Tabenkin, H., Goodwin, M.A., Zyzanski, S.J., Stange, K.C., & Medalie, J.H. (2004). Gender differences in time spent during direct observation of doctor–patient encounters. *Journal of Women's Health (2002)*, *13*(3), 341–349. doi:10.1089/154099904323016509

The Lancet. (2012). Counterfeit drugs: a growing global threat. *The Lancet*, *379*(9817), 685. doi:10.1016/S0140-6736(12)60289-X

The Royal Pharmaceutical Society England. (2013). New models of pharmacy: what is emerging and what is possible. A review of the literature. Retrieved November 4, 2014, from www.rpharms.com/promoting-pharmacy-pdfs/new-models-of-pharmacy-literature-review.pdf

Thongruang, C. (2008). Consumer purchasing behavior for herbal medicine in drugstore in Bangkok. *Naresuan University Journal*, *16*(3), 195–202.

Tonna, A.P., Stewart, D., & McCaig, D. (2008). An international overview of some pharmacist prescribing models. *Journal of the Malta College of Pharmacy Practice*, *14*, 20–26.

United Nations. (2013). World population aging. Retrieved November 4, 2014, from www.un.org/en/development/desa/population/publications/pdf/ageing/WorldPopulationAgeing2013.pdf

Wertheimer, A.I. (1996). Pharmaceutical marketing in lesser developed countries. *Journal of Pharmaceutical Marketing & Management*, *10*(2–3), 195–205. doi:10.3109/J058v10n02_13

WHO. (2000). Essential medicines and health products information portal: a World Health Organization resource. World Health Organization. Retrieved from http://apps.who.int/medicinedocs/en/d/Jh2963e/11.3.html

WHO. (2002). WHO | WHO launches the first global strategy on traditional and alternative medicine. World Health Organization. Retrieved November 4, 2014, from www.who.int/mediacentre/news/releases/release38/en/

WHO. (2014). WHO | The top 10 causes of death. World Health Organization. Retrieved from www.who.int/mediacentre/factsheets/fs310/en/

WTO. (2014). Overview: the TRIPS agreement. Retrieved November 4, 2014, from www.wto.org/english/tratop_e/trips_e/intel2_e.htm

Yahoo Finance. (2013). Teva settles Viagra® patent litigation with Pfizer. Retrieved November 5, 2014, from http://finance.yahoo.com/news/teva-settles-viagra-patent-litigation-213500085.html

You, J.H., Wong, F.Y., Chan, F.W., Wong, E.L., & Yeoh, E. (2011). Public perception on the role of community pharmacists in self-medication and self-care in Hong Kong. *BMC Pharmacology and Toxicology*, *11*(1), 19. doi:10.1186/1472–6904–11–19

Zhang, S. (2014). Big pharma plus big data could equal big savings. Retrieved November 4, 2014, from http://news.medill.northwestern.edu/chicago/news.aspx?id=228875

3 Global Health Care Systems and Market Access

Variations on a Theme

One of the most important issues from both a public policy and patient perspective is that of access to health care—who receives these goods and services and who pays for them, and how health care providers at all levels are paid for the delivery of their services. It is critical for marketers to understand how access to health care and pricing reimbursement policies affect their marketing programs. If the cost of a drug is not reimbursed by government and private payers, the choice of marketing strategies becomes very limited.

Until 2013, the US was the only country among the developed nations that did not provide some form of universal health care (True Cost, 2009). With the US Supreme Court decision in 2013 upholding the Affordable Care Act (and not without continuing controversy), the US now provides mandated health insurance benefits to its citizens. However, universal health care is not the same from country to country, and while similar models of care may be used to deliver health care services, they are delivered differently (or in some parts of the world, not delivered well or at all). It should be noted at the outset that all citizens pay for their health care directly or indirectly, whether through government taxation, payments to private providers, or some combination of the two. In fact, the research to be presented here suggests that some systems with single government payers are less costly to the patient and demonstrate greater patient satisfaction than those that rely on private systems.

In addition to health care services provided by physicians, the reimbursement of prescription drug costs to patients is also important from a regulatory perspective and is part of a process known as market access. This process is multifaceted and involves multiple departments within pharmaceutical companies; it also includes both government payers and private insurance companies (also known as third-party payers). The elements of this process include pricing and reimbursement; government affairs; health care economics and outcomes research; key account management; and the analysis of 'real world evidence.' A description of these elements appears later.

The government affairs function involves liaising with the government agencies and payers in different countries and may contain a lobbying component. This lobbying may be either to governments, private payer organizations, or through the recruitment of patient advocate groups which push for a drug's reimbursement in the treatment of a particular disease. Health care economics and outcomes research is tasked with showing that a particular drug therapy has value vis-à-vis its cost effectiveness: in other words, whether or not the drug saves money and provides similar efficacy at the same or lower cost as existing therapy; or, if it represents a significant breakthrough and a higher price can be justified. Outcomes analysis of 'real world evidence' is the effort to examine therapeutic trends based on the collection of patient data to show that a particular drug is worth the expenditure based on its effectiveness in a given patient population. Account management for

payers has become a critical part of the market access process, because these payers are important customers to the pharmaceutical industry; their needs must be addressed face-to-face by account representatives. Account management includes strategy development by specialist teams that consist of marketing, government affairs, and R&D, as well as the day-to-day management of specific payer accounts. Finally, pricing and reimbursement includes the development of appropriate pricing strategies to ensure patient reimbursement and the negotiation of specific contracts with payers for a price they are willing to pay.

How is this complex activity managed within the firm? Due to its multifunctional nature, different departments within a firm are involved with market access activities that include but are not restricted to R&D, marketing, and government affairs. However, specialized individuals within the firm handle the day-to-day activities associated with market access: Forcellina and Akannac (2013) reported that 69 percent of these professionals have an average of 12 years' work experience in this field. Payers comprise one of the key customer groups in the 4Ps of pharmaceutical marketing (physicians, patients, pharmacists, and payers), and therefore require a dedicated effort on the part of the firm. Essential in-depth training for those in market access includes negotiating contracts, understanding different reimbursement systems, and their requirements for both private payers and government payers, as well as the ability to communicate these requirements to the appropriate departments within the firm.

Further, market access differs from country to country. The approval of the payment for a drug will depend on the type of health care system in place and the methodology that is used by the particular organization to calculate the price they are willing to pay for a particular drug. The payer may be a government operating through an agency (single payer) that establishes and maintains an approved list of drugs or a drug formulary that contains drugs that are 'reimbursable' through the system. Another alternative is that of a third-party payer, such as a private insurance company, which also establishes and maintains a list of 'reimbursable' drugs and determines the drugs for which it will pay. This third-party payer system is usually combined with some form of universal health care.

Historically, it was a fairly straightforward process for a drug to reach the market. A new drug application would be submitted to a country's regulatory drug agency and once approved the drug would simply be available for sale. The current system of drug approval combined with pricing approval before a drug goes to market is the norm in many countries.

This chapter will focus on the pricing and reimbursement aspects of market access: a firm's ability to obtain the listing of their drugs on the approved drug list or formulary that allows patient access. Without drug listings in markets where it is required, it is extremely difficult to market new therapies, particularly those that carry high prices. There is tremendous downward pressure on prices as a result of the current demographics, the introduction of costly niche biologic drugs, and finally, a limit on how much income tax to cover health care costs can be levied on citizens in a public, single payer health system. There is also pressure on private payers, as there is equally a limit to the amount of money a plan participant is willing to pay (what is called co-pay—the portion that is paid by both the patient and the insurer). The utilization of all drug reimbursement systems is increasing and payers must determine how they will pay for this additional utilization.

This discussion provides a single source that brings together the available research and data on this subject. It is worth noting that the availability of sources is limited and specific information is not available for all countries. A case study of the Canadian health care system is provided as an example of universal health care combined with both public and private drug reimbursement because it combines almost all elements of drug pricing and reimbursement used in many countries with the exception of the US. It is important to examine the effects of these systems on patients and whether or not they get the quality of care they require.

Marketers must be well-versed about market access and health care systems in other countries, particularly those in non-Western markets. Simply put, the future in pharmaceutical marketing is no longer in the traditional Western markets. Countries in emerging markets, such as India and China, have differing ideas of what constitutes appropriate pricing policy, and Western countries, particularly those in the EU, already have highly developed market access systems. The pricing component of the marketing mix is one of the most important decisions a firm will make, as this key part of the marketing mix is highly influenced and in some cases solely determined by government agencies. Further, public and private payers are not just gatekeepers, but customers. They must be convinced of a drug's value, from a therapeutic and price perspective, and typically, this task requires marketer input in conjunction with market access experts. The pricing strategy of Gilead's Sovaldi as presented in this chapter may be a harbinger of things to come not only in the US market with respect to free market prices for health care and prescription drugs, but also in Europe and elsewhere: there are changing power relationships between the pharmaceutical industry and insurance payers, as well as increasing pressure from patients and their physicians to make prescription drugs more affordable.

Global Health Care Systems

No health system in any country follows one specific model in lock-step fashion; in fact, systems vary from country to country. However, they tend to fall into three general categories: single payer systems, two-tier systems, and those with an insurance mandate. In a single payer system, the payer is the government. They provide basic health care coverage which is sometimes augmented by public or private insurance for non-basic services. In a two-tier system, the government mandates a minimum level of coverage for its citizens, while allowing for voluntary insurance to cover extra expenses. Finally, in an insurance mandated system, all citizens must buy health insurance from a variety of sources that include public, private, or non-profit insurers. Under this system, no individual may be refused insurance because they have a pre-existing illness, and the system works because of high levels of participation. Table 3.1 provides a list of countries with the type of health care system they use. All health care systems have some protections in varying degrees for low income, the elderly, the disabled, and children.

Table 3.1 Global Health Care Systems

Single Payer		*Two-Tier*	*Insurance Mandate*
Bahrain	Norway	Australia	Austria
Brunei	Portugal	Denmark	Belgium
Canada	Slovenia	France	Germany
Cyprus	Spain	Hong Kong	Greece
Finland	Sweden	Ireland	Luxembourg
Iceland	United Arab Emirates	Israel	South Korea
Italy	United Kingdom	Netherlands	Switzerland
Japan		New Zealand	United States
Kuwait		Singapore	

Source: Adapted from True Cost, 2009

Physicians are paid for their services in a variety of ways. For example, Charlesworth et al. (2012) provide an excellent overview of the different types of payment structures in Europe which include: fee for service, capitation, and/or global budget, which include physician salaries. However, these fee structures are not limited to Europe, and are discussed in general here as they apply to systems in other countries. These methods are sometimes combined together in a 'bundled' payment system to health care providers, the most common of which is the combination of fee for service and capitation (Charlesworth et al., 2012), also called a diagnosis-related group (DRG) based payment.

A fee for service is simply that—a physician is paid each time they see a patient and deliver a service to that patient, and the payment is based on the volume of patients seen by that physician. A capitation payment is a fixed payment for each patient in the physician's practice, and covers a limited period of time. Whelan and Feder (2009) suggest that this gives the providers more flexibility in meeting the needs of their patients. Finally, the global budget is a lump sum that is paid to the physician and is not related to the number of patients they see (it also includes their salary). It is up to the individual physician to take that payment and use the money to manage their practice as they see fit.

Specific Health Care Systems

Information is provided below for the different systems used in specific countries. (Table 3.2 illustrates the information for Europe, Scandinavia, the Commonwealth countries, Japan, and the US.) As mentioned earlier, some systems include a mix of public and private services.

Europe

In Europe, there are different systems in each country and they range from a national health service in the UK to a statutory health insurance system in France (there is no single EU system in place at the present time) (Thomson et al., 2011). Payment for these services combines both public system financing and private insurance. There are several national bodies that provide advice on the effectiveness of health care delivery and how it can be improved that informs these P4P (pay for performance) programs: the National Institute for Health and Clinical Excellence (NICE) in the UK; the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) in Germany; and the Haute Authorité de Santé (HAS) in France (Charlesworth et al., 2012). (For a detailed history of the European health care system, see Mossialos et al., 1997.)

In addition to other types of payments, the Netherlands uses episode-based payments (Crosson et al., 2009). These are intended to cover the cost of services for a particular and ongoing problem. For example, if a patient needs a hip replacement, it covers the outpatient care, the surgery and hospital stay, as well as the necessary rehabilitation. It is seen as a way to predict what costs will be incurred for a particular health 'episode,' in order to potentially reduce these costs.

A new payment twist that has been introduced in several European countries is known as P4P: pay for performance. The purpose of this initiative is to tie a bonus payment to a specific aspect of a physician's performance, such as quality of care. These initiatives include incentives that are based on quality of care, meeting budget objectives, rewarding excellent performance, and as a bonus over the normal funding provided to the physician: the United Kingdom and France have the largest P4P systems (Charlesworth et al., 2012).

Patient registration with a GP is generally not required in Europe with the exception of the UK, Italy, and the Netherlands, and gatekeeping (access to specialists) is common in the region (Thomson et al., 2011).

Table 3.2 Public and Private Health Care Funding

Country	*Private Insurance*	*Public Funding*
Australia	50 percent buy coverage for access to private facilities and extra benefits	Regionally administered universal public insurance program (Medicare)
Canada	67 percent buy coverage for extra benefits	Regionally administered universal public insurance program (Medicare)
Denmark	40 percent buy coverage for cost-sharing, extra benefits, or access to private facilities	National health service
France	90 percent buy coverage for cost-sharing; some extra benefits	Statutory health insurance system, with all SHI insurers incorporated into single national union
Germany	Cost-sharing + amenities (20 percent); substitute: 10 percent opt-out of SHI system for private coverage only	Statutory health insurance system, with 180 competing SHI insurers ('sickness funds'); high income can opt-out for private coverage
Italy	15 percent buy coverage for access to private facilities and amenities	National health service
Japan	Majority buy coverage for cash benefits/cost-sharing	Statutory health insurance system, with 3,500+ non-competing public, quasi-public, and employer-based insurers
Netherlands	Private plans provide universal core benefits; 80 percent buy extra benefits	Statutory health insurance system, with universally mandated private insurance (national exchange)
New Zealand	33 percent buy for cost-sharing, access to specialists, and elective surgery in private hospitals	National health service
Norway	5 percent buy for private facilities	National health service
Sweden	5 percent buy for private facilities	National health service
Switzerland	Private plans provide universal core benefits; 70 percent buy extra benefits or amenities	Statutory health insurance system, with universally mandated private insurance (regional exchanges)
United Kingdom	10 percent buy private facilities	National health service
United States	Primary private insurance covers 56 percent of population (employer-based and individual); supplementary for Medicare	Medicare: age 65+, some disabled; Medicaid: some low income (most under age 65 covered by private insurance; 16 percent of population uninsured)

Source: Adapted from Thomson et al., 2011

Scandinavia

Denmark, Norway, and Sweden all have a national health service which is funded through either general tax revenue or earmarked income tax, with different levels of cost sharing for extra benefits, such as private facilities. Provider ownership is private or mixed, with a mix of fee for service and capitation as described above, and gatekeeping is common throughout the region (Thomson et al., 2011).

Commonwealth Countries (Canada, Australia, and New Zealand)

Canada and Australia utilize a regionally administered universal public insurance program, while New Zealand offers a national health service. There is availability in all systems for the purchase of extra coverage for private facilities and other health benefits in all countries. Fee for service is common, with some capitation in New Zealand. Gatekeeping is present in all countries.

Japan

Japan has a statutory health insurance system, with cost sharing for extra benefits. The system operates on fee for service and DRG, with no GP registration required or gatekeeping to specialists (Thomson et al., 2011).

Russia

In 1998, Russia implemented a single payer system that in theory covers the delivery of medical care and disease prevention and employs a budget/insurance model to finance the system (Davydov & Shepin, 2010). However, Russia is unable to provide its citizens with acceptable levels of health care due to lack of funding, availability of equipment and supplies, and inability to deliver services efficiently (Rozenfeld, 2014). Farmer et al. (2003) report that utilization of health care services is three times greater than that of Western Europe and North America, with patients seeing a physician an average of ten times a year. They describe the Russian health care system as comprised of polyclinics, which are large outpatient facilities. They further describe these organizations as fragmented with physicians focused on the treatment of a single disease. While access to a physician is free, there are reports in the press of unofficial and ad-hoc fees for service paid to nurses and physicians in order to receive access to care and better service, as well as patients supplying their own gauze and bandages (Masterova, 2011; Vasilyeva, 2012).

China

The Chinese health care system consists of a combination of public and private health coverage for its citizens. Urban Employee Basic Medical Insurance (UEBMI) is mandatory basic health insurance for those who live in urban areas, and is funded by the employers and employees. Urban Resident Basic Medical Insurance (URBMI) is a voluntary health insurance for those not eligible for UEBMI and is funded by both the government and individuals. Finally, the New Rural Cooperative Medical System (NRCMS) is voluntary insurance that covers rural residents, and is funded by both the government and individuals. Almost 90 percent of the population is now covered by one of these plans (Sussmuth-Dyerhoff & Wang, 2010).

India

India has two health care programs: the National Rural Health Mission (NRHM) and the Rashtriya Swasthya Bima Yojana (RSBY) (http://mohfw.nic.in/). The NRHM is managed by the Ministry of Health and Family Welfare, while the RSBY is a program managed by the Ministry of Labor and Employment. In most parts of India, RSBY covers health care for specific services for those who are classified as poor; the objective of the NRHM is to provide access to specific services. Health care in India covers a wide variety of diseases or specific individuals or particular groups (e.g. children)—it is extremely heterogeneous in both structure and

the way services are delivered (Singh, 2008). Luthra (2012) reports that Indians are likely to seek care from private health providers because the state of the public health care facilities suffers from a shortage of both supplies and staff. Further, physicians have both public and private practices, and the emphasis on private providers often results in a shortfall of available treatment in the public sector. The quality of health care varies as the system is unregulated and financed by individual payments to health care providers.

Brazil

Health care in Brazil has three components: the public subsector (called SUS), the private (both profit and not-for-profit) subsector, and the private health insurance subsector. While they are distinct, they are also interconnected and available to all citizens based on their ability to pay (Paim et al., 2011). The system is financed through income taxes, individual patient fees, and employer health care programs. Primary health care is intended to be universal, while secondary and tertiary care tends to be utilized by those with private health plans.

The United States

The health care system in the US has traditionally been and is primarily still private for most citizens. Private health insurance covers the majority of the population (employer based or individual coverage), with the exception of low income, the elderly, and some disabled citizens (who are publicly funded). Payroll taxes, federal taxes, and state tax revenues cover the costs of the public system financing. Physicians are paid using fee for service with some capitation in private plans, and there is some gatekeeping to specialists within certain payer programs (Thomson et al., 2011). However, with the passage of the Affordable Care Act (ACA), the US system now has health insurance for the public that is available through the federal government, but in a somewhat different way from the other countries discussed earlier.

While the private system still dominates the US landscape, under the ACA, the US public system is now called an 'insurance marketplace,' where citizens who previously could not get health care coverage from private carriers may register for health care coverage, compare different plans, and then enrol in a plan that is suitable. The plan covers medical care and prescription medications. Generally, no individual can be refused coverage for pre-existing conditions and no lifetime limits on coverage may be imposed. It is also meant to cover the gap in medication coverage for seniors on Medicare Part D (privately administered plans). The ACA is being implemented over several years, with 2015 as the final year by which all elements of the plan are to be implemented. This final stage will include the payment of physicians based on the quality of care they provide rather than the number of patients (the complete source for this information is available at the US Health and Human Services website for those who want further information).

Private Health Care Services

The use of private health care insurance is common in Western countries and increasing but still limited in its use in non-Western countries. According to Drechsler and Jutting (2005): "Measured in premium volume, the insurance industry in developing countries grew more than twice as fast as in industrialized countries" (p. 2), and "out of pocket insurance payments account for one third of total health expenditure in two thirds of all low-income countries" (p. 1). They cite the following reasons for this situation: growing dissatisfaction with the public system; increased availability of international health services; and greater consumer demand led by

Table 3.3 Top Ten Global Health Insurers

Company (in rank order)
Zurich Insurance Group
Express Scripts
United Healthcare
Aviva
Axa
Blue Cross Blue Shield
Aetna Foundation
AIA Insurance Group
Allianz
Humana

Source: Adapted from Healthcare Global, 2014

economic growth. The authors suggest that the role of private insurance in regions such as South America and East Asia may include its delivery by non-governmental organizations (NGOs) that operate in a given region or the offering of group plans that cover specific groups of individuals, similar to that of group health plans in Western countries. A list of the top global health insurers appears as Table 3.3; these companies provide services that range from comprehensive employee health insurance (that includes reimbursement for drugs) to the administration of Medicare programs in the US (Healthcare Global, 2014).

Global Citizen Satisfaction with their Health Care

It has been reported that many citizens worldwide are generally dissatisfied with their health care. Adams et al. (2008) suggest that the US has the lowest level of satisfaction with its health care services despite the highest health care spend as a percentage of GDP (approximately 17 percent), while the Netherlands has the highest level of satisfaction with its health care services, at approximately 8 percent of health care expenditure as a percentage of GDP. Thomson et al. (2011) confirm these findings and report that only 29 percent of US citizens view their health care system as working well and needing only minor changes, compared to 62 percent of UK citizens, who believe the same about their system. In the Thomson et al. (2011) study, the US was ranked next to last in citizen satisfaction with their health care system, with Australia ranked last.

Pricing Regulation and Drug Reimbursement Policies

It is useful to begin this section with a brief explanation of how multinational firms determine the price for a drug. The multinational pricing system is based on what is known as transfer pricing. Each subsidiary (local operation) within the company is assigned a transfer price. This price reflects the actual manufacturing cost of the drug, as well as R&D and other expenses that are used to calculate these costs. It also reflects current or forecasted exchange rates and tax laws, and subsidiaries are charged different transfer prices based on where it is most advantageous to the firm to assign its costs. In other words, some local operations will have lower transfer prices and others will have higher transfer prices. These transfer prices take into account parallel imports, so that countries where lower prices prevail will not be likely to sell drugs

to countries where higher prices for these drugs are in place. In addition, the determination of drug costs is a source of controversy, as some experts claim that these are highly inflated (see Goozner, 2005, for an in-depth discussion of drug costs).

Most countries have some form of pricing regulation for both new therapeutic compounds and generic drugs. Drug reimbursement to patients for the cost of their medication may vary by sector (i.e. hospital, pharmacy, and government/public programs) in systems that utilize either universal care or a two-tier care system. In a private system, an insurer may also have an authorized price list for both patented and generic drugs; the maximum price the insurer will pay the patient is usually negotiated between the insurer and the pharmaceutical company. In the case of a universal care or two-tier system, if a pharmaceutical company wants to sell a drug, it must submit an application to the appropriate pricing agency in that country and one of four methods may be applied to determine the final price of the drug: a price cap (used for generic drugs); internal reference pricing (for generic drugs); external reference pricing (for patented drugs); and negotiated price volume agreements (usually, but not always, for patented drugs). Some countries may use a range of different methods; however, the purpose of all methods is to both reduce and contain the cost of drugs. Even in the US, the Medicaid and Medicare public programs utilize drug reimbursement lists for the elderly, disabled, and indigent, and Medicare Part D is administered by private payers. A list of agencies that manage drug reimbursement policies appears as Table 3.4.

Table 3.4 Selected Pricing Agencies by Country

Country	*Agency*	*Website Address (where available)*
Australia	The Schedule of Pharmaceutical Benefits Pharmaceutical Benefits Scheme (PBS)	www.pbs.gov.au/
Austria	The Austrian Health Institute (ÖBIG)	www.goeg.at/en/OEBIG-Tasks.html
Brazil	National Listing of Essential Medicines	
Canada	Patented Medicines Pricing	www.pmprb-cepmb.gc.ca/
	Review Board (PMPRB)	www.health.gov.on.ca/en/pro/ programs/drugs/
	Provincial Benefit Formulary/ Comparative Drug Index (Formulary/CDI)	
China	Essential Drug List (EDL)	
	National Reimbursement Drug List (NRDL)	
Denmark	The Danish Medicines Agency	http://sundhedsstyrelsen.dk/en
France	Transparency Committee	www.has-sante.fr/
	Health Care Pricing Committee	
Germany	Social Code Book V (SGB V)	www.gesetze-im-internet.de/sgb_5/
India	National Pharmaceutical Pricing Authority (NPPA)	www.nppaindia.nic.in/index1.html
Italy	Italian Medicine Agency	www.agenziafarmaco.com/en
Malaysia	The Drug Control Authority (DCA)	http://portal.bpfk.gov.my/
Netherlands	The Ministry of Health and Sport	www.government.nl/ministries/vws
New Zealand	The Pharmaceutical Management Agency (PHARMAC)	www.pharmac.health.nz/
Norway	The Norwegian Medicines Agency	www.legemiddelverket.no/english/

(*Continued*)

Table 3.4 (Continued)

Country	*Agency*	*Website Address (where available)*
Russia	Essential Drugs List	
Spain	Ministry of Health and Social Services	www.msssi.gob.es/
Sweden	Pharmaceutical Benefits Board (PBB)	
United Kingdom	Pharmaceutical Price Regulation Scheme (PPRS)	www.gov.uk/government/organisations/department-of-health
	British National Formulary	www.bnf.org/
United States	US Department of Veterans Affairs, Veterans Health Administration	www.va.gov/
	FSS (Federal Supply Schedule)	www.fss.va.gov/
	Medicaid	
	Medicare	

Source: Adapted from WHO, 2013

Private health care payers in the US and other countries (insurance companies that may also provide managed care services) also have their own reimbursement lists; for example, some payers will only pay for the lowest cost drug if a generic is available. Some pharmaceutical companies established PAPs—Patient Assistance Programs (Chauncey et al., 2006) to help cover the cost of prescription drug coverage for those without access. However, according to the authors, the effects of these programs were limited due to the complexity of the process; the physician paperwork was burdensome to the physician; and the plans only covered those without insurance or demonstrated financial need. With the introduction of the ACA, it is unclear what the future role will be for these PAPs.

Price Cap Regulation

Price cap regulation sets an absolute maximum price that the generic manufacturer may charge for a particular drug. A drug's price is normally determined by the average price in other countries, and is set either at a certain percentage below the innovator's price, a maximum price, or a negotiated price based on volume (Puig-Junoy, 2010). The purpose of this type of regulation is to ensure that there is no excessively high price charged for a particular generic drug. Internal reference pricing (also called price indexing) sets a maximum price that will be reimbursed for a particular group of generic drugs. The price is based either on price comparisons for the same drugs in other countries (thus the use of the term 'reference' or 'index'); or a simple percentage of the original cost of the branded drug; or the use of a reference price to calculate the percentage. This percentage may range from 30 to 80 percent of the originator's price.

Are internal reference pricing and price caps effective in reducing drug prices? Two recent research studies shed some light on this question: an empirical study by Brekke et al. (2009) and an in-depth literature review by Puig-Junoy (2010). The Brekke et al. (2009) study compared internal reference pricing to price capping using the 2003 Norwegian experience, when the country had transitioned from price capping to reference pricing. Their results suggested that reference pricing significantly reduced the price of generic drugs and is more effective than price capping. There is also what the authors call a 'cross-price' effect: in other words,

there is a strong and significant downward effect on patent protected products because generic therapeutic substitutes are often used instead of the brand name drug. The results of this study are also supported by Puig-Junoy (2010) in an in-depth review of 16 seminal studies on price capping and internal reference pricing.

External reference pricing (or international price comparison as it is also called) is typically used for patented drugs. The general principle behind this method of pricing is that a basket of countries with a similar economic background are used to calculate the benchmark price for a particular drug. However, in practice, the number of countries used as comparisons varies significantly; in the EU, it can range anywhere from under five to over 20 (Leopold et al., 2012). The most common methods used are either the lowest price in the comparison group, an average of prices in the group, or a weighted average of the prices in the group (Stargardt & Schreyögg, 2006). Under a negotiating price scenario, the final price will depend on the agreement reached between the company and the pricing agency responsible. India, for example, uses a combination of average price calculation and the establishment of a ceiling price for existing drugs depending on whether or not the specific drug faces competition. They also use a Standing Committee of Experts for final price determination (www.nppandia.nic.in/index1.html).

In an external reference or negotiated price environment, the guiding principle is the value attached to a particular drug. What does this mean in practice? While each country has its own criteria, there are several that are common to most systems. The most important factors are the degree of innovation and whether or not a significant improvement over existing therapy is realized. This is usually achieved through the presentation of pharmacoeconomic (outcomes) studies, in addition to clinical trials that compare the new drug to existing therapies already on the market. Many authorities are relying on evidence-based medicine (EBM) and health technology assessment (HTA) in making these value-based decisions. An interesting example of this requirement is presented by Remuzat et al. (2013) in their discussion of recent changes to the French drug regulations and their impact on market access. The French regulations have now changed so that a drug's efficacy is more important than the severity of the condition being treated. In addition, the criteria to show this efficacy have become more stringent and specify the use of comparative evidence and real world data—the inclusion of cost-effectiveness studies is now an official requirement for drug reimbursement in France.

What is the effect of the external reference pricing on actual drug prices? Stargardt and Schreyögg (2006) examined 15 EU countries to determine these effects, and their findings suggest that the impact of a price change is dependent on the method used to set the prices, but a reduction in one country's prices will be felt in the prices of another country in the comparison basket. The authors state that the results are likely to be viewed favorably by policy makers; however, one important negative implication is that companies will launch products strategically in order to delay launches in those countries with the lowest price. As this would have the untoward effect of raising prices, they further recommend a weighted average pricing policy. It is likely that both internal and external reference pricing will be used for some time to come.

As mentioned earlier, negotiated agreements are also common when a pharmaceutical company is attempting to obtain a listing for its brand. Jarosławski and Toumi (2011) identified and describe three kinds of market access agreements: commercial agreements (CAs), pay for performance (P4P) agreements, and coverage with evidence development (CED), and their findings will be summarized here. CAs focus on reducing the cost of expensive drugs for the payer without consideration of outcomes data in the patient population, and these agreements may be renegotiated at a future date. P4P agreements are based on the per-patient result; in other words, the drug must work in a particular way in a specific group of patients if it is to be reimbursed. Finally, CED agreements are limited in term and a particular drug undergoes regular reassessment to determine its cost-effectiveness.

China—An Example of Government Bidding

China is an interesting example of price capping and price negotiation and worthy of a separate discussion given the industry's interests in this important market. Gross (2013) briefly outlines the process and his account is summarized here. There are two phases of pricing and reimbursement in the Chinese system: retail price approval and provincial bidding. China has two drug lists: the Essential Drug List (EDL) and the Nationally Reimbursed Drug List (NRDL) (drugs included in Part A of the drug list are reimbursed at 100 percent and drugs in Part B are only partially reimbursed). The first phase, price setting (capping), is limited to the government (specifically, key government officials and pharmaceutical experts), and thus, pharmaceutical firms have no involvement in this part of the process. The second phase is the bidding process, in which pharmaceutical manufacturers are asked to submit their bids, and the award decision is made by a committee of government representatives (NRDL), local officials, and pharmacists. The award is then determined by the wholesale price proposed by the manufacturer.

Liang et al. (2006) suggest that drug prices in China are comparatively high (2.5 to ten times higher than other countries) for several reasons: 1) physicians earn revenue from their prescriptions so they have an incentive to prescribe expensive drugs and charge a high markup; 2) the relationship between physicians and patients tends to be long term, so revenue earning activity from pharmaceutical prescribing faces little competition; and 3) the common practice of drug sale kickbacks. This relatively high price is accompanied by the fact that medicine accounts for 43 percent of China's total health care expenditures (WHO, 2011). It was recently reported that China was dropping the price capping practice used for the EDL in order to ease drug shortages and to increase the number of low cost medicines; however, it is widely recognized that China faces a health care crisis and the government is struggling for solutions (China Economic Review, 2014).

Canada—An In-Depth Examination of Drug Reimbursement

The Canadian pharmaceutical pricing environment is complex because of multi-layered decision making at both the federal government level and the provincial level. Pricing regulation in Canada begins at the federal level and then continues at the provincial level. This process will be discussed in detail below.

Payment for drugs is made in three ways. Public drug plans at the provincial (local) level cover the elderly, disabled, and indigent. Private drug plans, normally administered by employers, cover these costs with a co-pay arrangement similar to that in the US (note that in the provinces of Quebec and British Columbia everyone is required to have prescription drug insurance if they are not covered under a private plan or by the provincial plan). There are also federal plans for special populations such as the military, and some provinces cover catastrophic care and care for special populations (AIDS). Finally, there is cash payment for those not covered by any plan.

There are three 'regulators' who determine drug prices: the Patented Medicine Prices Review Board (PMPRB) for patented drugs, the Common Drug Review (CDR) for both patented and generic drugs, and the Pan-Canadian Oncology Drug Review (pCODR) for cancer therapy.

For patented drugs, the first step in the pricing pathway is the PMPRB, a federal agency. Its mandate is to ensure that drug prices are not excessive, and in addition, it reports to the Canadian Parliament on R&D activities. The PMPRB sets a maximum price on the first sale of a new patented drug, and then price increases are limited for the life of the patented drug. There are different rules depending on whether a drug is a breakthrough drug; is one that shows substantial or moderate improvement; or is one with slight to no improvement to existing therapy. Breakthrough drugs are subject to an international median price test; while drugs of moderate to slight improvement will be capped at the maximum international price. Canada uses

seven countries (including the US) to define median and highest prices. If a drug is already on the market, the PMPRB will limit the increase to a CPI (consumer price index) adjustment (either a three-year cumulative inflation or one-year inflation, whichever is lower), or will cap the price of the drug at the maximum international price. The penalties are fairly severe for breaking the rules: a corporation may be fined up to $25,000 per day; or an individual fined at $5,000 per day or up to six months in prison. Honest errors are not penalized and firms are given up to a week to make corrections (information in this section was accessed from www.pmprb-cepmb.gc.ca/english/). Generic drug pricing is not covered by the PMPRB; policy for these drugs is undertaken at the provincial level.

The next step in the pricing process is obtaining reimbursement from both private and public payers. As mentioned earlier, drug costs are paid for either by public or private plans for the majority of the population. As a general rule, public plans are more restrictive and have guidelines based on cost-effectiveness or improved performance in the population. The guidelines for reimbursement also differ by province. Private plans tend to have a less rigorous policy, and reimburse most drugs for their plan subscribers; but some drugs, particularly expensive ones, may be listed with restrictions. However, the Canadian private insurance landscape is changing as these payers are becoming more cost conscious and either mandating generic substitution, managing the use of costly biologics, or requesting lower pricing through confidential pricing arrangements known as PLAs (Lussier, 2012).

Once a patented drug has cleared PMPRB, the next step is what is called Common Drug Review (CDR) (information referenced in this section can be accessed at www.cadth.ca/en/products/cdr/cdr-overview). All provinces with the exception of Quebec participate in this process. The purpose of the CDR is to assist the provinces in determining the price that a drug will be reimbursed for in their drug formulary by providing evidence-based information and advice. The CDR only reviews new chemical entities or new indications for existing drugs. The final decision to reimburse generic drugs and line extensions is always at the discretion of the individual provincial formulary board. What is interesting about the CDR is that it solicits patient input as part of its decision making process—patient groups (not individuals) are encouraged to provide their opinions and this input is systematically considered by the CDR.

Provincial drug plans have scientific review committees and plan administrators in place to evaluate product line extensions and generic drugs, and they determine whether or not to list a drug based on both its therapeutic value and whether or not the province can afford to pay for the drug. As mentioned earlier, a province may put limited use restrictions on particular drugs, or choose not to list them at all, particularly in the case of line extensions.

Oncology drugs are treated separately from others through pCODR (www.pcodr.ca/idc/groups/pcodr/documents/pcodrdocument/pcodr-funding-tutorial.pdf); however, the process is very similar to that used by the CDR and it liaises with the CDR to ensure consistency in the review process. As with other types of drugs, the final decision to reimburse is always left to the individual provinces. An additional layer of price review called the pan-Canadian Pharmaceutical Alliance (pCPA) was established in 2010 to provide coordination for the negotiation of drug prices across Canada (pan-Canadian Pharmaceutical Alliance, n.d.), and this exercises further downward pressure on branded prescription drugs.

The Price of Sovaldi—Case Study

Gilead's Sovaldi (sofobusvir), a new and novel drug to treat chronic hepatitis C, has generated both high praise for its therapeutic profile and severe criticism for its price: in the US it is set at $1,000 per dose, with a total cost of $84,000 in the US. The drug is viewed as a convenient cure for hepatitis C

when compared to other therapies; and Gilead claims Sovaldi will save thousands of dollars in long-term care for patients with the disease based on their outcomes studies (including liver transplants and other needed therapies).

Steve Miller, President of Express Scripts US (a pharmacy benefits management company), sharply criticized Gilead, and stated that "when you look at the price of many new products coming to the marketplace, it's just not going to be sustainable" and announced they would not pay for the therapy (King, 2013). Other payers began to balk as well, with announcements from the American Health Insurance Plans (AHIP) calling the price of Sovaldi "astronomical" and "not sustainable for consumers" (Staton, 2014a). This was followed by the formation of a coalition of employers, unions, and the AARP (American Association of Retired Persons), which called for a "national dialogue" on pharmaceutical pricing policy (Staton, 2014b). Some insurers are already rationing the use of Sovaldi for the sickest patients and it is also reported that Gilead is discreetly reimbursing patients for the drug's costs (Brennan & Shrank, 2014).

Fourteen European countries banded together to press Gilead for deep discounts on Sovaldi; the French health minister stated that without these price concessions, the use of the drug would be rationed (Palmer, 2014a; Palmer, 2014b). Miller (2014) reported that the cost of Sovaldi is US$67,000 in Germany and approximately US$55,000 in the UK and Canada; he called the pricing of Sovaldi "irrational" and stated that the US pricing of Sovaldi is "essentially a tax on Americans to defray the costs of treatment for the rest of the world" (Staton, 2014c). Médecins Sans Frontières supports the government of India's opposition to the Sovaldi patent with charges of "profiteering" by the company, and recommends the launch of the drug as a generic so it will be more widely available (Herper, 2013).

Three members of the US House of Representatives Energy and Commerce Committee demanded justification for the high price of Sovaldi, particularly when costs in Europe are much less (Sadeghi-Nejad, 2014). LaMattina (2014) posed the following question in his commentary on Sovaldi: "What price are you willing to pay for innovation?"

Is the real question what price are you willing to pay, or, what price can payers and patients afford to pay and are pharmaceutical companies willing to supply drugs at that price? There are different answers to that question depending on which stakeholder group you represent. For those who support Gilead's pricing policy, the arguments are as follows:

a) Without high prices (and resulting profits), R&D costs will not be recouped quickly and there will be no incentives for companies to engage in innovative research.
b) Companies should be rewarded for innovation with prices that match what the market will bear and with a patent that grants a market monopoly.
c) Investors deserve the maximum return on their investments and public companies have a fiduciary responsibility to guarantee those returns to their shareholders.
d) Lifesaving drugs that will save money in the long term are worth the cost of those drugs today.

Those who oppose Gilead's pricing policy have differing views:

a) Payment for other important therapies may be reduced or rationed because payers may not be willing to pay and patients may not be able to pay (Brennan & Shrank, 2014).
b) Patients and payers ask why the price of the medication is so high when the manufacturing cost for Sovaldi is $130 (Miller, 2014).

c) It is inappropriate to price a drug based on future cost savings when these costs have not yet been incurred.
d) Angell (2008) stated that "the few innovative drugs that do enter the market are usually based on publicly-funded research conducted in university or government labs all over the world" (p. 17): in other words, some of these highly priced drugs have already been paid for with public funds. It is likely that university researchers will continue to conduct innovative research funded by public grants whether or not they receive outside compensation for this work.

A recent study by Ernst & Young (Reuters, 2014) may also shed some light on the Sovaldi pricing controversy and the two different perspectives discussed above. Its study compared the views of 60 payers in the US and Europe to 18 pharmaceutical companies in order to determine their understanding of their needs and attitudes. The findings suggest that for payers, cost containment, the ability to plan budgets, and comparative clinical trial data are the most critical issues and rank above outcomes study results. Payers also believe that drugs have the greatest effect on the increase in health care costs. In contrast, pharmaceutical companies increasingly seek to use what are called 'beyond the pill' services (drug adherence) and continue to use placebo-based trials to demonstrate a drug's therapeutic value for outcomes studies. However, payers do not trust pharmaceutical companies to use outcomes data in an unbiased way (43 percent of respondents) and believe this data is not credible either for measuring or improving patient outcomes. Until this disconnect is resolved, there will be continued controversy about the reimbursement of drugs, particularly expensive ones such as Sovaldi.

Access to Essential Drugs

The debate on prescription drug pricing will continue, whether it is Sovaldi or other new therapies yet to be launched. However, while some argue about expensive therapies, others are concerned about the availability of essential medicines, particularly in light of recent drug shortages that threaten to endanger the lives of many.

A recent WHO (2013) report defines market access differently from the pharmaceutical industry: "Access is defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population" (p. 36). Its research suggests that the availability of public sector medication in developing countries is low—the average was 34.9 percent. Many of the drugs needed in these countries are essential medications such as antibiotics or treatment for diseases endemic to these countries such as tuberculosis and malaria. An element compounding this problem is that when these essential medicines are not available in the public system, they must be purchased in the private sector at much higher prices. The WHO also found "[I]n the 33 developing countries for which data are available, that even generic medicines cost over six times the international reference prices in the private sector" (p. 38).

Kamtekar (2004) argues that lifesaving drugs should be treated as public goods and develops two interesting arguments to support her view: a benefit argument and a moral argument. Her benefit argument states that because developing countries have had no participation in the development of intellectual property laws, they have had little say in what therapies are targeted for research. Therefore, many of the drugs marketed by global pharmaceutical firms do not meet their specific needs. Her moral argument counters the traditional view that an individual (or corporation) owns its property: you may contribute the labor but if the good is available in nature, you do not have the right to own it: in other words, she states that one has "the power to share [what you make] or not, but that power and right are not the same thing."

While Kamtekar's (2004) views may appear to be simply philosophical, they are discussed by policy makers in the BRIC countries on a daily basis. The pharmaceutical industry must be cognizant of these philosophical differences, particularly those regarding private versus public property.

Implications and Conclusions

It is important for marketers to understand the different health care systems in use globally and how the philosophies of these systems dictate public health care policy, particularly in the area of pricing and drug reimbursement. Pricing is and will remain one of the most critical elements that determines market performance, and a deep understanding of how drug reimbursement is implemented in different parts of the world is strategically necessary for a pharmaceutical company to succeed. Reference pricing in some form will continue to be used by most drug reimbursement agencies in the foreseeable future.

Payers, whether public or private, remain concerned about excessive prices, particularly with respect to new therapies with high price tags, and objective and unbiased outcomes research studies will be essential in obtaining drug reimbursement by payers. Environmental forces continue to exert downward pressure on drug prices worldwide. Firms may need to re-examine premium pricing policies and in particular, the utilization of differential pricing. While differential pricing may seem to be a means of ensuring access in less-developed countries, it may cause political discord in countries such as the US when it is brought to the attention of the public that other world citizens are paying less for the same medication. This is a matter for public policy experts to study in order to balance the needs of different patient groups in ensuring access to necessary drugs.

References

Adams, S. M., Bosch, E., Balaresque, P. L., Ballereau, S. J., Lee, A. C., Arroyo, E., . . . Jobling, M. A. (2008). The genetic legacy of religious diversity and intolerance: paternal lineages of Christians, Jews, and Muslims in the Iberian Peninsula. *American Journal of Human Genetics*, *83*(6), 725–736. doi:10.1016/j.ajhg.2008.11.007

Angell, M. (2008). May 2008: the truth about the drug companies. *Canadian Centre for Policy Alternatives*, *15*(1), 16–17.

Brekke, K. R., Grasdal, A. L., & Holmås, T. H. (2009). Regulation and pricing of pharmaceuticals: reference pricing or price cap regulation? *European Economic Review*, *53*(2), 170–185. doi:10.1016/j.euroecorev.2008.03.004

Brennan, T., & Shrank, W. (2014). New expensive treatments for hepatitis C infection. *The Journal of the American Medical Association*, *312*(6), 593–594. doi:10.1001/jama.2014.8897

Charlesworth, A., Davies, A., & Dixon, J. (2012, August 23). Reforming payment for healthcare in Europe | KPMG | GLOBAL. Retrieved November 15, 2014, from www.kpmg.com/global/en/issuesandinsights/articlespublications/pages/reforming-payment-for-healthcare-in-europe.aspx

Chauncey, D., Mullins, C. D., Tran, B. V., McNally, D., & McEwan, R. N. (2006). Medication access through patient assistance programs. *American Journal of Health-System Pharmacy: AJHP: Official Journal of the American Society of Health-System Pharmacists*, *63*(13), 1254–1259. doi:10.2146/ajhp050457

China Economic Review. (2014). China drops cap on basic drug pricing. Retrieved November 15, 2014, from www.chinaeconomicreview.com/china-drops-cap-basic-drug-pricing

Crosson, F., Guterman, S., Taylor, N., Young, R., & Tollen, L. (2009). How can Medicare lead delivery system reform? Retrieved November 16, 2014, from www.commonwealthfund.org/publications/issue-briefs/2009/nov/how-can-medicare-lead-delivery-system-reform

Davydov, M. I., & Shepin, O.P. (2010). The Russian healthcare system. *Medical Solutions*, September, 74–78.

Drechsler, D., & Jutting, J. (2005). Private health insurance for the poor in developing countries? *OECD Development Centre, Policy Insights*, 11. Retrieved November 15, 2014, from www.oecd.org/dev/insights

Farmer, R.G., Sirotkin, A.Y., Ziganshina, L.E., & Greenberg, H.M. (2003). The Russian health care system today: can American–Russian CME programs help? *Cleveland Clinic Journal of Medicine*, *70*(11), 937–938. doi:10.3949/ccjm.70.11.937

Forcellina, A., & Akannac, C. (2013). Managing talent to meet pharma's next great challenge: global market access. Retrieved November 15, 2014, from www.egonzehnder.com/files/managing_talent_to_meet_pharmas_next_great_challenge.pdf

Goozner, M. (2005). *The $800 Million Pill: The Truth Behind the Cost of New Drugs*. Oakland, CA: University of California Press.

Gross, A. (2013). The key characteristics of China's pharmaceutical market. *pharmaphorum*. Retrieved November 15, 2014, from www.pharmaphorum.com/articles/the-key-characteristics-of-chinas-pharmaceutical-market

Healthcare Global. (2014). Top ten global health insurance providers. Retrieved November 15, 2014, from www.healthcareglobal.com/top10/25/Top-10-Global-Health-Insurance-Providers

Herper, M. (2013). Gilead's $1,000 pill could eradicate hepatitis C, but ethical and financial challenges loom. *Forbes*. Retrieved November 15, 2014, from www.forbes.com/sites/matthewherper/2013/12/19/can-gileads-1000-pill-eradicate-hepatitis-c/

Jarosławski, S., & Toumi, M. (2011). Market access agreements for pharmaceuticals in Europe: diversity of approaches and underlying concepts. *BMC Health Services Research*, *11*(1), 259. doi:10.1186/1472-6963-11-259

Kamtekar, R. (2004). Why life-saving drugs should be public goods. Retrieved November 15, 2014, from http://infochangeindia.org/hiv-aids/debates/why-life-saving-drugs-should-be-public-goods.html

King, S. (2013). Why talk of a hepatitis C price war should act as a warning to the pharma industry-at-large. *Forbes*. Retrieved November 15, 2014, from www.forbes.com/sites/simonking/2013/12/11/why-talk-of-a-hepatitis-c-price-war-should-act-as-a-warning-to-the-pharma-industry-at-large/

LaMattina, J. (2014). What price innovation? The Sovaldi saga. Retrieved November 16, 2014, from www.forbes.com/sites/johnlamattina/2014/05/29/what-price-innovation-the-sovaldi-saga/

Leopold, C., Vogler, S., Mantel-Teeuwisse, A.K., de Joncheere, K., Leufkens, H.G.M., & Laing, R. (2012). Differences in external price referencing in Europe—a descriptive overview. *Health Policy*, *104*(1), 50–60. doi:10.1016/j.healthpol.2011.09.008

Liang, X., Qiao, T., Zheng, D., Shen, H., & Ren, S. (2006). Study of drug price regulation in China: an international comparative perspective. In *2006 International Conference on Management Science and Engineering, 2006. ICMSE '06* (pp. 2185–2190). doi:10.1109/ICMSE.2006.314154

Lussier, S. (2012). *Pharmaceutical pricing and market access challenges in Canada* [PowerPoint Slides]. IMS Brogan. Montreal.

Luthra, S. (2012). Healthcare in India: a call for innovative reform. Retrieved November 15, 2014, from www.nbr.org/research/activity.aspx?id=298

Masterova, G. (2011). Health care you could live with. Retrieved November 15, 2014, from http://rbth.com/articles/2011/04/28/health_care_you_could_live_with_12816.html

Miller, S. (2014). The Sovaldi tax: Gilead can't justify the price it's asking for hepatitis C therapy. *Forbes*. Retrieved November 15, 2014, from www.forbes.com/sites/theapothecary/2014/06/17/the-sovaldi-tax-gilead-cant-justify-the-price-its-asking-americans-to-pay/

Mossialos, E., Kanavos, P., & Abel-Smith, B. (1997). Will managed care work in Europe? *PharmacoEconomics*, *11*(4), 297–305.

Paim, J., Travassos, C., Almeida, C., Bahia, L., & Macinko, J. (2011). The Brazilian health system: history, advances, and challenges. *The Lancet*, *377*(9779), 1778–1797. doi:10.1016/S0140-6736(11)60054-8

Palmer, E. (2014a). France health minister says EU will fight price of Gilead's Sovaldi. *FiercePharma*. Retrieved November 15, 2014, from www.fiercepharma.com/story/france-health-minister-says-eu-will-fight-price-gileads-sovaldi/2014-07-11

Palmer, E. (2014b). Payer pushback aside, Sovaldi, and so Gilead, has another huge quarter. *FiercePharma*. Retrieved November 15, 2014, from www.fiercepharma.com/story/payer-pushback-aside-sovaldi-and-so-gilead-has-another-huge-quarter/2014-07-23

pan-Canadian Pharmaceutical Alliance. (n.d.). Retrieved from www.conseildelafederation.ca/en/initiatives/358-pan-canadian-pricing alliance

Puig-Junoy, J. (2010). Impact of European pharmaceutical price regulation on generic price competition: a review. *PharmacoEconomics*, *28*(8), 649–663. doi:10.2165/11535360-000000000-00000

Remuzat. C., Mondher, T., & Falissard, B. (2013). New drug regulations in France: what are the impacts on market access? Part 1 – Overview of new drug regulations in France. *Journal of Market Access & Health Policy*, 1, http://dx.doi.org/10.3402/jmahpv1i0.20891

Reuters. (2014). Global pharmaceutical industry has significant opportunities for deeper engagement with payers but contingent on restoring trust. Retrieved November 15, 2014, from www.reuters.com/article/2014/05/07/ey-pharma-survey-idUSnPn7ZSzH+9d+PRM20140507

Rozenfeld, B.A. (2014). The crisis of Russian health care and attempts at reform | RAND. Retrieved November 15, 2014, from www.rand.org/pubs/conf_proceedings/CF124/CF124.chap5.html

Sadeghi-Nejad, N. (2014). Sovaldi and the cost-innovation paradox. *Forbes*. Retrieved November 15, 2014, from www.forbes.com/sites/natesadeghi/2014/03/27/breaking-the-bank-the-innovation-cost-paradox-of-us-healthcare/

Singh, N. (2008). Decentralization and public delivery of health care services in India. *Health Affairs (Project Hope)*, *27*(4), 991–1001. doi:10.1377/hlthaff.27.4.991

Stargardt, T., & Schreyögg, J. (2006). Impact of cross-reference pricing on pharmaceutical prices: manufacturers' pricing strategies and price regulation. *Applied Health Economics and Health Policy*, *5*(4), 235–247.

Staton, T. (2014a). Pricey hep C drugs plus thrifty payers equal thorny consequences for patients. *FiercePharma*. Retrieved November 15, 2014, from www.fiercepharma.com/story/pricey-hep-c-drugs-plus-thrifty-payers-equal-thorny-consequences-patients/2014-07-23

Staton, T. (2014b). Top payer group shoots down Gilead's hep C drug Sovaldi on price. *FiercePharma*. Retrieved November 15, 2014, from www.fiercepharma.com/story/top-payer-group-shoots-down-gileads-hep-c-drug-sovaldi-price/2014-05-21

Staton, T. (2014c). Why does Gilead's Sovaldi cost $84K in the U.S. and $57K in Britain? *FiercePharma*. Retrieved November 15, 2014, from www.fiercepharma.com/story/why-does-gileads-sovaldi-cost-84k-us-and-57k-britain/2014-05-29

Sussmuth-Dyerhoff, C., & Wang, J. (2010). China's health care reforms. Retrieved November 16, 2014, from www.google.ca/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.mckinsey.com%2F~%2Fmedia%2Fmckinsey%2Fdotcom%2Fclient_service%2FHealthcare%2520Systems%2520and%2520Services%2FHealth%2520International%2FHI10_China_healthcare_reform.ashx&ei=BQFpVKeYKoqrjALRyYHoBA&usg=AFQjCNHtqS2pKMABYGbkrNaf42Mxp41U9g

Thomson, S., Osborn, R., Squires, D., & Reed, S.J. (2011). International profiles of health care systems, 2011. Retrieved November 15, 2014, from www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2011/Nov/1562_Squires_Intl_Profiles_2011_11_10.pdf/

True Cost. (2009). True Cost – analyzing our economy, government policy, and society through the lens of cost-benefit. Retrieved November 15, 2014, from http://truecostblog.com/

Vasilyeva, N. (2012). Bribes part of everyday life in Putin's Russia. Retrieved November 15, 2014, from www.huffingtonpost.com/huff-wires/20120224/eu-russia-living-with-corruption/

Whelan, E., & Feder, J. (2009). Payment reform to improve health care. Retrieved November 16, 2014, from www.americanprogress.org/issues/healthcare/report/2009/06/24/6167/payment-reform-to-improve-health-care/

WHO. (2011). WHO | The world medicines situation report, 2011. *World Health Organization*. Retrieved November 15, 2014, from www.who.int/medicines/areas/policy/world_medicines_situation/wms_intro/en/

WHO. (2013). WHO | Research for universal health coverage: World health report 2013. WHO. Retrieved November 15, 2014, from www.who.int/whr/2013/report/en/

4 The Structure of the Global Marketing Organization and its Effect on Market Performance

The structure of the pharmaceutical marketing organization is critically important in a global setting and is the focus of renewed interest by the industry. Given the significant and continuous structural change in the pharmaceutical industry at this time, it seems particularly relevant to examine how marketing organizational structure specifically may affect the firm's performance, particularly in an external environment that is rapidly changing. This environment includes: the consolidation of firms with a corresponding reduction in all marketing functions; the increased importance of patients to the marketing mix; the use of Big Data for marketing decision making and the need for training about these analytic tools; the increased use of technology by sales representatives with physicians and its effect on marketing effectiveness; and the possible redeployment of sales representatives given the importance of outcomes monitoring and patient adherence.

The focus of this chapter will be on brand managers and sales representatives on the local and global levels, as their role has an important influence on the effectiveness of marketing activities and market performance. In large part, brand managers determine the success of both new brand launches and the management of in-line brands through the adoption of appropriate and effective messaging and promotional strategies to both physicians and patients. The sales representative is usually the first personal contact the physician has with a pharmaceutical company, and the impression they make has a strong and lasting impact on both brand and company reputation. The brand manager still remains the single most important marketing individual inside the company; and, the pharmaceutical sales representative functions as the most important external link between the physician and the company's products. Further, the interaction between these internal and external marketing functions, also known as closed loop marketing, may be critical to brand success, and ultimately, to the success of the firm.

An examination of the tasks of pharmaceutical brand managers and how they are evaluated is also included in order to provide insight into whether or not the appropriate tasks are being undertaken and reinforced by management. Brand manager and sales representative training efforts are also discussed with an eye to how appropriate training metrics may lead to improved marketing outcomes.

Often, the terms 'product' and 'product manager' are used when discussing the marketing function in pharmaceutical companies. However, both Kapferer (1998) and Leonard and Katsanis (2013) concluded that pharmaceutical products have attained brand status among both physicians and consumers and should be referred to as such. Their research is further supported by a recent PricewaterhouseCoopers report stating that:

> Many pharmaceutical companies treat the terms 'product' and 'brand' synonymously. But a brand is not a physical product; it is the set of associations a product or service engenders in the minds of its users. And

> the distinction is a critical one. Products have no long-term sustainability. They are eventually superseded by rival products with superior features or generic substitutes. Brands, by contrast, can be sustained indefinitely—and the potential for creating brands that physicians and patients value is very much greater with packages comprising different product-service combinations than it is with isolated products.
>
> (PricewaterhouseCoopers 2014, p. 20)

Therefore, 'product' terminology is considered to be outdated and this chapter reflects this by replacing the term 'product manager' with 'brand manager' as it more accurately reflects the current activity of marketing managers in the industry as well as the needs of the industry moving forward.

An analysis of the role of the sales representative within the global marketing organization is also part of this chapter, as it is a topic of vigorous debate on a regular basis in the industry press. The increased difficulty representatives face in calling on doctors combined with rapidly developing technologies have already changed their role in the marketplace. Some industry analysts have predicted their demise, while others believe their roles will evolve to meet the changing needs of the industry as part of outcomes monitoring, patient adherence, and scientific education.

Although not new to marketers in other industries, two relatively new types of marketing to the pharmaceutical industry are also discussed in this chapter as they affect the marketing organization: closed loop marketing and multichannel marketing. The use of these marketing tools has a direct effect on both the brand manager and sales representative and warrants close examination, as their successful implementation will require reorganization of the marketing and sales functions.

Types of Marketing Organizations in the Pharmaceutical Industry

To put the roles of the brand manager and sales representative into their proper context, a brief discussion of the different types of global marketing organizations is warranted. There are generally two types of marketing organizations in the pharmaceutical industry: the multinational organization and the global organization. Each of these organizational types has a specific structure that determines how they coordinate marketing activities.

The multinational organization generally relies on the local subsidiaries for all strategic and tactical decisions: these include messaging, advertising, and promotion. In this model, the local brand manager is independent from the company's headquarters, and would be responsible for developing marketing programs and executing these programs in their particular market. While there is usually a global brand manager at the headquarters level, local brand managers typically have no direct accountability to these global managers. The global organization, in contrast to a multinational one, has worldwide accountability for brand messaging, strategy, and performance, and local brand managers report either directly or indirectly to the global brand manager. They develop a unified brand image and determine all marketing activities that are executed by the local subsidiaries; in some organizations they are responsible for global sales and profitability. One approach is not necessarily better than another and will depend on the brand portfolio of a particular firm. One common thread in both organizational types is the presence of internal and external teams: there are multifunctional brand teams within the central operation that include R&D and manufacturing; and there are specific marketing functional teams between the central operation and local company operations.

Brand Management Team Structure

The traditional model of brand management emerged in the 1930s as a response to the needs of multi-product and diversified consumer goods firms. Brand management is well understood to be a boundary spanning activity (Lysonski, 1985): boundary spanners are individuals who have informal communication links with other individuals both inside and outside the firm. Typically, the brand manager's job is characterized as 'responsibility without authority': in other words, they must rely on persuading others to execute their tasks for the brand.

Regardless of the type of brand management system used, there is typically a multidisciplinary marketing team structure within the local firm, particularly those in large Western countries such as the US, Canada, and the EU. These teams consist of representatives from sales, manufacturing, finance, and R&D internally, and the advertising and market research firms as external members; however, the brand manager is typically the team leader. This type of organizational design eliminates the need for internal boundary spanning and permits more rapid market introduction. In contrast, non-Western pharmaceutical brand managers are part of multidisciplinary marketing teams in larger markets; or, in smaller markets, operate as individual brand managers who utilize boundary spanning to execute their tasks. In the marketing function, these formalized teams are critical to the implementation of complex marketing plans with multiple stakeholders. Further, teams ensure that the marketing organization is nimble—in other words, the marketing team can move more quickly to reach the customer (whichever one it may be—individual or organization) and successfully executes the marketing plan.

The Effects of Team Structure on Marketing Performance

Given the discussion about the current structure of the pharmaceutical marketing organization, a natural question to ask would be whether or not this structure, which consists of multidisciplinary teams usually led by brand managers, actually affects the bottom line performance of the organization. This should be important to the CMO and CEO of any global pharmaceutical company.

A recent working paper (Katsanis & Duffy, 2014) suggests, in fact, that marketing organizational structure does influence marketing performance. Brand managers from 55 different pharmaceutical companies ranging from local to global multinational firms were surveyed to determine the effects of team structure on marketing outcomes. The results suggest that team-based brand management systems are more market oriented; collect more information from the external environment and disseminate more information externally; are more responsive to market needs; have enhanced relationships with KOIs (key opinion influencers—physicians); and appear to implement marketing plans more quickly. Company size is important—the larger the company, the more likely a team approach will be effective in achieving desired market performance.

Chowdhury and Kabir (2012) also studied brand managers in Bangladesh, an emerging market, to understand what elements of their function had the greatest effect on sales growth by examining the strategies of three brands marketed by both a multinational company and a local pharmaceutical company. Their study suggests that sales growth was significantly and positively correlated with a brand manager's years of experience (including their seniority and training), dollar spending on promotion, and a focus on disease-based versus customer-based product positioning.

Teamwork and communication sharing is critical not only within the specific marketing unit, but from the global headquarters to the subsidiary. Each firm should develop key performance indicators at the global level

in addition to profit and ROI (return on investment); and these indicators should be synchronized in such a way that the marketing strategy and performance elements are communicated from the top to the bottom of the organization—from VP, Marketing and Sales, Global, to the Professional Sales Representative in the field at the subsidiary level (PricewaterhouseCoopers, 2014).

At this point, the discussion on the marketing organization will move from the macro level structure of the global organization to a discussion of the micro level structure of the marketing organization: the brand manager and the sales representative.

Brand Manager Profile and Responsibilities

A demographic description of pharmaceutical brand managers indicates that 75 percent of them are between 30 to 40 years of age, most have less than three years of experience as a brand manager, 66 percent have Bachelor's degrees in a variety of fields, and 34 percent have MBA degrees (Katsanis, 2006).

There are differences between the responsibilities of brand managers at the global headquarters level and their counterparts at the subsidiary or local level. As mentioned earlier, these responsibilities may differ significantly as the tasks at global headquarters are generally strategic, organizational, and have some direct reporting responsibility; while in a subsidiary organization, the function is that of coordination. Boundary spanning is utilized in the multinational model, as these brand managers must convince the subsidiaries that following the 'party line' is important. This is much easier in a digital world, because e-detailing materials may be altered easily to fit the specific market. In the global organization as well, technology allows greater ease in ensuring uniformity of marketing messaging and promotional materials for global branding purposes. For now, the discussion will focus on the tasks of the 'ground level,' or local brand manager.

Brand Manager Tasks

The tasks of brand managers fall into three primary groupings: business planning, team activities, and cross-functional activities. Business planning activities include the short, intermediate, and long-range brand planning; environmental scanning; all 4P planning activities including packaging, establishment of brand objectives, development of forecasts, product launches, idea generation (i.e. new indications), establishment of the budget, and budget mix; and ongoing planning and marketing plan adjustments. Team activities include organizing and conducting team meetings; fostering communication among team members; working with sales management to achieve brand objectives; directing projects which will have impact across product lines and influence future policies; and providing leadership and direction to the group to ensure that all programs conform to and support the product business plan. Cross-functional activities consist of maintaining linkages between product teams and functional resources (e.g. the advertising agency); communication with R&D; coordination with Market Research; final approval on promotion copy and field communications; assisting with sales training activities and the development of selling programs; and coordination with market access managers.

Most product managers spend over 70 percent or more of their time on ten key functional tasks and these appear in Table 4.1 (Katsanis, 2006). The most important task is the direction and implementation of marketing plans, followed by fostering product team communication, copy/promotional material approval, and establishing and monitoring budgets.

Table 4.1 Functional Brand Manager Tasks

- Develop annual, intermediate, long-range marketing/business strategies and plans
- Manage and recommend strategies and plans relative to pricing, distribution, labelling, and packaging associated with assigned brands
- Establish quantifiable product, project, and personnel objectives
- Develop unit and dollar sales forecasts
- Recommend and develop strategies for new dosage form
- Conduct team meetings, foster communications among team members and departments, and issue appropriate and timely minutes
- Work with sales management to achieve national and regional sales strategies and plans
- Direct selected projects that will impact across brand lines and influence business policies of the firm
- Ensure, through leadership and direction, that the planning, developing, implementation, and monitoring of the marketing programs confirm with and fully support the brand plan
- Initiate and maintain appropriate linkages between the product and project teams and other functional departments

Source: Adapted from Katsanis, 2006

One would think that brand management tasks in the pharmaceutical industry have changed since the Katsanis (2006) article. Interestingly enough, global firms appear to advertise for product managers with the identical skill sets identified eight years ago. For example, as of October 2014, the website pharmiweb.com had 4,398 available job openings in brand management worldwide; and an examination by the author of 50 randomly selected job descriptions suggests that pharmaceutical companies are still looking for the same skill sets in a marketing world that has expanded beyond these very basic functional tools. Some of the descriptions ask for cross-functional team experience and niche brand experience, but none of the job listings that were examined required any experience with digital marketing tools. It may be that these skills are assumed to be part of the brand managers' toolbox; however, a recent study suggests that training in the digital area is sorely lacking among pharmaceutical brand managers (eye for pharma, 2014).

Required Skill Sets for Brand Managers

It is clear that brand managers will need skills in the domains described earlier in this discussion in order to perform their basic job functions; however, pharmaceutical brand managers require additional skills that are not part of the functional aspects of their work. For example, high levels of technical and scientific knowledge are required, and in-house pharmacology and physiology training are particularly important for employees without a science background. It would be difficult, if not impossible, for a brand manager to effectively market a product without a deep understanding of the underlying science, because all marketing materials to physicians are required to be based on scientific information documented in clinical trials as a basic part of regulatory compliance. Further, ongoing training in medical/scientific domains is essential, as medicine is a rapidly changing field. New drug trials are always ongoing, with subsequent changes in treatment protocols and the use of particular drugs.

Legal and regulatory issues dominate branding decisions, particularly with respect to drug labelling and pricing. For example, in many countries, product pricing is highly regulated and there is little freedom

in setting drug prices. This is an important limitation for the pharmaceutical brand manager and a deep understanding of market access is needed. Finally, the brand manager is limited to what may be communicated to both physicians and patients by the product labelling, official regulatory policy, and the voluntary guidelines as established by the industry in a particular country. Brand managers must be knowledgeable about these regulations and guidelines; however, marketing materials are normally submitted by brand managers to both the medical and legal departments (or a compliance department in some firms) to ensure compliance.

Differences between Pharmaceutical and FMCG Brand Managers

The pharmaceutical industry considers its marketing activity, and thus, the responsibilities of its brand managers, to be significantly different than their counterparts in the FMCG (fast moving consumer goods) industry. There is research, however, to suggest that the functions of brand managers in both industries are similar, although the emphasis on particular tasks may play a different role in the day-to-day activities of the brand manager. Generally, pharmaceutical brand managers typically spend more time in the field than do their FMCG counterparts; and marketing activities are typically dominated by sales force concerns. Face-to-face interface with physicians is critically important to the success of the pharmaceutical brand manager, whether by accompanying a sales representative on his/her calls or at professional medical conferences and presentations. The details of this research are presented below.

Two empirical studies compared pharmaceutical brand managers in local subsidiary operations to those in FMCG companies (Panigyrakis & Veloutsou, 1999; Veloutsou & Panigyrakis, 2001) and showed that while their functions are similar in many ways, they uncovered several important differences: pharmaceutical brand managers are older with fewer qualifications; their product knowledge is more important than marketing skill; their primary role is to support the sales force; they have little involvement in pricing strategy due to pricing regulations in the industry; and they tend to make most of the strategic brand decisions. One interesting difference noted by Veloutsou and Panygyrakis (2001) is that pharmaceutical brand managers maintain an internal focus and are somewhat insular when compared to their counterparts in the FMCG industry (an in-depth read of this article is strongly recommended). This is likely due to the fact that pharmaceutical brand managers are hired either directly from the field sales force or from competitor firms. These differences are likely typical in countries where DTCA is not permitted.

However, in the US, New Zealand, and to some extent Canada, pharmaceutical brand managers deal with consumers and, thus, must be concerned with all the promotional channels that are open to consumers: the Internet and social media (these are global channels), as well as traditional broadcast media. The increased use of the Internet for drug information and the emergence of the global consumer as a key target market have fundamentally changed the brand management function in the pharmaceutical industry at the global/multinational level. The pharmaceutical brand manager in these countries now has a responsibility to reach two target markets: physicians and consumers. Advertising and promotional activities undertaken by brand managers are positioned by the pharmaceutical industry as informational and educational, and, therefore, are different from those of the FMCG industry, which are characterized by a certain degree of puffery. However, these informational characteristics in the presentation of drug information have not been the industry's primary emphasis in recent times, and this will be discussed in Chapter 6.

The Performance Evaluation of Brand Managers

In order to achieve successful performance, a brand manager must be appropriately trained and evaluated so that the evaluation reinforces the desired tasks. However, when examining the available research on this subject specifically concerning the pharmaceutical industry, neither training nor evaluative methods appear to be well-matched to the needs of the industry. There is little recent research in this area, so available studies will be used to provide some guidance for both researchers and managers.

A comprehensive study of the performance appraisal process was conducted by Katsanis and Pitta (1999) and consisted of brand managers and their supervisors from leading pharmaceutical companies. Their objective was to determine the congruence between brand managers and their supervisors on elements of the performance evaluation process: in other words, whether or not brand managers are evaluated on what is considered important by their supervisors. Their findings suggest that while all respondents believe the appraisal process is a fair one, supervisors have more faith in the value and their own role in the performance appraisal process than do the brand managers. It is important to note that brand managers do not believe they are evaluated on external environmental scanning or their performance as a team leader. This seems an important shortcoming to the appraisal process, as these are two critical areas in today's environment that are relevant to any brand manager's performance, particularly at the global headquarters level.

While these results may not be surprising, they do suggest a disconnect between the key metrics assumed to be measured of a brand manager's performance and what is actually assessed by the organization. Key performance indicators (KPIs) must be carefully selected so they align with the firm's overall marketing performance objectives. There must be a clear evaluative link between those KPIs that are important to the firm and those that will be evaluated.

A recent study speaks to the importance of understanding the relevant skill sets of marketing managers, building on these skill sets, and setting the appropriate metrics and KPIs to measure whether these skills are being used in developing brand strategies (eye for pharma, 2014). Three key areas where marketing managers are lacking may be directly related to organizational issues: lack of digital capability; setting metrics and KPIs; and leadership and cross-functional buy-in. The lack of communication in the organization is addressed in this study as follows:

> Another issue is lack of information sharing across an organization. Brand teams may launch similar strategies, but are unaware of each campaign and learnings are not gained . . . reward mechanisms should be put in place to encourage sharing of information and best practice within the organization, with a stronger leadership messaging on its importance. Part of the problem stems from a siloed team attitude.
>
> (eye for pharma, 2014, p. 9)

The implication of this research is that brand teams must communicate with each other so that a firm's best practices may be disseminated throughout the marketing organization. This is critical given the importance of teams to the overall performance of the organization. This activity should be undertaken at the higher levels within the organization, such as Global VP, Marketing; they are able to pass this information not just within the headquarters operation, but to field subsidiary operations as well.

The Importance of Brand Manager Training

Training is an important element of the brand manager's successful development and ultimately for the success of the global pharmaceutical enterprise in general. However, little research has been devoted to this topic, despite the numerous pharmaceutical brand manager training courses that can be found on the Internet. A foundational study of brand manager training practices is that of Katsanis (2006) in which the primary purpose was to determine the relationship between tasks performed by brand managers and the training they receive for these tasks. The study examined brand managers who received external training versus on-the-job training as well as the self-reported training needs of brand managers compared to their key functional tasks.

The results report that among the brand managers surveyed, 87 percent stated that their knowledge was acquired through on-the-job experience. This experience was supported by internal company-sponsored training (29 percent); university training (15 percent); and outside seminars (14 percent). They do not appear to receive company training in proportion to the frequency with which their tasks are performed. When on-the-job experience is higher, company training is subsequently lower. Overall, functional tasks performed frequently appear to receive less company-sponsored training than others. Senior management may believe that on-the job experience is sufficient for routine tasks; in other words, practice makes perfect. The level of outside training is relatively low, likely as a result of the perception that a brand manager's work is too important to take him/her off the job. However, heavy reliance upon on-the-job training may not provide new marketing ideas or provide sufficient training for new tasks that have been previously unidentified, and may lead to sub-standard performance. Finally, most brand managers themselves do not believe they need training on frequently performed tasks—this may reflect the practice-makes-perfect myopia of their managers.

A more recent survey suggests that training needs and the skill sets of brand managers have not changed significantly since 2006, with the exception of market access (Limones & O'Grady, 2011). For low-level marketers, the most important skills identified by the survey respondents requiring training were successful launch preparation, market research, life cycle planning, and strategic brand management strategy. For higher-level managers, forecasting, brand strategy, pricing, and market access were considered areas requiring training. However, when an assessment of the actual skill level of managers at both levels was taken into account, over 50 percent have only a low to medium capability in these areas, with the exception of tactical execution. Future training emphasis was seen as being high in all areas except for tactical execution.

In both studies, time is seen as a significant barrier to the training of marketing managers in general. Despite this, brand managers will need external training on new digital tools, and the slowness of the industry to adopt these digital tools may be suggestive that there is insufficient training in this area. Further research is needed to identify how proper brand manager training may lead to improved KPI performance.

The Professional Sales Representative

Much has been written in the business media about the demise of the pharmaceutical sales representative. Some declare that the professional sales representative (PSR) is a 'dinosaur' doomed to extinction with e-detailing and other digital methodologies in place at some firms; while others maintain that they are still a critical part of the marketing team, with face-to-face selling still an essential part of the marketing process. Others propose the use of nurses, pharmacists, or academic detailers as a replacement for the

pharmaceutical sales representative so that scientific information can be presented as opposed to promotional messages. However, all views appear to be highly critical of the way the pharmaceutical sales force has been managed to date. The purpose of the following discussion will be to shed some light on this debate based on published research and to help understand the future role of the sales representative in the marketing organization as a whole.

A Historical Perspective of the Sales Organization

Recent statistics may shed light on the status of sales representatives around the world. Cegedim (2014) reported that pharmaceutical sales force levels worldwide fell by 1.2 percent from 2012 to 2013—this represents 424,000 full-time representative equivalents. According to the report, these decreases were greatest in North America and the top five countries in Europe with a drop of 7.4 percent and 7 percent respectively. The emerging markets did not experience such declines, however, with China growing 9 percent and Brazil growing 4 percent during the same time period. The overall trend in sales force reduction is moving at a slower rate than in previous years. The report attributes this drop in sales force levels to the management of the patent cliff, the move to specialized or niche areas such as oncology, as well as the fact that PSR coverage of primary care physicians may no longer be required.

One additional reason for the decline not addressed by the Cegedim (2014) report may also be the overhiring of sales representatives during the blockbuster years (the use of sales teams called 'pods,' for example, which consisted of three to six sales representatives calling on the same physician). An examination of the available research at the time would have clearly indicated that excessive detailing does not provide additional sales. Gönül et al. (2001) found that excessive detailing and sampling is counterproductive—too much detailing and sampling is suboptimal and results in frustration, promotion fatigue, and negative perceptions of the pharmaceutical manufacturer. Their findings were later confirmed by Manchanda and Chintagunta (2004), who reported that there are diminishing returns to excessive detailing.

A study of sales representative practices suggests that too many representatives calling on the same physicians resulted in over-competition and overcrowding in physicians' offices, the result of which was the unwillingness of these physicians to spend time with any given representative (Slatko, 2008). The implication of this research is that the pharmaceutical companies themselves may be in part responsible for the current lack of access to physicians: Whalen (2011) called this phenomenon "an escalation most companies came to regret as a burdensome arms race." Representative access to physicians is not just a problem in North America: a recent UK study of 1,000 GPs suggests that 52 percent of them did not see any sales representatives in a given week and 26 percent of GPs only saw one representative during the same period (PMLive, 2012).

The Sales Representative Profile and Responsibilities

Sales is the entry-level position in all pharmaceutical companies, as it is believed that regardless of educational background, the direct contact with physicians and other HCPs (health care professionals) is essential in understanding the industry and how it operates. A typical sales representative is a new college or university graduate who holds at minimum a Bachelor's degree, and increasingly, an MBA, MSc, or advanced degree in the Life Sciences. The primary responsibility of a pharmaceutical sales representative is to promote a drug company's products at hospitals, clinics, and physician offices. Sales representatives are usually given responsibility for a particular brand (e.g. cardiovasculars) in a specified territory. A sales representative must

identify the appropriate physicians to visit within the territory; determine their prescribing habits and needs; provide advice and assistance about the drugs they sell; understand the various treatment modalities in their therapeutic area; organize meetings with physicians to provide information through KOIs; and have familiarity with pricing and market access information for their territory. The role of the sales representative has changed gradually over time given the difficulty with physician access and the changing environment, and these changes are discussed in the following section.

The Changing Role of the Sales Representative

Some pharmaceutical firms have altered their traditional approach from a scripted hard sell to an unscripted soft sell, also known as consultative selling (Spirer, 2012). Shilling (2013) reported that 68 percent of pharmaceutical companies have either implemented or are planning to implement a customer-centric approach to sales. This new approach emphasizes the sales representative as a resource: one who helps the physician in their practice by offering practical help for patients or assisting with burgeoning reimbursement requirements (Rockoff, 2012). Some individuals using this approach may also be called medical science liaisons. This change in sales methodology will require retraining of most pharmaceutical sales representatives, and some resistance may be expected from more senior representatives. It should be noted that this approach is not a new one and is routinely used in most professional selling environments today.

Sales representatives play an important role by creating demand for specific brands, and thus maintaining their importance to the organization as part of the marketing mix. Ching and Ishihara (2012) suggest that detailing has persuasive effects and this plays an important role in the demand for brands that have a similar chemical composition. Given the importance of the sales representative to branding, the implication would be that sales representatives still have a critical role to play in the marketing organization; however, that role is evolving for both new and niche products, particularly biologics that may require extensive explanation and education, as well as brand name recognition and familiarity.

An examination of research on electronic detailing (e-detailing) may also be helpful in understanding the role of the sales representative. Gönül and Carter (2010) examined whether or not e-detailing is effective in generating prescriptions when compared to face-to-face detailing. Their results suggest that prescriptions were boosted by increasing both e-detailing and traditional detailing; however, some physicians do not like having to deal with both the e-detail and the in-person sales representative. Manufacturers have not fully understood how to best utilize the synergy between the two types of detailing. The study also reports that products that treat acute conditions are more likely to generate new prescription sales using e-detailing than for chronic conditions. It would appear that face-to-face meetings with physicians are likely to remain an important part of the marketing organization.

Despite these findings, some firms view digital selling as a complete replacement or important supplement for sales representatives with the use of websites and other e-tools. For example, Whalen (2011) reported that Astra Zeneca created 'AZ Touchpoints' (a website that physicians might use to ask questions, order samples, or request information about market access) with some calls handled by a third-party contractor. Other examples of digital selling designed to either replace or augment some sales representative activity are Sanofi-Aventis at www.ipractice.com and Merck at www.merckservices.com: other firms, however, believe in an emphasis on face-to-face selling and see the move to digital as very gradual (Whalen, 2011).

The Importance of Sales Training

Given the changes in the role of sales representatives, their training is even more critical at this particular time in the industry's development. Sales training usually occurs at the local level, as sales representatives are deployed in a specific country and make sales calls on the physicians in that market. Traditional sales training included an emphasis on transaction selling, product detailing (the term used for how a sales representative presents information to the physician), the development of specific selling skills (presenting features and benefits, handling objections, and closing), as well as the identification of specific physicians for particular product messages. The focus of this training has been a short-term one, with the emphasis on ensuring an immediate agreement to prescribe from the physician.

Training usually takes place both internally and externally: experts may be brought into the firm to train them on specific selling skills. Typical training modes consist of both 'classroom' and external settings for delivering the training that include: the initial training of a sales representative on company policies and procedures (including customer relationship management software, and compliance policies, for example); in-house training on particular products and diseases; on-the-job training (working with sales managers or trainers); 'double calling' (sales rep, manager, and brand manager or senior sales representative); training modules presented at sales 'cycle' meetings (routine meetings every four to six months to introduce new strategies or refresh sales representatives on existing brand strategies); and finally, e-learning, for training on specific aspects of the selling function or medical training.

However, a new direction in sales training based on the changing market trends is currently underway. More emphasis is placed on building strong relationships with customers (including physicians, pharmacists, and other HCPs that a representative may encounter); a deeper understanding of these customers (including the matching of the 'right brand to the right customer'); the development of partnering skills for better sales team cohesiveness; and a longer-term view to developing these customer relationships, rather than the single transaction to 'get the sale.'

Although the training of individual representatives takes place at the local level, the global organization must be involved in setting the agenda for sales training in order to ensure consistent training across markets. O'Grady and Bye (2014) suggest a strong global design for the sales training function. They point out the following elements that will likely lead to success: understanding of the cultural differences across markets (including language and an understanding of the approach to selling); consideration of the different infrastructures in place at the local level and whether or not the specific subsidiary can deliver the training; the use of outside vendors when indicated to ensure consistent delivery; and consultation with local markets to assist with proper implementation of the program. One illustrative example they present is that of Japan and China. For example, in Japan, role playing as part of the training process may not be well accepted because of traditional social roles; in China, unlike some other countries, sales representatives are always well-prepared for their training sessions, and this may eliminate the need for certain background training modules.

Global training becomes more important when one considers the changing marketing environment. Wartenberg and Gores (2008) suggest that sales training needs and the sales model itself will differ by the type of market: emerging markets (gradual change), mature markets (need to change), and advanced markets (essential change required). In the emerging markets, the authors suggest that the industry needs to develop new models of sales deployment; in mature markets, basic sales models may still be used; and in advanced markets, market access challenges and a changing brand portfolio have resulted in an immediate need to change both training and deployment models. Eye for pharma (2014) suggests that technology training is important, particularly in the use of both devices and software for e-detailing.

Academic Detailing and Other HCPs in Pharmaceutical Sales

Canada, Australia, New Zealand, the UK, the Netherlands, and the US have experimented with what is called 'academic detailing'—the use of an independent individual presenting evidence based on information about best prescribing practices to physicians through one-on-one or small group visits (Maclure et al., 2006). Fischer and Avorn

> suggest that academic detailing-direct outreach education that gives clinicians an accurate and unbiased synthesis of the best evidence for practice in a given clinical area can translate comparative effectiveness research findings into actions that improve health care decision making and patient outcomes.
>
> (Fischer and Avorn 2012, p. 2206)

There is little empirical research on academic detailing when compared to pharmaceutical company-sponsored detailing, and that which is available is inconclusive (Chui et al., 2011). Some efforts to implement academic detailing have been withdrawn because of cost considerations and some physicians "found office visits inconvenient and weren't thrilled having CME [continuing medical education] provided by non-physicians" (Kondro, 2007, p. 431). There appears to be no empirical evidence to date that the pharmaceutical sales representative will be replaced with academic detailers in the near future.

Some suggestions have been made to use nurses as replacements for sales representatives. Arndt (2006) reported that nurses as both educators and monitors have already been deployed in markets for some time, particularly where outcomes research is important for market access: they monitor patient progress, measure patient adherence, and train patients in the proper use of the medication. He cites firms such as Pfizer, Sanofi-Aventis, and Roche as using nurses extensively in their marketing efforts to support patients and this effort appears to have physician support; however, a nurse's influence is limited as he/she cannot prescribe or diagnose. In addition, sales representatives with a life science background may also be employed in these patient support roles. There is little empirical research to indicate how effective this effort is with respect to generating market performance.

Closed Loop Marketing and Multichannel Marketing—The Interface between Marketing and Sales

The term closed loop marketing (CLM) is sometimes used interchangeably or together with the term multichannel marketing (MCM); the two tools may be used simultaneously to enhance the execution of marketing and sales programs. However, they describe different aspects of how information in a marketing organization is disseminated: the two combined together allow both the marketing and sales groups to have access to information almost simultaneously and to then communicate it back to the customer. A marketing organization must be structured in a way which permits this type of communication. While CLM is relatively new in pharmaceutical marketing, objectively speaking, it is not new in the world of marketing generally. There are two aspects to both concepts: one is organizational and the other is tactical (the tactical to be discussed in Chapter 7 on e-detailing). Each will be defined below, and then their importance to the marketing and sales organizations will be discussed.

Closed loop marketing is the process by which marketing and sales share information: it links together customer behavior, marketing activity, and sales activity. Sales representatives send information to the

marketing department after a sales call and this information is analyzed. This analysis is then passed along to brand managers, who refine their branding strategies and, in turn, send these strategies back to the sales representatives for execution. For example, 'Dr. Jones' might be interested in Product A, but not Product B. This information would be transmitted back to the marketing department, and a tailored marketing solution would be developed for 'Dr. Jones.' CLM captures the ability to rapidly present marketing messages for a specific physician to that physician. The precursor to CLM was customer relationship management (CRM); but CRM was unable to capture the specific nature of the messages. The use of tablets and the Internet now allows the rapid transmission of information from the sales representative to the brand manager, thus allowing the use of what is called multichannel marketing. Faden (2009) reported that among 30 of the top 50 pharmaceutical firms, only 25 percent were engaged in full CLM. However, the number of firms that began to adopt CLM technology within their marketing organizations increased by 50 percent in just one year.

Rangaswamy and Van Bruggen (2005) define multichannel marketing as "simultaneously offering their customers and prospects information, products, services, and support (or any combination of these) through two or more synchronized channels" (p. 6). What multichannel marketing allows is the transmission of the information gathered through CLM through multiple communication channels, both traditional and electronic—thus ensuring the same message is delivered immediately and consistently across these channels to the audience that needs to receive it. However, multichannel marketing in the pharmaceutical industry is proving to be an organizational challenge, particularly on a global level, and largely will be in the hands of the subsidiary operations and local brand managers. Adoption of these tools by pharmaceutical brand managers will require significant training and organizational adaptation, and both global and local operations will need to adapt their marketing organizations in order to properly utilize these marketing tools.

Implications and Conclusions

The structure of the marketing organization is critical to a firm's success. The coordination of tasks at the global level combined with solid implementation at the local level must be carefully monitored through the setting of KPIs in the system.

Team structure is a primary component that contributes to a firm's success. The creation of interdisciplinary teams within the global headquarters and their ability to link to their local subsidiaries will ensure the successful development and implementation of strategic branding plans. Teams must share information, not only among their own team members, but across teams at both the global and local levels to ensure the communication of best practices.

Brand managers, both at the global and local levels, are central to the marketing function. In particular, their evaluation has a direct effect on the choice of tasks deemed important to the firm, and their training reinforces those tasks to ensure that the brand manager is capable of performing them.

The sales representative's role, equally as critical as that of the brand manager, has changed profoundly over the last decade. Their tasks are gradually changing to reflect the needs of the new pharmaceutical marketplace. The shift from transaction selling to customer-centric selling is a critical element in ensuring the continued relevance of the sales representative. While e-detailing is important, it still does not supplant the need for face-to-face interaction with physicians. Further, while sales training occurs at the local level, this does not mean that the global organization should not have input in order to coordinate both the profile of the sales representative and the continuity of the information and sales approach used in the local markets.

Finally, CLM, while an important tool to optimize the performance of the marketing organization, does not replace the fundamental elements of training and performance appraisal to reinforce KPIs that contribute to the performance of both brand managers and sales representatives.

References

Arndt, M. (2006). Big pharma's nurse will see you now. *BusinessWeek*, (3988), 77–78.

Cegedim. (2014). Worldwide pharma industry sales force trends. Retrieved November 26, 2014, from www.noodls.com/view/7C68895C7EC8CFFA63255A3101A7A5079E0C7C5C?5222xxx1397136102

Ching, A.T., & Ishihara, M. (2012). Measuring the informative and persuasive roles of detailing on prescribing decisions. *Management Science*, *58*(7), 1374–1387. doi:10.1287/mnsc.1110.1499

Chowdhury, N., & Kabir, E.R. (2012). Study on the factors ruling pharmaceutical product management in Bangladesh. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *12*(3), 159–164. doi:10.1177/1745790412445293

Chui, D., Young, F., Tejani, A. M., & Dillon, E.C. (2011). Impact of academic detailing on proton pump inhibitor prescribing behaviour in a community hospital. *Canadian Pharmacists Journal/Revue Des Pharmaciens Du Canada*, *144*(2), 66–71. doi:10.3821/1913-701X-144.2.66

eye for pharma. (2014). Innovative sales strategies and metrics report, 2014. Retrieved November 16, 2014, from www.eyeforpharma.com/innovative-sales-strategies-report/index3.php

Faden, M. (2009). Will closed-loop marketing energize the pharma sales process? Retrieved November 16, 2014, from http://pharmaceuticalcommerce.com/index.php?pg=brand_communications&articleid=1511

Fischer, M.A., & Avorn, J. (2012). Academic detailing can play a key role in assessing and implementing comparative effectiveness research findings. *Health Affairs (Project Hope)*, *31*(10), 2206–2212. doi:10.1377/hlthaff.2012.0817

Gönül, F.F., & Carter, F.J. (2010). Impact of e-detailing on the number of new prescriptions. *Health Care Management Science*, *13*(2), 101–111. doi:10.1007/s10729-009-9110-2

Gönül, F.F., Carter, F., Petrova, E., & Srinivasan, K. (2001). Promotion of prescription drugs and its impact on physicians' choice behavior. *Journal of Marketing*, *65*(3), 79–90. doi:10.1509/jmkg.65.3.79.18329

Kapferer, J.-N. (1998). The role of branding in medical prescription. Research Paper Series, HEC Graduate School of Management, Paris.

Katsanis, L.P. (2006). An assessment of professional training for product managers in the pharmaceutical industry. *Journal of Product & Brand Management*, *15*(5), 324–330. doi:10.1108/10610420610685721

Katsanis, L.P., & Pitta, D.A. (1999). The performance appraisal process of pharmaceutical product managers in Canada: an empirical study. *Journal of Product & Brand Management*, *8*(6), 463–493. doi:10.1108/10610429910299719

Katsanis, L.P., & Duffy, J. (2014). The influence of brand manager teams on marketing organizational performance in the pharmaceutical industry (Working Paper). Montreal.

Kondro, W. (2007). Academic drug detailing: an evidence-based alternative. *Canadian Medical Association Journal*, *176*(4), 429–431. doi:10.1503/cmaj.070072

Leonard, E., & Katsanis, L.P. (2013). The dimensions of prescription drug brand personality as identified by consumers. *Journal of Consumer Marketing*, *30*(7), 583–596. doi:10.1108/JCM-08-2013-0662

Limones, D., & O'Grady, G. (2011). Overcoming challenges to develop an effective marketing training program. Retrieved November 16, 2014, from www.campbellalliance.com/services/getfile.cfm?id=215

Lysonski, S. (1985). Role portrayals in British magazine advertisement. *European Journal of Marketing*, *19*(7), 37–55. doi:10.1108/EUM0000000004724

Maclure, M., Allen, M., Bacovsky, R., Bugden, S., Lopatka, H., MacNair, K., Morrow, R., Nguyen, A., & Regier, L. (2006). Show me the evidence. Retrieved November 26, 2014, from www.puppem.com/Documents/CADC_Report_AcademicDetailing.pdf

Manchanda, P., & Chintagunta, P.K. (2004). Responsiveness of physician prescription behavior to salesforce effort: an individual level analysis. *Marketing Letters*, *15*(2–3), 129–145. doi:10.1023/B:MARK.0000047389.93584.09

O'Grady, G., & Bye, J. (2014). Six keys to effective global sales training design. Retrieved November 16, 2014, from www.campbellalliance.com/services/getfile.cfm?id=261

Panigyrakis, G. G., & Veloutsou, C. (1999). Brand managers' relations with industrial service providers in pharmaceutical and other companies. *Journal of Business & Industrial Marketing*, *14*(3), 229–247. doi:10.1108/08858629910272256

PMLive. (2012). Doctors.net.uk survey finds many GPs favour digital channels for independent product information. Retrieved November 26, 2014, from www.pmlive.com/digital_handbook/online_audiences/online_physician_communities/doctors.net.uk_survey_finds_many_gps_favour_digital_channels_for_independent_product_information

PricewaterhouseCoopers. (2014). Pharma 2020: Marketing the future. PwC. Retrieved November 26, 2014, from www.pwc.com/gx/en/pharma-life-sciences/pharma-2020/pharma-2020-marketing-the-future-which-path-will-you-take.jhtml

Rangaswamy, A., & Van Bruggen, G. H. (2005). Opportunities and challenges in multichannel marketing: an introduction to the special issue. *Journal of Interactive Marketing*, *19*(2), 5–11. doi:10.1002/dir.20037

Rockoff, J. D. (2012, January 10). Drug reps soften their sales pitches. *Wall Street Journal*. Retrieved November 26, 2014, from http://online.wsj.com/news/articles/SB10001424052970204331304577142763014776148

Shilling, C. (2013). 'Customer-centric' sales strategies: how will this benefit pharma? Retrieved November 26, 2014, from www.cuttingedgeinfo.com/2013/defining-customer-centricity-benefits-pharmaceutical-sales-forces/

Slatko, J. (2008). Too many reps hinders relationships. *Med Ad News*, *27*(1), 36.

Spirer, J. (2012). Pharma – new challenge, new sales strategy, new sales training | Sales Training Connection. Retrieved November 26, 2014, from http://salestrainingconnection.com/2012/01/27/pharma-new-challenge-new-sales-strategy-new-sales-training/

Veloutsou, C. A., & Panigyrakis, G. G. (2001). Brand teams and the brand management structure in pharmaceutical and other fast-moving consumer goods companies. *Journal of Strategic Marketing*, *9*(3), 233–251. doi:10.1080/09652540121770

Wartenberg, F., & Gores, M. (2008). The evolution of pharmaceutical sales: new models for a changing environment. Retrieved November 16, 2014, from www.imshealth.com/deployedfiles/imshealth/Global/Content/Document/Sales%20and%20Marketing%20Effectiveness%20TL/Evolution_PharmaSales_new_models_changing_environment_PEE.pdf

Whalen, J. (2011). Drug makers replace reps with digital tools. *Wall Street Journal*. Retrieved November 16, 2014, from http://online.wsj.com/articles/SB10001424052748703702004576268772294316518

5 Global Pharmaceutical Branding

Moving from Blockbuster to Niche Strategies

Branding is a complex process for pharmaceutical companies and a necessary tool for communicating with both physicians and consumers in both traditional and electronic media. Most pharmaceutical brand managers are familiar with branding to physicians, which has traditionally taken place in a personal selling environment and profession-specific media. In countries where marketing to consumers takes place, firms are more familiar with consumer branding strategies as they are those used by FMCG companies. In most markets, branding strategies are primarily focused on physicians, although this scenario is gradually changing due to the availability of information about pharmaceutical brands through electronic media. The current wave of blockbusters is drawing to a close with pharmaceutical companies now emphasizing the importance of specialized therapies in smaller markets, also known as niche marketing. Finally, branding is further complicated by market access and payer policies that affect the availability of certain brands to the end user, the patient.

A Historical View of Pharmaceutical Branding

The sea change that caused branding to be important in the pharmaceutical industry occurred in 1997. This date is significant because prior to 1997, most pharmaceutical brands were well known to physicians and pharmacists, but not to consumers (unless they had a prescription for that particular brand). In fact, it was rare to hear the word 'brand' used when speaking about prescription drugs—as mentioned in Chapter 4, pharmaceutical drugs were called 'products' and while they had brand names that were relevant to the medical profession, these names did not matter much to consumers.

Although DTCA in the US had been legal since 1985 (and although legal in New Zealand since 1981, it had little impact on the worldwide market due to its small population of approximately 4 million), 1997 was the year the FDA eased its rules for DTCA. It allowed pharmaceutical companies to dispense with a lengthy recitation of side effects in their advertising and permitted the use of standard length ads. For the first time, millions of consumers (and physicians) were seeing numerous ads for prescription drugs: the purpose was to establish strong brand names with the public and to present both functional and emotional messages to generate prescription drug requests from physicians. This communication channel was critical for the industry to establish pharmaceutical products as household name brands to consumers.

At the same time, pharmaceutical companies were utilizing their websites to communicate brand information and attributes (Andreou & Katsanis, 2003). This convergence of communication channels also took place at a time when consumers were beginning to take a strong interest in their own health and seeking information from these channels prior to visiting their physicians. These websites were available not only

to American consumers, but to consumers around the globe. No longer were the names of key pharmaceutical products familiar only to physicians and pharmacists, but to the public at large. Further, this branding of pharmaceuticals-to-consumers process took place not just in the US, but globally, and in particular for certain products such as Viagra and Lipitor. One only needed to go to any major airport or newsstand in major cities around the world to find copies of US consumer magazines filled with advertisements for prescription brands, or view global network television stations either online or via satellite with similar advertising. While most full-scale DTCA originates in the US, its importance to consumer branding extends far beyond its borders and cannot be underestimated.

Soon after 1997, several conceptual articles and books about pharmaceutical branding generally were written, primarily with physicians in mind. Moss (2001) initiated the discussion as to whether or not brands actually exist in pharmaceuticals and concluded at the time that DTCA might be a catalyst that would contribute to branding in the industry (this was followed with several articles and an in-depth book on the use of brand architecture in pharmaceutical branding—see Moss, 2007a; Moss, 2007b). Blackett and Harrison (2001) also suggested that the development of strong brands that connect with both consumers and physicians would be critical to sustaining the future of a company's products in the OTC arena, and also presented differing perspectives on the future of pharmaceutical branding.

Schroff (2003) summarizes the views of both the proponents and opponents of pharmaceutical branding. Proponents suggest that it generates brand awareness and loyalty by attracting new customers, fending off me-too competitors, higher evaluation of brand quality, and greater brand awareness. Opponents of pharmaceutical branding believe that the branding process is oversimplified in a world where managed care dominates the landscape and where there are so many audiences to satisfy: payers, pharmacists, physicians, and patients (the 4Ps).

It is important to note that branding in the pharmaceutical industry has certain limitations as a function of the patent protection component of the drug. Even though a patent is valid for 20 years, typically, only eight to ten years of the patent may remain once a drug reaches the market due to the long-term nature of R&D. There are some ways to extend a brand's life cycle, such as OTC conversions, brand extensions, and branded generics—aspirin is one example of an OTC-branded pharmaceutical product with a long product life cycle (it was introduced by Bayer in 1899). However, branding in the pharmaceutical industry tends to be a short- or medium-term strategy because of the short product life cycle of a particular brand. This differs from FMCGs, where brands such as Levi Strauss and Coke have maintained product life cycles for over one hundred years.

Unfortunately, while numerous opinions abound, little empirical research exists in the pharmaceutical branding area, despite some conceptual frameworks that exist for a branding model. This chapter will present some of the more comprehensive conceptual work and empirical work where available.

The Reality of Global Branding

It is difficult to argue that global pharmaceutical brands do not exist when one considers the worldwide success of the 'little blue pill' (Viagra) and the 'Purple Pill' (Nexium). These colors are inextricably linked with the names of the brands—and in the case of Viagra, one does not even need to know the brand's name in order to recognize it due to the success of Pfizer's branding efforts. According to Colyer (2002), pharmaceutical brands by definition are global, since the molecules are introduced worldwide, even if under different trade names. Moss (2007a; 2007b) also confirms that the same trade name is not necessary for a pharmaceutical brand to be recognized as global. However, globalization in the pharmaceutical industry does not have the

Table 5.1 Top Ten Global Brands

Brand Name	*Chemical Name*	*Therapeutic Class*	*Sales ($US billions)*
Humira	adalimumab	Rheumatoid arthritis	11.1
Enbrel	etanercept	Oncologic	8.8
Remicade	infliximab	Oncologic	8.3
Seretide/Advair	fluticasone propionate/ salmeterol xinafoate	Anti-asthma	8.3
Lantus	insulin glargine recombinant	Anti-diabetic	7.6
Rituxan	rituximab	Oncologic	7.5
Avastin	bevacizumab	Oncologic	6.8
Herceptin	trastuzimab	Oncologic	6.5
Januvia/Janumet	sitaglipin phosphate	Anti-diabetic	6.3
Crestor	rosuvastin calcium	Lipid regulator	6.1

Source: Adapted from Evaluate Pharma, 2014

same context as that of FMCGs and there are different elements that encourage globalization, such as: the geographic expansion to emerging markets; the internationalization of clinical trial locales to attract particular market channels (China and India for example); the identification of experts to act as key opinion leaders (KOLs) at international health care centers; the standardization of some drug regulations in different countries; and the desire to increase profit margins and shareholder value.

Certain elements of branding cannot necessarily be applied to the pharmaceutical industry. Some argue that because of the differing local conditions, cultures, and languages across countries, as well as local subsidiary structure, a true global brand is difficult to create. There are often turf wars between the global headquarters and subsidiary operations as to what the brand strategy should be in a particular country. In addition, the brand management function experiences high turnover in most global firms, and this lack of continuity in brand management may cause discontinuity in brand messaging over time and may create problems in establishing a strong global brand identity.

One rationale for global branding is that it increases sales and cuts costs; however, empirical research does not support this rationale. Colyer (2002) suggests that managed care erases any possible benefits to global branding, and this point is also argued by Moss (2007a; 2007b). For example, even if a drug was available in both the UK and the US, it might not be reimbursed under the UK health care system while it might in the US, so any possible gains would not be realized. The major global brands and their therapeutic classes are presented in Table 5.1.

Pharmaceutical Brand Personalities

As mentioned earlier, the effects of DTCA, the Internet, and social media as well as physician advertising have created both brand knowledge and awareness. Professional sales representatives and specialized advertising and promotion to physicians have equally created this brand knowledge and awareness to this audience. It is important to examine whether or not this branding activity has created identifiable personalities for these brands with both physicians and consumers.

Marketers define brand personality as a set of human traits that the target audience applies to a particular brand. It allows marketers to create a human image of a brand in the minds of consumers (and professionals as well). It is commonly accepted that brand personality enhances marketing effectiveness, allows an emotional connection with the brand, and may influence the choice of a particular brand.

Research has shown that physicians do apply personality characteristics to prescription drugs. For example, Bednarik (2005) identified the importance of the emotional component attached to drug brands by Czech physicians. Kapferer (2008) identified 15 different personality elements that were associated with three different classes of drugs that included anti-hypertensives, antibiotics, and anti-ulcer drugs. These elements included adjectives such as optimistic, empathetic, and serene, and are included in Table 5.2.

When a me-too brand with similar functional benefits was compared to the original brand with 'personality,' the original brand was prescribed three times more often. In addition, the original one was evaluated as having greater status, which included both a good reputation and superior quality. Kapferer's (2008) results suggest that a strong brand personality contributes to favorable product choice. His work also suggests that the pharmaceutical firm itself is of great importance in brand choice; this may imply that corporate branding should be an important part of the overall brand strategy for prescription brands when advertising to physicians.

Consumers also ascribe brand personalities to prescription drugs, and some of these elements differ from those associated with consumer brands and physicians' rating of prescription drugs. Leonard and Katsanis (2013) asked 483 US respondents to rate 15 well known prescription drugs on 22 personality characteristics, and the result was the Prescription Brand Personality Scale (PBPS) which appears in Table 5.3.

Table 5.2 Physician Brand Personality Elements

List of Elements	
Caring	Cold
Optimistic	Empathetic
Generous	Prudent
Rational	Severe
Calm	Close
Creative	Elegant
Hard	Class

Source: Adapted from Kapferer, 2008

Table 5.3 The Prescription Brand Personality Scale (PBPS)

Competence	*Innovativeness*
• Dependable	• Unique
• Reliable	• Innovation
• Responsible	• Original
• Successful	
• Stable	
• Practical	
• Solution Oriented	

Source: Adapted from Leonard and Katsanis, 2013

There are two elements that contributed to consumer prescription drug brand personality: competence and innovativeness. It was noted that existing brand personality scales that were developed for measuring consumer brand personalities did not apply to prescription drugs. Further, the personality characteristics identified by physicians as important did not emerge as being important to consumers. "Prescription brand personality appears to be inherently more complex, with different personality traits for professional and consumer audiences," and these differences lend support to the notion that "one scale does not fit all" (Leonard & Katsanis, 2013, p. 590). The personality elements that emerged from this research are consistent with that portrayed in many of the DTC advertisements.

One interesting element of this research was that consumers did not associate negative personality traits with prescription drugs. It is possible, the authors opined, that consumers bestow personality characteristics to what is observed in the content of advertising, or that consumers have the expectation that prescription drugs will either cure them or relieve uncomfortable symptoms and thus do not view them in a negative light. However, this research also suggests that if patients develop an emotional attachment to a prescription drug brand, they may request inappropriate prescriptions or may not ask physicians important information about a drug. Physicians, in turn, may feel pressure to prescribe a drug because the patient has a particular attachment to the brand, and this could result in higher costs to the patient and payer if a less expensive drug is available that provides the same therapeutic benefit.

Different Approaches to Branding

There are various approaches to branding, and the major ones include corporate branding, disease branding, franchise branding, niche branding, and branded generics. The focus of this discussion will be on the effectiveness of these particular branding strategies.

Corporate Branding

Corporate branding is the attempt to link the name of the brand and the company in order to capitalize on those positive attributes held by physicians and the general public about the firm. Schuiling and Moss (2004) suggest that this strategy holds potential because both physicians and consumers look for quality and safety and may seek this from the corporation rather than relying on the individual brand. DeLor (2004) states that corporate branding is particularly important in the pre-launch preparation for a brand as both physicians and the press are likely to pay attention to companies they prefer over others: "A safety record, expertise, professionalism and reputation are all elements of a corporate brand" (p. 149). Schuiling and Moss (2004) suggest that this strategy is fraught with problems should one or the other fall into disrepute, as occurred with Merck's Vioxx as well as several other brands. This has not stopped many firms such as Pfizer and Abbott from adopting significant corporate branding strategies. In 2012, Pfizer launched their 'Get Old' corporate strategy designed to improve their corporate image with the public. In December 2014, Abbott launched a new global corporate branding strategy called 'Live Life to the Fullest,' which uses billboards and TEDx talks to communicate its message.

Rubin et al. (2008) outline two case studies of Novo Nordisk, a Danish company and niche player that has been extremely successful at positioning its company in the global market as environmentally and socially sustainable. They examine whether or not these values are translatable in the larger markets, such as the US,

given the "aggressive and controversial marketing of brand name or blockbuster drugs" (p. 32). This study is of particular interest because the authors address the issue of cultural differences at the corporate level between two different countries, the US and Denmark, with differing health care systems. In their view, the keys to successful corporate branding are: a) the adoption of a company position that emphasizes awareness and prevention; b) investment in internal branding by taking "core messages to global subsidiaries" (p. 36); c) identifying a brand platform that captures the goals of the firm; and d) viewing its own business interests as intertwined with those of its stakeholders (patients, physicians, managed care providers, and governments). It is possible that the Novo experience is one that may be transferrable to other global firms.

Based on existing research, which is admittedly limited, no firm conclusions can be drawn about corporate branding. Corporate branding may be helpful for therapeutic area portfolio branding (also known as franchise branding) in establishing strong company positioning in that field. In addition, heavy M&A activity may have an effect on the rebranding of different firms and may increase the possibilities for corporate branding when complementary lines of brands from the merging firms are combined together. Corporate branding may not be the best strategy, however, if the brand has a more positive attitude than the company. In addition, the current unfavorable reputation of the industry may have a negative impact on the public's view of the corporation, and by extension, its brands. The PatientView (2014) survey of health care industry rankings listed multinational pharmaceutical companies at seventh out of eight as having a good or excellent reputation, next to last before private health insurers. Generic drug manufacturers and biotechnology companies did not fare much better with a ranking of fifth and sixth respectively. Therefore, corporate branding should be used depending on the market and reputational position of the particular firm and its brand offerings.

Disease Branding

Disease (or condition) branding has been defined by Parry (2003) as "defining a particular condition and its associated symptoms in the minds of physicians and patients . . . [to] predicate the best treatment for that condition" (p. 43). The objective of disease branding is to increase the awareness and seriousness of a disease; reduce stigma attached to a disease; or develop a new condition of a previously unmet need and then introduce a product to help (Hall & Jones, 2007). From the perspective of the brand manager, the value in branding a condition is that it creates internal and external consensus and allows for a "single story with a lock and key problem/solution structure" (Parry, 2003, p. 44). Disease branding has been used successfully as a global branding strategy. Hall and Jones (2007) referenced the disease branding campaign for LAMASIL in the Netherlands (and worldwide), a drug used to treat onychomycosis (a fungal infection of the toenails/fingernails). The campaign was directed to physicians by referencing the disease using 'Digger,' a 'critter' that represented the disease and was then presented to consumers in a DTCA campaign. The authors reported that while the prescriptions for LAMASIL increased, the campaign was criticized by Dutch medical authorities, among others, as focusing on a relatively minor health problem.

From an EU perspective, Angelmar et al. (2007) suggest that a strong condition brand will be successful when: the symptoms are easily recognizable by the patient and they want to follow the treatment protocol; physicians are willing to treat the condition; third-party payers are willing to finance the treatment; and research and condition management seminars are available. In condition branding, no individual company owns the particular condition and different parties have their own interests in shaping the discussion that

surrounds a particular disease, from the government to consumer advocacy groups. These interests may or may not complement one another, and in fact, may be contradictory.

For example, there is some evidence that disease branding may have negative effects on patients. Moynihan et al. (2002) describe disease branding as "selling sickness" and "medicalizing ordinary life" and refer to this type of branding as "disease mongering." These authors believe that the reframing of medical conditions as widespread and severe turns ordinary ailments into serious problems, and further, exaggerates the prevalence of the disease in order to create new markets for their brands. The language of disease branding has made its way into the everyday language of consumers and affects how they think about themselves: "You may have erectile dysfunction or irritable bowel syndrome, but you are bipolar or ADHD. Your diagnosis is part of who you are" (Elliott, 2011, p. 3). Parsons (2007) applied the Five Pillars for Ethics in Public Communication as a framework for analyzing the unbranded approach to pharmaceutical advertising and found that the strategy failed to meet the standards of this framework for four out of the five pillars.

With the expiry of blockbuster medications, it is predicted that 'unbranded' disease branding strategies will increase given the niche focus of the industry as well as the popularity of disease-oriented websites and apps (Robinson, 2010): "Consumers these days are looking for relevant information, not marketing messages and any marketer worth his or her salt will provide good content over sales pitches" (p. 2). A study on cholesterol screening and disease awareness campaigns in Australia (Hall et al., 2008) suggests that disease branding is a double-edged sword:

> The Unilever and Pfizer cholesterol awareness campaigns do have some potential benefit for public health, but also some potential for creating considerable public confusion over who should have their cholesterol levels tested. This in turn may cause unnecessary public anxiety about cholesterol and unnecessary visits to Australia's already pressured GPs.
>
> (Hall et al., 2008, p. 327)

Franchise Branding

Franchise branding is also known as portfolio branding or the 'house of brands' strategy, and may be complementary, therapy oriented, or of product origin, and this strategy is the most widely used by the pharmaceutical industry. For example, a complementary franchise would position two brands with different indications together that are used for the same disease. A therapy franchise groups together a family of brands for a particular indication, such as osteoarthritis. Product origin branding seeks to have separate strategies for different divisions of the company in order to create distinct brand identities for each brand group. This branding strategy is one of the most commonly used in the pharmaceutical industry, as products are often developed as an outgrowth of the parent brand and has often been the default branding strategy in many therapeutic classes. The brand Januvia, a drug for the treatment of diabetes, is an excellent and current example of franchise branding (refer to Corner (2013) for an in-depth analysis of its franchise branding strategy). Moss (2007a; 2007b) also provides an extensive discussion on franchise branding for readers who wish to delve more deeply into this subject. No empirical studies appear to be available about the effectiveness of this particular branding strategy; however, anecdotal case studies regarding its use are widely available in industry publications.

Niche Branding

It is well understood by marketers that a niche brand is one that is offered in a narrowly defined and specialized market segment: it is often likened to being a big fish in a small pond. Typically, a firm expects to attain a high market share within a smaller target market. Ideally, a niche segment has the potential for high margins, a certain degree of stability, and limited or no competition. One of the characteristics of niche branding is that suppliers develop close relationships with their customers and this is expected to lead to brand loyalty. There are different categories of niche brands in the pharmaceutical industry: specialty medicines (including personalized medicine and biologics) in fields such as oncology and virology; and orphan drugs (for rare diseases). Pines (2012) reported that there are over 450 medications currently in research for those who suffer from rare diseases. Niche brands also include limited competition drugs (generic drugs that are difficult to manufacture and have a limited number of firms willing to undertake the work) and differential products (patent-protected or generic molecules that utilize different dosing or novel drug delivery systems such as polymers and sprays) (Sharma, 2013). The focus of the discussion below will be on personalized medicine and branding strategy.

Personalized medicine (PM) brands are seen by many as the future of the drug industry given that the market for these brands is expected to reach US$148 billion by 2015 (Business Wire, 2011). This therapy offers immediate profits due to its high price, as traditional 'pill' therapies no longer provide this type of opportunity due to the current patent cliff. It also provides a sales buffer to a firm while it is waiting to discover the next blockbuster brand. PM and the resulting brand also permit the possibility of extending a patent's life by altering either dosing or drug delivery and offering the possibility of early diagnosis and disease prevention. These branding benefits may be realized provided that barriers to the use of personalized brands, which include pricing reimbursement and the mechanics of supplying the patient with the medication, can be overcome (Hitz & Katsanis, 2014). It is likely that smaller marketing budgets will be needed due to the small market pool, and that specialized sales representatives will be required who act in a consultative and supportive role, with fewer sales calls required (Pines, 2012).

PM brands will also need to be accepted by physicians who are outside well-established areas of oncology and virology. Myshko and Robinson (2014) detailed a Bioceutics study in which 443 US and EU physicians provided their opinions of PM brands. Their results suggest that 90 percent of physicians expect PM to have a great effect on their practices, but with the exception of oncology, they do not believe they are sufficiently up-to-date on the technology to use it. Even if physicians are accepting of PM, consumers will also need to understand and accept the use of these drugs. In addition, pricing regulators may refuse to reimburse the high prices of these new drugs. It is interesting to note that despite being defined as 'niche' by the industry, the dollar sales of some PM brands to date has already catapulted them into the blockbuster drug category because of their high prices: this is in spite of the narrow target markets and limited use for these drugs.

Hitz and Katsanis (2014) surveyed over 300 Canadian consumers to determine what elements would contribute to the adoption of PM. Their work suggests a strong general acceptance of PM with this audience, particularly in oncology, given the maturity of the brands in this field. Generally, consumers appear interested in PM and would like physician endorsement before considering its use. However, they expressed concerns about their medical privacy, find PM difficult to understand, and are unsure about whether it is better than existing therapy. In rank order, factors that influence consumer adoption are

knowledge of PM, its relative advantage, the compatibility of PM with their existing value systems, and homophilous character traits. From a branding perspective, pharmaceutical firms will need to provide education about PM to show it has greater benefits and fewer risks as well as to address their privacy concerns.

Brand Extensions

In marketing, a brand (or line) extension is defined as some variation on an existing product. This may be either a new formulation of an old drug or a new modification of an existing molecule (Hong et al., 2005). It is also an important branding strategy in the pharmaceutical industry. A seminal study by Grabowski and Vernon (1992) suggested that it is a critical strategy for keeping market share of patent-expiring drugs—demand is shifted from the older drug to the new extension. This is also known as product evergreening or 'layering innovations' (Pearce, 2006), where small changes are made to a molecule, typically one about to come off patent, so that the life of the patented drug can be extended. The original patent is supplemented by later or 'secondary' patents used to protect the brand. This innovation layering may include "alterations in active ingredients, strength, dosage form, route of administration or conditions of use" (Pearce, 2006, p. 76).

Other forms of product extension include different modes of delivery, such as extended release tablets, ointments, or injectables, and in these instances, studies are required to support claims of efficacy and safety (Pearce, 2006). A different form of a brand extension is also the renaming of a drug and its subsequent marketing for a new indication under a new brand name (Greenslit, 2002). One classic example is that of fluoxetine, which was marketed both as PROZAC for depression and SARAFEM for premenstrual dysphoria disorder (PMDD) (Greenslit (2002) provides an interesting case study of this branding strategy). Brand extensions of this sort are not new and are regaining popularity as firms need sales from older products while waiting for new molecules and results from overseas markets. Palmer (2013) reports that Johnson & Johnson has planned 25 brand extensions to be launched in 2017, and according to PR Newswire (2014) 57 percent of the top pharmaceutical companies have begun researching line extensions for brands close to patent expiry.

Originator pharmaceutical companies have been quite successful at extending their brands' lives, using line extensions despite ongoing legal challenges from generic firms. Countless hours and millions of dollars have been spent on court challenges by generic companies seeking to 'break' a patent, while the originator firm spends an equal amount defending these patents. In an ironic twist to the traditional patent fight, Teva Pharmaceuticals, a firm with a core generic business, is now vigorously defending its multiple sclerosis drug Copaxone from patent attack from other generic firms. Teva has gone so far as to file a citizen petition with the FDA to push for clinical trials for all copies of this drug and offered new scientific data on gene expression that it believes supports its position (Helfand, 2014). The US Supreme Court will hear its patent argument in court, but any decision it reaches will be too late to prevent potential harm to the Israeli drugmaker.

Is adding a brand extension or evergreening an appropriate strategy? It depends on who you ask. Generic firms believe that patent evergreening cheats the system, keeps prices artificially high, and extends the patent beyond its legal life. Originator firms believe that they have the right to maintain their patent's standing. Further, not all brand extensions are for the purpose of patent life extension, but to provide legitimate patient benefits (Humira, for example, with its pen delivery system versus a syringe). Public policy makers, who are typically concerned about price, seek definitive answers about the effects of evergreening on drug costs. Some empirical findings presented below may shed some light on this phenomenon.

Do brand extensions maintain existing price levels or increase prices? In a study of 27 drug brands that lost their patents, Hong et al. (2005) demonstrated that the brand extension maintained the existing price for the original brand despite the entry of generic drugs. Further, they showed that the most successful brands were 16 times more likely to be extended than others. A recent Swiss study (Vernaz et al., 2013) examined eight follow-on (extension) drugs between 2000 and 2008 to determine whether or not the use of these drugs increased drug costs to payers. They reported that if the use of brand and follow-on drug prescriptions had been replaced with generic drugs, approximately 30.3 million Euros would have been saved. Further, although generic replacement and co-payment incentives were already in place to reduce drug expenses, these measures were counterbalanced by the use of branded line extensions that are typically priced at higher prices to the generics.

A unique study examined the effects of alternate formulation/method of administration patents to determine how these patent filings affected the lives of two antiretroviral drugs, ritonavir and lopinavir/ritonavir (Amin & Kesselheim, 2012). The authors subjected 108 patents to expert review and concluded that these secondary patents would extend the life of the original molecule for up to "12 years after the expiration of the patents on the drugs' base compounds and 39 years after the first patents on ritonavir (the original molecule) were filed" (p. 2286). They expressed concern about the inventiveness of some of the patents from a public policy perspective.

Value Added or Beyond the Pill Strategies and Patient Centricity

The idea of value added, or beyond the pill branding strategy, is a relatively new idea in pharmaceutical branding. This strategy ties together different offerings (for example, a selection of branded products and authorized generics which is combined with services such as patient monitoring through novel devices or mobile apps from the same pharmaceutical company) in order to provide a complete brand package to managed care firms and government payers. This is also tied together with what is called patient centricity: the focus on the patient, their adherence to medication, and the promise of the brand to deliver benefits directly to patients. This strategy has received some attention in the US as a way to maintain brand longevity and gain leverage with payers. Some industry analysts have posited that the industry should examine the possibility of merging with insurance companies or other health care providers to enhance their abilities to execute this type of branding strategy. However, there is currently only limited and anecdotal evidence available as to the use of this strategy with few examples; it is unclear whether this branding model is realistic given the current focus of the industry on molecules and biologics.

Generic Drugs, Branded Generics, and Authorized Generics

Although technically not 'brands' per se, it is important to briefly discuss generic products and their variants as they significantly affect branding efforts and strategies. A generic drug is defined as "a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights" (WHO Glossary, 2014). Branded and authorized generics are two other forms of generic drugs that are frequently confused, and some researchers and industry experts have incorrectly used the terms interchangeably. Branded generics are "products that are either novel dosage forms of off-patent products produced by a manufacturer that is not the originator of the molecule or a molecule copy of an off-patent product with a trade name" (IMS 2002, as cited by Lamb, 2008). Authorized generics are defined as "the actual brand name

drug product, manufactured by the brand company, but sold as a generic by a licensee or subsidiary of the brand, competing with independent generics" (Hollis & Liang, 2006).

The effects of generic drugs on branded products are immediate and significant—it is well known that a brand will lose up to 80 percent of its sales volume within six months of a generic drug launch. Most countries have either compulsory substitution upon presentation of a prescription, or pharmacist choice to substitute the generic alternative in place of the branded drug. Typically, pharmacists are the primary target audience for generic drugs because of their right to dispense and substitute generic drugs for branded ones. For example, Mott and Cline (2002) studied 6,630 prescription orders and determined that 84 percent of available brand name prescriptions were replaced with generic substitutes. Consequently, the branding emphasis for generic drug companies is on corporate branding to the pharmacist.

With respect to the effects of generic drugs on prices, Rizzo and Zeckhauser (2009) reported a 10 percent overall increase in generic prescription share; this share increase resulted in a 15.6 percent decline in the average price paid for brand name drugs. Some firms, such as Pfizer, have introduced discount cards in the US to maintain sales of their brands, such as Lipitor, with some success (Johnson, 2011); however, there has been pushback from payers as some of these discount cards may increase payer costs. There have been some recent concerns about generic drug quality with recent recalls for Dr. Reddy's generic products (Siddiqui & Sikka, 2014); however, generic drugs are generally regarded as safe. A meta-analysis by Kesselheim et al. (2008) suggests that there is no evidence that brand name drugs are superior to generic ones.

The use of authorized generics is increasing given the pressure to maintain the sales of blockbuster drugs in the face of patent expiry. Hollis and Liang (2006) suggest that the presence of authorized generics results in fewer discounted drug prices and brand name price increases. They opine that the use of authorized generics may reduce the incentive for independent generic firms to challenge patents and, ultimately, result in increased prices for consumers.

Key Elements That Contribute to Brand Success: A Case Study

Little empirical research is available on pharmaceutical branding and most work found when researching this chapter consists of anecdotal evidence or prescriptive recommendations for successful branding. However, some general observations can be made based on an analysis of seven brand histories as described in the industry publication *Pharmaceutical Executive*, from the period 2007 to 2014. These brands were selected by the publication as the recipients of its 'Brand of the Year' awards. Some limited, qualitative evidence for those factors that contribute to successful branding efforts is identified here based on these brand histories. This author is unable to comment on either the method of brand selection by the publication or whether they are a representative sample of brands in the industry. However, these articles contain relevant information about key events in the life of these brands, despite the enthusiastic tone used by the publication to describe them. A complete review of each individual article is recommended to readers for specifics, and follow-up from third-party sources, where available, is provided. There are some common threads that suggest that a multifaceted branding approach is often utilized, and it is evident that one branding approach does not provide all the answers. This discussion will also avoid the evaluation of specific promotional tactics and their effectiveness. It should be noted that there may be problems with particular branding approaches which might lead to inappropriate drug prescribing by physicians or a drug's end use by patients. Table 5.4 contains the list of brands included in this discussion with a brief description of their branding activities.

Table 5.4 Brand of the Year Strategies

Year	*Brand*	*Selected Strategies*
2007	Gardasil	• Disease awareness/education • Drug innovation
2008	Chantix	• Disease awareness/creation • Consumer drug education • Narrow target market
2009	Crestor	• Patient targeting • Continued R&D for additional claims
2010	Avastin	• Scientific Phase II and Phase IV innovation • Technically trained sales force • Multiple indications
2011	Humira	• Emerging market development • Patient education
2012	Januvia	• New chemical class • Disease education to physicians and patients • Patient engagement • Emerging market development
2013	Copaxone	• Scientific innovation • Sustained scientific development • Disease awareness • Disease education and patient engagement

Source: *Pharmaceutical Executive*, 2007–2014

Based on an analysis of the brand histories, the following were identified as key elements to brand success:

1) Continuous brand development remains the number one contributor to brand success in almost all cases examined, and this must exceed the initial development of the chemical or biologic entity by the originator firm. This ongoing development includes new delivery systems, new formulations, and both new and significant indications for use. The success of marketing efforts is tied to the results of clinical research; and further, this success is dependent on the continuation of Phase II and III trials, particularly after an M&A, as well as the development of Phase IV studies. Phase IV studies, in particular, appear to contribute to brand longevity as they often support new drug indications.
2) The use of simultaneous, multiple branding approaches was a common characteristic across all seven brand histories. All the brands examined used some combination of (or all) types of branding: disease branding; franchise branding (both brand families and line extensions); corporate branding; and global branding (particularly in emerging markets).
3) Prelaunch efforts directed to physicians, payers, and patients to ensure rapid brand adoption plays an important role in brand success. This includes medical information to physicians; personal contact with key payer organizations or governmental agencies to ensure acceptance at launch with evidence to support proposed pricing; and mass communication strategies directed to patients to announce upcoming therapy advancements.

4) The use of patient tracking and global outcomes data as part of a successful branding strategy is particularly important for payers. This includes the identification of potential patients eligible for the drug as well as the use of safety and efficacy data for the development of future research studies to support the branding effort.
5) Patient engagement through the creation of an emotional connection to a brand (brand personality) is now a vital component of branding strategy, particularly in Western markets. This includes the understanding of patient attitudes toward their disease and treatment; the use of DTCA where legal; the development of online and social media programs that include branded websites; unbranded disease awareness webinars; non-branded mobile apps; and self-directed adherence programs. Patient assistance programs are utilized in most branding strategies to help with the cost of medication as part of this patient engagement.
6) Successful brands appear to use small, dedicated sales forces that are well trained about the drug, the disease, the patient, the scientific data, and partnering (or consultative selling) versus the scripted 'hard' transactional sell (an outdated model in most industries today and rapidly disappearing in the pharmaceutical industry).
7) Successful strategic and competitive positioning in a brand environment with multiple competitors is used by all brands examined. This positioning also includes a deep understanding of how to use their brand's strengths to take advantage of a competitor's weaknesses.

Criticisms of Pharmaceutical Branding

There is much criticism about the industry and its branding strategies. One consequence of successful branding is that the results may have more serious consequences for the end user than with FMCG brands because of the very nature of prescription drugs and their inherent risks. A summary of this criticism is presented below.

1) The overpromising of brand benefits and exaggeration of efficacy or safety profiles. This includes the lack of full disclosure to physicians about side effects. For five of the seven drugs examined, patient lawsuits are underway as a result of side effects that emerged post-launch, and some medical experts believe that some marketing efforts contribute to endangerment of patient health.
2) Aggressive and excessive pricing policies. Several of the drugs examined received significant criticism over their pricing policies, and some of the patient assistance programs did not provide sufficient help given the high cost of the drug.
3) The use of mass communication strategies. This augments the effects of branding exponentially, as information travels at lightning speed around the world, and the media also play a role, as in some cases they may exaggerate both the benefits and the risks of certain medications. The media's effect due to the sometimes inaccurate reporting of drug information cannot be minimized (Parker-Pope, 2008).
4) Scientific evidence (Phase III and IV studies) used to support the branding effort is often criticized as biased and the presentation of results as misleading. To avoid criticism, this evidence must be meaningful, valid, and unbiased—in other words, provide drug information on both benefits and risks that are presented in real terms rather than using extrapolations or percentage reductions in disease incidence.
5) Patients have legitimate privacy concerns when it comes to their identification as potential users of a drug as part of brand patient engagement or patient adherence programs. This is a criticism often levelled at the pharmaceutical industry, as there are significant public policy implications to the availability of private medical data.

6) The issue of overmedicalization has been discussed earlier in the chapter, but raised again here due to the use of disease branding by all brands in this admittedly limited sample. A real question exists as to whether or not certain diseases should be treated or if they are simply part of the human condition.
7) There are public policy implications over whether or not a pharmaceutical company should lobby governments for mandatory inclusion of their brand on insurance or government formulary drug lists. Merck received negative publicity as a result of its efforts to make Gardasil a mandatory vaccine for young girls in countries around the world without long-term data to support its use (Tomljenovic & Shaw, 2012).

Implications and Conclusions

Global branding has been present for some time with physician audiences, but was developed for consumer audiences, in part, by the advent of direct-to-consumer advertising and the easy availability of information through the Internet and other electronic media. Pharmaceutical branding differs from FMCG branding in that drug brands have shorter product life cycles and rely heavily on continuous, long-term R&D programs for product innovation.

Pharmaceutical brands possess personalities in the minds of both physicians and consumers. These human characteristics ascribed to drugs differ between the two audiences, however, and emphasize different traits. While these personalities may be useful from a branding perspective, one potential policy issue that may arise is the inappropriate attachment that may develop to a particular brand based on these personalities.

There are different types of branding strategies used in the industry; the most relevant at the present time are niche branding, corporate branding, and disease branding. Often, more than one branding strategy is used to create a successful brand, and 'one size does not fit all' when considering the use of these strategies. It is important to note that niche branding as it is now used by the industry is of limited utility—it may be a helpful short-term strategy while it fills its pipelines, but is likely not sustainable over the long term.

Successful branding strategies appear to possess certain characteristics that include continuous innovation, pre-launch activity, patient tracking and engagement, strategic positioning, and small, dedicated sales forces using consultative selling. However, these branding strategies are also the subject of criticism because they may overpromise on the benefits and minimize potential risks.

Generic drugs hinder branding efforts through the shortening of the product life cycle and rapid price erosion of the original brand. However, they provide lower prices to consumers and greater drug accessibility as well as an important public good. Generic firms must produce a high-quality, safe product to maintain their product's usefulness and reputation in the market.

More research is need in the pharmaceutical branding area to identify those elements that lead to successful branding with physicians and consumers. Policy makers must be cognizant of branding efforts to ensure that the serious nature of pharmaceutical brands is not minimized to professionals or the public with the use of these strategies.

References

Amin, T., & Kesselheim, A. S. (2012). Secondary patenting of branded pharmaceuticals: a case study of how patents on two HIV drugs could be extended for decades. *Health Affairs (Project Hope)*, *31*(10), 2286–2294. doi:10.1377/hlthaff.2012.0107

Andreou, A., & Katsanis, L. P. (2003). A content analysis of pharmaceutical web sites. *Journal of Pharmaceutical Marketing & Management*, *15*(2), 63–79. doi:10.3109/J058v15n02_05

Angelmar, R., Angelmar, S., & Kane, L. (2007). Building strong condition brands. *Journal of Medical Marketing*, *7*(4), 341–351. doi:10.1057/palgrave.jmm.5050101

Bednarik, J. (2005). Does brand differentiate pharmaceuticals? *Neuro Endocrinology Letters*, *26*(6), 635–652

Blackett, T., & Harrison, T. (2001). Brand medicine: use and future potential of branding in pharmaceutical markets. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *2*(1), 33–49. doi:10.1057/palgrave.jmm.5040053

Business Wire. (2011). Research and markets: personalized medicine market worldwide (2010–2015) – by segments, technologies, opportunities, challenges & future forecast. Retrieved November 26, 2014, from www.researchandmarkets.com/reports/1543385/personalized_medicine_market_worldwide_2010

Colyer, W. (2002). Prescribing a global identity. Retrieved November 26, 2014, from www.brandchannel.com/features_effect.asp?pf_id=102

Corner, B. (2013). Brand of the year: Januvia. Retrieved November 26, 2014, from www.pharmexec.com/pharmexec/Profiles/Brand-of-the-Year-Januvia/ArticleStandard/Article/detail/808518?contextCategoryId=106

DeLor, K. (2004). What's in a name? *Pharmaceutical Executive*, *24*(9), 149–152

Elliott, C. (2011). Create a disease to market a new drug. *KevinMD.com*. Retrieved November 26, 2014, from www.kevinmd.com/blog/2011/01/create-disease-market-drug.html

Evaluate Pharma. (2014). World Preview 2014, Outlook to 2020. Retrieved from http://info.evaluategroup.com/ep-wp-2014-lp-ep.html

Grabowski, H.G., & Vernon, J.M. (1992). Brand loyalty, entry, and price competition in pharmaceuticals after the 1984 Drug Act. *Journal of Law and Economics*, *35*(2), 331–350.

Greenslit, N. (2002). Pharmaceutical branding: identity, individuality, and illness. *Molecular Interventions*, *2*(6), 342–345 doi:10.1124/mi.2.6.342

Hall, D.V., & Jones, S.C. (2007). Branding of prescription medicines to Australian consumers. *Australasian Marketing Journal (AMJ)*, *15*(2), 97–107. doi:10.1016/S1441-3582(07)70046-0

Hall, D.V., Cobcroft, M.D., & Ketelbey, J.W. (2008). High levels of confusion for cholesterol awareness campaigns. *Medical Journal of Australia*, *189*(6). Retrieved November 26, 2014, from www.mja.com.au/journal/2008/189/6/high-levels-confusion-cholesterol-awareness-campaigns

Helfand, C. (2014). Teva trots out genetics in new petition against Copaxone copies. *FiercePharma*. Retrieved November 26, 2014, from www.fiercepharma.com/story/teva-trots-out-genetics-new-petition-against-copaxone-copies/2014-07-03

Hitz, A., & Katsanis, L.P. (2014). A consumer adoption model for personalized medicine: an exploratory study. *International Journal of Pharmaceutical and Healthcare Marketing*, *8*(4), 371–391. doi:10.1108/IJPHM-07-2013-0039

Hollis, A., & Liang, B.A. (2006). An assessment of the effect of authorized generics on consumer prices. Retrieved November 26, 2014, from http://emmanuelcombe.org/hollisliang.pdf

Hong, S.H., Shepherd, M.D., Scoones, D., & Wan, T.T.H. (2005). Product-line extensions and pricing strategies of brand-name drugs facing patent expiration. *Journal of Managed Care Pharmacy: JMCP*, *11*(9), 746–754

Johnson, L. (2011). Pfizer maneuvers to protect Lipitor from generics. Retrieved November 26, 2014, from http://yourlife.usatoday.com/health/medical/treatments/story/2011-11-29/Pfizer-maneuvers-to-protect-Lipitor-from-generics/51475288/1

Kapferer, J.N. (2008). *The New Strategic Brand Management: Creating and Sustaining Brand Equity Long Term* (4th edition). London; Philadelphia: Kogan Page.

Kesselheim, A.S., Misono, A.S., Lee, J.L., Stedman, M.R., Brookhart, M.A., Choudhry, N.K., & Shrank, W.H. (2008). Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. *Journal of the American Medical Association*, *300*(21), 2514–2526. doi:10.1001/jama.2008.758

Lamb. (2008). Branded generics: misunderstood, but lucrative. *Pharmacy Times*. Retrieved November 26, 2014, from www.pharmacytimes.com/publications/issue/2008/200810/2008108707

Leonard, E., & Katsanis, L.P. (2013). The dimensions of prescription drug brand personality as identified by consumers. *Journal of Consumer Marketing*, *30*(7), 583–596. doi:10.1108/JCM-0820130662

Moss, G. (2001). Pharmaceutical brands: do they really exist? *International Journal of Medical Marketing*, *2*(1), 23–32.

Moss, G.D. (2007a). What can the pharmaceutical world learn from consumer branding practice? *Journal of Medical Marketing*, *7*(4), 315–320. doi:10.1057/palgrave.jmm.5050102

Moss, G.D. (2007b). Pharmaceuticals—Where's the brand logic? Branding lessons and strategy. Retrieved November 26, 2014, from www.asiabooks.com/book_detail/9780789032584/Pharmaceuticals-Where-s-the-Brand-Logic-Branding-Lessons-and-Strategy

Mott, D.A., & Cline, R.R. (2002). Exploring generic drug use behavior: the role of prescribers and pharmacists in the opportunity for generic drug use and generic substitution. *Medical Care*, *40*(8), 662–674. doi:10.1097/01.MLR.0000020926.85284.8E

Moynihan, R., Goetzsche, P.C., Heath, I., & Henry, D. (2002). Selling sickness: the pharmaceutical industry and disease mongering commentary: medicalisation of risk factors. *British Medical Journal*, *324*(7342), 886–891. doi:10.1136/bmj.324.7342.886

Myshko, D., & Robinson, R. (2014, June). Personalized medicine from bench to bedside. *PharmaVOICE*, 10–17. Retrieved November 26, 2014, from www.pharmavoice.com/archives/article.esiml?id=2936#

Palmer, E. (2013). J&J plans 25 line extensions in next four years. *FiercePharma*. Retrieved November 26, 2014, from www.fiercepharma.com/story/jj-plans-25-lines-extensions-next-four-years/2013-05-24

Parker-Pope, T. (2008). Blaming the media for Gardasil Hype. *Well*. Retrieved November 26, 2014, from http://well.blogs.nytimes.com/2008/08/29/blaming-the-media-for-gardasil-hype/

Parry, V. (2003). The art of branding a condition. *Medical Marketing & Media*. Retrieved November 26, 2014, from www.highbeam.com/doc/1G1–101942641.html

Parsons, P.J. (2007). Integrating ethics with strategy: analyzing disease-branding. *Corporate Communications: An International Journal*, *12*(3), 267–279. doi:10.1108/13563280710776860

PatientView. (2014). Corporate reputation of pharma – the patient perspective, February. *PatientView*. Retrieved November 26, 2014, from http://alexwyke.wordpress.com/2014/02/13/corporate-reputation-of-pharma-the-patient-perspective-february-2014/

Pearce II, J.A. (2006). How companies can preserve market dominance after patents expire. *Long Range Planning*, *39*(1), 71–87. doi:10.1016/j.lrp.2005.04.006

Pines, N. (2012). Specialty pharma niches to riches. Retrieved October 7, 2014, from www.mmm-online.com/specialty-pharma-niches-to-riches/article/228656/

PR Newswire. (2014). The doctor won't see you (Mr. Pharma Rep), now. *PR Newswire*. Retrieved November 26, 2014, from www.prnewswire.com/news-releases/the-doctor-wont-see-you-mr-pharma-rep-now-92964699.html

Rizzo, J.A., & Zeckhauser, R. (2009). Generic script share and the price of brand-name drugs: the role of consumer choice. *International Journal of Health Care Finance and Economics*, *9*(3), 291–316. doi:10.1007/s10754-008-9052-0

Robinson, R. (2010). Unbranded strategies move from the back seat to the driver's position. *Pharmavoice*. November/December.

Rubin, J., Schultz, M., & Hatch, M.J. (2008). Coming to America: can Nordic brand values engage American stakeholders? *Journal of Brand Management*, *16*(1), 30–39. doi:10.1057/bm.2008.17

Schroff, K. (2003). Why pharma branding doesn't work. *Pharmaceutical Executive*, *23*(10), 50–58.

Schuiling, I., & Moss, G. (2004). How different are branding strategies in the pharmaceutical industry and the fast-moving consumer goods sector? *Journal of Brand Management*, *11*(5), 366–380. doi:10.1057/palgrave.bm.2540182

Sharma, K.E. (2013). Niche drugs key to growth of pharma industry in 2014. Retrieved November 26, 2014, from http://businesstoday.intoday.in/story/niche-drugs-key-to-growth-for-pharma-industry-in-2014/1/201927.html

Siddiqui, Z., & Sikka, K. (2014). Ranbaxy recalls some batches of generic Lipitor in latest quality blow. Reuters. Retrieved from www.reuters.com/article/2014/03/08/us-ranbaxylab-lipitor-usa-recall-idUSBREA27034201308

Tomljenovic, L., & Shaw, C.A. (2012). Too fast or not too fast: the FDA's approval of Merck's HPV vaccine Gardasil. *The Journal of Law, Medicine & Ethics: A Journal of the American Society of Law, Medicine & Ethics*, *40*(3), 673–681. doi:10.1111/j.1748-720X.2012.00698.x

Vernaz, N., Haller, G., Girardin, F., Huttner, B., Combescure, C., Dayer, P., & Bonnabry, P. (2013). Patented drug extension strategies on healthcare spending: a cost-evaluation analysis. *PLoS Medicine*, *10*(6), e1001460. doi:10.1371/journal.pmed.1001460

WHO Glossary. (2014). Generic drugs. Retrieved November 26, 2014, from www.who.int/trade/glossary/story034/en/

6 Traditional Industry Communication to Physicians

Promotional and Informational Elements

The global pharmaceutical industry communicates with physicians in a variety of ways. The traditional forms of promotion include face-to-face selling called 'detailing' by a professional sales representative (PSR); drug sampling (in person or electronically); advertising in professional publications (either hard copy or online); leave-behind materials (e.g. copies of clinical trial papers); sponsorship of continuing medical education (CME) and attendance at professional meetings; professional gifts; and participation in Phase IV and post-marketing surveillance (PMS) studies. Both historically and at present, the largest marketing expenses for any pharmaceutical company are for detailing and sampling—on average, they account for 50 to 75 percent of a brand's promotional budget (a detail to a physician is almost always accompanied by brand samples). Promotional elements are used in combination with others because physicians have different preferences and usage habits with respect to the different marketing mix tools. For marketers, physicians are still the most important target audience for their brands.

It would be an understatement to say that physician communication by the pharmaceutical industry is a controversial subject. Hundreds of articles in the scholarly literature, business press, and popular press refer to this communication as either promotion or education, depending on the author's perspective. Several books have also been written about the negative effects of the marketing to physicians on patients and the health care system overall. The industry's position is that all communication with physicians is intended to educate them on the drugs available so they are able to make appropriate prescribing decisions for their patients. Industry critics claim that physician marketing is linked to inaccurate information that results in higher rates of inappropriate prescribing as well as higher costs to patients and the health care system at large. The questions to be addressed are: first, whether or not this communication is effective at generating sales; and second, whether it is information, promotion, or some combination of the two. These questions are important because traditional forms of communication still remain the primary means of reaching physicians in a global context.

Physician Prescribing Characteristics

In order to fully appreciate the effects of industry communication on physicians, it is important to understand how a physician decides how much to prescribe and what drug to prescribe. Typically, a physician has several ways to obtain information about drugs: their own clinical experience; keeping up-to-date on the clinical research in their field via scientific studies; feedback from colleagues; and detailing. It is important to understand how this takes place in a practical sense.

A qualitative, in-depth study by Campo et al. (2005) suggests that the decision to prescribe a particular drug is a hybrid one. For example, while physicians prefer to be the key decision maker in the prescribing process, patients and other specialists may intrude on these decisions. Further, the notion of rational prescribing is not the only goal pursued by a physician; they also have personal and status goals that affect their prescribing decisions. (Bechara and Damasio's (2005) somatic marker hypothesis also supports this finding: the more complex the decision, the more likely an emotional process may take over to guide behavior.) Physicians also suffer from information overload and this has significant consequences for the preferred choice of information sources. Finally, it is challenging for physicians to make a diagnosis on the multiple disease possibilities that face them when evaluating a patient, as well as the uncertainties of the drug therapy they may choose. In other words, most physicians typically adopt risk avoidance strategies, such as following recommendations from their peers; consultation with their peers; and prescribing drugs with a well-established track record. The research also indicates that physicians use both routine and non-routine decision making rules. In the non-routine process, the patient's clinical presentation reduces the number of choices available and then different alternatives are examined before a decision is reached. The routine decision making process, on the other hand, involves fewer products in the choice set and a certain degree of "inertia" (Campo et al., 2005, p. 87) in the product that is ultimately prescribed.

In a recent review of 146 different US health plans, Joyce et al. (2011) found that in eight out of ten different therapeutic classes, the average physician may prescribe at least three different drugs and less than 16 percent prescribe brand name drugs only. Their detailed findings suggest that: 1) physicians do not exclusively prescribe either brand or generic drugs and their choice depends on the status of the particular therapeutic class; 2) physicians whose patients are covered by health plans/formularies are broader prescribers and try to match specific drugs with a patient's health plan; and 3) physicians are willing to try new therapies and are not necessarily loyal to one particular medication. (This last finding contradicts the notion of inertia as expressed by Campo et al., 2005.)

Do all physicians adopt new medications in the same way? Glass and Rosenthal (2004) examined the prescribing behavior of physicians to determine if any could be classified as early adopters of particular medications for both first-in-class and follow-on medications. They successfully determined that in fact, some physicians are early adopters of first-in-class drugs based on the following variables: pre-launch prescribing loyalty; pre-launch prescribing volume; age; marketing support; type of practice; investigator experience; and their specialty. These early adopter physicians write both a greater percentage and actual number of prescriptions at least three months prior to launch (these are the most important determinants of early adoption). The youngest and oldest doctors were the least likely to be early adopters. Higher promotion expenditures were also associated with rapid drug adoption by the 'early adopters.' Office-based physicians were associated with early adoption of first-in-class drugs; and those who participated in at least one Phase III trial were also likely to be early adopters. For follow-on drugs (brand extensions), their findings were somewhat different, as pre-product launch drug class prescribing was only significant if the drug was part of an established therapeutic category; company pre-launch prescribing loyalty was not a significant factor in a physician's prescribing decision.

For the prescribing of newer drugs in the face of older drugs, Gönül and Carter (2012) suggest that heavy prescribers in the US are likely to be specialists in solo practice with more experience; willing to see more sales representatives, receive samples, and allow longer representative visits; have both HMO (Health Maintenance Organization) affiliations and see more patients with these affiliations; are heavy prescribers in all therapy areas; and see more patients in their practices.

An Overview of Physician Detailing

As mentioned earlier, physician detailing is one of the most important elements in the pharmaceutical marketing mix, and the most "potent driver of primary demand" (Fischer & Albers, 2010, p. 118). A traditional sales call is a face-to-face meeting between a sales representative and a physician. It typically takes place in a physician's office, but has been known to occur in an office corridor, parking lot, or hospital cafeteria—in other words, wherever the PSR can find the physician and get the time to discuss the medication. Today, PSRs typically use electronic devices to support their sales efforts. A study by Encuity Research (2014) reported that physicians saw sales representatives using tablets (91 percent) during sales calls and gave them the highest usefulness rating as a sales aid during the call. Tablets enable the sales representatives to access multiple data sources during the sales call to augment their presentations.

Time pressures are a significant problem for physicians, and in part, they meet with PSRs because they view sales calls as a quick way to obtain information about new drugs in specific therapeutic areas without having to engage in reading journal articles, conducting Internet searches, or consultating with colleagues. Cegedim Strategic Data (2011) reported that the average physician receives approximately 246 details per year, with internists, GPs, and cardiologists receiving the most sales calls. The report further indicates that in 2011, 47 percent of sales calls were less than five minutes long and 45 percent between five and ten minutes long. The 2011 figures represent a decline in the length of sales calls when compared to 2006—at that time, only 26 percent of calls were just five minutes long or less. In addition, fewer products are being detailed per call—in 2006, 27 percent of sales calls covered two products compared to 10 percent of sales calls in 2011. Campo et al. (2005) reported that physicians do not want to spend any more time than necessary to obtain information from sales representatives because these visits take time away from patients.

Despite the apparent convenience of PSR visits, however brief, an increasing number of physicians are refusing to see sales representatives. According to PR Newswire (2014), 49 percent of all physicians are placing significant restrictions on pharmaceutical sales visits. This is an increasing trend not only in GP offices, but also among specialties such as dermatology, gastroenterology, and pediatrics. The reasons for this decline are cited as increased physician workload, heavier payer/provider considerations, and changing physician demographics—younger doctors prefer digital communication channels.

Partly as a result of these difficulties in accessing physicians, electronic detailing, or e-detailing, has emerged as a potential alternative to the in-person detailing model. There are different forms of e-detailing, which include interactive (virtual) and video e-detailing. The use of technology as a substitute for an in-person interaction has not yet been extensively researched; however, some recent studies will be presented in Chapter 7 on digital marketing to physicians.

One interesting aspect of the sales call not often discussed is its content. Steinman and Baron (2007) studied the content of sales representative visits for the drug gabapentin using subpoenaed court documents (*US ex rel. David Franklin v Pfizer Inc and Parke Davis*) in order to determine the content of a pharmaceutical sales call. Forty-six percent of the detailing calls contained messages in line with the approved uses of the drug, compared to 38 percent of the detailing calls containing messages that were unapproved uses, or off-label messages. Gabapentin was not compared to competing products in 83 percent of the calls. Supporting materials were used in 74 percent of the calls and they were evaluated as average or better by 67 percent of physicians with the informative value of the detail rated as acceptable or good in 69 percent of the calls. Seventy-six percent of physicians evaluated the overall sales call as very good to excellent. Samples were given in 39 percent of the sales calls, and 75 percent of these physicians were already prescribing gabapentin. Physicians indicated that

they would either increase (46 percent) or maintain (54 percent) their current use of gabapentin (60 percent were already medium to high prescribers). The authors suggest that even brief encounters have the possibility to influence physicians to prescribe, with a median duration of five minutes for each call.

The Effectiveness of Detailing as a Promotional Tool

An often-asked question is whether or not detailing is effective in increasing the number of prescriptions written for a particular drug and creating brand loyalty. The excessive levels of detailing during the recent blockbuster era also raised the issue of 'how much detailing is too much?' and whether or not detailing is informational. A recent meta-analysis of the pharmaceutical promotional literature (Spurling et al., 2010) identified 29 studies specifically about pharmaceutical sales visits, and the results are summarized here. Out of the studies identified, 17 found any association with increased prescribing of the drug being promoted. The remaining studies included in their analysis showed mixed results, with positive effects for some variables studied, but not all. The measures for which positive results were found in this meta-analysis included:

1) More frequent prescribing of a drug that showed initially lower prescribing rates prior to a sales call;
2) Longer sales visits for a particular drug were associated with higher rates of prescribing;
3) Increased rates of prescribing for a particular drug were observed in physicians receiving sales calls who were already high volume prescribers overall;
4) More sales visits for a particular brand were associated with lower market share for the brand competitor;
5) Sales visits were associated with a greater increase in market share for new products when compared to exposure to clinical information about the brand; and lastly,
6) More frequent sales calls were associated with diminishing returns for the brand with each additional sales call.

While some of these studies originate in the marketing literature, others come from the medical and public policy fields. Additional studies are presented here to shed light on these meta-analytic findings. Venkataraman and Stremersch (2007) found a positive effect of detailing on 58 percent of the brands they studied; and the addition of sampling to this group of brands resulted in a positive effect on prescriptions for all brands. Ching and Ishihara (2010) suggest that the effectiveness of detailing depends on the amount of information available to a physician and the degree to which the physician is already informed about the drug.

Detailing has a significant and positive effect on physicians that may increase the likelihood of prescribing a particular medication; however, excessive detailing is counter-effective (Gönül et al., 2001). In other words, too much detailing (combined with sampling) may lead to potential promotional fatigue and the perceived wasting of time—or a physician may sense that the company is overly desperate to sell their product. Campo et al. (2005) also confirmed that the perceived wasting of time by physicians was the reason for diminishing returns on too frequent or too lengthy sales calls. Gönül et al. (2001) further determined that a drug's price might detract from the positive effects of detailing, particularly if a physician is working with a specific drug formulary list. The authors suggest that physicians whose patients are covered by private insurance are more likely to be positively affected by detailing and sampling efforts than those covered by a public payer or health management organization.

Given the potential informational aspects of detailing, some research has examined how physicians learn about new drugs and how they use this information to make prescribing decisions. Narayanan and Manchanda

(2009) found that there is no consistent pattern in the rate of physician learning about a new drug's quality, and that a physician's responsiveness to detailing efforts changes over the life cycle of the brand. They posit that there are two types of effects to detailing: informative effects and persuasive effects. In the introductory phase of a product, both informative and persuasive effects are present; however, in the later phases of the product's life cycle, only the persuasive effect is present. They also note that physicians differ significantly in how they acquire knowledge about a particular drug, and that the level of detailing may vary based on how amenable a particular physician is to persuasion by a sales representative.

With respect to how physicians evaluate brand attributes that include effectiveness and side effects, Venkatamaran and Stremersch (2007) found that detailing has stronger positive effects both for drugs that are more effective and for drugs with more side effects. They conclude that detailing is effective in these two situations because in both instances a PSR must provide information to support the claims of efficacy and reduce the potential risk of side effects (this paper is highly important and should be read *in toto* by the reader). The authors strongly suggest that there is a need for unbiased, evidence-based marketing. This sentiment is echoed by physicians, who say they want highly trained and more credentialed representatives, more use of clinical studies and evidence-based medicine in the detail call, and presentation of unbiased information (Publicis, 2014).

The Role of Sampling to Physicians

Pharmaceutical sampling is the second most important tool used by pharmaceutical marketers. A sample is a trial package of a medication given to a physician for the purpose of evaluating the clinical effects of the drug in their patients. There are multiple forms of sampling available to physicians identified by Groves and Pendlebury (2005) that include: in-person and electronic methods of delivery; in-person delivery by sales representatives; full-service sample fulfillment houses; professional association portals; and drop-ship programs with tracking capability; multiple media integrators (companies that issue coupons redeemable for samples); low-tech trial prescribing (physicians put stickers on a prescription and the patient gets a sample at the pharmacy); pharmacy dispensed sampling systems (this is similar to trial prescribing); and smart card technology (a card signed by the physician and then used by the patient for samples at the pharmacy). The samples acquired by smart card are delivered either in person to the physician or the patient; or to the physician via delivery to his/her office. In the mid-2000s, 38 percent of physicians complained that they did not receive enough samples and 22 percent stated that the supply of samples was unpredictable (Datamonitor, 2006). However, later research reported that sample supplies were reduced by 25 percent since the patent cliff and have declined by 25 percent since 2007 (O'Reilly, 2012). Comer (2010) reported that family physicians overwhelmingly prefer samples hand-delivered by sales representatives (73 percent); e-sampling "may be cost-efficient, [but] the end result could negatively affect the overall promotional mix for the brand."

Samples are a key element of the promotional mix used by marketers. From the industry perspective, samples are an important way for a physician to evaluate a drug in their practice, to assist patients with their drug adherence, and to help indigent patients who would not otherwise receive the drug. Critics of sampling view it as a 'bribe' to induce a physician to use a particular drug. Anecdotally, it is often said by sales representatives that without samples, a physician will not prescribe a particular drug. However, there is research to answer the age-old question about whether or not sampling generates prescriptions and influences physicians—it does, but to varying degrees.

Numerous studies support the notion that sampling encourages the increased use of a particular drug. A review of the literature on prescription drug sampling (Groves et al., 2003) uncovered 23 different studies that support the following: 1) sampling has a positive influence on prescribing; 2) sampling is an important service provided by pharmaceutical companies; 3) physicians would not see PSRs without samples; 4) sampling is an accepted practice in physician offices; 5) distribution and storage of samples is not well controlled in physician offices and hospital clinics (see Soucy et al., 2009); and 5) samples are important for indigent patients.

Mizik and Jacobson (2004) found that free drug samples have a positive but modest effect on the number of new prescriptions issued by a physician. Their study focused on three different drugs with varying magnitudes of sales (from $0.5 billion to over $1 billion) and different lengths of time on the market (from six months to 11 years). On average, it takes between 6.44 samples to 73 samples to generate one new prescription depending on the drug. It should be noted here, however, that sampling levels considered modest by academic scholars are not necessarily modest from an industry perspective. The authors found diminishing returns with excessive sampling, and their results support those of the Gönül and et al. (2001) detailing study. Campo et al. (2005) also found oversampling is a problem because it results in the physician's expectation that samples will always be provided, and that belief diminishes the effects of the samples. Additionally, Venkataraman and Stremersch (2007) found a positive but weak effect of sampling on prescription volume. (For those readers interested in the modeling of sampling effects, see Joseph and Mantrala (2009).)

Three observational studies support the association between sampling and increased prescribing. Boltri et al. (2002) found that residents were more likely than medical faculty to prescribe a drug that was sampled, and an increase in lower-cost first-line therapies was the result when samples were discontinued. Adair and Holmgren (2005) also determined that residents who have access to samples were likely to choose those drugs that were sampled. In a review of administrative health plan prescription data for three clinics, Symm et al. (2006) reported that GPs who receive free samples are more likely to prescribe those medications than those that do not. The most recent study by Hurley et al. (2014) suggests that the use of samples in dermatology offices increased the use of branded drugs versus generics: this resulted in a two-fold increase in the cost of these drugs over those in medical centers that did not allow the distribution of samples.

Interesting evidence from the industry suggests that sampling does not help patients to adhere to their medical regimen. Chase (2007) reports that samples may actually have a negative impact on patient adherence: those patients who receive the greatest number of free samples for the longest time have the lowest number of filled prescriptions. Blauvelt (2008) also reports on the fact that sampling alone does not help patients adhere to drug regimens and that other interventions are needed.

Some research challenges the view that samples are used in greater quantities for the poor and uninsured. A landmark study by Cutrona et al. (2008), based on a nationally representative US sample, suggests that in fact, the poor and uninsured are less likely to receive free drug samples than either the wealthy or insured. According to the authors, 12 percent of patients received at least one free sample; a higher percentage of persons with health insurance received a free sample than those who were not insured (12.9 percent versus 9.9 percent), and the poorest patients in the sample received the fewest samples.

The Effectiveness of Journal Advertising

Journal advertising is a global issue for marketers, as physicians worldwide read these medical journals and receive the messages contained in the advertising. Industry publications suggest that a pharmaceutical company may receive approximately $2.43 in revenue for every dollar spent on journal advertising (Liebman,

2000). Advertising is an important source of revenue for medical journals as it reduces costs to the subscriber (Gettings et al., 2014). Dehaas (2010) states that journal advertising is a "straightforward arrangement that works to the mutual benefit of publishers, advertisers, physicians, and ultimately, the health care system" (p. 980). However, Lexchin (2009) and others (Fugh-Berman et al., 2006) disagree and call for an end to journal advertising.

The content and quality of journal advertising is a topic of much debate. Othman et al. (2009) stated that the "low quality of advertising is a global issue" (p. e6350). In a study that examined adherence to FDA guidelines for safe prescribing, Korenstein et al. (2011) found that only 18.1 percent of journal ads were fully compliant with the guidelines, with 41 percent as non-adherent for both bias and incomplete information about risks. Almost half of the ads examined in their study were missing proper references, and 28.9 percent did not properly quantify the drug's efficacy.

Gettings et al. (2014) note that there are differences among medical journals in their acceptance of advertisements: their study examined six medical journals in Canada, the US, and the UK, and their findings suggest that Canadian journals contain five times more advertisements than either the US or British journals. In fact, Vlassov (2007) intimates that there is a relationship between journal content and the placement of journal ads; his examination of seven medical journals in the US, UK, and Russia concludes that "journal content is manipulated to place more emphasis on the advertisements" (p. 786).

The available research suggests that journal advertising influences prescribing habits and physician attitudes. Spurling et al. (2010) reported eight studies on journal advertising in their meta-analysis of pharmaceutical promotion, four of which were observational (with data) and four of which used statistical testing. It should be noted here that it is commonly accepted by marketers that no direct causation between advertising and sales (in this case prescriptions) can be established, as the use of multiple promotional efforts is usually simultaneous and advertising effects are difficult, if not impossible, to capture. Given this caveat, their meta-analytic findings suggest a positive effect of journal advertising on physician attitudes and prescribing levels.

A summary of the findings in the Spurling et al. (2010) review indicates that two studies showed a decrease in prescriptions after advertising was stopped; one study showed an increase in prescriptions where the drug had not been introduced previously prior to advertising; one study showed inconclusive results; and finally, one study showed that ad recognition led to higher market share. Of the studies they reported that included statistical testing, three found a positive association, and one resulted in mixed findings. An examination of some recent studies may shed light on the uses of journal advertising to physicians.

Campo et al. (2005) provide some insight into the effects of journal advertising to physicians. Their physician sample preferred receiving information orally versus in writing because it is less time consuming, and they suggest that younger physicians may prefer to rely on electronic databases for the type of information presented in an advertisement. It is possible that their sample might not have wanted to admit to the effects of advertising to their interviewers. In contrast to the Campo et al. (2005) findings, Fischer and Albers (2010) showed that professional journal advertising has both short- and long-term positive effects on sales revenue by using statistical modeling.

Continuing Medical Education—No Free Lunch

Continuing medical education (CME) is essential for physicians, as they are required by their licensing boards to maintain their professional standing by registering for these courses, which may be delivered either in person or online. These courses provide updated information on treatment modalities in the field as well as

upcoming trends, and experts in a particular therapeutic area develop the content for the courses. The specific licensing board usually sponsors these courses; however, some courses receive financial support from the pharmaceutical industry. Any financial contributions from outside parties toward CME courses are required to be disclosed to the participants of the course.

As part of the pharmaceutical industry's marketing mix, CME allows the company to provide information about its new drugs by experts in the field. Steinman and Baron (2007) reported that the industry sponsorship of CME in the US accounts for approximately 65 percent of the revenue generated from these programs, which amounts to approximately $1 billion. While some physicians are strongly opposed to industry-sponsored CME because of the inherent bias in these activities (Lexchin & Vitry, 2012), other physicians believe that they are entitled to this benefit, unlike other professionals such as lawyers, who pay for their own courses. One reason for this attitude is that the physician believes the burden of having to pay office overheads and lose income during their time away entitles them to this subsidized educational service (Marlow, 2004). Current international self-regulatory policies suggest that any reimbursement for CME be given to the professional organization sponsoring the event to reduce overall fees to the individual physician and that meals be paid for by the individual physician or as part of the fee for the event.

The research suggests that CME activity generates revenue to the sponsoring pharmaceutical company. Walker (2001), citing a study by Neslin (2001), stated that the ROI for CME was $3.56, and ranked second to journal advertising at $5.00, detailing at $1.72, and consumer ads at $0.19. (The original study is no longer available and these findings should be interpreted with caution, as the results are highly correlated with one another.) The Spurling et al. (2010) meta-analysis found eight studies that evaluated company-sponsored CME and its effects on prescribing with mixed results—five found a positive association, while the remainder did not. However, another literature review by Cervero and He (2008) indicated that no empirical studies exist that specifically address the relationship between bias (and by extension, increased sales) and industry-sponsored CME. Brody (2009) noted that: "the data on the impact of CME are weaker than in some other areas of the medicine/pharmaceutical industry relationship" (p. 455).

A larger concern that was raised by Cervero and He (2008) is that more than half of physicians believe there is no potential for bias in CME activities. Steinman and Baron (2007) and Brody (2009) suggest that there are ways of dealing with this potential bias, such as avoiding meetings with a single sponsor, or as Brody succinctly states, "American physicians as a group are wealthy enough to pay for their own CME programs" (p. 458). This may not necessarily be true for physicians in other non-Western countries.

Industry-Sponsored Clinical Trial Publications

A key component of the marketing materials distributed to physicians (in hard copy or electronically) is the evidence that supports the efficacy and side effect claims made for a particular brand: the clinical trial. The foundation of the research presented to physicians during the initial marketing efforts of a new drug are the Phase III trials: these are double-blind, randomized trials in controlled, experimental settings that are designed to show a drug's efficacy and safety when compared to a placebo. After a drug is launched, Phase IV or PMS trials are presented to physicians and are viewed as helpful in developing marketing strategies (Mauriello, 2010). It should be noted that while these terms are used interchangeably in both the scientific and business literature, not all Phase IV studies are PMS studies. Typically, PMS studies have more to do with drug safety and the monitoring of side effects, whereas Phase IV studies are more concerned with either new indications for a drug or competitor drug comparisons. Given this distinction, any clinical study conducted post-launch may

compare a drug to a competitor; measure a drug's outcomes and patient adherence; and review drug safety, drug cost-effectiveness, and drug performance in a natural 'field' environment versus an experimental setting (van Thiel & van Delden, 2008). Many countries, including Japan, the Philippines, India, and Germany, all have regulatory requirements that include PMS trials for use in safety and adverse reaction monitoring, as well as any change in dosing (Suvarna, 2010).

It is expected and assumed that all clinical trials are conducted based on sound scientific practices with the appropriate use of data methods because these trials are the basis for evidence-based medicine and practice guidelines. The industry's position is that all clinical trials are conducted in an ethical and rigorous manner. However, some research suggests that there is bias in industry studies that favors the companies sponsoring the research (Lexchin et al., 2003). The authors report that while industry studies were of good quality, the sponsored studies were more likely to favor the company and they were less likely to be published than studies from other sources. A later study by Turner et al. (2008) suggests that there is selective publication of clinical trials that may lead to erroneous opinions about the effectiveness and riskiness of drugs—in other words, studies that do not have the desired outcome may never be submitted for publication.

The industry and some physicians believe that Phase IV studies are valuable because they present different information for drugs that are not 'first-in-class'; they look at different end points other than just safety and efficacy; and they provide a 'real world' view of the drug versus the artificial setting of Phase III trials (Tunnah, 2011). Polygenis (2005) suggests that trials that measure outcomes and health economics issues cannot be conducted in the experimental setting which is used for other types of Phase IV trials because of the nature of the variables being measured. Critics of Phase IV trials argue that there are doubts about the "rigor and clinical value of Phase IV research" (van Thiel & van Delden, 2008, p. 416), and that "there is much room for improvement in the design of Phase IV trials that seek to add benefit claims" (Bernabe et al., 2013).

Another controversy that surrounds both Phase III and Phase IV clinical studies is the ghostwriting of these studies undertaken by MECCs (medical education and communications companies) that has been widely reported in the media. This ghostwriting industry is well established, with McHenry (2010) reporting that approximately 182 MECCs operate in the US, and charge fees that range from $18,000 to $40,000 per manuscript. According to the author, there are three types of ghostwriting: collaborative research (technical write-up of findings) with some authors actually having done the research and others for honorary purposes; in-house research with honorary authors (usually review articles); and research that summarizes positive prescribing experience with a drug. Eight companies were sued on the basis of case studies identified as ghostwritten with misleading information contained in the articles. Bosch et al. (2012) point out that this activity "openly infringes academic standards . . . and contributes to fraud" (p. e1001163).

Gift Giving to Physicians

Prior to the changes in policies by medical societies and some governments (the US and France) in the form of Sunshine laws, as well as the current policies of the industry self-regulatory groups IPFMA (2012) and the US PhRMA (2008), high levels of gift giving to physicians was a common promotional practice by the pharmaceutical industry in most countries. Generally speaking, gift giving is a culturally bound phenomenon and attitudes toward gifts vary across cultures. Gifts may include office items, travel subsidy or full payment for conference or symposia attendance, and meals; they also include items like textbooks and stethoscopes, and medical bags for students. Under the current self-regulatory codes, small gifts such as pens or mugs are not permitted, nor are tickets to entertainment or recreational events; however, gifts that serve an educational

purpose may be given if they are $100 or less. Meals may also be provided, but they should be of modest value.

A meta-analysis of gift giving prior to the current guidelines (Wazana, 2000) concluded that gift giving affected prescribing behavior and was a serious problem to be addressed by public policy makers. Why is gift giving so effective? The answer lies in an interesting study by Dana and Loewenstein (2003) in their discussion about self-serving bias. This concept is defined as the perception of fairness by individuals of what they believe is right, but which is tainted by their own self-interest. Physicians do not believe they are biased when they make prescribing decisions; however, they are, in fact, biased and this bias is unintentional. Physicians also believe that 'it's somebody else' who is biased—they do not believe they suffer from bias themselves. A later study by Zipkin and Steinman (2005) also supports Dana and Loewenstein's (2003) findings. Ironically, the effect of small gifts is greater than that of more expensive ones. Katsanis et al. (2004) showed an inverse relationship between the size of the gift and the effect on the physician. If a gift was small ($50 or less), a physician was more likely to accept it and to reciprocate with a change in prescribing behavior. Physicians perceived larger gifts to be 'bribes' and therefore subject to greater scrutiny by colleagues or patients. Further, there was a positive relationship between seeing PSRs and availability of gifts: physicians would not see PSRs without some gift being given.

Will recent changes in gift policy make a difference? Some research about the influence of small gifts to medical students on their attitudes toward the pharmaceutical industry may be useful in answering this question. Grande et al. (2009) compared third and fourth year medical students at two different universities to study whether those exposed to promotional items had more favorable attitudes toward the industry. Their findings suggest that: "subtle exposure to small pharmaceutical items influences implicit attitudes toward marketed products among medical students" (p. 887). An Australian study (Carmody & Mansfield, 2010) determined that most medical students had been exposed to gift giving and that its appropriateness varied from 23 percent to 80 percent in favor of gift giving. Siddiqui et al. (2014) conducted a study of medical students in Pakistan and determined that 81 percent of respondents favored pharmaceutical sponsorship of student seminars/events at medical college, and as well, one-third of students surveyed found gift giving by pharmaceutical companies an acceptable practice. Despite self-regulatory guidelines, this research suggests that it is difficult to change attitudes toward gift giving in cultures where it is a commonly accepted practice.

Implications and Conclusions

Physician detailing remains one of the most important and effective elements of the marketing mix. It is important to understand the nuances of this activity, which the research suggests has informative and promotional elements. While physicians seem to rely on PSRs for drug information because of their time constraints, the ultimate purpose of detailing is promotional—to sell a firm's brands—and detailing is still the most effective way to accomplish this objective. The research also suggests that excessive detailing results in diminishing returns to the firm.

Samples provide a means for physicians to evaluate a new drug in their practice to observe its effects in a 'real world' setting, and they are also a strong promotional tool that generates prescriptions and influences prescribing. As with detailing, excessive sampling also results in diminishing returns. Journal advertising is intended to inform physicians about new drugs and indications, or to provide a reminder to physicians about an existing brand. It is an effective way to communicate with physicians, and the research suggests there are positive effects on prescription volume in both the short and long term. There are concerns about the placement of journal advertising and that its use by medical journals as a source of revenue may create bias.

While the objective of CME from a physician's point of view is educational, from a pharmaceutical firm's point of view, it is also revenue producing because it generates prescriptions, as suggested by the research. The primary concern with CME activity is that it may create a bias toward a particular drug. A similar concern exists for the use of Phase IV trials as part of the promotional mix to physicians. Gift giving both causes bias and positively affects prescribing: despite the fact that it is restricted by self-regulatory groups, it remains a global issue of concern due to cultural differences in different countries.

If the industry is able to provide physicians with unbiased, evidence-based clinical research combined with a consultative selling approach that is focused on their practice, then physician communication may have the potential to be elevated from a promotional function to an educational one. At present, the research suggests its purpose is primarily promotional, despite the informational elements present in the material, and more time will be needed for the industry to adapt to the current needs of physicians.

References

Adair, R. F., & Holmgren, L. R. (2005). Do drug samples influence resident prescribing behavior? A randomized trial. *The American Journal of Medicine*, *118*(8), 881–884. doi:10.1016/j.amjmed.2005.02.031

Bechara, A., & Damasio, A. R. (2005). The somatic marker hypothesis: a neural theory of economic decision. *Games and Economic Behavior*, *52*(2), 336–372. doi:10.1016/j.geb.2004.06.010

Bernabe, R. D., Wangge, G., Knol, M. J., Klungel, O. H., Delden, J. J. van, Boer, A. de, . . . Thiel, G. J. van. (2013). Phase IV non-inferiority trials and additional claims of benefit. *BMC Medical Research Methodology*, *13*(1), 70. doi:10.1186/1471-2288-13-70

Blauvelt, B. M. (2008). The future of sampling. *Med Ad News*, *27*(1), 30

Boltri, J. M., Gordon, E. R., & Vogel, R. L. (2002). Effect of antihypertensive samples on physician prescribing patterns. *Family Medicine*, *34*(10), 729–731.

Bosch, X., Esfandiari, B., & McHenry, L. (2012). Challenging medical ghostwriting in US courts. *PLoS Medicine*, *9*(1), e1001163. doi:10.1371/journal.pmed.1001163

Brody, H. (2009). Pharmaceutical industry financial support for medical education: benefit, or undue influence? *The Journal of Law, Medicine & Ethics: A Journal of the American Society of Law, Medicine & Ethics*, *37*(3), 451–460, 396. doi:10.1111/j.1748–720X.2009.00406.x

Campo, K., De Staebel, O., Gijsbrechts, E., & van Waterschoot, W. (2005). Physicians' decision process for drug prescription and the impact of pharmaceutical marketing mix instruments. *Health Marketing Quarterly*, *22*(4), 73–107.

Carmody, D., & Mansfield, P. (2010). What do medical students think about pharmaceutical promotion? *Australian Medical Student Journal*. Retrieved November 26, 2014, from www.amsj.org/archives/300

Cegedim Strategic Data. (2011). Physicians overwhelmed with sales calls. Retrieved November 26, 2014, from http://worldofdtcmarketing.com/physicians-overwhelmed-with-sales-calls/marketing-to-health-care-professionals/

Cervero, R., & He, J. (2008). The relationship between commercial support and bias in continuing medical education activities: a review of the literature. Retrieved November 26, 2014, from www.accme.org/news-publications/publications/articles-presentations/relationship-between-commercial-support-and

Chase, J. (2007). The pursuit of persistence. *MMM*. Retrieved November 26, 2014, from www.mmm-online.com/the-pursuit-of-persistence/article/35890/

Ching, A., & Ishihara, M. (2010). The effects of detailing on prescribing decisions under quality uncertainty. *Quantitative Marketing and Economics*, *8*(2), 123–165. doi:10.1007/s11129-010-9082-z

Comer, B. (2010). Primary care docs prefer rep delivered samples, says study. *MMM*. Retrieved November 26, 2014, from www.mmm-online.com/primary-care-docs-prefer-rep-delivered-samples-says-study/article/175611/

Cutrona, S. L., Woolhandler, S., Lasser, K. E., Bor, D. H., McCormick, D., & Himmelstein, D. U. (2008). Characteristics of recipients of free prescription drug samples: a nationally representative analysis. *American Journal of Public Health*, *98*(2), 284–289. doi:10.2105/AJPH.2007.114249

Dana, J., & Loewenstein, G. (2003). A social science perspective on gifts to physicians from industry. *JAMA: The Journal of the American Medical Association*, *290*(2), 252–255. doi:10.1001/jama.290.2.252

Datamonitor. (2006). Reaching doctors through the Internet. Retrieved November 26, 2014, from www.pharmafield.co.uk/features/2006/06/Reaching-doctors-through-the-Internet

Dehaas, D. (2010). Should medical journals carry pharmaceutical advertising? *Canadian Family Physician*, *56*(10), 978–980.

Encuity Research. (2014). Is there a next level for e-promotion? Retrieved November 26, 2014, from www.campbellalliance.com/articles/Encuity%20-%20eAnswers%20Report%20-%20March%202014.pdf

Fischer, M., & Albers, S. (2010). Patient- or physician-oriented marketing: what drives primary demand for prescription drugs? *Journal of Marketing Research (JMR)*, *47*(1), 103–121. doi:10.1509/jmkr.47.1.103

Fugh-Berman, A., Alladin, K., & Chow, J. (2006). Advertising in medical journals: should current practices change? *PLoS Medicine*, *3*(6), e130. doi:10.1371/journal.pmed.0030130

Gettings, J., O'Neill, B., Chokshi, D.A., Colbert, J.A., Gill, P., Lebovic, G., & Persaud, N. (2014). Differences in the volume of pharmaceutical advertisements between print general medical journals. *PLoS ONE*, *9*(1), e84790. doi:10.1371/journal.pone.0084790

Glass, H.E., & Rosenthal, B. (2004). Demographics, practices, and prescribing characteristics of physicians who are early adopters of new drugs. *P&T*, *29*, 699–708.

Gönül, F.F., & Carter, F.J. (2012). Estimation of promotional strategies for newer vs older drugs based on physician prescribing data. *International Journal of Pharmaceutical and Healthcare Marketing*, *6*(1), 39–54. doi:10.1108/17506121211216897

Gönül, F.F., Carter, F., Petrova, E., & Srinivasan, K. (2001). Promotion of prescription drugs and its impact on physicians' choice behavior. *Journal of Marketing*, *65*(3), 79–90.

Grande, D., Frosch, D.L., Perkins, A.W., & Kahn, B.E. (2009). Effect of exposure to small pharmaceutical promotional items on treatment preferences. *Archives of Internal Medicine*, *169*(9), 887–893. doi:10.1001/archinternmed.2009.64

Groves, K.E.M., & Pendlebury, J.W. (2005). Prescription drug sampling—is the status quo about to change? Some new sampling methods bring pharmacists into the picture. *Canadian Pharmacists Journal/Revue Des Pharmaciens Du Canada*, *138*(6), 60–66. doi:10.1177/171516350513800613

Groves, K.E.M., Sketris, I., & Tett, S.E. (2003). Prescription drug samples—does this marketing strategy counteract policies for quality use of medicines? *Journal of Clinical Pharmacy and Therapeutics*, *28*(4), 259–271.

Hurley, M.P., Stafford, R.S., & Lane, A.T. (2014). Characterizing the relationship between free drug samples and prescription patterns for acne vulgaris and rosacea. *JAMA Dermatology*, *150*(5), 487–493. doi:10.1001/jamadermatol.2013.9715

IPFMA. (2012). Retrieved November 26, 2014, from www.ipfma.com/

Joseph, K., & Mantrala, M. (2009). A model of the role of free drug samples in physicians' prescription decisions. *Marketing Letters*, *20*(1), 15–29. doi:10.1007/s11002–008–9045–2

Joyce, G.F., Carrera, M.P., Goldman, D.P., & Sood, N. (2011). Physician prescribing behavior and its impact on patient-level outcomes. *The American Journal of Managed Care*, *17*(12), e462–471.

Katsanis, L.P., Thakor, M.V., & Ahmed, S. (2004). Pharmaceutical company gift-giving to physicians: some effects on perceived information value, prescribing, and acceptance of representative visits. *Academy of Marketing Science Annual Conference*, May 26–29, Vancouver, B.C.

Korenstein, D., Keyhani, S., Mendelson, A., & Ross, J.S. (2011). Adherence of pharmaceutical advertisements in medical journals to FDA guidelines and content for safe prescribing. *PLoS ONE*, *6*(8), e23336. doi:10.1371/journal.pone.0023336

Lexchin, J. (2009). CJEM and pharmaceutical advertisements: it's time for an end. *Canadian Journal of Emergency Medicine*, *11*(4), 375–379.

Lexchin, J., & Vitry, A. (2012). Should the C in CME stand for commercial? *Southern Med Review*, *5*(1), 3–5.

Lexchin, J., Bero, L.A., Djulbegovic, B., & Clark, O. (2003). Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *British Medical Journal*, *326*(7400), 1167–1170. doi:10.1136/bmj.326.7400.1167

Liebman, M. (2000). Listen up, publishers say—journal advertising sells! *Medical Marketing & Media*. Retrieved from www.highbeam.com/doc/1P3–52420910.html

McHenry, L. (2010). Of sophists and spin-doctors: industry-sponsored ghostwriting and the crisis of academic medicine. *Mens Sana Monographs*, *8*(1), 129–145. doi:10.4103/0973–1229.58824o

Marlow, B. (2004). The future sponsorship of CME in Canada: industry, government, physicians or a blend? *Canadian Medical Association Journal*, *171*(2), 150–151. doi:10.1503/cmaj.1040629

Mauriello, D. (2010). The importance of phase 4 clinical research. Retrieved November 26, 2014, from http://danteresources.blogspot.ca/2010/03/importance-of-phase-4-clinical-research.html

Mizik, N., & Jacobson, R. (2004). Are physicians 'easy marks'? Quantifying the effects of detailing and sampling on new prescriptions. *Management Science*, *50*(12), 1704–1715. doi:10.1287/mnsc.1040.0281

Narayanan, S., & Manchanda, P. (2009). Heterogeneous learning and the targeting of marketing communication for new products. *Marketing Science*, *28*(3), 424–441. doi:10.1287/mksc.1080.0410

O'Reilly, K.B. (2012, March 26). Pharma scales back drug samples to physician offices. Retrieved November 26, 2014, from www.amednews.com/article/20120326/profession/303269956/2/

Othman, N., Vitry, A., & Roughead, E.E. (2009). Quality of pharmaceutical advertisements in medical journals: a systematic review. *PLoS ONE*, *4*(7), e6350. doi:10.1371/journal.pone.0006350

Polygenis, D. (2005). Phase IV study or patient registry? Post-marketing research differs in scope and process. *Canadian Pharmaceutical Marketing*, September, 41–43. Retrieved November 26, 2014, from www.stacommunications.com/journals/cpm/2005/September/PDF/041.pdf

PR Newswire. (2014). The doctor won't see you (Mr. Pharma Rep), now. *PR Newswire*. Retrieved November 26, 2014, from www.prnewswire.com/news-releases/the-doctor-wont-see-you-mr-pharma-rep-now-92964699.html

Publicis. (2014). What physicians want! Survey. *Publicis Touchpoint Solutions, Inc.* Retrieved November 26, 2014, from www.publicishealthcare.com/Libraries/News_Documents/2012_What_Physicians_Want_Survey.sflb.ashx

Siddiqui, U.T., Shakoor, A., Kiani, S., Ali, F., Sharif, M., Kumar, A., & Farid-ul-Husnain, S. (2014). Attitudes of medical students towards incentives offered by pharmaceutical companies—perspective from a developing nation—a cross sectional study. *BMC Medical Ethics*, *15*(1), 36. doi:10.1186/1472–6939–15–36

Soucy, G., Bussières, J.-F., Tardif, L., & Bailey, B. (2009). Inventory of drug samples in a health care institution. *The Canadian Journal of Hospital Pharmacy*, *62*(4). doi:10.4212/cjhp.v62i4.811

Spurling, G.K., Mansfield, P.R., Montgomery, B.D., Lexchin, J., Doust, J., Othman, N., & Vitry, A.I. (2010). Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: a systematic review. *PLoS Medicine*, *7*(10), e1000352. doi:10.1371/journal.pmed.1000352

Steinman, M.A., & Baron, R.B. (2007). Is continuing medical education a drug-promotion tool? YES. *Canadian Family Physician*, *53*(10), 1650–1653.

Suvarna, V. (2010). Phase IV of drug development. *Perspectives in Clinical Research*, *1*(2), 57–60.

Symm, B., Averitt, M., Forjuoh, S.N., & Preece, C. (2006). Effects of using free sample medications on the prescribing practices of family physicians. *Journal of the American Board of Family Medicine: JABFM*, *19*(5), 443–449.

Tunnah, P. (2011). Clinical continuity: the commercial role of Phase IV studies. Pharmaphorum. Retrieved from www.pharmaphorum.com/articles/clinical-continuity-the-commercial-role-of-phase-iv-studies

Turner, E.H., Matthews, A.M., Linardatos, E., Tell, R.A., & Rosenthal, R. (2008). Selective publication of antidepressant trials and its influence on apparent efficacy. *The New England Journal of Medicine*, *358*(3), 252–260. doi:10.1056/NEJMsa065779

US PhRMA. (2008). Pharmaceutical Industry Profile 2008. Washington, DC: PhRMA; March, 2008. Retrieved November 26, 2014, from www.phrma.org/profiles_&_reports and www.phrma.org/files/2008%20Profile.pdf

van Thiel, G.J.M.W., & van Delden, J.J.M. (2008). Phase IV research: innovation in need of ethics. *Journal of Medical Ethics*, *34*(6), 415–416. doi:10.1136/jme.2007.023911

Venkataraman, S., & Stremersch, S. (2007). The debate on influencing doctors' decisions: are drug characteristics the missing link? *Management Science*, *53*(11), 1688–1701. doi:10.1287/mnsc.1070.0718

Vlassov, V.V. (2007). Is content of medical journals related to advertisements? Case-control study. *Croatian Medical Journal*, *48*(6), 786–790.

Walker, L. (2001). ROI for meetings beats detailing and DTC. *MeetingsNet.* Retrieved November 26, 2014, from http://meetingsnet.com/medicalmeetings/meetings_roi_meetings_beats

Wazana, A. (2000). Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA: The Journal of the American Medical Association*, *283*(3), 373–380.

Zipkin, D.A., & Steinman, M.A. (2005). Interactions between pharmaceutical representatives and doctors in training. A thematic review. *Journal of General Internal Medicine*, *20*(8), 777–786. doi:10.1111/j.1525–1497.2005.0134.x

7 Digital Communication to Physicians

Closed Loop and Multichannel Marketing

Physicians may be reached via digital channels of communication in addition to personal channels such as face-to-face detailing, and these channels include websites (branded, corporate, and independent content sites), social media, and smartphone/tablet applications. Physicians today have at least three or more devices that include a combination of a desktop, laptop, smartphone, and tablet—the smartphone is currently the most popular of the devices (Bard, 2014). The same study, however, reports that only 14 percent of physicians consider social media important to them as a clinical resource.

As with all media, it is important to understand that different digital channels will reach different physician audiences, so some mix of traditional and electronic channels is recommended by those in the industry to ensure adequate target market coverage (this is also known as multichannel marketing). In addition, the prevalent use of tablet technology as part of detailing now permits the rapid transmission of information about physician visits back to the head office for analysis and subsequent action back to the sales representative or brand manager. This process is known as closed loop marketing, and is used by some pharmaceutical companies to improve the way they reach their physician audience.

In addition to digital media, another important use of the Internet by physicians is to communicate with patients: approximately 48 percent of physicians use e-mail for this purpose (Cooper et al., 2012). It is considered to be safe, effective, and efficient; it also improves patient satisfaction and saves time for patients. However, the flip side of this coin is that e-mail increases physician workload unless fewer patients are seen (Bishop et al., 2013).

Although digital marketing is an important topic of conversation for pharmaceutical marketers, they have been reluctant to allocate a significant portion of their promotion budgets to these promotional channels. Mack (2014), citing a report from Cegedim Strategic Data, indicates that digital expenditure amounted to approximately 6 percent of total audited marketing expenditures in 2014. The bulk of this expenditure was spent on corporate websites (55 percent), e-detailing (24 percent), e-mailing (15 percent), and e-meetings (4 percent), with social media and apps accounting for approximately 2.1 percent of these expenses. eMarketer (2013) predicts that the pharmaceutical industry's share of US digital advertising will decline from 2013–2017 as a result of growing privacy concerns, regulatory uncertainty, and patent expirations. They also report that the pharmaceutical industry spends the least on paid online and mobile media when compared to other industries. In Europe, although spending on digital channels grew by approximately 40 percent, their overall expenditure is even less than that in the US (PMLiVE, 2012).

Despite great interest in this area, the data reported above suggests that industry and medical professionals are dipping their toes into the digital water very carefully. It was believed that the situation would change with

the FDA's long-awaited guidelines on the use of social media (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf). However, Staton (2014) reports that brand managers believe that the new FDA rules preclude the use of Twitter because of the nature of the disclosure requirements and the inherent limit of 140 characters. The general tone of the response from the industry is one of dissatisfaction with the social media guidelines.

Some recent and very limited research may provide an explanation for the caution exercised by physicians and pharmaceutical companies in the use of certain digital media, as well as the evaluation of current digital strategies.

E-Detailing

In a comprehensive review of e-detailing, Heutschi et al. (2003) and Alkhateeb and Doucette (2008) outline the key reasons for the emergence of e-detailing in Europe and North America respectively. Heutschi et al. (2003) cite the following reasons for the emerging importance of e-detailing: limited opportunities to speak to a physician in person; infrequent physician calls; short duration of each sales call; high costs associated with each sales call; lack of sales representative continuity due to frequent M&A activity; lack of message standardization among sales representatives; and improper classification of physicians. The cost of a traditional sales call can be twice as expensive as that of an e-detail (Gönül & Carter, 2010).

What are the physician characteristics of those who use e-detailing? In the US, they tend to be younger, rural, in solo practices, and high prescribing (Alkhateeb & Doucette, 2008). However, the number of physicians currently taking part in e-detailing is small but growing (Gönül & Carter, 2010).

There are two basic types of e-detailing: interactive (virtual or remote) detailing and live (video) detailing (Alkhateeb & Doucette, 2008). Interactive detailing is accessed at the convenience of the physician. A typical e-detailing call lasts between five and 15 minutes, contains multi-media content, and is used in the US, the UK, and France (Bates et al., 2002). The benefit of this type of detailing is that the physician can control the timing of the encounter and the amount of content they wish to access. An opportunity to request samples or literature, in addition to a face-to-face meeting with a sales representative (and possibly an incentive without conditions for participation), is usually part of the virtual e-detail. The new Sunshine law in the US may put a damper on incentives in the future. This would pose problems for pharmaceutical companies as Schmukler and Mack (2005) suggest that one of the main reasons for physician participation is the incentives (40 percent); for those not yet participating in e-detailing, incentives would sway their decision to participate (55 percent).

Live (video) detailing is a face-to-face videoconference with the physician speaking to the sales representative on a smartphone, tablet, or computer with webcam. The PSR directs the encounter and guides the physician through the presentation. Alkhateeb and Doucette (2008) report that video detailing is the closest type of sales encounter to the traditional detail.

Does e-detailing affect the number of new prescriptions? Gönül and Carter (2010) suggest that "both e-detailing and traditional detailing have positive effects on the number of new prescription sales" (p. 110). In addition, products for acute conditions that have more medical citations, earlier market entry, and more indications are likely to receive more prescriptions if e-detailing is used. They further opine that the relationship between the two forms of detailing is still emerging and more study is needed. The importance of e-detailing early in the product life cycle is also supported by Perry (2008); in addition, she points to the importance of integrated components when using e-detailing, such as a brand's own website, a destination site, an e-sampling site and the ability to contact a sales representative.

Two studies in India (Banerjee & Dash, 2011a; Banerjee & Dash, 2011b) discuss the use of e-detailing from a pharmaceutical company and physician perspective. From the perspective of the firm, their findings suggest that e-detailing assists in managerial readiness, audience acceptance, a firm's operational capability, market accessibility, brand acceptance, the potential to deepen physician relationships, enhanced ROI, and convenient communication. Eighty-nine percent of Indian physicians use face-to-face detailing and e-detailing, and 70 percent rate e-detailing favorably. The authors posit that it is an important adjunct to traditional detailing in non-Western countries because of the remoteness of many communities. Further, e-detailing saves them time and gives them the ability to easily communicate to obtain scientific information quickly. One important potential limitation to its widespread use is that the appropriate IT hardware and software must be in place for the e-detail to be useful. The authors also found a positive association between the numbers of invitations received, the numbers of PSR visits, and prescription volume.

Closed Loop Marketing

The widespread adoption of tablets by sales representatives and the increased use of e-detailing has led to the adoption of closed loop marketing (CLM) by some pharmaceutical companies, primarily in Western countries, and in particular, in the US. CLM is not a new process; in fact, it is currently used in many industries other than the pharmaceutical industry and has been for some time now. In the context of the pharmaceutical industry, companies identify and refine the materials their physician audience find most interesting and then seek to use this information to adapt their promotion efforts and direct it back to the physician—in other words, 'closing the loop.' These are the steps a firm may take to implement this process:

1) A company will provide a sales representative with a tablet that contains detailing software; this software enables the PSR to show a physician different promotional aids, clinical article reprints, and video material. While the physician is viewing these materials, a record is made of which ones were used and what length of time was spent on each one.
2) This information is now sent to a central system at the company's head office. Most companies already have traditional customer relationship management (CRM) systems as part of their customer tracking efforts. The tablet data is now analyzed together with the CRM information, and this analysis may reveal the type of content and its delivery preferred by a specific physician. This data may be accessed by an individual physician, or aggregated either regionally or nationally.
3) The results of the analysis are sent to both the sales force and the brand manager, so that each group may adapt its tactical approaches accordingly. The sales representatives may now adapt their presentations to individual physicians, and the brand managers may develop branding strategies either nationally or for specific geographic regions based on physician preferences.

The execution of CLM is easier said than done; in fact, many companies find it difficult to implement. While some firms are using various aspects of CLM, few have adopted the process in a comprehensive fashion. Hagemeyer (2013) cites the following reasons for the reluctance to implement CLM:

1) It is difficult to analyze the data generated at either the physician or geographic level;
2) Firms have a limited ability to understand the large quantity of data generated and then convert this data into concrete action;

3) The continued barriers to physician visits and lack of confidence in remote/virtual detailing create difficulties to data analysis and the direct relationship between CLM and ROI.

Multichannel Marketing

Multichannel marketing (MCM) is simply the use of multiple communication channels to reach a target audience; in the case of the pharmaceutical industry, it is primarily the physician audience. These communication channels include both traditional and electronic ones; however, the focus of this chapter will be on electronic channels. MCM is used in many countries where digital access by physicians is readily available, and is not an exclusively US phenomenon. MCM is often tied to CLM, because CLM can integrate the use of different digital channels such as websites and social media as part of the detailing efforts of a firm, thus helping to 'close the loop' when providing information to physicians.

Moore and Qanadilo (2012) cite the following benefits to an MCM approach:

1) MCM is important because it allows physicians to access materials with a consistent brand message at their convenience through their preferred channel;
2) The ability to access this material may lead to requests for face-to-face or virtual visits by a PSR or Medical Services Liaison.

The authors, through Capgemini Consulting, conducted a study of physicians and pharmaceutical firms to determine what digital channels physicians use for the different aspects of their work activities. The key findings of their study suggest that 76 percent of physicians surveyed prefer digital channels over visits with a sales representative for information on products and diseases, with independent websites as their preferred channel. For educational activities and reimbursement information, most physicians prefer digital channels instead of PSR visits, with independent websites as the preferred channel. Finally, for peer collaboration activities, the majority of physicians prefer digital channels instead of PSR visits, with independent medical websites as the preferred channel. Mobile apps were the least preferred channel, with less than 10 percent of physicians expressing this choice in all categories. Physicians appear to prefer information from independent sources that they access by themselves, and this research suggests that the reliance on PSR visits is waning in the face of these electronic channels. A discussion of the various electronic channels available to physicians and their use is presented below.

Independent and Company-Sponsored E-Physician Websites

Company and branded websites have been used since the early 2000s to reach physicians, and almost all physicians are now online and spend approximately eight hours per week searching for professional information. In addition, physicians are most influenced by their peers online; they do not browse through multiple websites, but rather seek out specific information to be used in their practice (Katsanis & Maddox, 2010). Datamonitor (2004a; 2004b) reported that physicians in the US and Europe use general information websites as well as physician-targeted websites as primary online sources of information. Eighty percent of European physicians who use the Internet professionally state that it is essential to their practices (Katsanis & Maddox, 2010). A recent UK study (PMLiVE, 2012) suggests that 23 percent of GPs prefer independent online resources for finding drug information, with 42 percent never visiting a pharmaceutical company website.

Further, PMLiVE (2012) reports that there is significant growth in the use of independent websites in the UK, Germany, and Scandinavia.

Generally speaking, physicians use websites because they can access information at their convenience and receive this information when they are most receptive (Ross, 2002). Their data suggests that physicians in the UK and US use a single health information website more frequently than physicians in other European countries. Physicians are seeking more disease information, as well as treatment pattern information on these websites. Leo et al. (2006) indicate that physicians prefer targeted sites versus using a search engine, and that on these targeted sites, they prefer edited/secondary data sources; research databases with access to medical journals; sites dedicated to specialty areas; and a small percentage prefer medical website portals. The authors also indicate that search engines are not accurate sources of information. Some popular physician websites in the US include Medscape, emedicine, and PubMed. As mentioned earlier, this form of digital marketing is the most popular among pharmaceutical companies at the present time based on budgetary allocations. In Europe, some key physician websites include bmj.com (UK); doccheck.com (Germany); univadis.fr (France); diariomedico.com (Spain); and ministeriosalute.it (Italy) (Katsanis & Maddox, 2010).

Physicians also use the Internet to communicate with patients: approximately 48 percent of physicians use e-mail for this purpose (Cooper et al., 2012). It is considered to be safe, effective, and efficient; it also improves patient satisfaction and saves time for patients. However, the other side of the coin is that it increases physician workload unless fewer patients are seen (Bishop et al., 2013).

Social Media

Until recently, US pharmaceutical marketers would not join the social media conversation due to the lack of guidance from the FDA. However, even since the advent of these guidelines, the industry is reluctant to dive in with the most important reasons remaining adverse reaction reporting and legal compliance (Alkhateeb et al., 2008). However, a second and more strategic reason is the complete lack of control in the social media world. Web 1.0 is a static universe and allows for absolute domination of the material (there is no conversation). There is a distinct lack of comfort for pharmaceutical marketers with the uncontrolled social media environment. Finally, the inability to quantify ROI is equally disturbing to pharmaceutical marketers.

How do physicians feel about professional social media? About two-thirds of online physicians in Europe have expressed interest in joining a social media network (Katsanis & Maddox, 2010). A recent US study (McGowan et al., 2012) found that 24 percent of their physician respondents used social media several times a day to find medical information; and 14 percent contributed new information via social media. Approximately two-thirds of respondents believed social media allows them to get up-to-date and relevant information; enabled them to better care for their patients; and improved their quality of care. Physicians found the medium useful, easy to use, and like the ability to connect with their peers. Although the study indicated that some barriers to use existed, these were overcome by the motivation to connect with their peers. More than half the sample preferred physician-only communities. This study found no differences based on demographics or age with respect to social media usage.

Cooper et al. (2012) found contradictory results in their US survey with respect to demographics and adoption of social media, as did the authors Bottles and Kim (2013). The Cooper et al. (2012) study found that social media users are younger, male, and have teaching hospital privileges, with 67 percent of respondents using social network sites professionally. They also reported that 59 percent used social networking websites. Bottles and Kim (2013) found that older physicians resist social media because they believe it undermines

patients' confidence in them when they are focused on their iPhones. Younger physicians believe that time is wasted with face-to-face discussions, phone calls, and e-mails.

In Europe, the UK is at the forefront of social media usage with Spain in last place; local content and language are extremely important because physicians in different countries prefer to work in their own language (Katsanis & Maddox, 2010). It should be noted here that the regulatory environment in Europe is significantly more restrictive than that of the US with respect to social media, and specific rules differ by country.

O'Donnell (2012) reported on social media sites that are popular with physicians: QuantiaMD (video PowerPoint presentations with medical cases); Ozmosis (its benefit is that all MDs in the system are vetted); GooglePlus (physicians can differentiate here between their public and private personas); Sermo (the original and largest social media community for physicians); and doc2doc (offers forums, discussions, and blogs—connects physicians all around the world). For an interesting case study of how social media has been used to transform a medical practice, see Hawn (2009). Table 7.1 provides the percentages of physicians in different countries who participate in online professional communities.

There are potential problems for physicians when using social media professionally with peers. For example, Bottles and Kim (2013) reported that 92 percent of US state medical boards uncovered online violations of professionalism. These included inappropriate contact with patients; inappropriate prescribing; and misrepresentation of their credentials or the potential clinical outcomes that a patient could expect. Chretien et al. (2011) point out that information on Twitter is unverified, and therefore, it is nearly impossible to provide sources for the information that appears in tweets. The authors analyzed physician Twitter feeds with 500 or more followers and conducted a content analysis of the tweets. Of the tweets they examined, 49 percent were health related; 21 percent were personal communications; 14 percent were retweets; 12 percent were self-promotional; and 58 percent contained links. A small number of tweets were categorized as unprofessional (3 percent), and included conflicts of interests, privacy violations, and medical misinformation or treatment guidelines; the biggest concern is that through retweeting, these unprofessional and potentially dangerous tweets (in the case of treatment guidelines) may reach a potential 190 million users.

Table 7.1 Physician Participation in Online Medical Communities

Country	*Percentage*
Japan	78
China	55
India	54
Russia	52
Spain	48
USA	47
UK	40
Germany	39
Brazil	29
Italy	15
France	9

Source: Adapted from Cegedim Strategic Data, 2012

mHealth and the Use of Apps

It is reported that there are approximately 250 apps developed by pharmaceutical companies for use on iOS and Android systems. The mHealth market is highly fragmented, with poor alignment between what physicians say they want and what pharmaceutical companies are working on (based on the low numbers of downloads) (Aneculaesei, 2013). It appears from the information available that physicians want apps that are not sponsored by pharmaceutical companies at the present time. This is because these apps fail to meet what is considered best practice criteria: this includes their usefulness to the daily practice of medicine. In addition, physicians are still unsatisfied with what is available—Glenn (2013) reported that only 28 percent of smartphone users and 18 percent of tablet users were satisfied with the quality of available apps. In addition, they are developing their own apps and adapting other technology such as Google Glass and smart watches for use in what one physician calls "the intelligent OR" (Prevel, 2014).

The availability of useful apps is changing the way physicians are practicing medicine. Some physicians say that the apps save them time and may speed the time to diagnosis, the ability to monitor patients, and reducing face-to-face office time (Whalen, 2013). Some apps that have unique characteristics with respect to monitoring and diagnosis include: Isabel (takes symptoms and generates differential diagnoses with appropriate medications); Alivecor (a portable heart monitor and app that produces electrocardiograms); Resolution MD (X-ray and imaging viewer); Cellscope OTO (functions as an otoscope); Iscrub (tracks whether hospital staff are washing their hands); and Clinicam (takes photos of a patient's condition and then uploads photos to their clinical records) (Whalen, 2013).

The top independently rated physician apps listed below contain the following capabilities: Epocrates for prescribing, drug safety information, insurance formulary information, and news; Medscape for drug formulary information, medical news, continuing medical education, and information about medical procedures; MedCalc for scales, formulas, and calculations; Skyscape for evidence-based information and journal article summaries; Doximity for compliance with regulations and social networking; and UpToDate for reference tools, CME tracking, evidence-based recommendations, and a mobile optimized calculator (Glenn, 2013). Of course, this list is not exhaustive and new apps are being added every day.

There are potential regulatory problems with physician apps that go beyond the marketing considerations. In the EU, there is currently a debate about whether or not an app is a medical device; some legal experts suggest that it is considered a device in the UK (Thompson, 2012). In the US, the Federal Trade Commission (not the FDA) regulates apps, but any apps that convey information about prescription drugs will be regulated as drug labelling (Thompson, 2012). Thompson (2012) opines that the FDA is still considering the status of apps as a medical device if they contain clinical decision support software or software that provides information on the treatment of disease; but they will probably not act on what they consider low risk apps. He further reported that those apps that would not be regulated include: e-copies of textbooks; medical training apps; general health apps; and electronic record apps.

At present, while there may be proprietary pharmaceutical industry reports for sale with information medical apps, there is no freely available empirical research either on the use of apps by physicians or their effectiveness as a marketing tool at the time this book was written, although private consultant reports are available for purchase. This topic is currently in its genesis, so research should appear in the near future.

Implications and Conclusions

Digital communication is an important way for pharmaceutical companies to reach physicians and for physicians to access essential information for their practices. E-detailing is a relatively new, but an essential, addition to the pharmaceutical communication mix for gaining access to difficult-to-reach physicians. However, the available research suggests that e-detailing will not replace the face-to-face sales call, despite the continued difficulty sales representatives face in obtaining appointments with physicians.

CLM is a process that some firms believe holds great promise for improved delivery of brand messages and meeting physician needs. However, its adoption is slow due to concerns about its implementation and a firm's ability to measure tangible results. MCM is also in the early stages of use by the industry, despite its widespread use in other industries. Given the importance of electronic channels to physicians, it will be critical for the industry to utilize these channels more heavily in the future.

Independent websites are among the most popular e-channel used by physicians for accessing medical research, as well as disease and treatment information. Pharmaceutical company-sponsored websites are less popular with physicians, but still a major communication channel used by firms to reach the physician audience. Physicians are receptive to social media and see some utility for it in their practices. However, they face potential difficulties due to ethical and professional restrictions. Pharmaceutical companies have moved slowly in this area for regulatory reasons. Apps continue to be developed by pharmaceutical firms; however, they generally do not meet physicians' needs. Further, there are regulatory hurdles on a global basis that restrict the use of these apps.

Research about digital communication to physicians is in the early stages due to the relatively new adoption of some of these modalities. As these channels are used more frequently, research will emerge about its uses and usefulness to both pharmaceutical companies and physicians.

References

Alkhateeb, F., Clauson, K., Khanfar, N., & Latif, D. (2008). Legal and regulatory risk associated with Web 2.0 adoption by pharmaceutical companies. *Journal of Medical Marketing*, *8*(4), 311–318. doi:10.1057/jmm.2008.20

Alkhateeb, F. M., & Doucette, W. R. (2008). Electronic detailing (e-detailing) of pharmaceuticals to physicians: a review. *International Journal of Pharmaceutical and Healthcare Marketing*, *2*(3), 235–245. doi:10.1108/17506120810903999

Aneculaesei, A. (2013). Pharma companies far from realizing their app market potential. Retrieved November 26, 2014, from http://research2guidance.com/pharma-companies-far-from-realizing-their-app-market-potential/

Banerjee, S., & Dash, S. K. (2011a). Effectiveness of e-detailing as an innovative pharmaceutical marketing tool in emerging economies: views of health care professionals of India. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *11*(3), 204–214. doi:10.1177/1745790411413631

Banerjee, S., & Dash, S. K. (2011b). Factors influencing scope and acceptability of E-detailing as a pharmaceutical marketing communication tool in emerging economies like India. *International Journal of Pharmaceutical and Healthcare Marketing*, *5*(2), 153–168. doi:10.1108/17506121111149253

Bard, M. (2014). When the 'digital physician' is just the . . . physician. *PM360*. Retrieved November 26, 2014, from www.pm360online.com/when-the-digital-physician-is-just-the-physician/

Bates, A., Bailey, E., & Rajyaguru, I. (2002). Navigating the e-detailing maze. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *2*(3), 255–262. doi:10.1057/palgrave.jmm.5040083

Bishop, T. F., Press, M. J., Mendelsohn, J. L., & Casalino, L. P. (2013). Electronic communication improves access, but barriers to its widespread adoption remain. *Health Affairs (Project Hope)*, *32*(8), 1361–1367. doi:10.1377/hlthaff.2012.1151

Bottles, K., & Kim, J. (2013). Generational attitudes affect adoption of social media by physician leaders. *Physician Executive*, *39*(4), 94–96.

Cegedim Strategic Data. (2012). Physicians in emerging markets more open to using social networking sites compared to their European counterparts. Retrieved from www.cegedimstrategicdata.com/Press/Documents/CSD_Physician-ProfessionalUseSocialMedia_26062012_eng.pdf

Chretien, K.C., Azar, J., & Kind, T. (2011). Physicians on Twitter. *JAMA: The Journal of the American Medical Association*, *305*(6), 566–568. doi:10.1001/jama.2011.68

Cooper, C.P., Gelb, C.A., Rim, S.H., Hawkins, N.A., Rodriguez, J.L., & Polonec, L. (2012). Physicians who use social media and other Internet-based communication technologies. *Journal of the American Medical Informatics Association: JAMIA*, *19*(6), 960–964. doi:10.1136/amiajnl-2011-000628

Datamonitor. (2004a). Physician targeted websites: understanding the online needs of physicians. *Business Wire*. Retrieved November 26, 2014, from www.thefreelibrary.com/Research+and+Markets%3A+Physician+Targeted+Websites%3A+Understanding+the . . . -a0116336864

Datamonitor. (2004b). Website benchmarking service – European physician and consumer targeted websites. Retrieved November 26, 2014, from www.biomarketgroup.com/market-research-report/website-benchmarking-service-european-physician-and-consumer-targeted-websites.html

eMarketer. (2013). Healthcare and pharma digital spend rises, but outlays stay low. *eMarketer Inc*. Retrieved November 26, 2014, from www.emarketer.com/Articles/Print.aspx?R=1010296

Glenn, B. (2013, June 13). Physicians' top 5 most-used medical apps for smartphones and tablets. *Medical Economics eConsult*. Retrieved November 26, 2014, from http://medicaleconomics.modernmedicine.com/medical-economics/news/physicians-top-5-most-used-medical-apps-smartphones-and-tablets

Gönül, F.F., & Carter, F.J. (2010). Impact of e-detailing on the number of new prescriptions. *Health Care Management Science*, *13*(2), 101–111.

Hagemeyer, D. (2013). Closed-loop marketing in pharma has yet to close the loop. Retrieved November 26, 2014, from www.gartner.com/doc/2589927/closedloop-marketing-pharma-close-loop

Hawn, C. (2009). Take two aspirin and tweet me in the morning: how Twitter, Facebook, and other social media are reshaping health care. *Health Affairs (Project Hope)*, *28*(2), 361–368. doi:10.1377/hlthaff.28.2.361

Heutschi, R., Legner, C., Schiesser, A., Barak, V., & Österle, H. (2003). Potential benefits and challenges of e-detailing in Europe. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *3*(4), 263–273. doi:10.1057/palgrave.jmm.5040130

Katsanis, L.P., & Maddox, L. (2010). Social media (Web 2.0) to physicians: current methods and their future in the EU. *American Academy of Advertising European Conference*. Milan, Italy.

Leo, G., LeRouge, C., Ceriani, C., & Niederman, F. (2006). Websites most frequently used by physician for gathering medical information. *AMIA Annual Symposium Proceedings*, *2006*, 902.

McGowan, B.S., Wasko, M., Vartabedian, B.S., Miller, R.S., Freiherr, D.D., & Abdolrasulnia, M. (2012). Understanding the factors that influence the adoption and meaningful use of social media by physicians to share medical information. *Journal of Medical Internet Research*, *14*(5), e117. doi:10.2196/jmir.2138

Mack, J. (2014). Pharma marketing blog: globally, pharma's digital spend is (still) only 6% of total promotional budget. Retrieved from http://pharmamkting.blogspot.ca/2014/06/globally-pharmas-digital-spend-is-still.html

Moore, T., & Qanadilo, H. (2012). Multichannel closed loop marketing. Retrieved November 26, 2014, from www.capgemini.com/resources/multichannel-closed-loop-marketing-digitally-transforming-the-life-sciences-industry

O'Donnell, M. (2012). Top 5 social media sites for physicians. *HealtheCareers Network*. Retrieved November 26, 2014, from www.healthecareers.com/article/top-5-social-media-sites-for-physicians/168490

Perry, S. (2008). E-detailing: how to stop worrying and love the Internet. *eyeforpharma*. Retrieved November 26, 2014, from http://social.eyeforpharma.com/uncategorised/e-detailing-how-stop-worrying-and-love-internet

PMLiVE. (2012, August 15). Doctors.net.uk survey finds many GPs favour digital channels for independent product information [text]. Retrieved November 26, 2014, from www.pmlive.com/digital_handbook/online_audiences/online_physician_communities/doctors.net.uk_survey_finds_many_gps_favour_digital_channels_for_independent_product_information

Prevel, C.D. (2014). *The Intelligent OR: Orlando VAMC Experience*. Wearable Healthcare: Google Glass, Smart Watches & Beyond, mHealth Summit, December 7–12, Washington, D.C.

Ross, W. (2002). Internet portals open gateways to marketing opportunities. *Medical Marketing & Media*. Retrieved November 26, 2014, from www.highbeam.com/doc/1P3–110139931.html

Schmukler, M., & Mack, J. (2005). The impact of eDetailing: will it complement, replace, or become integrated with the sales force? Retrieved November 26, 2014, from www.pharma-mkting.com/news/PMNSupplementEdetail.htm

Staton, T. (2014). FDA's social media translation for brand managers: don't use Twitter. *FiercePharmaMarketing*. Retrieved November 26, 2014, from www.fiercepharmamarketing.com/story/fdas-social-media-translation-brand-managers-dont-use-twitter/2014–06–25

Thompson, B.M. (2012). How the FDA regulates pharmaceutical apps. *MobiHealthNews*. Retrieved November 26, 2014, from http://mobihealthnews.com/17699/how-the-fda-regulates-pharmaceutical-apps/

Whalen, J. (2013). Health-care apps that doctors use. *Wall Street Journal*. Retrieved November 26, 2014, from http://online.wsj.com/news/articles/SB10001424052702303376904579137683810827104

8 Direct to Consumer Advertising

Broadcast and Print Media

Consumer communication takes a variety of forms in the pharmaceutical industry and includes both traditional and electronic methods of promotion. This chapter will focus on direct to consumer advertising (DTCA). Some examples of DTCA include the use of print and broadcast media for disease awareness advertising (DAA; permitted in Australia and Japan) and product-specific DTCA both in traditional media channels and online (where legal in the US and New Zealand, and while not legal in Canada, is permitted with restrictions). Mack (2014) reported that DTCA accounted for 21 percent of total industry expenditure (this percentage includes all forms of consumer promotion, not just advertising). He indicates that DTC expenditures are down in all promotional channels (including digital) from the previous year. This is largely the result of the patent cliff and the reluctance to use these tools because of the difficulty in analyzing digital usage data to calculate brand ROI. This decline in promotional activity is demonstrated by the 2012 Rodale DTC Study (as cited by World of DTC Marketing, 2012) that shows a steady decline in consumer promotional expenditures from a historical high point in 2007.

Patients are important to the pharmaceutical industry as a promotion target even though they do not have the power to write a prescription (other than the obvious fact that they are the end users of the product). It is well established that consumers play an important role in the health care marketing environment given their interest and participation in their own health care decisions. The study of this phenomenon is known as consumer health informatics, and is based on the notion that more health information improves consumers' health knowledge (Eysenbach, 2000). Physicians are also affected by this consumer empowerment to some degree, and there is research to suggest that patients do have some influence over the prescription drugs they receive from their doctors. A recent report suggests that patients rely on multiple sources when seeking health care information before speaking to their physicians that include (in order of magnitude): online health sites (50 percent); physician office brochures (49 percent); DTC ads (44 percent); magazines and TV (42 percent each); health insurance companies (34 percent); and patient community websites and newspapers (29 percent each) (Rodale, 2012 as cited by World of DTC Marketing, 2012). It should be noted that all advertising and promotional effort to the consumer has synergistic effects, not only among consumer vehicles, but together with physician promotion as well. It is the combined effect of this promotion that has great influence on both consumers and physicians, as they are not immune to DTCA.

Some readers may question why there should be any specific discussion of DTCA in a book on global marketing since it is illegal in most countries. It is well accepted that media crosses many borders (and oceans as well) and it would be both naïve and incorrect to assume that only Americans or New Zealanders have access to DTCA. For example, while GlaxoSmithKline and Astra Zeneca have community Facebook pages that state

the content is for US customers only, non-US users also have access to the site; additionally, Novartis seeks out online consumers/users from Canada and Korea, while Roche targets French patients online (Liang & Mackey, 2011).

Additionally, there are non-US-based pharmaceutical companies that rely on the US market as a major source of their revenue. They use DTCA where it is legal, regardless of whether or not it is legal in their home country. Further, governments in other countries are exploring the possibility of permitting the limited use of DTCA in their markets for particular medical conditions. It is important for both marketers and policy makers in these countries to understand the dynamics of DTCA and its effects, both positive and negative. It is simply a fact that most consumer-directed promotion originates in the US; and the origin of most of the research available on this subject is generated in the US. This does not limit its potential usefulness to other markets, however, and where available, research from other countries where DTCA is used is included here.

As is the case with all pharmaceutical advertising and promotion, DTCA generates heated and well-entrenched positions between two very opposite poles, particularly in the US, New Zealand, and Canadian markets.

The following discussion will examine the characteristics of the health care consumer as well as the different promotional vehicles and types of advertising used to reach consumers. The key question to be answered is whether or not it is advisable to promote or advertise prescription drugs to consumers from a financial, reputational, or public policy perspective based on existing research.

DTCA Health Care Consumer Profiles

Traditionally, pharmaceutical companies have relied on standard profiling data such as demographics to identify health conscious US consumers as advertising targets. Alternatively, a PwC (2013) report suggests the use of four new and different psychographic customer profiles based on behavioral variables may be more useful: "Basic Bob" (self- reliant, older, prefers basic, affordable options, p. 3); "Motivated Monica" (well-off, middle-aged, has multiple conditions, face-to-face advice preferred, p. 3); "Invincible Izzie" (younger, rarely ill, unhealthy lifestyle, prefers to search online and self-treat, p. 3); and "Routine Ron" (older, manages at home, relies on friends and family versus experts for advice, p. 3). This report also indicates that insurance coverage and physician recommendations are overwhelmingly preferred by consumers as sources of information prior to purchasing health care services, and to a lesser extent, online medication information and patient testimonials are also important. Deloitte University Press (2012) also identified six distinct psychographic consumer segments that include: "Casual and Cautious" (low interest in health care—34 percent); "Content and Compliant" (passive patient approach—22 percent); "Online and Onboard" (high use of health system and medications—17 percent); "Sick and Savvy" (most proactive and prepared—14 percent); "Out and About" (alternative treatment approaches—9 percent); and "Shop and Save" (shop for lowest price on health care and medications—4 percent).

Despite the potential use of this type of profiling for DTCA (and other types of consumer promotion), consumers remain skeptical about the information provided by pharmaceutical companies. They place more emphasis on information provided by peers, and this type of information is more readily available through digital channels rather than traditional forms of advertising. The 13th Annual Prevention Magazine DTC Survey (Rodale, 2010) stated that 62 percent of online customers are not interested in hearing from either pharmaceutical companies or insurance companies about health and medical issues. They reported on a new consumer trend (a form of crowdsourcing) where consumers want to find out what people like themselves

think about their health condition: "consumers are now the gatekeepers when it comes to their own personal healthcare issues" (p. 1). (Consult Friedman and Gould (2007) for a longitudinal study that also suggests consumer negativity toward information from pharmaceutical companies.) However, despite this apparent negativity on the part of consumers, DTCA remains part of the promotional budget for many prescription drug brands in the US.

It should also be noted that while these health consumer profiles may be applicable to other Western cultures, they are likely not extendable to non-Western countries where health care options are more limited due to costs or supply of medication; and computers or handheld devices may be unavailable for financial or technological reasons.

Physician Views on DTCA

Physicians generally do not support the use of DTCA as they believe it leads to unnecessary treatment, and more importantly, they view DTCA as increasing the likelihood both of receiving and granting patient requests for a specific drug. However, they also recognize that it may potentially contribute to better communication with their patients (Mukherjee et al., 2013). While there is a large body of research that provides further insight into these views (see the detailed list at the end of the chapter), an official position for physicians to follow regarding their behavior toward DTCA is codified in the American Medical Association's Code of Medical Ethics. This code states that physicians should engage in research about DTCA and maintain their professional standards, which ensure full disclosure to patients without false expectations about a particular drug. Further, a physician is expected to refuse any request for a drug that is inappropriate and educate the patient about the reasons for their refusal. The American Medical Association (AMA) does not oppose the use of DTCA; however, it expects physicians to be vigilant about non-compliant advertising and to report it to the FDA whenever possible.

An Overview of Recent DTCA Research

There are two comprehensive reviews of the research on DTCA: Mukherjee et al. (2013) and Dave (2013). Between the two papers, over 150 references are cited that contribute to the knowledge in this area from different perspectives (these papers are highly recommended reading). Mukherjee et al. (2013) discuss DTCA's effects on consumer attitudes; patient–physician interactions; content; literacy and memory; information source and search; financial performance; and physician attitudes. The authors also provide useful suggestions for future research. In addition to touching on some of these areas, Dave (2013) examines studies that contribute to knowledge on the general market effects of DTCA as well as specific effects on drug prices and costs to both payers and consumers. While earlier reviews exist (Cox & Cox, 2009) that address similar questions, the Mukherjee et al. (2013) and Dave (2013) studies provide the latest reviews of the available research.

Mukherjee et al. (2013) present a summary of seven different themes, as mentioned above, in their comprehensive literature review and this section summarizes their findings. Their review suggests that most consumers have favorable attitudes toward DTCA and that it may affect their future information search intentions. A consumer's high levels of involvement in health care influences their intention to consult with a physician and that their exposure to DTCA is associated with willingness to consult with physicians. Broadcast DTCA in particular may positively affect patient requests for a particular prescription. A large body of research focused on the content of DTCA and revealed that advertising with incomplete disclosure of risks is more

favorably viewed than ads with a complete disclosure of these risks. The authors note that the research on literacy and memory is generally critical of DTCA's role in this area, and that the advertising fails to provide useful information with respect to dealing with specific health conditions. Further, emotional appeals do not appear to improve the memorability of the drug.

Not surprisingly, there are few studies on the effects of DTCA on sales because only an associative relationship rather than a direct causal effect between these two variables can be measured. In addition, those studies that exist are contradictory and inconclusive: some studies show no effect, while others suggest either a positive, U-shaped, or declining effect. Physicians generally do not support DTCA as they believe it leads to unnecessary treatment, despite these findings.

Dave (2013) examines DTCA from the perspective of whether it is persuasive or informative, and whether or not it increases demand, affects drug costs, and has competitive effects. He notes that while there is some informative effect to DTCA, there is also a danger of overtreatment or inappropriate care. He further reports that DTCA has both market expansion and brand specific effects: a drug class expands in size because ads encourage patients to seek help and encourage patient–physician communication. However, he points out that brand market share effects are not as pronounced and the data in this regard are inconclusive, with physician directed communication such as detailing and sampling as more important for brand-related performance versus DTCA. Fischer and Albers' (2010) work supports these findings and they conclude that detailing is more important than DTCA for driving primary demand. However, they also suggest that DTCA has a synergistic effect on overall promotional efforts and that the combination of detailing and DTCA is more effective than either used alone.

With respect to pricing effects, the results are also unclear. Dave (2013), Capella et al. (2008), and Law et al. (2009) all provide conflicting findings. Capella et al. (2008) found no evidence that consumers pay higher prices for drugs with DTCA. Law et al. (2009), however, found significant price increases for the drug Plavix when examining Medicaid-reimbursed pharmacy costs. In another study, Dave and Saffer (2012) found that DTCA raised both demand for a drug and its average wholesale price: broadcast DTCA raised demand by 10 percent and price by 5 percent, with print media having a smaller effect on both demand and price. Dave (2013) opines that it is difficult to assess price effects because there is no way to calculate the negotiated prices paid by either Medicare or private payers.

A source list is included at the end of this chapter for those interested in further research about DTCA; there is simply too much work to include here and this list will be of interest primarily to US readers. However, there are two areas that deserve special attention, due to their interest to policy makers: prescription effect requests and the perception of risks of prescription brands by consumers based on DTCA. Some highlighted studies in these areas are presented in the following section.

The Effects of DTCA on Prescription Requests

A Rodale Prevention Study (as cited by World of DTC Marketing, 2012) sheds light on the effects of DTCA on prescription requests in the US. The study notes that while DTCA has declined from a high of $15.4 billion in 2007 to $14.6 billion in 2012, the percentage of the population that talked with a doctor has also declined from 31 percent in 1997 to 26 percent in 2012, with an average decline of 30 percent over the 15-year period. The study also reports that the percentage of consumers who talked with a physician after seeing DTCA rose from 68 percent in 1997 to 76 percent in 2012, with a 15-year average of 72 percent. However, at the same time, the percentage of patients who asked their physician for a prescription declined from 29 percent in 1997

to 24 percent in 2012, with a 15-year average of 26 percent. This suggests that despite the existence of DTCA, the relative percentage of those who speak to their physician about a drug versus asking for a prescription has remained relatively constant over the 15-year period.

A more significant finding from this study is the percentage of requested prescriptions that were received by patients. Of the 75 percent of respondents that simply asked the physician about the medication, 20 percent of them received that medication. Of the 24 percent of patients who requested a specific medication, 76 percent of them received the prescription for that medication. These data suggest that the effects of DTCA are significant among those who are motivated to ask for a specific drug. It also indicates that physicians may be more willing to consider requests for specific prescription drugs than in the past (this finding supports the work of Mintzes et al. (2002) who suggest that patients who ask for a specific drug prescription are likely to receive it after exposure to DTCA because of physician ambivalence).

The Perceived Risk of DTCA by Consumers

The 13th Annual Prevention Magazine DTC Survey (Rodale, 2010) suggests US consumers are highly aware of broadcast DTCA (79 percent), and "pay a lot or some attention" to the risk information (76 percent). However, recent research (Ho-Young et al., 2014) demonstrates that consumers who believe they are less likely to experience side effects also pay less attention to risk disclosures, and are also less likely to seek out additional information about these risks. Early research by Menon et al. (2003) about the use of the brief patient summary of a drug's risk profile (included as part of print DTCA) showed that 40 percent of consumers did not even notice this risk disclosure. Further, their work suggests that existing prescription drug use was associated with failure to read the patient summary, and a thorough reading of the summary is associated with an increased perception of drug risk. This work is supported in part by Kavadas et al. (2007), who liken the risk profile of drugs that appears in DTCA to fear appeals found in other types of advertising: they suggest that a high level of disclosure causes a consumer to block out risk information in favor of the benefit information found in the ad. David et al. (2010) found increased levels of DTCA were associated with a greater number of adverse medical events for specific medical conditions, because when a drug becomes more widely used and discussed, these adverse events come to the attention of regulators and are likely to receive their attention (this paper should be read *in toto* for a deeper understanding of this issue).

The DTCA Controversy: An Ongoing Debate

The debate concerning DTCA has been ongoing since it was legalized in the US and New Zealand as well as Canada under its restricted guidelines. The positions of both the industry and its critics are well established. Although there are numerous articles that offer opinions on the subject (some ideological and some supported by empirical data), Calfee (2002) captures the important elements of this debate from the perspective of the proponents of DTCA; while Lexchin and Mintzes (2002) argue against the use of DTCA. Both articles are supported by survey data and/or observational research. As these arguments have remained unchanged over time, the two positions will be outlined below, with additional issues presented separately by other researchers. Toop and Mangin (2007) in New Zealand provide opposing viewpoints to DTCA that mirror the arguments given in the US context; Wong-Rieger (2009) provides a Canadian perspective.

Calfee (2002) argues that DTCA provides important information to consumers on both potential treatments for disease, but also on risks and side effects. He suggests that there is no evidence to suggest consumer

deception or the inappropriate presentation of risks and side effects. The information in DTCA may motivate consumers to speak to their physicians or pharmacists about a particular medical condition, and in particular, physicians generally have no difficulties discussing a specific drug with their patient. Finally, he posits that there are additional benefits to DTCA, such as greater awareness of the risks of prescription drugs, better adherence to drug regimens, and, possibly, that it provides an impetus to make lifestyle changes that may benefit patients' health.

In contrast, Lexchin and Mintzes (2002) argue that current FDA regulation does not sufficiently protect the public from the potential risks of prescription drugs; in addition, patients have no way to evaluate the benefit/risk balance as it is presented in DTCA. They argue that even if patients are more likely to speak with their physician about a drug, this conversation may take valuable time away from more important topics that should be the focus of their discussion. They posit that patients are not capable of self-diagnosis because they are not in a position to compare different drug therapies in terms of safety, cost, and efficacy. Finally, they cite the fact that physicians are influenced by pharmaceutical promotion themselves; therefore, if a physician is unable to resist this influence, it is logical to assume that consumers will not be able to resist either.

One additional argument against DTCA not presented by either Calfee (2002) or Lexchin and Mintzes (2002) is its influence on what is called the 'over-medicalization' of society (Moynihan & Cassels, 2005). The authors suggest that DTCA creates disease out of health conditions that are a normal part of life and that do not necessarily need to be treated with medication, such as social anxiety disorder (this is also called disease mongering).

The Use of DTCA in Other Countries

DTCA is fully legal in the US and New Zealand, permitted but not legal in Canada, and illegal in most other countries. Disease awareness advertising (DAA) is legal in Australia, Japan, and Europe. At present, US-style DTCA is illegal in Europe; however, the EU Parliament has entertained the possibility of its legalization twice: once in 2004 (www.pharmafield.co.uk, 2005) and ultimately rejected in 2009; and then again in 2013 (www.epha.org, 2013). At present, the EU Parliament is considering proposals to this end and has adopted a proposal to amend the current status of DTCA for three disease categories: AIDS, asthma and COPD, and diabetes (www.epha.org, 2013).

However, even in countries where DTCA is not legal, the effects of this advertising are still experienced by consumers due to the global nature of media. The use of DTCA and DAA will be discussed for Canada, New Zealand, Australia, and Japan, and some preliminary studies from Europe will be presented.

Canada

One country in particular that is affected by DTCA is Canada, due to its geographic proximity to the US, as well as what some call a legal 'loophole' that allows for the advertising of the brand name alone, or the disease alone, but not both at the same time. It is reported anecdotally that the Canadian pharmaceutical industry is not disappointed that US-style DTCA is technically illegal in Canada, as they benefit from the 'bleeding across the border' and save millions of dollars in advertising expenses. In fact, it was not the pharmaceutical industry but the now-defunct media company CanWest Global who sought to overturn the ban on DTCA in Canada by claiming that it was a violation of the Canadian Charter of Rights and Freedoms (Greyson, 2009). It sought permission from the court to legalize DTCA in Canada, but the case was adjourned and not revived because CanWest Global reorganized and did not pursue the matter further.

Wong-Rieger (2009) suggests that the debate about DTCA in Canada is unproductive because Canadians are seeing US ads whether they are legal or not; and also that a Canadian style of DTCA should be developed more in keeping with Canadian values. Some research may shed light on the Canadian experience. Law et al. (2008) conducted a quasi-experiment using three different drugs to determine the effects of US-style DTCA on a representative sample of 2,700 Canadian pharmacies and US Medicaid prescription data. Their findings suggest that exposure to DTCA in both countries increased the number of prescriptions; however, the effects of DTCA in the US were larger than those in Canada. They also reported that out of the three drugs studied, DTCA led to increased Canadian prescribing rates for only one of the drugs (tegaserod). This finding may be explained because tegaserod was the only drug approved for its indication, unlike the two other drugs, which faced competition in addition to a limited patient pool. Van den Engh and Bonertz (2010) examined the effect of DTCA on prescribing in a remote northern Canadian community on the US border and found that patient requests for DTC advertised drugs was almost double in the DTCA exposure group, particularly with younger patients. Similar results were found by Mintzes et al. (2002) with respect to an increase in prescription requests after DTCA exposure to both US and Canadian patients. Maddox and Katsanis (1997) found that DTCA caused Canadian consumers to initiate fewer conversations with physicians because these patients assumed that they already knew enough about the drug after exposure to the advertisement and did not feel the need to ask their physician additional questions.

New Zealand

Surprisingly, little research exists for the New Zealand experience with DTCA. Coney (2002) provides two examples of complaints about DTCA for the drugs Xenical and Depo-Provera, in which the companies were found to have violated "high standards of social responsibility" and "appropriate terminology and clear communication" (p. 218). Hall et al. (2011) compared attitudes about DTCA from New Zealand consumers and DAA from Australian consumers. Their findings about the New Zealand consumer suggest that 84 percent of respondents believe that DTCA puts undue emphasis on drug benefits and does not provide balanced information. While the majority of respondents (78 percent) found that they were more aware of different options to treat their condition, over 80 percent believe that they do not possess the knowledge to assess a drug's safety and risks. The researchers further reported that while DTCA assists with physician consultations, it may lead to inappropriate drug requests. Finally, 60 percent of those surveyed believe that money on DTCA would be better spent on advertising from an independent source, such as a government agency.

Australia

In a similar fashion to Canada, in Australia there is 'bleeding' from the DTCA campaigns in New Zealand. Australia permits DAA sponsored by pharmaceutical companies, in a somewhat similar situation to Canada. Hall et al.'s (2011) study concludes that Australians believe that DAA creates greater awareness of disease and treatment options (80 percent), and that this information assists them when they consult their physicians. However, 72 percent of respondents also believed that the advertising was designed to sell specific medications and to increase their visits to physicians.

Japan

While product-specific DTCA is illegal in Japan, DAA is permitted, and these expenditures have grown exponentially (however, they still remain at less than 1 percent of a company's total promotional budget) (Paek

et al., 2011). There are five different types of DA ads in Japan: awareness/education of disease; symptom identification; treatment options; disease understanding; and consult your physician (Furukawa, 2009 as cited by Paek et al., 2011). These messages are often combined together in an integrated marketing communication campaign and utilize celebrity endorsement, a popular advertising strategy in Japan. Pharmaceutical companies in Japan also use 'below the line' communication strategies. These include sponsorships, sales promotions, and product placements as well as websites and other online activities that are not directly addressed by the DTCA restrictions (Ham et al., 2008).

Europe

There is little DTCA research from Europe; however, Velo and Moretti (2008) provide a background on the history of the DTCA discussions in Europe provided earlier, and proffer the opinion that patient information presented in DTCA merely masks their promotional intent. They further opine that the Internet is potentially a bigger concern with respect to patient promotion because of the lack of quality and reliability of the information, as well as the difficulty in regulating the promotional channel. Reast et al. (2008) surveyed both physicians and consumers in the UK to determine the potential impact of DTCA in that market. Their findings suggest that neither UK physicians nor consumers are particularly in favor of DTCA. While neither group supports DTCA, both groups are "supportive of a continuation of unbranded 'disease awareness' campaigns" (p. 450), and these campaigns are ongoing at present.

Implications and Conclusions

The US experience with DTCA has resulted in a wealth of information about the potential benefits and risks with this type of advertising. The results of this research may provide guidance to marketers and policy makers when considering the appropriateness of its use in other countries.

US consumers generally have favorable attitudes toward DTCA and this type of advertising fits into their interest in their own health care. Some research suggests there are limited informative effects to this type of advertising, and that it may lead to improved communication between physicians and patients. The percentage of consumers who speak with their physicians after seeing these ads has risen, although these consumers do not ask for specific drug prescriptions any more frequently than they did 15 years ago. However, if they do ask for a prescription for a particular drug, they are more likely to receive it, which suggests that physicians are granting patient requests for specific drugs. These findings are supported by additional research indicating the positive effects of DTCA on the demand for specific drug brands.

As a result of increased demand for brand name drugs, there may be potential upward effects on US drug prices from DTCA; however, the research to date is conflicting, with some studies showing no price effects and others indicating significant price increases. While it may be difficult to quantify pricing effects, the fact that some studies show upward price movement should be a concern not only to US policy makers and payers, but to government agencies in countries that have public drug systems where control of drug prices is a concern; branded drugs may be inappropriately prescribed in place of less expensive generic products.

Many consumers do not pay attention to the brief prescribing information about a drug or to drug disclosure in DTCA, and several studies suggest that there is an association between risk information provided about a brand and less attention given to these risks. This finding should also be a concern to policy makers, as

patients may request drugs that are inappropriate, and believe they possess greater knowledge than they do in reality about a particular brand.

The acceptance of DTCA in other countries where it is used is not as favorable as it is in the US market. In New Zealand, consumers believe that DTCA is biased in favor of drug benefits and does not provide sufficient information about drug risks. In Australia, where DAA is used, consumers feel that the sole purpose of the advertising is to sell medication and increase physician visits. While no research exists about DTCA consumer attitudes in Canada, the available research suggests that it increases the number of prescriptions for the advertised brand. Europe is still grappling with whether or not to permit DTCA—evidence in the UK research suggests that both patients and physicians have negative attitudes toward DTCA with more positive attitudes toward unbranded DAA for chronic diseases such as asthma.

It is possible that DTCA has outlived its usefulness in the US market, particularly with health information readily available through digital channels, where consumers may spend more time reading about both drug benefits and risks. Other countries may wish to consider the potential upward price effects of DTCA and the resulting increase in health care costs. Given the downward price pressure from payers and governments, it is not clear that the costs of DTCA are worth the benefits to the industry. In a later chapter, research will be presented suggesting that DTCA has a negative reputational effect on the industry, and this may be yet another variable that causes the industry to rethink its use of this promotional tool in the US market and elsewhere.

References

Calfee, J.E. (2002). Public policy issues in direct-to-consumer advertising of prescription drugs. *Journal of Public Policy & Marketing*, *21*(2), 174–193.

Capella, M.L., Taylor, C.R., & Campbell, R.C. (2008). Does DTC advertising raise the price of sleeping pills? The impact of pharmaceutical advertising on price sensitivity. In *American Academy of Advertising. Conference. Proceedings (Online)* (pp. 219–225). Lubbock, United States: American Academy of Advertising. Retrieved from http://search.proquest.com/docview/192403892

Coney, S. (2002). Direct-to-consumer advertising of prescription pharmaceuticals: a consumer perspective from New Zealand. *Journal of Public Policy & Marketing*, *21*(2), 213–223.

Cox, A.D., & Cox, D. (2009). A defense of direct-to-consumer prescription drug advertising. *Business Horizons*, *53*(2), 221–228. doi:10.1016/j.bushor.2009.11.006

Dave, D.M. (2013). Effects of pharmaceutical promotion: A review and assessment (Working Paper No. 18830). National Bureau of Economic Research. Retrieved from www.nber.org/papers/w18830

Dave, D., & Saffer, H. (2012). Impact of direct-to-consumer advertising on pharmaceutical prices and demand. *Southern Economic Journal*, *79*(1), 97–126. doi:10.4284/0038-4038-79.1.97

David, G., Markowitz, S., & Richards-Shubik, S. (2010). The effects of pharmaceutical marketing and promotion on adverse drug events and regulation. *American Economic Journal: Economic Policy*, *2*(4). Retrieved from www.aeaweb.org/articles.php?doi=10.1257/pol.2.4.1

Deloitte University Press. (2012). 2012 survey of US health care consumers: five year look back. Retrieved from http://d2mtr37y39tpbu.cloudfront.net/wp-content/uploads/2012/12/DUP218_Health-Care-Consumer_FINAL.pdf

Eysenbach, G. (2000). Consumer health informatics. *British Medical Journal*, *320*(7251), 1713–1716.

Fischer, M., & Albers, S. (2010). Patient- or physician-oriented marketing: what drives primary demand for prescription drugs? *Journal of Marketing Research*, *47*(1), 103–121. doi:10.1509/jmkr.47.1.103

Friedman, M., & Gould, J. (2007). Consumer attitudes and behaviors associated with direct-to-consumer prescription drug marketing. *Journal of Consumer Marketing*, *24*(2), 100–109. doi:10.1108/07363760710737102

Greyson. (2009). Canadian DTCA charter challenge indefinitely adjourned . . . and a tree falls in the forest. Retrieved November 21, 2014, from http://sjlibrarian.wordpress.com/2009/06/19/canadian-dtca-charter-challenge-indefinitely-adjourned%e2%80%a6and-a-tree-falls-in-the-forest/

Hall, D.V., Jones, S.C., & Hoek, J. (2011). Direct to consumer advertising versus disease awareness advertising: consumer perspectives from down under. *Journal of Public Affairs*, *11*(1), 60–69. doi:10.1002/pa.379

Ham, C.D., Jun, J.W., & Lee, H.-S. (2008). How to reach consumers in a market where DTC is not allowed. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *8*(2), 159–168. doi:10.1057/palgrave.jmm.5050123

Ho-Young, A., Seong Park, J., & Haley, E. (2014). Consumers' optimism bias and responses to risk disclosures in DTC prescription drug advertising: the moderating role of subjective health literacy. *The Journal of Consumer Affairs*, *48*(1), 175–194. doi:10.1111/joca.12028

Kavadas, C., Prevel Katsanis, L., & LeBel, J. (2007). The effects of risk disclosure and ad involvement on consumers in DTC advertising. *Journal of Consumer Marketing*, *24*(3), 171–179. doi:10.1108/07363760710746175

Law, M.R., Majumdar, S.R., & Soumerai, S.B. (2008). Effect of illicit direct to consumer advertising on use of etanercept, mometasone, and tegaserod in Canada: controlled longitudinal study. *British Medical Journal (Clinical Research ed.) BMJ*, *337*, a1055.

Law, M.R., Soumerai, S.B., Adams, A.S., & Majumdar, S.R. (2009). Costs and consequences of direct-to-consumer advertising for clopidogrel in Medicaid. *Archives of Internal Medicine*, *169*(21), 1969–1974. doi:10.1001/archinternmed.2009.320

Lexchin, J., & Mintzes, B. (2002). Direct-to-consumer advertising of prescription drugs: the evidence says no. *Journal of Public Policy & Marketing*, *21*(2), 194–201.

Liang, B.A., & Mackey, T. (2011). Direct-to-consumer advertising with interactive internet media: global regulation and public health issues. *Journal of the American Medical Association*, *305*(8), 824–825. doi:10.1001/jama.2011.203

Mack, J. (2014). Promotional spending in 2013 of the top 20 Big Pharma spenders. Pharma Marketing Blog. Retrieved from http://pharmarkting.blogspot.ca/2014/d05/promotional-spending-in-2013-of-top-20.html

Maddox, L., & Katsanis, L.P. (1997). Direct to consumer advertising and its influence on patient/physician interaction. *Journal of Pharmaceutical Marketing and Management*, *12*(1), 1–21.

Menon, A.M., Deshpande, A.D., III, M.P., & Zinkhan, G.M. (2003). Consumers' attention to the brief summary in print direct-to-consumer advertisements: perceived usefulness in patient–physician discussions. *Journal of Public Policy & Marketing*, *22*(2), 181–191.

Mintzes, B., Barer, M.L., Kravitz, R.L., Kazanjian, A., Bassett, K., Lexchin, J., & Marion, S.A. (2002). Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: two site cross sectional survey. *British Medical Journal*, *324*(7332), 278–279. doi:10.1136/bmj.324.7332.278

Moynihan, R. & Cassels, A. (2005). *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning us All into Patients*. New York: Nation Books.

Mukherjee, A., Limbu, Y., Mukherjee, A., Limbu, Y., & Wanasika, I. (2013). A review of research on direct-to-consumer advertising of prescription drugs. *International Journal of Pharmaceutical and Healthcare Marketing*, *7*(3), 226–243. doi:10.1108/IJPHM-07-2013-0037

Paek, H.-J., Lee, H., Praet, C.L.C., Chan, K., Chien, P.M., Huh, J., & Cameron, G.T. (2011). Pharmaceutical advertising in Korea, Japan, Hong Kong, Australia, and the US: current conditions and future directions. *Health Communication Research*, *3*(1), 1–63.

PwC. (2013). Customer experience in the pharmaceutical sector: getting close to the patient. Retrieved from www.pwc.com/mx/es/industrias/archivo/2013–11-customer-experience-pharma.pdf

Reast, J., Palihawadana, D., & Shabbir, H. (2008). The ethical aspects of direct to consumer advertising of prescription drugs in the United Kingdom: physician versus consumer views. *Journal of Advertising Research – JAR*, *48*(3). doi:10.2501/S0021849908080458

Rodale. (2010). Prevention magazine releases 13th annual DTC survey results. Retrieved from www.rodaleinc.com/newsroom/ipreventioni-magazine-releases-13th-annual-dtc-survey-results

Toop, L., & Mangin, D. (2007). Industry funded patient information and the slippery slope to New Zealand. *British Medical Journal*, *335*(7622), 694–695. doi:10.1136/bmj.39346.525764.AD

Van den Engh, M., & Bonertz, L. (2010). The effects of direct-to-consumer-advertising on patients in a northern Canadian community: a cross-sectional survey. *Canadian Pharmacists Journal/Revue Des Pharmaciens Du Canada*, *143*(3), 126–133. doi:10.3821/1913-701X-143.3.126

Velo, G., & Moretti, U. (2008). Direct-to-consumer information in Europe: the blurred margin between promotion and information. *British Journal of Clinical Pharmacology*, *66*(5), 626–628. doi:10.1111/j.1365-2125.2008.03283.x

Wong-Rieger, D. (2009). Should Canada allow direct-to-consumer advertising of prescription drugs? *Canadian Family Physician*, *55*(2), 130–132.

World of DTC Marketing. (2012). *A New Era for DTC Marketing*. Retrieved from http://worldofdtcmarketing.com/a-new-era-for-dtc-marketing-study/focus-on-patients/

Additional Reading

Ahn, H.-Y. (Anthony), Park, J.S., & Haley, E. (2014). Consumers' optimism bias and responses to risk disclosures in direct-to-consumer (DTC) prescription drug advertising: the moderating role of subjective health literacy. *Journal of Consumer Affairs*, *48*(1), 175–194. doi:10.1111/joca.12028

AMA. (2014). Opinion 5.015 – Direct-to-consumer advertisements of prescription drugs. Retrieved from www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion5015.page?

Andreou, A., & Katsanis, L.P. (2003). A content analysis of pharmaceutical web sites. *Journal of Pharmaceutical Marketing & Management*, *15*(2), 63–79. doi:10.3109/J058v15n02_05

Epha. (2004). Direct-to-consumer advertising – for or against? Retrieved from www.epha.org/a/533

Gönül, F.F., Carter, F., & Wind, J. (2000). What kind of patients and physicians value direct-to-consumer advertising of prescription drugs. *Health Care Management Science*, *3*(3), 215–226. doi:10.1023/A:1019005827097

Huh, J., DeLorme, D.E., & Reid, L.N. (2005). Factors affecting trust in on-line prescription drug information and impact of trust on behavior following exposure to DTC advertising. *Journal of Health Communication*, *10*(8), 711–731. doi:10.1080/10810730500326716

Kees, J., Bone, P.F., Kozup, J., & Ellen, P.S. (2008). Barely or fairly balancing drug risks? Content and format effects in direct-to-consumer online prescription drug promotions. *Psychology and Marketing*, *25*(7), 675–691. doi:10.1002/mar.20231

LaFonte, T. (2013). Should Europe preserve the ban on DTC advertising of prescription drugs? Retrieved from www.conformlaw.com/blog/should-europe-preserve-the-ban-on-dtc-advertising-of-prescription-drugs/

Macias, W., & Lewis, L.S. (2003). A content analysis of direct-to-consumer (DTC) prescription drug web sites. *Journal of Advertising*, *32*(4), 43–56.

Maddox, L.M. (1999). The use of pharmaceutical Web sites for prescription drug information and product requests. *Journal of Product & Brand Management*, *8*(6), 488–501. doi:10.1108/10610429910299728

Mintzes, B., Barer, M.L., Kravitz, R.L., Bassett, K., Lexchin, J., Kazanjian, A., & Marion, S.A. (2003). How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *CMAJ: Canadian Medical Association Journal*, *169*(5), 405–412.

Sheehan, K.B. (2007). Direct-to-consumer (DTC) branded drug web sites: risk presentation and implications for public policy. *Journal of Advertising*, *36*(3), 123–135.

Public Policy and DTCA

Donohue, J.M., Cevasco, M., & Rosenthal, M.B. (2007). A decade of direct-to-consumer advertising of prescription drugs. *The New England Journal of Medicine*, *357*(7), 673–681. doi:10.1056/NEJMsa070502

Handlin, A., Mosca, J.B., Forgione, D.A., & Pitta, D. (2003). DTC pharmaceutical advertising: the debate's not over. *Journal of Consumer Marketing*, *20*(3), 227–237. doi:10.1108/07363760310472254

Hoek, J., & Gendall, P. (2002). To have or not to have? Ethics and regulation of direct to consumer advertising of prescription medicines. *Journal of Marketing Communications*, *8*(2), 71–85. doi:10.1080/13527260210137181

Porter, D. (2011). Direct-to-consumer (DTC) pharmaceutical marketing: impacts and policy implications. *SPNHA Review*, *7*(1). Retrieved from http://scholarworks.gvsu.edu/spnhareview/vol7/iss1/5

Royne, M.B., & Myers, S.D. (2008). Recognizing consumer issues in DTC pharmaceutical advertising. *Journal of Consumer Affairs*, *42*(1), 60–80. doi:10.1111/j.1745–6606.2007.00094.x

DTCA Effect on Rx Requests and Physician–Patient Relationship

Blose, J. E., & Mack, R. W. (2009). The impact of denying a direct-to-consumer advertised drug request on the patient/physician relationship. *Health Marketing Quarterly*, *26*(4), 315–332. doi:10.1080/07359680903304294

Choi, S. M., & Lee, W. N. (2007). Understanding the impact of direct-to-consumer (DTC) pharmaceutical advertising on patient–physician interactions adding the web to the mix. *Journal of Advertising*, *36*(3), 137–149.

Friedman, M., & Gould, J. (2007). Physicians' attitudes toward direct-to-consumer prescription drug marketing. *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing*, *7*(1), 33–44. doi:10.1057/palgrave.jmm.5050063

Hausman, A. (2008). Direct-to-consumer advertising and its effect on prescription requests. *Journal of Advertising Research*, *48*(1), 42–56.

Hébert, P. C. (2008). Direct-to-consumer advertising: end the compromise. *Canadian Medical Association Journal*, *179*(2), 119–119. doi:10.1503/cmaj.080927

Huh, J., & Langteau, R. (2007). Presumed influence of direct-to-consumer (DTC) prescription drug advertising on patients: the physician's perspective. *Journal of Advertising*, *36*(3), 151–172.

Iizuka, T., & Jin, G. Z. (2007). Direct to consumer advertising and prescription choice. *The Journal of Industrial Economics*, *55*(4), 771. doi:10.1111/j.1467-6451.2007.00329.x

Liu, Q., & Gupta, S. (2011). *The impact of direct-to-consumer advertising of prescription drugs on physician visits and drug requests: empirical findings and public policy implications* (SSRN Scholarly Paper No. ID 1804854). Rochester, NY: Social Science Research Network. Retrieved from http://papers.ssrn.com/abstract=1804854

Silversides, A. (2008). Abramson: direct-to-consumer advertising will erode health care. *Canadian Medical Association Journal*, *178*(9), 1126–1127. doi:10.1503/cmaj.080442

Consumer Attitude Toward DTCA

BusinessWire. (2008, June 10). 11th annual survey on consumer reaction to DTC advertising of prescription drugs reveals. Retrieved August 27, 2014, from www.businesswire.com/news/home/20080610006469/en/11th-Annual-Survey-Consumer-Reaction-DTC-Advertising#.U_4cO2NeXaI

Dolliver, M. (2008, June 23). Better to consult your own doctor than to see one in DTC advertising. *Adweek*, *49*(21), 40.

Huh, J., & Langteau, R. (2007). Presumed influence of DTC prescription drug advertising: do experts and novices think differently? *Communication Research*, *34*(1), 25–52. doi:10.1177/0093650206296080

Content Analysis of DTCA

Frosch, D. L., Krueger, P. M., Hornik, R. C., Cronholm, P. F., & Barg, F. K. (2007). Creating demand for prescription drugs: a content analysis of television direct-to-consumer advertising. *The Annals of Family Medicine*, *5*(1), 6–13. doi:10.1370/afm.611

Handlin, A. (2006). Depictions of health care consumer empowerment: a comparative content analysis of DTC advertising at two points in time. *The Business Review*, Cambridge, *5*(2), 43–47.

Handlin, A. (2008). Reevaluating visuals in direct-to-consumer print advertising for prescription drugs: an argument for active vs. passive depictions of product benefits. *The Business Review*, Cambridge, *9*(2), 37–42.

Mack, J. (2014). Patient storytelling marketing creativity vs. truth in pharma advertising. *Pharma Marketing News*, *13*(7), 1–5.

Rollins, B., & Bhutada, N. (2014). Impact of celebrity endorsements in disease-specific direct-to-consumer (DTC) advertisements. *International Journal of Pharmaceutical and Healthcare Marketing*, *8*(2), 164–177. doi:10.1108/IJPHM-05-2013-0024

Welch Cline, R. J., & Young, H. N. (2004). Marketing drugs, marketing health care relationships: a content analysis of visual cues in direct-to-consumer prescription drug advertising. *Health Communication*, *16*(2), 131–157. doi:10.1207/S15327027HC1602_1

Risk and DTCA

Beltramini, R. F. (2006). Consumer believability of information in direct-to-consumer (DTC) advertising of prescription drugs. *Journal of Business Ethics*, *63*(4), 333–343.

Khanfar, N., Loudon, D., & Sircar-Ramsewak, F. (2007). FDA direct-to-consumer advertising for prescription drugs: what are consumer preferences and response tendencies? *Health Marketing Quarterly*, *24*(1–2), 77–91. doi:10.1080/07359680802125899

Polen, H. H., Khanfar, N. M., & Clauson, K. A. (2009). Impact of direct-to-consumer advertising (DTCA) on patient health-related behaviors and issues. *Health Marketing Quarterly*, *26*(1), 42–55. doi:10.1080/07359680802473521

DTCA and Demographics

DeLorme, D. E., Huh, J., & Reid, L. N. (2006). Age differences in how consumers behave following exposure to DTC advertising. *Health Communication*, *20*(3), 255–265. doi:10.1207/s15327027hc2003_5

Herzenstein, M., Misra, S., & Posavac, S. S. (2004). How consumers' attitudes toward direct-to-consumer advertising of prescription drugs influence ad effectiveness, and consumer and physician behavior. *Marketing Letters*, *15*(4), 201–212. doi:10.1007/s11002-005-0458-x

Joseph, M., Spake, D. F., & Finney, Z. (2008). Consumer attitudes toward pharmaceutical direct-to-consumer advertising. *International Journal of Pharmaceutical and Healthcare Marketing*, *2*(2), 117–133. doi:10.1108/17506120810887916

Yuan, S. (2008). Public responses to direct-to-consumer advertising of prescription drugs. *Journal of Advertising Research*, *48*(1), 30–41.

9 Consumer Digital Communication Channels

eDTCA 1.0, 2.0, and mHealth

Unlike traditional DTCA, digital communication to consumers (eDTCA) requires the use of new and continuously evolving tools with different messaging modalities. Examples of eDTCA include branded and unbranded disease websites; website display advertising; social media platforms such as Facebook and Twitter; and health care apps (mHealth) to assist consumers with health information, monitoring of disease, and treatment adherence. In addition, the profiles of consumers who use eDTCA differ somewhat from traditional DTCA, particularly in the use of social media tools and mobile apps. The Nielsen Measured Media Audit (as reported by Mack, 2014) reported an expenditure of $59 billion on consumer Internet advertising in 2013, a 22.3 percent decline from 2012. Mack (2014) posits that this decline suggests firms are likely putting funds toward building their own Internet health sites or diverting funds to non-measured media such as brand websites, social media platforms, and for online paid spokespersons.

While pharmaceutical companies have embraced Internet advertising and Web 1.0, they have been very slow to adopt social media and mHealth (mobile apps). Some reasons for this lag include concerns about risk disclosure, adverse reaction reporting, and the industry's desire to control content; while other reasons relate to the structure of the Web 2.0 media itself (for example, Twitter and its 140 character limitation). While Web 1.0 has been successful for the industry, Web 2.0 is relatively new territory. Consequently, there is a scarcity of scholarly research about both Web 1.0 and Web 2.0 specific to the pharmaceutical industry. As a result, there is little to examine from a research perspective, but no shortage of commentary and opinions on the use of digital channels by industry analysts. Due to the rapidly changing nature of this area, the research presented here is likely to be outdated quickly; nevertheless, it presents a snapshot of developments to date.

eDTCA 1.0 and the Health Care Consumer

A recent survey reported that nearly 50 percent of consumers use online health videos when seeking out medical information, followed by independent health information websites (43 percent); websites sponsored by a pharmaceutical company (14 percent); sites for video sharing (9 percent); and social networking sites (6 percent) (Rodale, 2009). A comScore benchmarking study indicated that 3 to 7 billion website ads appear monthly in the health sector, and that these ads drive brand awareness, favorability, and conversions. Finally, online direct to consumer marketing had the highest viewability rates (51 percent) out of ten industries surveyed by comScore, and the advertising in this venue resulted in a 9.4 point increase in new patient starts on a particular medication. Consumers also want information about specific conditions; alternative treatment information; and rankings and reviews of prescription medication (Rodale, 2009).

When consumers search for health care information online, Makovsky Health and Kelton (as cited by Mack, 2014) reported in their study that WebMD was the most popular website with 53 percent of respondents, followed by Wikipedia at 22 percent, and patient advocacy websites at 16 percent. Pharmaceutical company websites were the least popular with 9 percent of respondents accessing these resources. They further state that consumers are most likely to access pharmaceutical company-sponsored websites after they receive a diagnosis (51 percent); before filling a prescription (23 percent); and after experiencing symptoms (16 percent). Finally, physicians are most likely to drive consumers to company-sponsored websites (42 percent of referrals), followed by news articles (33 percent); personal recommendations (30 percent); and TV ads (25 percent). Web ads and digital ads were among the lowest as likely to result in a visit to a company website at 11 percent for both. Social media scored the lowest as a driver for pharmaceutical company websites at 6 percent.

However, a recent IMS (2014) study suggests that Wikipedia is now the "leading single source of healthcare information for patients and professionals" (p. 16). The study found a strong association between the use of Wikipedia and medications used to treat specific diseases. This study also reports on online trends outside the US: on average, 80 percent of Europeans and 56 percent of UK residents search for health care information online. Maddox (1999) examined Swedish consumers and their use of Web 1.0 to determine how consumers use pharmaceutical company websites for the purpose of deciding which drug was the right one; as well as whether or not they would request a prescription from a physician. Her findings suggest that the primary reason for visiting the website was to learn about a specific drug (rated the most important at 55 percent). Other areas of importance (in rank order) included: disease information (48 percent); a second opinion for a diagnosis (43 percent); information from a medical expert (34 percent); determining the right drug (34 percent); and getting information to discuss with a physician (25 percent).

Consumer Trust in Online Health Information

A Rodale (2010) study suggests that US consumers generally find online health care information useful (66 percent) and trustworthy (58 percent). A recent Canadian poll by CBC News (2011) reported that the poll subjects trusted the information 67 percent of the time, with women more likely to seek out the Internet for advice on health conditions. However, this trust may be misplaced, as the same report indicates that only 39 percent of websites actually provided the correct information about a disease and 11 percent gave incorrect information. Keselman et al. (2008) gave their study participants a list of medical symptoms and asked them to use the Internet to identify the source of information. The researchers classified the participants' search strategies into three groups: those who confirm their own beliefs about their condition first (verification search); those who identify the diagnosis first (problem area search); and those who listed symptoms looking for the diagnosis (bottom up search). All three groups consistently committed errors in finding the correct information: the verification first group would stop a search prematurely; the problem area first group would begin with a diagnosis and lack the knowledge to find information; and the bottom up group suffered from the lack of knowledge in order to find the information. This research suggests that consumers may be unable to find accurate information on websites even if the information on the website is correct.

Two scholarly studies may provide insight into the question of trust (Menon et al., 2002; and Huh et al., 2005). Menon et al. (2002) found that traditional media sources were an important predictor of trust on the part of consumers and that one's health also affected the perception of trust in online information. Further,

they reported that trust in traditional sources was also linked to trust in information found online; but consumers who received information from health care professionals were not likely to view the Internet as trustworthy. Huh et al. (2005) supported their findings with respect to the transfer of traditional media trust to online sources. However, their findings differed from Menon et al. (2002) in that they found online drug information to be untrustworthy. Additionally, they reported that trust in online drug information is linked to exposure to DTCA; this may lead to discussion with physicians and others about the advertised drug as well as additional online information searching.

eDTCA 1.0: Direct to Consumer Websites

The need to use the Web for reaching consumers in the industry is important, and its popularity with marketing managers may be easily understood for several reasons. The brand information provided can be changed easily when required (for updating information for example), and Web 1.0 also allows interactivity by using infographics, interesting copy, and videos. The 'contact us' feature permits feedback from the user and the sense of two-way communication with the advertiser. The semi-permanent quality about the website allows the pharmaceutical company to provide the proper balance of benefits and risks without concern about what a drug can or cannot do, as exists in a Web 2.0 environment—it allows for total control over the content of the material. Additionally, there is no limit to the amount of information that a website can contain, and this may provide an easier way for a firm to comply with regulatory guidelines on fair and balanced content. Finally, websites are available globally and may be accessed by consumers around the world with a consistent brand message.

Critics of eDTCA argue that it may result in lack of transparency, as consumers may not be able to distinguish between company-sponsored material and independently produced material. Further, consumers may misinterpret medical information and fail to consult their physicians, which could result in lack of proper treatment.

Pharmaceutical Company Website Content

A pharmaceutical company may use multiple websites for different purposes: there are branded websites that are used specifically to promote a particular drug, as well as unbranded websites that provide information on disease conditions and available treatments. Finally, there are corporate websites that also contain both consumer and corporate information.

A content analysis of pharmaceutical corporate websites found that the home pages for these websites targeted both consumers and corporate visitors equally and did not differentiate between the two (Andreou & Katsanis, 2003). Macias and Lewis (2003) undertook a content analysis of branded, stand-alone websites that were not part of the primary pharmaceutical corporate website. They reported that inducements such as rebates, coupons, and free trials were offered as well as additional information to be sent to the consumer. In addition, medical information was a large portion of the material found on the websites, and the vast majority encouraged consumers to talk to their physicians and pharmacists. Their study also found that the following adjectives were used in describing the promoted medication: effective; convenient; enhancing lifestyle; innovative; safe and preventative. The sites were largely multi-media in nature, with the use of video and audio as well as links to related websites (such as to non-profit organizations).

With respect to risk information on branded websites, Sheehan (2007) provides detailed information on how and where risk information appears and the type of risk information included on pharmaceutical branded websites (she used the same websites as the Macias and Lewis (2003) study). In Sheehan's

study, a typical pharmaceutical website contained 19 unique pages, including the home page. These home pages included both risk and benefit information using the same font, type size, and color. In terms of placement of risk information, three patterns emerged: the all benefit pattern (no risk information on home page at 39 percent); primarily benefit information (27 percent); and equal amounts of space for benefits and risks (36 percent). The majority of home pages supplied links to the complete prescribing information for the drug, and there appeared to be an appropriate balance between risk and benefit information. Three patterns emerged for the presentation of this information: the disclaimer pattern (small print used in 36 percent of websites); the matched pattern (27 percent showed risk and benefits together); and the stand-alone pattern (36 percent had risk on separate pages). Finally, Sheehan's study results suggest a lack of consistency and standardization in the way risks are presented for different drug categories and this may result in confusion for consumers.

When seeking information about drugs online, consumers may perceive a greater risk in using a prescription drug when risk factors are emphasized rather than using no drug at all: this phenomenon is called a "bias of omission" (Kees et al., 2008, p. 675). The authors of this study also suggest that patients may suffer from information overload and that this may cause them to avoid seeking medical treatment. This effect is also noted in research on traditional DTCA (Kavadas et al., 2007), where the findings suggest that the response to high risk disclosure in DTC advertisements resembles that of fear appeals. In that study, when respondents were shown a balanced presentation of benefits and side effects, they tended to have high recall of the drug's risks. However, consumers reacted negatively to DTCA that contained a high content of risk information and failed to recall the risks associated with the advertised drug.

eDTCA 2.0 and the Health Care Consumer

According to Deloitte University Press (2012), 26 percent of consumers primarily used social media to learn more about a specific illness. Social media sources sponsored by pharmaceutical companies are ranked 12th out of 15 among the least preferred sources. There are some generational differences in social media use for health care, according to this report: 40 percent of Millenials use social media for any health-related purpose, followed by Gen-Xers at 29 percent, with Boomers at 17 percent and Seniors at 10 percent. Seniors tend to rely heavily on their health care professionals for information about prescription drugs.

Additional insight into consumer attitudes is provided by Govette (2013), who reported the following in his study: 40 percent of respondents stated that social media affects how they deal with their health; 30 percent of respondents will share personal health information through social media with other patients, 47 percent with physicians, 43 percent with hospitals, 38 percent with payers, and 32 percent with a pharmaceutical company. He additionally reports usage among the various social media outlets to consumers: Facebook (17 percent); YouTube (15 percent); blogs (13 percent); patient communities (12 percent); and Twitter (6 percent). He confirms the generational differences reported by Deloitte University Press (2012): Millenials are twice as likely to use social media for their health conversations, and 90 percent of them would trust medical information shared by others on their social media networks. Makovsky Health and Kelton (as cited by Mack, 2014) reported that social media tools such as Facebook and blogs were the least used of any online tools (except for pharmaceutical company websites) at 10 percent of their study's respondents. Based on this research, it is possible that social media is not the best way for pharmaceutical companies to reach consumers about health care information.

Social Media—An Underutilized Digital Tool

If one follows industry chatter in the blogosphere, the impression given is that firms are overly cautious about communicating with consumers and suffer from what one reporter calls "social anxiety" (Staton, 2013), and another referring to pharmaceutical social media as "the communications black hole" (Koroneos, 2009). This is due to a variety of reasons according to the Digital Health Coalition (2012): the difficulty in measuring ROI and effectiveness (78 percent); regulatory concerns (78 percent); legal liability concerns (74 percent); the need to educate staff about social media (70 percent); concerns about compliance (67 percent); the need to respond to consumer comments (52 percent); adverse reaction reporting (41 percent); and lack of a specific digital strategy (41 percent). There is also some lack of familiarity on the part of the industry in dealing directly with consumers through interactive media (i.e. a two-way dialogue versus a one-way message). A timeline of social media events in the industry has been compiled by Mack (2011), which provides an interesting look at how social media has evolved since 2005 for different tools such as blogging and YouTube and is useful for tracking the regulatory timeline in the US with respect to Web 2.0.

While some commentators bemoan the lack of involvement with social media, others, such as Richman (2010), are tired of hearing about the industry's woes regarding social media. He has asked his readers to stop talking about social media as the 'holy grail'; how they are unable to use social media because of regulation; e-patients; the problem with imprecise FDA guidelines; the need for a social media strategy; the notion of 'trying something small' to get started; and the impossibility of measuring ROI. He also points out that consumers do not trust pharmaceutical companies; therefore, industry-sponsored social media may not provide a consumer with better information than that which exists from independent sources (and which may be more highly regarded).

That said, the recent FDA guidelines for social media, particularly Twitter, make the usage of this medium somewhat more challenging for drugmakers than for FMCG companies because of the necessity to balance brand benefits and risks in a limited space. For example, prior to the guidelines in 2010, Novartis was cited for sharing features on Facebook because of misleading content and lack of risk information. After the FDA guidelines were released in 2014, AMARC Enterprises was cited for Facebook 'likes' because customers claimed that AMARC products cured their cancer. A second letter was sent to Zarbees for 'liking' six unapproved product claims that appeared on Facebook (Gaffney, 2014). The FDA has posted 11 warnings about the inappropriate use of Twitter on its electronic reading room (www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?webSearch=true&qryStr=Twitter&Search=Search) that include violations such as unapproved new drugs or false labelling. Although none of these letters were directed at large pharmaceutical companies, the industry's concern is not without merit. Monitoring social media for adverse effects can be an expensive proposition: Edwards (2008) reported that costs can range from $100,000 to $1 million depending on the number of visitors to the site and its size. Gaffney (2014) also reports that the larger companies such as Merck and GlaxoSmithKline (GSK) have avoided 'favorited' tweets and in particular, those that specifically mention their brands; Boeringer Ingelheim has favored hundreds of tweets, but also avoids those that favor its brands. It is possible that the larger firms have already instituted policies to ensure that they do not receive FDA letters.

There is much commentary but little available research in the public domain about consumer health care social media, although privately commissioned reports certainly exist with specific recommendations for individual firms. The available research shows that social media in the industry is underutilized by half the industry, but nonetheless, this preliminary work may provide interesting ideas for future scholarly research in this area. It is also possible that social media may have both limited and very specific uses as a pharmaceutical

marketing tool despite its appeal, but may offer interesting health care applications for regulatory agencies and health care providers with respect to the monitoring of adverse events.

Social Media Platforms Used by Leading Pharmaceutical Companies

The limited research available suggests that the biggest firms in the industry are taking full advantage of social media, even if the percentage of the promotional budget allocated to these activities is relatively small when compared to physician and other marketing expenditures. A descriptive study by Liang and Mackey (2011) examined the prevalence of eDTCA for the top ten pharmaceutical companies and ten highest drugs based on IMS sales for 2009. The authors noted that eDTCA uses varied content that includes reminder advertising; consult your physician recommendations; brand information including specific claims; and help seeking advertisements. They reported that 40 percent of the top ten firms had dedicated social media corporate websites that linked together all the firm's social media tools. In addition, all these companies had Facebook pages, Twitter feeds, RSS, or sponsored blog feeds, with eight out of ten providing dedicated YouTube channels and mobile applications. When they examined data for the leading brands in the market, they found that 90 percent have dedicated brand pages; 70 percent have dedicated Facebook pages; 90 percent have Twitter/Friendster commentary; and 80 percent use YouTube DTCA.

A recent IMS (2014) study on social media provides updated information about the industry's use of these digital channels and presents its Social Media Engagement Index. This index is based on three variables: the number of participants (Reach), the quality of content (Relevance), and the level of interaction (Relationship). The authors' findings suggest that 50 percent of the top ten companies participate in social media, which represents a 10 percent increase from Liang and Mackey's (2011) figures; the remaining half do not participate in social media. According to IMS (2014), only ten companies use all three basic social media tools: Twitter, Facebook, and YouTube. Based on their findings, the leading social media company in social engagement is Johnson & Johnson, with 70 index points, representing 50 points higher than the next largest firm, GSK with 25 index points. These firms are closely followed by Novo Nordisk (23) and Pfizer (20). IMS (2014) suggests that many firms are risk averse and need further training and experience in the use of social media tools. In addition, the authors note the one-way, non-conversational nature of the industry's social media, and recommend they find a way to more closely mirror the conversational nature of the tool for greater success.

The Use of Social Media in Europe

An EPG Health Media study (2010) examined the use of social media platforms in five European countries: the UK, Germany, France, Spain, and Italy. Although there were a small number of consumer respondents (265), the findings are revealing: 49 percent of them said they would be willing to use social media for medical information if there were clear and established guidelines, and 87 percent stated that there is likely a need for regulatory control of social media. In terms of accessing social networks for health related discussions, the percentage across countries was relatively consistent with 42 percent of respondents reported as never accessing social media for this purpose, and 19 percent using it occasionally at several times per year. Those who use social media for health care indicate that they use discussion forums and message boards (17 percent) and dedicated health care social networks (15 percent). However, the researchers noted a shortage of social media opportunities for the non-English speaking countries, despite significant interest from German

and French respondents, and correspondingly, higher participation from the UK. Finally, only 13 percent of respondents expressed any interest in communicating with pharmaceutical companies for health related conversation, while 52 percent of respondents want dialogue with health care providers using social media. The study concludes by recommending that European consumers are interested in accurate information, the proper governance of information, and information which is easily understood. However, it does not appear that the pharmaceutical industry is a favored source for this information in Europe.

Social Media and Adverse Reaction Reporting

Given the concern about adverse reaction reporting, a study by Freifeld et al. (2014) provides some information about the use of Twitter and its potential in recognizing adverse drug effects in the population. The researchers examined 6.9 million tweets over a seven-month period and found that approximately 4,000 of these describe adverse effects that merited reporting to the FDA. The authors further conclude that patients showed a varied range of sophistication in reporting their experiences with a particular drug, and suggest that Twitter may be an interesting way to access adverse reaction reports. The lead author, Clark Freifeld, created the MedWatcher app in cooperation with the FDA that allows consumers to search the FDA database for drug side effects and also allows them to report their own experiences, which are then sent to the FDA (Tozzi, 2014). This identification of adverse effects through the use of consumer media was also found by David et al. (2010) in their study on DTCA and adverse reaction reporting.

The Market for mHealth

According to Martins (2014), the global market for health care apps is $3 billion and expected to reach $26 billion by 2017. While consumers use apps on a daily basis to manage both their health and fitness with 100,000 apps currently available, 10 percent or less of these apps have the qualities to maintain a steady user group. Additionally, pharmaceutical companies have self-reported disappointment with their use of this media channel. They also face health information privacy concerns and the reticence of physicians to recommend apps to their patients unless they demonstrate the ability to affect patient outcomes.

A Profile of the mHealth Consumer

The typical mobile health consumer is skewed female, between the ages of 18 and 34, has children under the age of 18, and is actively engaged in her health. Smartphone users are 36 percent more likely to specifically ask for branded medication compared to the general population, and are likely to use their smartphone or tablet to research health conditions in preparation for a doctor's visit, read reviews about doctors, or posts from those with similar health issues (World of DTC Marketing, 2014). Eighty-three percent of consumers used PCs in 2013, with 11 percent using tablets (an almost three-fold increase from 2012) and 6 percent using smartphones (Makovsky Health and Kelton as cited by Mack, 2014).

Examples of Pharmaceutical Consumer Apps

Consumer apps typically fall into three general categories: medication reminders and adherence, device demonstration, and disease education. The majority of these apps tend to be biased toward some form of company

promotion, often with a direct link to their brand. Some examples of consumer apps developed by the pharmaceutical industry include (Taylor, 2013): Genetech's Ralph's Killer Muenster (to teach kids about DNA and genetics); Novartis' Clinical Trial Seek (to find clinical trials for participation); Boehringer Ingelheim's Complications Combat (to educate about diabetes); Janssen's Care4Today (alerts to family members when patients are not taking their medication); Bristol-Myers Squibb's wellB (for hepatitis B patients); Vivus' Q and Me Support (weight loss monitoring); Bayer's My iPill (reminder for birth control pill compliance); and Novo Nordisk's NovoPen 5 (demonstration of use for the device). This is not meant to be an exhaustive list of apps, but merely to provide examples of pharmaceutical company activity in this domain.

The pharmaceutical industry has not developed high-quality apps for consumers. Martins (2014) provided IMS data that suggested that 90 percent of consumer apps did not rate well based on their functionality (an average rating of 40 percent on a scale from 1 percent to 100 percent). One of the challenges in app development is the number of different devices that need to be accommodated when developing these apps, although this is changing according to Taylor (2013) with simultaneous launches on Apple and Android devices. Another difficulty is the acceptance of industry-sponsored apps by consumers because they are perceived as exclusively for promotional or branding purposes. Independently developed apps from firms that specialize in this business are available that are perceived as doing a better job without the potential for industry bias.

In addition, eMarketer (as cited by Mack, 2014) reports that mobile devices are not used just for apps, but for advertising as well, and the information from these sources is ranked as follows from high to low: mobile location targeted ads; Facebook mobile ad formats; mobile reward-based ads; mobile sponsorships; and mobile video ad formats. It has been suggested that mobile optimization (converting your website to mobile friendly) has greater potential than mobile applications themselves with respect to ROI. Maher (as cited by Mack, 2012) stated that only 19 percent of pharmaceutical sites are mobile optimized; this may cause a user to click off the site.

The Availability of Health Care Apps Worldwide

According to research2guidance (2013), the US market offers the largest market for mHealth apps regardless of the platform, and whether or not they are offered for free. In other countries, they suggest that chances to generate reach on Android is higher in the UK than in Germany, Japan, or Brazil. US apps are likely to be successful on three platforms, with the Japanese app market as the most difficult for multiple platforms. There is currently no available research in the public domain on the effectiveness of different consumer health care apps. This is an area of great potential for independent research from academic scholars as well as those in market research organizations.

GlaxoSmithKline, Boehringer Ingelheim, and Novo Nordisk: Three Case Studies in Social Media

As part of the IMS (2014) Social Media Engagement study, firms were ranked by the individual Reach, Relevance, and Relationship indices as well as the overall Social Media Engagement Index. One company from each IMS 'index' was chosen specifically for this case study in order to take an in-depth look at the use of social media in the industry: GSK for its reach, Boehringer Ingelheim for its relevance, and Novo Nordisk for its relationships. While large firms such as GSK are experienced in the use of social media to large audiences because of their consumer goods divisions, mid-size and small firms demonstrate the ability to use social

media in a more personal way because of their smaller, more targeted audiences. In addition, the global focus of this book made the choice of non-US firms an important one, and communicates the fact that the reach of pharmaceutical consumer media is now truly global. The companies' media sites were accessed in November, 2014.

GlaxoSmithKline

GSK has strong businesses in both pharmaceuticals and consumer goods, and its use of social media is a reflection of its strength in the consumer goods industry as a result of the 2000 merger with SmithKlineBeecham (one notable brand—Tums Antacids). GSK's home webpage directs the visitor to all of its social media, and the content of the consumer-directed media is strongly linked: Facebook, Twitter, YouTube, and Flickr. The primary message (accompanied by the same image) used in all platforms is: 'We are dedicated to improving the quality of human life by enabling people to do more, feel better, live longer.' The primary focus of all social media is the firm's public service activity, such as the current development of an Ebola virus vaccine with a spotlight on Keyna. The company tends not to mention brand names, but focuses primarily on corporate and disease branding in its social media efforts.

GSK has two Facebook pages, one for GSK, and the other for its dermatology division, Stiefel Laboratories. The focus of GSK's page is primarily on diseases and the personal stories of individuals affected by these diseases, or, about researchers helping to find treatments for them. The page features posts about vaccines, diabetes, and COPD, as examples. Links on the page direct visitors to the WHO and World Asthma Day pages. The company has three Twitter feeds (one for Stiefel), and their tweets are event announcements or links to disease sites, videos, or reports relating to their therapeutic classes, such as vaccines and COPD. GSK has 19 YouTube playlists with assorted videos about health education and the environment, with most of the videos featuring general information about the company. The emphasis is on health care community partnerships and the company's charitable work, as well as company information, such as careers. The GSK Flickr page contains numerous photos of the company's community service work around the world. There are pictures taken both in on-site settings and company settings, with the GSK logo prominently displayed.

Boehringer Ingelheim

The emphasis of Boehringer Ingelheim's social media is on disease and corporate branding. It uses Facebook, Twitter, Pinterest, YouTube, Instagram, and Vine, and runs its social media marketing efforts from Germany. It is one of the more experimental firms using social media, with playful clay images and plush toy monkeys featured in its loops on Vine. It also created an online game called Syrum to teach Facebook visitors how drugs are developed which has achieved some popularity. Its primary theme in all social media is 'Think-Act-Breathe,' but it is not the headline as in the GSK platforms. Brand names of its products are not featured in its social media.

The company Facebook page emphasizes lung cancer and asthma and directs the visitor to different postings about the disease as well as the game Syrum. Boehringer Ingelheim runs two Twitter feeds: one US and one non-US/Canada/UK feed, although both feeds are still accessible to all with no tweets permitted for those outside the geographic region. These feeds are used primarily for launches of new programs or announcements of corporate events, primarily about lung cancer. The company presents 25 disease-focused boards on Pinterest: lung cancer, diabetes, COPD, respiratory, AFib, and stroke. Photos of clay figures and plush animals appear on this platform, as well as the Vine looping platform. Boehringer Ingelheim has six YouTube channels and 25 playlists for different countries including Greece and the Netherlands. The content

of these videos is focused on personal testimonials of individuals being treated for various diseases, with a focus on hepatitis C.

Novo Nordisk

The primary message delivered by Novo Nordisk's social media efforts is caring for patients, with an emphasis on disease and corporate branding. The disease focus is diabetes and hemophilia, with the primary emphasis on diabetes, and brand names are not mentioned in its social media. Its social media has the most personal feel of the three companies examined in these case studies, as well as being the most strongly focused on one disease—diabetes. This personal touch is largely the result of its cycling team, Team Novo Nordisk, which has created a strong human link to the company. The team is composed of athletes who suffer from diabetes, and they are featured on all the different Novo Nordisk social media platforms.

Novo Nordisk has one Facebook page, which is used to promote its patient education material. It is also used for promoting events, such as its recent announcement thanking its visitors for helping Novo Nordisk to reach the 200,000 visitor mark, and emphasizing the company's efforts in battling diabetes and hemophilia. The company runs five Twitter feeds. Its US feed focuses on diabetes and news about the disease; the Global feed provides messages about diabetes and hemophilia; and the Live feed tweets information about diabetes conferences around the world. Its largest feed belongs to Team Novo Nordisk, which has over 40,000 followers. Novo Nordisk's Pinterest page contains numerous photos about diabetes and individuals who suffer from the disease. Its YouTube page features videos about diabetes, hemophilia, R&D, and careers at the company, as well as videos about Team Novo Nordisk. Many videos are available in different languages in 75 countries worldwide.

Company Similarities and Differences

It is instructive to compare and contrast the three companies with respect to the emphasis and feel of their social media strategy. All three firms focus primarily on disease and corporate branding—GSK has a dedicated social media home page, while the other two firms provide direct access to their social media from their company home pages. GSK has the most institutional and polished feel of the three companies in its social media platforms because of its consumer goods experience as well as the emphasis it places on its community service activities. Boehringer Ingelheim and Novo Nordisk have a more personal and friendly touch, likely because their target markets are somewhat smaller and their emphasis on specific therapeutic classes is more focused than a larger company like GSK. However, all three firms tend to use one-way messages with little two-way conversation, and no specific prescription drug brand names are mentioned. In some ways, the social media sites appear to be modeled after the companies' home page on their websites: they use photographs and announcements through different platforms to communicate a personal, conversational feeling without actually engaging in two-way conversation with visitors. As mentioned earlier, this one-directional conversation strategy is a way to avoid regulatory scrutiny in the use of these digital platforms, while still maintaining consumer visibility on all digital 1.0 and 2.0 channels.

Implications and Conclusions

The use of branded and corporate websites is the primary choice for the pharmaceutical industry in the digital space, largely due to the level of control available in this digital medium. However, the research suggests its websites are not trusted by consumers, as they prefer to receive their health care information from their peers or other personal sources.

Some in the industry have already embraced social media, yet at the same time, others are cautious and concerned about entering the space due to the conversational elements that are present, the perceived vagueness of the guidelines provided by regulatory authorities, and the lack of training and experience in creating a successful social media forum. Unfortunately for the industry, the research suggests that consumers do not view industry-sponsored social media either as a trustworthy source of information or a destination for conversation. They prefer to receive information directly from other patients with their condition or their health care providers. Given the limitations of social media platforms, it is likely that its usefulness to the industry will remain in the areas of disease and corporate branding in the near future, and its content will continue to model that of company websites with the use of photographs and announcements versus conversations with visitors. Opportunities for companies may be limited to eDTCA 1.0 for branded advertising and promotion.

mHealth is proving to be a challenge for the industry due to the fact that at the present time, firms which specialize in app development are simply better at this work than pharmaceutical companies. There is some potential for the development of industry apps for patient adherence and outcomes research, and some apps are already being used for this purpose; however, consumers have concerns about the privacy of the information collected on these apps. In addition, they are skeptical about company-sponsored apps, as their purpose is largely brand-driven.

There is ample opportunity for research about social media and the use of apps in the pharmaceutical marketing space, for both industry analysts and academic scholars, as there is much to learn about how these tools will be used by the pharmaceutical industry, as well as their limitations and potential difficulties.

References

Andreou, A., & Katsanis, L. P. (2003). A content analysis of pharmaceutical web sites. *Journal of Pharmaceutical Marketing & Management*, *15*(2), 63–79. doi:10.3109/J058v15n02_05

CBC News. (2011). Online health advice sought by more Canadians. Retrieved August 29, 2014, from www.cbc.ca/1.982301

David, G., Markowitz, S., & Richards-Shubik, S. (2010). The effects of pharmaceutical marketing and promotion on adverse drug events and regulation. *American Economic Journal: Economic Policy*, *2*(4), 1–25. doi:10.1257/pol.2.4.1

Deloitte University Press. (2012). 2012 survey of US health care consumers: five-year look back. Retrieved December 11, 2014, from http://dupress.com/articles/2012-survey-of-u-s-health-care-consumers-five-year-look-back/

Digital Health Coalition. (2012). Social media & healthcare. Retrieved December 4, 2014, from http://worldofdtcmarketing.com/social-media-healthcare/

Edwards, J. (2008). Why pharma fears social networking. Retrieved December 4, 2014, from www.adweek.com/news/advertising-branding/why-pharma-fears-social-networking-104687

EPG Health Media. (2010). Social media in healthcare: how do healthcare professionals, patients/consumers and pharmaceutical companies use social media in relation to health? Retrieved December 4, 2014, from www.epghealthmedia.com/industry-reports/socialmedia-healthcare.cfm

Freifeld, C. C., Brownstein, J. S., Menone, C. M., Bao, W., Filice, R., Kass-Hout, T., & Dasgupta, N. (2014). Digital drug safety surveillance: monitoring pharmaceutical products in Twitter. *Drug Safety: An International Journal of Medical Toxicology and Drug Experience*, *37*(5), 343–350. doi:10.1007/s40264-014-0155-x

Gaffney, A. (2014). FDA targets companies for Facebook 'likes'. Is Twitter next? *Regulatory Affairs Professionals Society*. Retrieved December 4, 2014, from www.raps.org/Regulatory-Focus/News/2014/08/12/20014/FDA-Targets-Companies-for-Facebook-Likes-Is-Twitter-Next/#

Govette, J. (2013). 24 outstanding statistics & figures on how social media has impacted the health care industry. Retrieved December 4, 2014, from www.linkedin.com/today/post/article/20140428161148-39605227-24-outstanding-statistics-figures-on-how-social-media-has-impacted-the-health-care-industry

Huh, J., DeLorme, D.E., & Reid, L.N. (2005). Factors affecting trust in on-line prescription drug information and impact of trust on behavior following exposure to DTC advertising. *Journal of Health Communication*, *10*(8), 711–731. doi:10.1080/10810730500326716

IMS. (2014). Engaging patients through social media. Retrieved December 4, 2014, from www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=ff71ad0087c73410VgnVCM10000076192ca2RCRD&vgnextchannel=a64de5fda6370410VgnVCM10000076192ca2RCRD

Kavadas, C., Katsanis, L., & LeBel, J. (2007). The effects of risk disclosure and ad involvement on consumers in DTC advertising. *Journal of Consumer Marketing*, *24*(3), 171–179. doi:10.1108/07363760710746175

Kees, J., Bone, P.F., Kozup, J., & Ellen, P.S. (2008). Barely or fairly balancing drug risks? Content and format effects in direct-to-consumer online prescription drug promotions. *Psychology and Marketing*, *25*(7), 675–691. doi:10.1002/mar.20231

Keselman, A., Logan, R., Smith, C.A., Leroy, G., & Zeng-Treitler, Q. (2008). Developing informatics tools and strategies for consumer-centered health communication. *Journal of the American Medical Informatics Association: JAMIA*, *15*(4), 473–483. doi:10.1197/jamia.M2744

Koroneos, G. (2009). An open conversation? *Pharmaceutical Executive*, *29*(9). Retrieved from www.highbeam.com/doc/1P3-1882140341.html

Liang, B.A., & Mackey, T.K. (2011). Prevalence and global health implications of social media in direct-to-consumer drug advertising. *Journal of Medical Internet Research*, *13*(3), e64. doi:10.2196/jmir.1775

Macias, W., & Lewis, L.S. (2003). A content analysis of direct-to-consumer (DTC) prescription drug web sites. *Journal of Advertising*, *32*(4), 43–56.

Mack, J. (2011). The Pharmaguy social media timeline™: a record of social media events impacting the pharmaceutical industry. *Pharma Marketing News*, 10(10). Retrieved December 4, 2014, from www.news.pharma-mkting.com/pmn1010-article01.htm

Mack, J. (2012). Mobile apps vs. mobile optimization: which offers pharma the best ROI? Retrieved December 4, 2014, from http://pharmamkting.blogspot.ca/2012/11/mobile-apps-vs-mobile-optimization.html

Mack, J. (2014). Is online pharma DTC ad spend continuing its downward slide? Retrieved December 4, 2014, from http://pharmamkting.blogspot.ca/2014/04/is-online-pharma-dtc-ad-spend.html

Maddox, L.M. (1999). The use of pharmaceutical Web sites for prescription drug information and product requests. *Journal of Product & Brand Management*, *8*(6), 488–501. doi:10.1108/10610429910299728

Martins, M. (2014). Health of health apps. Retrieved December 4, 2014, from http://healthexperienceproject.com/health-health-apps/

Menon, A.M., Deshpande, A.D., Perri, M., & Zinkhan, G.M. (2002). Trust in online prescription drug information among internet users: the impact on information search behavior after exposure to direct-to-consumer advertising. *Health Marketing Quarterly*, *20*(1), 17–35. doi:10.1300/J026v20n01_03

research2guidance. (2013). mHealth app performance benchmarking. Retrieved December 4, 2014, from www.research2guidance.com/shop/index.php/downloadable/download/sample/sample_id/293/

Richman, J. (2010). 10 things I'm tired of hearing about pharma social media. Retrieved December 4, 2014, from www.doseofdigital.com/2010/06/10-thing-tired-hearing-pharma-social-media/

Rodale. (2009). 12th annual survey on consumer reaction to DTC advertising of prescription drugs reveals. Retrieved August 29, 2014, from www.rodaleinc.com/newsroom/12th-annual-survey-iconsumer-reaction-dtc-advertising-prescription-drugsi-reveals

Rodale. (2010). Prevention magazine releases 13th annual DTC survey results. Retrieved from www.rodaleinc.com/newsroom/ipreventioni-magazine-releases-13th-annual-DTC-survey-results

Sheehan, K.B. (2007). Direct-to-consumer (DTC) branded drug web sites: risk presentation and implications for public policy. *Journal of Advertising*, *36*(3), 123–135.

Staton, T. (2013). Top 10 drugmakers in emerging markets. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/top-10-drugmakers-emerging-markets

Taylor, N.P. (2013). 20 big pharma and biotech mobile apps—2013. Retrieved December 4, 2014, from www.fiercebiotechit.com/special-reports/20-big-pharma-and-biotech-mobile-apps-2013

Tozzi, J. (2014, May 15). Searching social media for drug side effects. *BusinessWeek: Technology*. Retrieved December 4, 2014, from www.businessweek.com/articles/2014-05-15/searching-social-media-for-drug-side-effects

World of DTC Marketing. (2014). A new era for DTC marketing (study). Retrieved from http://worldofdtcmarketing.com/a-new-era-for-dtc-marketing-study/focus-on-patients/

10 Industry Self-Regulation

Finding the Balance

There are two sets of rules that govern the behavior of industry marketers: formal regulations and voluntary guidelines (self-regulation). Formal regulations govern basic drug information distributed to physicians and the public such as drug labelling, package inserts, and the approved indications for its use. These types of formal regulations are designed to protect the health and safety of the public, as well as to inform physicians about how these products are to be prescribed, and although there may be some differences across countries, they are fairly consistent throughout the world. Global pharmaceutical companies have compliance frameworks in place in order to comply with these regulations.

Advertising and promotion to physicians is legal; however, the language used in these materials must be based on the approved labelling and specific indications for which the drug is approved. In general, there is no official regulation of specific advertising and promotional materials to physicians in most countries. Printed materials or conversations with physicians which violate the drug's approved labelling and indications are subject to regulatory scrutiny and possible sanctions in some countries, such as the US. It is interesting to note that according to the WHO World Medicines Situation Report (2004), only 49 percent of countries reported that they regulate pharmaceutical promotion, and even then, to varying degrees. This legal void regarding advertising and promotion is filled by self-regulatory frameworks that govern the industry's behavior, and these frameworks are in place at the international, regional, and national levels. Self-regulation has received greater attention recently with the enactment of new Sunshine laws in France, the US, and Japan, and the industry is coming under increasing scrutiny due to the failure of some self-regulatory frameworks to enforce its guidelines. In most countries, DTCA is prohibited; where it is legally allowed, there are formal regulations for this type of advertising.

This chapter will focus on self-regulation and the success or failure of these voluntary arrangements as they relate to physician promotion. Marketers must be aware of these voluntary self-regulatory codes of conduct and how they apply to their brands. It is important for marketing managers to develop materials that adhere to the agreed-upon guidelines, whether in their own country or internationally (many local guidelines exceed the international ones). Pharmaceutical promotion must be both accurate and balanced to ensure the safety of the general public, and in absence of formal regulation, pharmaceutical companies have an obligation to protect the public. Inappropriate marketing materials will result in unfavorable publicity and possibly additional regulatory scrutiny. Further, there are watchdog groups which have already placed pressure on regulators, and this has resulted in the imposition of increased regulation as well as the addition of stronger voluntary

guidelines. There is little formal research about this topic, although there are many opinions expressed in the business press and industry media; therefore, this chapter is meant to serve as a reference for the various codes and existing research on this subject.

Self-Regulation—The Debate

Self-regulation may be defined as the development of rules by an industry group or trade association that are voluntarily agreed upon and followed by its members with punitive sanctions in place for violators. Lexchin (2003) suggests that most, but not all, voluntary codes tend to be reactive versus proactive—in other words, they act on complaints rather than attempting to prevent violations at the start of the process.

These rules are normally developed in absence of formal regulations, and there are two opposing views of the purpose and rationale for these voluntary codes. The industry's view is that it is capable of policing its own members to ensure they abide by the guidelines that govern their behavior with respect to marketing and promotion. They believe that self-regulatory codes are more responsive to violations and can deal with these problems more quickly than formal regulations. Francer et al. (2014) view the current system as generally working well, although they recognize that continuous improvement in the codes will be needed on an ongoing basis. There are financial costs associated with formal regulation, and the industry believes that these costs are unnecessary if they are able to monitor themselves. Industry critics believe these codes of conduct are ineffective under most circumstances; they are viewed as self-serving and exist in order to avoid the intrusion of the government. They also suggest that the lack of transparency about how these codes are administered masks the effects of marketing to physicians (e.g. fees paid to physicians for speaking engagements and gifts that may influence their prescribing habits). Arnold and Oakley (2013) call the current position of the pharmaceutical industry a "collective blocking strategy" (p. 536): this is one which is facilitated by an industry group in response to the threat of oversight, and typically both violated and unenforced. The threat of formal regulation is an area of great concern for the industry; on this subject, Hack (2007) opined that "[T]here will be more policing of the sales and promotion of drugs than ever before" (p. 348).

Voluntary Codes of Conduct

There are voluntary codes of conduct at three levels: international, regional, and local, and these are discussed in the following sub-section. The local codes are administered by various organizations within each country; the international and regional codes have separate organizations to administer the codes. Please note that these codes of conduct are not to be confused with official advertising and promotional regulations or guidelines issued by the FDA in the US or regulatory authorities in other countries. All codes cover similar aspects of promotion, and these aspects are summarized in Table 10.1. A detailed analysis and comparison of some international and European codes is available from Putzeist (2007) for those who require additional reading on this subject. Francer et al. (2014) provide a source of country codes of conduct and their affiliated organizations worldwide.

Table 10.1 Global Regional and Local Self-Regulatory Organizations

Country	*IFRMA-Affiliated Organization*
Global	
All countries (applies to international pharmaceutical companies' activities in countries not listed below)	International Federation of Pharmaceutical Manufacturers and Associations
Regional	
Europe	European Federation of Pharmaceutical Industries and Associations
Central America	Federación Centroamericana de Laboratorios Farmacéuticos (FEDEFARMA)
Local	
Argentina	Cámara Argentina de Especialidades Medicinales (CAEMe)
Australia	Medicines Australia
Austria	Association of the Austrian Pharmaceutical Industry (PHARMIG)
Belarus	Association of International Pharmaceutical Manufacturers (AIPM)
Belgium	Pharma.be
Brazil	Interfarma
Canada	Rx&D
Chile	Cámara de la Industria Farmacéutica de Chile (CIF)
China	R&D-based Pharmaceutical Association in China (RDPAC)
Colombia	Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollo (AFIDRO)
Czech Republic	Asociace inovativního farmaceutického průmyslu (International Association of Pharmaceutical Industries)
Denmark	Lägemiddelindustriforeningen (LIF)
Ecuador	Industria Farmacéutica de Investigación e Innovación (IFI)
Finland	Pharma Industry Finland (PIF)
France	Les entreprises du médicament (LEEM)
Germany	Verband Forschender Arzneimittelhersteller e.V. (VFA) (German Association of Research-Based Pharmaceutical Companies)
Guatemala	Fedefarma: La Federación Centroamericana de Laboratorios Farmacéuticos
Hong Kong	Hong Kong Association of the Pharmaceutical Industry (HKAPI)
Hungary	MAGYOSZ Hungarian Pharmaceutical Manufacturers Association
India	Organisation of Pharmaceutical Producers of India (OPPI)
Indonesia	International Pharmaceutical Manufacturer Group (IPMG)
Ireland	Irish Pharmaceutical Healthcare Association (IPHA)
Italy	FARMINDUSTRIA Associazione delle Imprese del Farmaco
Japan	Japan Pharmaceutical Manufacturers Association (JPMA)
Korea	Korean Research-based Pharmaceutical Industry Association (KRPIA)
Malaysia	Pharmaceutical Association of Malaysia (PhAMA)
Netherland	NEFARMA vereiniging innovatieve geneesmiddelen Nederland
Norway	Legemiddelindustriforeningen (LMI)

Country	*IFRMA-Affiliated Organization*
Peru	ALAFARPE Asociación Nacional de Laboratorios Farmacéuticos
Philippines	Pharmaceutical and Healthcare Association of the Philippines (PHAP)
Portugal	Associação Portuguesa da Indústria Farmacêutica (APIFARMA)
Russia	Association of International Pharmaceuticals Manufacturers (AIPM)
Singapore	Singapore Association of Pharmaceutical Industries (SAPI)
South Africa	Marketing Code Authority
Spain	FARMAINDUSTRIA: The National Association of the Pharmaceutical Industry in Spain
Sweden	Läkemedelsindustriföreningen (LIF)
Switzerland	Interpharma Scienceindustries Switzerland: Business Association Chemistry Pharma Biotech
Taiwan	International Research-Based Pharmaceutical Manufacturers Association (IRPMA)
Thailand	Pharmaceutical Research and Manufacturers Association (PReMA)
Turkey	Association of Research-Based Pharmaceutical Companies (AIFD)
United Kingdom	Association of the British Pharmaceutical Industry (ABPI)
United States	Pharmaceutical Research and Manufacturers of America (PhRMA)

Source: Adapted from Francer et al., 2014

International Codes

The international code of conduct for the industry is enforced by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and all major multinational companies as well as some larger firms are members; those countries without a national code are expected to abide by IFPMA's rules (www.politicsofmedicine.org). According to IFPMA rules, an individual country's code is followed if one is in existence, whether it is more or less restrictive in its content. Its Code of Practice lists seven guiding principles on ethical conduct and promotion that are summarized below (IFPMA, 2012):

1) The health and well-being of patients are the first priority for the industry;
2) Quality, safety, and efficacy must be adhered to in keeping with the laws determined by regulatory authorities;
3) Interactions with stakeholders must be at all times ethical, appropriate, and professional and without undue influence;
4) Companies must provide ethical, accurate, and balanced information and not mislead;
5) Privacy of patient's personal information must be respected;
6) All scientific research sponsored by companies will be transparent and conducted in order to benefit patients and advance science; and
7) Companies should adhere to the spirit and letter of codes, and in order to achieve this, relevant personnel must be suitably trained.

In 1998, the WHO established a set of criteria for advertising and promotion entitled: Ethical Criteria for Medicinal Drug Promotion (http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf). The

purpose of these criteria as stated by WHO was to establish some basis for individual countries to adopt guidelines based on their differences in culture, the economy, as well as other considerations detailed in the document. Some regional and national codes are based on the WHO guidelines. The WHO criteria are strictly guidelines and compliance is voluntary.

Regional Codes

There are currently three regional codes in place: The European Federation of Pharmaceutical Industries and Associations (EFPIA); the Pan American Network for Drug Regulatory Harmonization (PANDRH) Ethical Criteria for Promoting, Advertising and Publicizing Pharmaceuticals; and the Federación Centroamericana de Laboratorios Farmacéuticos (FEDEFARMA). These three codes govern the interactions of the pharmaceutical industry with physicians.

The EFPIA code states that any national codes in place should be equally as rigorous as their code, and the EFPIA code should be viewed as the minimum standard to be followed. It further encourages compliance with IFPMA's code when appropriate. The PANDRH and FEDEFARMA code guidelines are similar to those in IFPMA and EFPIA.

National Country Codes

There are approximately 42 national codes of conduct for pharmaceutical advertising and promotion worldwide. Generally, these codes follow the same principles as those covered by the international and regional organizations mentioned earlier.

Code Enforcement and the Complaint Process

The formal complaint process is straightforward—any individual or organization may complain to the organization that administers the code of conduct in their particular country. It is interesting to note that most of the complainants are the pharmaceutical companies themselves, although physicians and interested patient organizations also file complaints (Chepsiuk, 2012 and Science 2.0, 2013). Francer et al. (2014) point out that if an individual or group wishes to make a complaint about a particular advertisement and there is no code in that particular country, then a complainant may file their complaint with the IFPMA.

Sanctions for Code Violations

The sanctions administered tend to be common across codes; for example, one universal sanction is that the offending material must be removed from the market immediately. Other sanctions that may differ by country include public reprimands; publication of the outcome; monetary penalties; requirements for pre-screening; formal audit of the offending company; possible suspension from the self-regulatory organization; or the issuance of a corrected item (Francer et al., 2014). Many critics view these sanctions as insufficient to deter violators.

The Effectiveness of Self-Regulation

While there are few studies that specifically examine the effectiveness of self-regulation in the pharmaceutical industry, those that do tend to be highly critical based on their findings (and extend to countries other than the US). These studies are presented below.

A recent study of US self-regulation (Arnold & Oakley, 2013) used a multi-method approach with multiple data sources to analyze the frequency and violations of industry developed standards for DTCA. First, the authors selected products from the erectile dysfunction class of drugs (this included Viagra, Cialis, and Levitra). Second, they examined each of the 15 guiding principles for PhRMA (Pharmaceutical Manufacturers and Research of America) and determined that nine of the principles were appropriate for study. Their results suggest that violations of the Pharmaceutical Research and Manufacturers of America's Guiding Principles for DTCA for Prescription Medicines for the three brands under study (five different companies) were "routine during the four-year period of [the] study," with a "consistent pattern of noncompliance among the direct to consumer advertising for all three brands . . . " (p. 533). With respect to the risk versus benefits and help for the uninsured principles, all firms were compliant most of the time. However, firms were non-compliant to varying degrees for prescription labelling and non-prescription options; health promotion and disease awareness; educational value (unreadable ads); and age-appropriate audiences (ads directed at children). When the authors submitted comments on multiple occasions to PhRMA about these violations, they were never answered (as they are required to by Principle 13 of the Code).

In a study of Indian promotional material, Mali et al. (2010) used WHO criteria for ethical drug promotion to determine if these criteria were being met. After studying 592 different drugs in 513 pieces of promotional literature, their findings indicate that none of the literature they examined met the WHO criteria; therefore, they suggest that the industry is not following any guidelines that meet these criteria.

Knowledge Wharton (2010) reported the findings from the Spanish industry association Farmindustria (Unit for Supervising Ethical Practices, or USD). They noted that in 2009, 91 percent of the cases reported showed some infraction of the self-regulatory guidelines.

In Sweden, Zetterqvist and Mulinari (2013) identified numerous code breaches reported by the Pharmaceutical Industry Information Examiner (IGM) and the Information Practices Committee (NBL): 34 percent of advertisements for antidepressants violated the industry's code of conduct. These voluntary organizations failed to act quickly upon the company's inflated claims of efficacy: in most cases, approximately 15 weeks passed before censure of the offending company; and in 25 percent of cases, 47 weeks passed before a company was censured. The authors suggest that because fines are low for non-compliance and there are lengthy lags in the system before action is taken, companies do not feel compelled to follow the guidelines. This lag time results in the non-compliant material remaining on the market and the company continuing to disseminate incorrect information about a drug.

Lexchin (1997) compared the self-regulatory codes in Canada, Australia, and the UK and notes that the codes in the three countries are consistent with each another. Canada has two self-regulating organizations: Rx&D which provides oversight to the industry and the PAAB—the Pharmaceutical Advertising Advisory Board with its Code of Advertising Acceptance. The PAAB independently pre-clears all promotional material that is directed to physicians on behalf of Rx&D to ensure compliance with the code. In the area of pre-clearance of material, Lexchin opines that the Canadian PAAB Code is superior to both the UK and Australia, and that previous deficiencies in the Rx&D Code were addressed with its recent revisions (Lexchin & Ziganshina, 2014). Doran and Lofgren (2013) noted that in 2012, Australia updated its Code of Conduct and it is now enforced for a three-year period of time in order to permit more frequent revisions to the guidelines. The authors suggest that this update brings Australia more in line with the US, as it reflects certain provisions in the new US Sunshine laws, and was in part the result of grass-root activists who were critical of the pharmaceutical industry.

Non-Governmental Activist Organizations

There are several NGOs that are working to change the self-regulatory landscape (www.politicsofmedicines.org): Health Action International (HAI); BEUC (the European Consumer Organization); PharmFree; No Free Lunch; and Healthy Skepticism. Each organization's objectives will be summarized in the following sub-sections as reported in the WHO/HAI manual entitled, "Understanding and Responding to Pharmaceutical Promotion: A Practical Guide" (available at www.politicsofmedicines.org). Please note that this is not intended to be an exhaustive list, but to identify some of the more prominent groups in the field.

Health Action International

This group networks consumer and public health groups in approximately 70 different countries (www.haiweb.org). Its particular area of interest is the critique of self-regulatory groups in the pharmaceutical industry, and it has frequently called for bans on DTCA. It also works with the WHO on selected projects. In 2010, HAI released a report in conjunction with the Medicines Transparency Alliance (MeTA) and provided an assessment tool for the investigation of regulatory frameworks.

BEUC

This group lobbies for the continued ban on DTCA in Europe, among other issues, to both uncover and stop unethical behavior on the part of the pharmaceutical industry (www.beuc.org).

PharmFree

This organization's objective is to educate medical students and physicians about the closeness between physicians and the pharmaceutical industry. It encourages restricting contact between the industry and physicians as in its view it leads to conflicts of interest (www.pharmfree.org).

No Free Lunch

This group is part of the Corporation for Non-Promotion Based Medicine and includes doctors, pharmacists, medical ethicists, and others as members. It encourages evidence-based medicine and discourages acceptance of gifts from industry and industry promotion (www.nofreelunch.org).

Healthy Skepticism

This group also has an international membership of health care professionals. Its primary objective is to reduce potential harm from pharmaceutical promotion (www.healthyskepticism.org).

Industry Transparency and Sunshine Laws

Three countries have recently enacted Sunshine laws in order to provide transparency about pharmaceutical industry payments to physicians: the US, France, and Japan. On September 30, 2014, the US Sunshine laws were enacted as part of the Affordable Care Act (ACA). On the basis of this data, Ornstein et al. (2014)

disclosed its Dollars for Docs list: US$4 billion in payments were made to health care professionals by 17 different companies and represent 50 percent of total industry sales for 2013. Payments to physicians primarily include research expenses and speaking engagements, among other types of expenses. They report that 21 US physicians earned approximately US$500,000, with one doctor earning in excess of US$1 million. This law has generated much criticism from physicians and the industry. Even before the report was issued, there was concern about database errors and the failure to disclose details about the nature of the payments. In addition, some in the industry suggest that research payments are critical for the dissemination of medical research findings. Industry critics laud the effort and view it as an essential way to ensure the integrity of the health care system.

In France, the recent Réforme du Médicament resulted in what is known as the French Sunshine Act, or the Loi Bertrand. This law, part of the French Public Health code, dictates that all interactions with health care providers, medical students, and any businesses that deal with them be disclosed on an official website (Roussel, 2012; Lantrès, 2013). It covers not only payments made to health care professionals, but also any type of representative visit and advertising activity. All financial dealings must be disclosed on a company's website within 15 days, and as well, a formal report must be delivered to the six professional organizations for health care providers (Roussel, 2012).

In Japan, the government just released its list of payments to physicians by the top ten drugmakers, which amounted to US$1.6 billion in 2013. Almost half of these payments were to cover research costs, with the balance going to speaking fees, entertainment, and 70,000 medical seminars (Staton, 2014).

Implications and Conclusions

Self-regulatory codes continue to be an important part of the way physician advertising and promotion is monitored. There are international, regional, and local voluntary codes of conduct in place with financial sanctions for violators.

Some critics of the self-regulatory structure in the pharmaceutical industry argue for more regulation of marketing and promotional materials because of the perceived weakness of self-regulation. WHO/HAI points out that there are several situations that arise in a promotional context that are not covered either by regulation or self-regulatory codes and, thus, fall through the cracks. They suggest that health professionals take a proactive role to report violations of illegal or unethical marketing activity to the authorities. Others recognize that additional regulation will not be a panacea and that voluntary codes are part of the way in which marketing activity is monitored. Grande (2010) argues that self-regulation is needed, as all formal regulation contains loopholes; the industry will always find ways around these rules to market their products without some other form of oversight.

The available research suggests that some additional regulation may be helpful for specific matters, and this can be seen with the enactment of new Sunshine laws. However, there appears to be a role for self-regulation, and these voluntary organizations need to do a better job at surveillance of promotional materials and tougher sanctioning of violators if they expect to maintain their role in the process. The problem appears to be the implementation of the codes rather than the codes themselves: this includes their enforcement and the response to complaints. In most cases, code enforcement seems to be weak at best, and at a level that is not in the best interests either of the public or the industry. The sanctions, when imposed, appear to be insufficient in punitive value to induce compliance. Additionally, if the new Sunshine laws just enacted are a bellwether for the future, increased regulation of the industry worldwide is likely unless these self-regulatory organizations do a better job at enforcement and imposition of sanctions.

References

Arnold, D. G., & Oakley, J. L. (2013). The politics and strategy of industry self-regulation: the pharmaceutical industry's principles for ethical direct-to-consumer advertising as a deceptive blocking strategy. *Journal of Health Politics, Policy and Law*, *38*(3), 505–544. doi:10.1215/03616878-2079496

Chepsiuk, R. (2012). PAAB CCPP. *Presentation to Concordia University* on February 3, 2012, Montreal, Canada.

Doran, E., & Lofgren, H. (2013). Drug promotion in Australia: policy contestation and the tightening of regulation. *Australian Review of Public Affairs*, 11(2), 19–41.

Francer, J., Izquierdo, J. Z., Music, T., Narsai, K., Nikidis, C., Simmonds, H., & Woods, P. (2014). Ethical pharmaceutical promotion and communications worldwide: codes and regulations. *Philosophy, Ethics, and Humanities in Medicine*, *9*(7), 1–17 doi:10.1186/1747-5341-9-7

Grande, D. (2010). Limiting the influence of pharmaceutical industry gifts on physicians: self-regulation or government intervention? *Journal of General Internal Medicine*, *25*(1), 79–83. doi:10.1007/s11606-009-1016-7

Hack, E. I. (2007). Pharmaceutical global marketing practices: increased scrutiny ahead. *Food and Drug Law Journal*, *62*, 343–348.

IFPMA. (2012). IFPMA code of practice. *IFPMA.org*. Retrieved December 4, 2014, from http://ifpma.org/fileadmin/content/Publication/2012/IFPMA_Code_of_Practice_2012_new_logo.pdf

Knowledge Wharton. (2010). The global pharma industry: will self-regulation improve its image? Retrieved December 4, 2014, from http://knowledge.wharton.upenn.edu/article/the-global-pharma-industry-will-self-regulation-improve-its-image/

Lantrès, O. (2013). French Sunshine Act equivalent published. *Fieldfisher*. Retrieved December 4, 2014, from www.fieldfisher.com/publications/2013/05/french-sunshine-act-equivalent-published#sthash.zGXEL8fl.dpbs

Lexchin, J. (1997). Enforcement of codes governing pharmaceutical promotion: what happens when companies breach advertising guidelines? *CMAJ: Canadian Medical Association Journal = Journal de l'Association Medicale Canadienne*, *156*(3), 351–356.

Lexchin, J. (2003). Voluntary self-regulatory codes: what should we expect? *The American Journal of Bioethics: AJOB*, *3*(3), 49–50. doi:10.1162/15265160360706570

Lexchin, J., & Ziganshina, L. (2014). Regulation of pharmaceutical promotion: why does regulation matter? *Politics of Medicines*. Retrieved December 4, 2014, from www.politicsofmedicines.org/articles/regulation-of-pharmaceutical-promotion-why-does-regulation-matter

Mali, S. N., Dudhgaonkar, S., & Bachewar, N. P. (2010). Evaluation of rationality of promotional drug literature using World Health Organization guidelines. *Indian Journal of Pharmacology*, *42*(5), 267–272. doi:10.4103/0253-7613.70020

Ornstein, C., Weber, T., & Nguyen, D. (2014). About the dollars for docs data. Retrieved December 4, 2014, from www.propublica.org/article/about-our-pharma-data

Putzeist, M. (2007). Self-regulation of drug promotion a cross-sectional analysis of pharmaceutical marketing codes and the WHO ethical criteria for medicinal drug promotion. Retrieved December 4, 2014, from www.pharmaceuticalpolicy.nl/Publications/Reports/putzeistreview.pdf

Roussel, G. (2012, June 14). France firm on pharma regulation [text]. Retrieved December 4, 2014, from www.pmlive.com/pharma_news/france_firm_on_regulation_405190

Science 2.0. (2013). Can pharmaceutical advertising regulate itself? Retrieved December 4, 2014, from http://science20.com/print/111035

Staton, T. (2014). Japan unveils sunshine data of its own, raising eyebrows after Diovan scandal. Retrieved December 4, 2014, from http://firecepharma.com/story/japan-unveils-sunshine-data-its-own-raising-eyebrows-after-diovan-scandal/2014–11–10

WHO World Medicines Situation Report (2004). Retrieved from www.who.int/medicines/areas/policy/world_medicines_situation/en/

Zetterqvist, A. V., & Mulinari, S. (2013). Misleading advertising for antidepressants in Sweden: a failure of pharmaceutical industry self-regulation. *PLoS ONE*, *8*(5), e62609. doi:10.1371/journal.pone.0062609

11 Emerging Markets and OTC Markets

Future Opportunities and Current Challenges

According to some industry experts, emerging markets represent the future of the pharmaceutical industry. These are often called the BRIC markets (an acronym for Brazil, Russia, India, and China), but other countries also fall into this category, such as Egypt, Argentina, and Pakistan. Recent research suggests that emerging markets are viewed as having great promise because of a growing middle class and improved infrastructure: these markets currently represent approximately 25 percent of pharmaceutical multinational sales (Staton, 2013). In the immediate future, there is a strong probability that many global marketing budgets will be allocated to these markets with both US and European marketing budgets and organizations shrinking in size. Global marketing divisions will need to be aware of how these markets function and more importantly, how each market is different despite their apparent similarities. While opportunities certainly exist, managing the differences in these markets from the more traditional Western markets presents significant challenges to the industry.

Other research presents evidence that there is untapped potential in some Western markets for OTC consumer brands, particularly because of their consumers' strong interest in their health care. There may exist an even greater opportunity in emerging markets for OTC brands because of the importance of self-care in these countries. Some large firms like GlaxoSmithKline and Johnson & Johnson already have sizeable consumer health divisions; however, others may need to learn this business either through experience, merger, or acquisition. There is little scholarly research specific to the pharmaceutical industry on some of these topics, so this chapter will rely largely on general marketing research, industry studies, and industry media reports.

Emerging Markets

Emerging markets represent 80 percent of the world's population and 20 percent of the world's economies (Heakal, 2014). According to Amadeo (2014), five characteristics distinguish these markets from others:

1) Lower than average per capita income based on the World Bank estimate of $4,034;
2) Rapid growth as a result of aggressive changes for conversion to an industrialized economy with an expanding middle class;
3) High volatility due to natural disasters, external price shocks, and internal policy instability;
4) Susceptibility to currency and commodity fluctuation; and
5) Higher than average returns for investors due to export-driven strategies.

Beck (2013) also reports that these markets are characterized by larger rural populations and significantly limited access to health care. There are many different classifications of emerging markets, but it is usually agreed that the BRIC countries are among the top markets.

How did these emerging markets come to be of such great interest to the pharmaceutical industry, particularly given the challenges mentioned above? From a marketing perspective, it began with an article by Prahalad and Hart (2002) entitled, "The Fortune at the Bottom of the Pyramid." The authors posited that there was an "aspiring poor" joining the economy for the first time and that MNEs (multinational enterprises) should position themselves to take advantage of this particular target market because they could sell to the poor and earn profits at the same time. Karnani (2006) published a strong criticism of their work and characterized it as a "dangerous delusion" (Karnani, 2007, p. 9). He presented an alternative view that the poor should be the producers rather than the purchasers if poverty was to be eradicated. It is interesting to note that this recommendation is being implemented in the BRIC countries through the establishment of their own local industries and their divergence from Western thinking with respect to intellectual property. With respect to health care demographics in emerging markets, Baker (2012) reports the existence of a small but monied health care consumer in large city centers that bears some similarities to Western consumers who are at the top of the pyramid (with a much larger, limited income consumer at the base of the pyramid); the middle class in these markets has limited but growing potential.

Rao (2008) discusses this local industry phenomenon with a focus on the strong local pharmaceutical industry in both India and China. He points out that the MNEs must move R&D to local markets through offshoring in order to: ensure relevance and participation; focus on neglected diseases needed in these countries because BRICs will find ways to produce these drugs at affordable prices (the MNE pricing strategies led to the creation of strong local generic industries with treatments for these diseases); and finally, develop creative pricing strategies to provide access to the poor by not seeking patent protection or waiving their patent rights. He points out that even if the TRIPS Agreement is heavily enforced, the BRIC companies will find a way to manufacture and sell drugs they need at affordable prices and will research neglected diseases on their own:

> given the importance of the pharma industry to the *health of nations*, there is little doubt that pharmaceutical firms in rich and poor countries alike will continue to come under public pressure to develop and market the needed drugs at affordable prices.
>
> (Rao, 2008, p. 114)

These local industries are expanding beyond their own borders and becoming major global competitors—for example, India's pharmaceutical industry has already made significant inroads in the US generic market. Baker (2012) also reports that Western brands in emerging markets represent less than 40 percent of dollar volume and consist largely of locally produced generic drugs. However, he also suggests that a small biosimilars segment with drugs produced by local manufacturers is developing in India and the Republic of Korea.

In an important and seminal work, Sheth (2011) posited that the very characteristics of emerging markets must lead to a rethinking of the key assumptions of marketing, such as market orientation, market segmentation, and differential advantage, with the core guiding concept moving away from the classic market orientation to that of market development. He identifies five characteristics of emerging markets that distinguish them from mature markets: market heterogeneity (bottom of pyramid consumers); sociopolitical governance (religious, governmental, NGO, and local community influences); unbranded competition (on average 60 percent); classic shortage of resources (electricity, raw material, and skill-based labor); and

inadequate infrastructures (roads, logistics, and transaction technology such as bank machines). He also discusses the advantages of these markets, which include policy-based comparative advantages (government mandated market organization); raw-material based comparative advantage (human capital, industrial materials, and agricultural resources); and NGO-based comparative advantage (the blending of modern business practice with social purpose).

Sheth (2011) recommends three changes in strategy focus for marketers who wish to succeed in emerging markets: a focus on market development by engaging in "share of wallet" (p. 173) versus share of market; the rethinking of market policies to include all consumers, not just those who can afford high market prices; and lastly, engaging in "purpose-driven marketing" (p. 176), which includes marketing to all stakeholders, not just target customers. One of his most relevant recommendations to the pharmaceutical industry is the move to what he calls "democratization of innovation" (p. 177): in other words, firms must make innovations more affordable to those below the official poverty level and this must be a key element in marketing practice. He points out that the traditional brand life cycle moves from patent protected innovations that are high priced to value position and finally, price position. Emerging markets move in the other direction and marketing strategies must accommodate this, and he presents the example of the Indian pharmaceutical industry which started with generics and then moved to proprietary branding.

Finally, Sheth recommends changes in the marketing organization for managing emerging markets as "stakeholder marketing": he suggests it becomes a corporate staff function that will require corporate social responsibility competency and partnering with NGOs, versus the traditional line function with functional specializations and a single stakeholder: the end customer. (This work is a must-read for marketing managers and those in the marketing C-suite as well as market researchers and research scholars.) As will be seen below, the suggested approaches to emerging pharmaceutical markets by MNEs are already reflecting some changes in thinking about how marketing should be conducted in these countries.

Pharmerging Markets

In 2010, IMS coined the term 'pharmerging' markets to illustrate the pharmaceutical industry's shift from highly developed markets to these emerging economies (IMS, 2010). According to Beck (2013), there are three 'tiers' of emerging markets: Tier 1 (China); Tier 2 (Brazil, Russia, and India); and Tier 3 (Algeria, Argentina, Colombia, Egypt, Indonesia, Mexico, Nigeria, Pakistan, Poland, Romania, Saudi Arabia, South Africa, Thailand, Turkey, the Ukraine, Venezuela, and Vietnam). Tier 3 countries have also been called "fast followers" (IMAP, 2011, p. 7). IMS has further classified these pharmerging markets with a group it calls "frontier countries" (Van Arnum, 2014b). In rank order, these countries include the Philippines, Malaysia, Bangladesh, Chile, Peru, Ecuador, Kazakstan, Iran, UAE, Lebanon, Morocco, Tunisia, Ghana, Kenya, and Ethiopia.

Van Arnum (2014b) reports IMS projections that China will move into the number two ranking in the worldwide pharmaceutical market with a 15 percent share (and 13–15 percent growth), followed by Brazil, Russia, and India, collectively holding 8 percent (with 10–13 percent growth), and Tier 3 countries are estimated to reach a 10 percent share (with 6–9 percent growth). In comparison, the US will capture a 31 percent share (with 1–4 percent growth) and the EU5 (the European Union 5: France, Germany, Italy, Spain, and the UK) is estimated at 13 percent (with 0–3 percent growth) (Van Arnum, 2014b). Finally, she reports that 50 percent of drug sales by volume are estimated to occur in pharmerging markets while the US and EU5 will represent only 13 percent, largely due to the dominance of generic drugs in these markets, and branded

generics are expected to make some inroads in these markets. Mooraj (2013) opines that there are six barriers to entry to these pharmerging markets: poor supply chain logistics; inadequate manufacturing infrastructure; varied regulatory structures; pricing and reimbursement uncertainty; complex taxation; and a shortage of qualified talent.

In addition, government funding represents one of the greatest challenges these markets face, with financial assistance increasing in some markets and decreasing in others: there is a need for international aid, particularly in frontier markets, and the growing importance of private health insurance due to the high out-of-pocket costs of medication (Beck, 2013). For example, Hill and Chui (2009) report that India, Mexico, Brazil, and Russia have the highest percentage of out-of-pocket costs in rank order (India is at the top with 90 percent, followed by China with 49 percent). Other characteristics of these markets include the importance of pharmacists due to the prevalence of self-medication; the influence of payers away from physicians; relatively low marketing expenditures; and increasing numbers of physicians spending less time with sales representatives (PMLive, 2012). However, these markets are by no means homogeneous. For example, China's market is highly complicated and has much local competition; Brazil has highly skewed income distribution with high out-of-pocket health care costs and a strong local generic industry; Russia suffers from poor health awareness, high prices, and an emphasis on local industry by the government; and finally, India presents particular challenges with respect to the enforcement of intellectual property rights (IMAP, 2011), in spite of the TRIPS Agreement.

Presently, the therapeutic categories of cephalosporins (antibiotics), anti-diabetes, oncologics, vitamins and minerals, and anti-ulcerants dominate the market and account for the largest proportion of dollar volume, with oncologics moving from 15th place in 2003 to third place in 2013 (Beck, 2013). The reason for the rise in oncologics is that they are among the most expensive drugs presently on the market; however, they are not necessarily the most important for the populations in emerging markets. Baker (2012) suggests that the model of oncology treatment used in the West may not necessarily be valued by emerging markets. Further, as mentioned earlier in the book, reimbursement for these drugs by payers and government agencies is proving to be a challenge. This is likely one reason that pharmaceutical executives identified pricing and market access as the most critical issue facing their companies for the next three to five years (Beck, 2013).

According to Baker (2012), emerging markets are dominated by INN (international non-proprietary name) generic and branded generic compounds. He suggests that the current focus on niche drugs, such as biologics, will prove to be an uphill climb for most multinational pharmaceutical companies because sales in these markets are correlated with per capita government expenditure, the role of government in health care financing, and the high levels of poverty. These act as "brakes" (p. 3 online version) to market potential, and he points to the importance of the advice from NGOs such as WHO, who advise these countries to focus on diseases such as measles, malnutrition, malaria, chronic diarrheal disease, and respiratory infection.

However, there is evidence that this scenario is changing at the local level. For example, the Brazilian government has developed science and education reform to establish national R&D research centers with training to develop skilled staff (Puentes & Cahill, 2012). The existing Brazilian biotech industry is centered in major universities and scientific research centers (73 percent) and focuses on stem cell research, genomics, and vaccines (Osec, 2010). The Chinese government has also introduced policies to prioritize a domestic biotech industry (Deloitte, 2011). In India, biopharmaceuticals are one of the biggest contributors to domestic industry growth (*The Economic Times*, 2010). The individual BRIC pharmerging markets are profiled in the following subsections with data on their pharmaceutical markets as well as information of importance to marketers.

China

While China is home to several multinational corporations such as Bayer and Pfizer, its domestic industry dominates the country's landscape with one of the world's largest domestic industries. The five largest domestic companies in rank order are Guangzhou Pharmaceutical Holding, Xiuzheng Pharmaceuticals, Yangtze River Pharmaceutical Group, Harbin Pharmaceutical Group Holding, and Weigao Holding (Flannery, 2013). The pharmaceutical business in China is also highly concentrated: as of 2011 the top three pharmaceutical companies held 96 percent market share (Deloitte, 2011). This local industry concentration combined with a fragmented distribution system makes China a challenging pharmaceutical market in which to do business. Spigarelli and Wei (2014) reported that in 2010, there were 507 state-owned pharmaceutical enterprises with a market value of US$223 billion; 3,118 local privately owned pharmaceutical enterprises with a market value of US$449.8 billion; and 1,140 foreign-owned pharmaceutical enterprises with a value of US$468.4 billion. China spends 40 percent of its health care dollars on medication compared to the average 16 percent OECD expenditure (*The Economist*, 2014). With respect to marketing activity, it is dominated by physician promotion, with prescription drug advertising prohibited to consumers.

According to Deloitte (2011), key drivers of pharmaceutical market expansion include increased health care awareness which is augmented by its large, aging population; increased expenditures on health; and ongoing health care reform. It forecasts that China will have the largest elderly population in the world by 2016 with out-of-pocket health care expenses growing at 8.5 percent. On average, government expenditures will grow by 12.1 percent, with a per capita expenditure of US$437 by 2016. It further reports a rapidly rising annual net income and proportion of expenditure on health care that has risen to 7.2 percent.

Other trends in the Chinese pharmaceutical market include the domination of generic drugs (80 percent) with a small but highly growing patented drug segment (from 14 percent in 2007 to a forecasted 20 percent in 2015) (Deloitte, 2011). In addition, the Chinese OTC market is increasing rapidly (15 percent annually) as more drugs are approved for OTC use and owing to the aging population's preference for self-medication for cold and gastrointestinal symptoms (BioSpectrum, 2012).

Brazil

Brazil has a healthy and growing local pharmaceutical industry: it is home to four of the six largest pharmaceutical companies in the world and local generic product manufacturing accounts for approximately 21 percent of Brazilian pharmaceutical sales (Kelly, 2013). Twenty-five percent of medications sold in Brazil are generics; retail outlets are required to maintain a stock of approximately 70 percent generics and physicians must write prescriptions by their INN (Puentes & Cahill, 2012). The leading domestic pharmaceutical companies include EMS Pharma, Ache, Medley (acquired by Sanofi-Aventis in 2009), and Europharma (all of these are generic manufacturers) (Osec, 2010). The Brazilian market is the largest in Latin America, with 9 percent of GDP spent on health care and US$9,000 per capita expenditures (Puentes & Cahill, 2012).

Medications are primarily purchased with cash by patients due to the lack of health insurance programs, and 15 percent of the population accounts for 50 percent of drug consumption (Osec, 2010). It is reported that physicians are skeptical of generic drugs despite their popularity, as they are concerned about counterfeiting as well as bioequivalence standards as these illegal drugs are imported from Paraguay (Puentes & Cahill, 2012). The most popular therapeutic classes include analgesics and pyretics, contraceptives, anti-inflammatories, antidepressants, anti-ulcers, and cholesterol drugs (Osec, 2010). However, herbal medications are extremely

popular in Brazil, with sales of $1 billion in 2010 and 20 percent annual growth. As of 2010, the six major firms held 60 percent market share and included Nycomed, Herbarium, Marjam, and Farmasa (Osec, 2010).

Agarwal et al. (2012) reported that Brazil's growing middle class have a strong interest in health care and education and will pay a premium for these services. They identified four specific Brazilian consumer market segments that would be of interest to pharmaceutical companies: 'committed' (will spend out of pocket for medications they want), 'self-assured' (want to get value out of health care spending), 'SUS compliant' (no insurance and spend little on drugs), and 'struggling' (rely on generics exclusively). The authors suggest that physicians' attitudes toward 'committed' and 'self-assured' patients influences the prescriptions they write; in fact, they prescribe based on the social status and appearance of their patients.

Drug marketing activity is highly restricted, with specific guidelines for safety and product information and text size of warnings; drug warnings must be made clear to the consumer, and broadcast advertising is prohibited when young children or teens are likely to be watching (Puentes & Cahill, 2012).

Russia

The Russian pharmaceutical market is the most opaque market for pharmaceutical firms for a variety of reasons. Van Arnum (2014a) observes that Russia has a less-developed manufacturing base and is largely dependent on imports for its drugs. Pharma 2020—a policy that is expected to increase the production of domestic medications by 50 percent by 2020, as only 27 percent of medications are domestically produced—is likely to change the way foreign firms do business in Russia. This policy was funded at US$4 billion in 2011 and has already resulted in some multinational corporations increasing their manufacturing presence in Russia (PMLive, 2013). For example, Novartis, AstraZeneca, Sanofi, and Takeda have all made recent multi-million dollar investments in manufacturing facilities through direct investment or purchase of existing local firms; others, such as Bayer and Merck, have formed partnerships with local Russian firms (Van Arnum, 2014a). Roche, Johnson & Johnson, and Abbott are collaborating with Pharmastandard (the largest domestic manufacturer in Russia) on manufacturing, marketing, and distribution (Pharmastandard, 2011). These investments and collaborations to manufacture are spurred by the expectation that locally manufactured drugs will be given preferential access to drug reimbursement lists (PMLive, 2013).

Consequently, the Russian market is highly fragmented and dominated by multinational players, with only one leading domestic manufacturer as mentioned earlier, Pharmastandard. Pharmastandard relies largely on OTC sales in its product line (78 percent) with a focus on analgesics, cough and cold medication, vitamins, anti-virals, and anti-fungals; its prescription sales (22 percent) consist of coronary therapy, proton pump inhibitors, nitrites, ACE inhibitors, and gastrointestinal medications (Pharmastandard, 2011). In rank order, the leading firms in Russia by market share are Sanofi-Aventis (5.3 percent), Novartis (5.1 percent), Pharmastandard (3.7 percent), Teva (3.2 percent), and Takeda (3.2 percent) (IHS, 2014). The market is divided into three segments based on total sales: commercial (58 percent), government (25 percent), and parapharmaceutical (or naturopathic medication, at 17 percent) (IHS, 2014).

However, it is reported that excessive bureaucracy, incomplete legislation, and lack of governmental assurances are interfering with efforts to bring Pharma 2020 to fruition despite the best efforts by the government (Panin, 2014). For example, "On the Circulation of Medicinal Drugs" is intended to regulate the registration and pricing of drugs; "On the Fundamental Principles of Public Healthcare" imposes restrictions on sales representatives and their interactions with health professionals (Volkov, 2014). In addition, it is also reported that corruption is one of the great challenges facing foreign multinationals in Russia despite laws recently

enacted to curb the problem: Russia changed its law "On Combatting Corruption" in 2013 in an attempt to enforce stricter anti-corruption standards (Volkov, 2014). In a survey of industry executives, Deloitte (2013) reported that corruption was one of the biggest problems facing multinational companies in Russia, in addition to the inadequate legislation, lack of health care financing, competition, the economic climate, and lack of adequate income in the population.

The traditional marketing focus remains on medical professionals, with detailing and sampling comprising 96 percent of marketing budgets; there is little Internet marketing presence for physicians because only 21 percent of them use it for professional purposes (Railean, 2012). There is no direct advertising or promotion to consumers; however, Puzakova et al. (2010) note that in Russia there is significant ethnocentrism toward local versus foreign products. These products are seen as culturally disenfranchising and as damaging to the continuation of cultural values; therefore, Russians may resist openly foreign products.

India

Despite an important domestic pharmaceutical industry, India is a challenging market for MNEs due to its notoriously weak patent protection, lack of infrastructure, and complex health care system. It has been ranked last for patent protection out of 25 countries by the Global Intellectual Property Center of the US Chamber of Commerce (Graham, 2014). Its industry is highly fragmented with approximately 24,000 companies; however, the top 20 companies comprise about 60 percent of the market (equitymaster.com, 2014). The leading domestic companies include Ranbaxy Labs, Cipla, Dr. Reddy's, Lupin, Aurobindo Pharma, and Sun Pharma (Pharmaceutical Drug Manufacturers, 2014), with Abbott as one of the leading multinational firms in the group (IBEF, 2014).

The domestic industry is known for its concentration on exported generics to the US, Europe, and other markets, and to further this important segment, the Indian government has provided funding of US$70 million to local companies in order to develop biosimilars (brandindiapharma, 2011). This is due to the levelling out of the small chemical molecule business in the US and other Western markets (IBEF, 2014). Its growth is expected to be fueled by pharmaceutical outsourcing by MNEs, combined with a growing domestic economy, increased availability of health insurance, and improved health care facilities (IBEF, 2014).

In addition, Indian firms now specialize in contract manufacturing for differential products (new delivery systems) (Sharma, 2013) and already act as an important drug manufacturing segment for MNEs with respect to novel drug delivery systems and drug reformulations. Hollmer (2012) identified five Indian "drug delivery companies to watch" that include QLT (new ocular delivery system); Bend Research (spray-dried dispersion); BIND Biosciences (blends polymers with existing drugs to enhance potential); Endocyte (oncology and corresponding diagnostic tool); and Polymer Factory (high-quality dendrimer technology). This local segment may continue to strengthen the Indian pharmaceutical industry as a global competitor, given the importance of reformulations as a way for a firm to protect its patented drugs. Barnes (2007) reported that up to 39 percent of new products launched were as a direct result of drug reformulation.

The Indian government initiated PharmaVision 2020 in order to create what is called an 'end-to-end' drug manufacturing environment in addition to a US$640 million fund to boost local R&D (brandindiapharma, 2011). In addition, as part of its 12th five-year plan, the government is attempting to launch universal health coverage prior to 2017 (Beck, 2013).

While traditional therapies such as anti-infectives are considered the most important therapeutic classes due to a large rural population, it is forecasted that segments such as cardiovasculars and anti-diabetics will

grow due to the increasing middle class segment and the requisite lifestyle changes that are expected to occur as a result (equitymaster.com, 2014).

Recent difficulties have put a damper on India's generic export business. The US FDA is concerned about the quality of generic drugs imported from India, and has fined Ranbaxy US$500 million for safety violations (C.H., 2014). Drug pricing is another area of concern, with the Indian government mandating reduced prices in order to make drugs affordable for the majority of the population, who live on less than US$2 per day; as a result, MNEs are "chasing volume" in order to make up the difference (Hirschler & Siddiqui, 2014). The Indian government is known for overturning valid patents: most recently, the Bayer drug Nexavar was overridden with a compulsory license issued to Natco Pharma, a local firm (Hirschler & Siddiqui, 2014). While some suggest that the lack of Indian patent protection is hindering innovation and drug availability in India (Graham, 2014), there is another perspective to consider: basic drug needs must be met before innovative (and expensive) drugs can be offered, and the distinct possibility that drug prices are too high must be taken into account.

It is expected that new marketing strategies will emerge, such as consumer health care products, disease marketing campaigns, disease awareness in rural market segments, and the cultivation of hospitals and third-party payers (McKinsey, 2010). McKinsey (2010) further posits that as the number of physicians increases in India, so will the number of sales representatives, with the ratio shifting from approximately one rep to every seven physicians to one rep per three physicians by 2020. Given these country profiles and the difficulties the industry faces in participating in these markets, what strategies does the research suggest will work?

Successful Emerging Market Strategies: A Case Study

London and Hart (2004) identified three key strategies for successful entry and longevity in emerging markets, which included the following: collaborating with non-traditional partners, co-inventing custom solutions, and building local capacity. With respect to collaboration, the authors found that firms that proactively established relationships with NGOs for expertise on infrastructure and legitimacy tended to be more successful than those who relied on their own local subsidiaries or familiar partners. Co-inventing custom solutions was linked with user and product modification, product innovation, product functionality, and customized distribution. Finally, building local capacity was correlated with the recognition of local institutions, training of local partners, and filling gaps in local infrastructure and missing services.

Saboo (2013a–h) prepared a list of ten drugmakers and identified successful strategies they are using in emerging markets. On average, these companies have an investment of 25 percent of their total sales in emerging markets. A discussion of these pharmaceutical company profiles combined with the London and Hart typology is presented here as a case study for this book. (A complete read of these company descriptions as well as the London and Hart research is recommended for in-depth understanding.) Table 11.1 provides the names and describes the key activities for ten global pharmaceutical firms in emerging markets.

Collaborating with Non-Traditional Partners

Pharmaceutical firms are creating alliances and strategic partnerships with both local firms and NGOs for marketing, R&D, and investment in OTC products to serve the local community. They have also

Table 11.1 Emerging Market Strategies

Company	*Emerging Market*		*Key Strategies*
	Sales ($US billions)	*% Total Sales*	
Johnson & Johnson	16.8	23	• Building manufacturing facilities and R&D centers • Consumer health focus • Hiring local employees
Sanofi	15.0	32	• Public health initiatives • Branded generics
Novartis	13.8	24	• Building manufacturing facilities • Public health initiatives • Discounted pricing
Pfizer	12.0	20	• Local acquisition • Local strategic alliances • Development of consumer health
Roche	10.2	20	• Local health care coverage with price discounts • Local marketing partners and joint venture
GSK	11.0	26	• Local joint venture • Tiered pricing
Bayer	8.1	33	• Research alliances • Strategic partnerships/manufacturing • Local marketing
AstraZeneca	5.8	21	• Local hiring • Local acquisitions • Building manufacturing facilities and R&D centers
Novo Nordisk	3.1	22	• Local HCP training • Hiring local employees • Free drug programs • Tiered pricing • Building manufacturing facilities and R&D centers
Merck KGaA	2.3	34	• Focus on growing middle class • Local partnership • Hiring local employees

Source: Saboo, 2013a–h

formed partnerships with governments such as the Russia government to build domestic manufacturing capabilities.

Co-Inventing Custom Solutions

Some firms have acquired local generic companies that sell both patented and generic versions of the same drug; awarded local manufacturing contracts; tailored US OTC products for local markets; set up mobile treatment clinics for rural areas; distributed free goods; and created multi-tiered pricing strategies that offer discounts up to 70 percent for highly priced drugs.

Building Local Capacity

Some firms have begun to train local physicians; increased marketing staff in emerging markets while downsizing in the US and Europe; and offered management development programs to develop local talent.

Despite some successes, Buente et al. (2013) suggest that many mistakes have been made in pursuing these markets that include: insufficient tailoring of approaches to local needs; slow decision making and execution; underestimating the potential challenges, risks, and investment requirements; poor management of human resources; lack of appropriate partners; and a lack of patience and long-term strategy. To quote the authors: "Too late, too fast, too overconfident: The sorry list of mistakes that international pharmaceutical companies have made in emerging markets is long, and the resultant squandering of resources has been great." As one manager stated, "One of our biggest mistakes was to treat emerging markets like mature markets. We were wrong. Pharmaceutical strategies have to fit a country's individual needs and its development" (p. 10). These errors were previously identified by London and Hart (2004): heavy reliance on familiar partners; limited contact with NGOs; lack of product adaptation; overreliance on intellectual property protection; and viewing the market as lacking in infrastructure rather than providing the infrastructure needed to succeed.

It is clear that these markets require both a significant investment and a long-term view if firms are to be successful. However, the strategies required for success in these markets may also create inequities in other markets. For example, a multi-tiered pricing strategy may be viewed by other markets as disadvantageous to them—in other words, they may believe they are subsidizing other economies. This pricing discrepancy may lead to a rise in parallel imports, as well as travel to emerging markets for expensive treatments (consider Sovaldi at half the US price in Western Europe and even greater price differentials in Egypt and other markets). Travel for medical reasons is already popular for cosmetic surgery to such destinations as Brazil and India.

The Global OTC Market

The global OTC market holds an important place in the pharmaceutical industry as a result of demographic trends that include consumer involvement in health care; the lack of access to physicians and the resulting need for self-treatment; regulatory changes; and as a means of extending a drug's life after patent expiration. One of the biggest considerations in the OTC market is its importance in the BRIC countries, where it represents a significant portion of pharmaceutical sales and growth, and therefore, great potential for the industry.

Rx to OTC Switching

One of the key issues facing pharmaceutical companies is determining which prescription products are appropriate for switching from Rx to OTC status and the likelihood that these proposed switches will be accepted. The evaluation criteria include benefit-to-risk comparisons and condition recognition by patients as well as the potential for toxicity whether used as recommended or from misuse (this is important in the US and Europe; less so in other markets such as India). Regulations also differ by country; for example, in the US, current law permits a patent extension of three years for drugs that are switched from prescription to OTC if a firm required additional studies to submit the application. Dolcera (2011) estimates that the potential worldwide

opportunity for Rx/OTC switches is US$44 billion with top categories for switching as asthma/respiratory, antacids, insomnia, analgesics, and acne.

Originator firms would prefer to keep their patent protected prescription drug, because it can be difficult to maintain the same market share and profit level. Harrington and Shepherd (2002) suggest that maintaining prescription status is in the best interests of the firm until just prior to patent expiry in order to ensure marketing exclusivity and name recognition in the OTC market. However, they also point out that managed care may also influence the decision to switch from Rx to OTC, as most insurers will not pay for OTC drugs. Finally, the authors discuss the issue of costs, and note that while prescription drug fees were higher than OTC drug prices, those without insurance often paid more for OTC drugs than those with insurance coverage for a prescription.

OTC Market Data

It is projected that the OTC drug market will attain US$106.3 billion by 2017 (Visiongain, 2014), and the US and Western Europe are the global market leaders with 43 percent of the market (Tisman, 2010). However, this dynamic is expected to change as BRIC countries already represent 77 percent of global OTC growth (Tisman, 2010) and are projected to contribute 44.1 percent of global sales by 2023 (Visiongain, 2014).

The largest segments of the consumer health care market include OTC drugs and vitamins and dietary supplements (VDS) at US$89 billion and US$75 billion respectively. The market is a highly fragmented one, with 84 percent of the market distributed among small to medium-sized firms and the rest controlled by fewer than ten companies (Nguyen-Quang, 2012). IMS reported that the OTC market surpassed the prescription drug market in 2008, and this trend is expected to continue for the foreseeable future (Tisman, 2010). The recent asset swap between Novartis and GlaxoSmithKline and resulting joint venture for a consumer health care business (Al-Bazergan, 2014) suggests the growing importance of the market for self-medication. Earlier examples of this segment's importance are evident from the acquisition of Wyeth by Pfizer and the merger of Merck with Schering Plough.

In fact, traditional pharmaceutical companies should expect competition from outside their industry: there is growing interest in the business of 'wellbeing' by food companies such as Danone and Nestlé (Tisman, 2010). Further, the emerging nutraceutical business (functional foods) is expanding into the consumer health care market. Das et al. (2012) define nutraceuticals as natural products that carry nutritional value (prebiotics, probiotics, etc.). Sloan (2011) points out that diabetes is a key therapeutic market for nutraceutical firms, as their products may provide improved insulin sensitivity; Henson et al. (2010) suggest that phytosterols may be used for the lowering of cholesterol.

From a behavioral perspective, there are certain characteristics of the OTC market that differ from the traditional prescription market. For example, consumers seek out OTC therapies when they choose not to consult a physician or cannot afford one (US); where they often rely on pharmacists for medical advice (Europe); or where physicians may not even be available, such as the BRIC markets. Other characteristics that have been mentioned elsewhere in this book include consumer responsibility for their own health and the use of plant-based, natural products in many parts of the world (Asia and the BRIC countries), with their increasing use in Western markets. An examination of the individual regions of the world may shed some details on the movements in this important segment.

The BRIC Markets

As mentioned earlier, the BRIC countries are among the most important markets for OTC products. For example, Russia experienced growth of 10.3 percent from 2006–2012 (NovaMedica, 2014) and it is expected to grow to US$16 billion (CAGR 12.4 percent) (Butschli, 2012). OTC products are particularly important there due to the aging of the population, rising obesity, and one of the largest percentages of smokers in the world (Butschli, 2012).

Yeh and Gladers (2008) suggest that China's potential for OTC drugs is enormous given the use of these drugs to ease the burden on the health care system there. The authors provide an excellent description of the way OTC drugs (which include traditional medicines) are used in China, and this will be summarized here. Traditional Chinese medicines (TCM) are a critical portion of pharmaceutical treatments in the country. These medications are usually provided by pharmacists after the patient has seen a physician, but may also be purchased without a prescription. They are prepared at home by the patient, but are increasingly available in manufactured forms, such as liquids, granules, or capsules. TCM is generally viewed as resulting in fewer side effects as well as the treatment of the disease rather than just the symptoms. Western OTC medications are used in urban centers for some health problems, such as colds, headaches, allergies, and fevers. They are seen as providing more rapid relief, but at the cost of greater side effects.

India is the 11th ranked market for OTC products globally with 8–9 percent annual growth; the largest category of OTC medications are the Ayurvedic (traditional) medicines, and they account for 27.3 percent of drugs sold followed in rank order by cough and cold preparations, vitamins and minerals, and analgesics (Khan et al., 2013). It should be noted that 'OTC' has no legal meaning in India; any drug that is not included as a 'prescription only' drug holds non-prescription drug status (Saha, 2013). The market is highly fragmented with over 70,000 brands available (NCK Pharma, 2014). Khan et al. (2013) examined consumer attitudes in India toward OTC medications and found that 45 percent of Indian consumers will go to a pharmacy for self-medication, 24 percent seek a physician's guidance, and 9 percent take no action at all. Most respondents consider OTC products safe to use and will ask the pharmacist for additional information; however, 50 percent of respondents were unaware of side effects. Technology, improving literacy, increased health awareness, and high stress are leading the population to seek out more medication for common ailments.

Brazil's OTC market generated US$4 billion in 2013, with a growth rate of 11 percent and representing 26 percent of pharmaceutical products sold in the country; it is expected to reach US$6 billion in 2014 with a growth rate of 20 percent. According to EMIS (2013), the sale of OTC drugs is influenced by the economy and changes in household incomes. EMIS (2013) also reported on changes in the availability of OTC medications in Brazil. In 2009, they were removed from self-service areas in order to encourage the proper use of drugs and, to some extent, eliminate self-medication. However, this change did not reduce OTC use, but increased it. Therefore, in 2012, the rule was changed to allow OTC drugs to be sold in self-service areas; however, they must be placed in a separate section from other products.

Europe

The Central and Western European markets accounted for almost 30 percent of pharmaceutical sales with 7 percent growth, with the largest segments in this market including cough and cold remedies, analgesics, and digestive medications, representing almost 51 percent share of all remedies. Tisman (2010) reports some significant channel changes in the region that will greatly affect the future of OTC medications there. This includes a multi-channel model in the UK with a move toward retail outlets versus pharmacy only and a

move away from pharmacy only in countries such as Denmark, Norway, Portugal, Italy, and Hungary. There appears to be some interest in mail order and online pharmacy sales, particularly in Germany (Tisman, 2010).

There are also significant changes in the European pharmacy landscape in the direction of chain ownership and retailer own brands. Regulatory access for the Rx to OTC switch has improved with the centralized EU application process, and this may increase access to European OTC markets; however, individual markets still retain their own pharmacy structure, local culture, and local regulation.

The United States

The US market is the largest OTC market in the world with approximately $23 billion in sales and OTC medications are available at 750,000 retail outlets that include grocery stores, mass merchandisers, convenience stores and food stores, and 54,000 pharmacies (Booz & Company/CHPA, 2012). Eighty-one percent of adults use OTC medications for minor ailments and make 26 trips a year to purchase OTC brands in comparison to three visits per year to physicians. There is some discussion about whether or not OTC drugs contribute to the lowering of health care costs, with some US researchers suggesting that those without insurance bear the brunt of drug costs when they use OTC drugs (Harrington & Shepherd, 2002) and others suggesting that it saves money due to the reduction in physician visits or avoidance of emergency room visits (Booz & Company/CHPA, 2012).

Implications and Conclusions

While emerging markets represent a future opportunity for the pharmaceutical industry, they hold significant challenges as well due to the lack of infrastructure, political instability, and low per capita income. Western MNEs have had difficulty understanding the cultural differences in these markets. This is due to some lack of understanding about the 'way things work'—governments and industry in these countries have a different value system from the West, and they do not view practices such as patent protection and pricing in the same way. In fact, their objective is to make drugs accessible to everyone via lower prices, and they have little regard for the patent laws that protect the prices charged by Western firms. These attitudes have a significant impact on policy decisions that affect pharmaceutical MNEs; for example, differential pricing is already used in some emerging markets as a result of these differences in societal values.

Each emerging market has its own particular structure and political framework, and establishing a strong foothold in these markets will not be a straightforward or short-term process. Further, some of these countries, such as India, already have a strong local and global market presence, and serve as both suppliers and competitors to Western MNEs. Countries like Russia want to develop their own local industry, and may create certain barriers to entry for pharmaceutical MNEs. Research has identified three key elements for success in emerging markets: collaboration with non-traditional partners, custom solutions, and establishing local capacity.

The OTC consumer market also represents a significant opportunity for the industry in both Western and emerging markets, particularly for those companies with existing consumer and OTC divisions. However, these firms will need to place greater focus on the development of their consumer drug brands to capitalize on this opportunity. In addition, those companies without consumer divisions may need to partner with local consumer goods firms, or seek consumer expertise through joint venture, licensing, or some form of acquisition.

References

Agarwal, S., d'Almeida, J., & Francis, T. (2012). Capturing the Brazilian pharma opportunity | McKinsey & Company. Retrieved October 8, 2014, from www.mckinsey.com/insights/health_systems_and_services/capturing_the_brazilian_pharma_opportunity

Al-Bazergan, A. (2014). Pharma M&A and market trends. Retrieved December 4, 2014, from www.finance-monthly.com/wp-content/uploads/2014/06/PharmaMAMarketTrends.pdf

Amadeo, K. (2014). 5 traits of emerging markets. Retrieved October 8, 2014, from http://useconomy.about.com/od/glossary/g/emerging_market.htm

Baker, T. (2012). The big sell: biologics in emerging markets. Retrieved December 4, 2014, from www.pharmexec.com/pharmexec/Strategy/The-Big-Sell-Biologics-In-Emerging-Markets/ArticleStandard/Article/detail/788390

Barnes, K. (2007). India's drug makers set for business influx. Retrieved December 11, 2014, from www.in-pharmatechnologist.com/Processing/India-s-drug-makers-set-for-business-influx

Beck, E. (2013). Global pharma market outlook – with focus on emerging markets. Retrieved December 4, 2014, from www.apteka.ua/wp-content/uploads/2013/09/8-EBeck.pdf

BioSpectrum. (2012). China OTC drug market grows 15% to $32 bn. Retrieved October 8, 2014, from www.biospectrumasia.com/biospectrum/analysis/122444/china-otc-drug-market-grows-usd32-bn

Booz & Company/CHPA. (2012). The value of OTC medicine. Retrieved December 4, 2014, from www.chpa.org/ValueofOTCMeds2012.aspx

brandindiapharma. (2011). Indian pharma market. Retrieved December 4, 2014, from www.brandindiapharma.in/files/pdf/Indian-Pharma-Market-Infographic.pdf

Buente, M., Danner, S., Weissbacker, S., & Ramme, C. (2013). Pharma emerging markets 2.0: how emerging markets are driving the transformation of the pharmaceutical industry [White paper]. Retrieved December 4, 2014, from www.strategyand.pwc.com/media/file/Strategyand_Pharma-Emerging-Markets-2.0.pdf

Butschli, J. (2012). Russian pharmaceutical market developing. Retrieved October 7, 2014, from www.healthcarepackaging.com/trends-and-issues/global/russian-pharmaceutical-market-developing

C.H. (2014). On closer inspection. *The Economist*. Retrieved December 4, 2014, from www.economist.com/blogs/schumpeter/2014/02/indias-booming-drugs-industry

Das, L., Bhaumik, E., Raychaudhuri, U., & Chakraborty, R. (2012). Role of nutraceuticals in human health. *Journal of Food Science and Technology*, *49*(2), 173–183. doi:10.1007/s13197-011-0269-4

Deloitte. (2011). The next phase: opportunities in China's pharmaceuticals market. Retrieved December 4, 2014, from www2.deloitte.com/content/dam/Deloitte/ch/Documents/life-sciences-health-care/ch_Studie_Pharmaceutical_China_05052014.pdf

Deloitte. (2013). Trends and practical aspects of development of the Russian pharmaceutical market – 2013. Retrieved December 4, 2014, from www.google.ca/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCQQFjAA&url=http%3A%2F%2Fwww.deloitte.com%2Fmultifiledownload%3FsolutionName%3Ddeloitte.com%26fileIds%3D6891fdaff4b00410VgnVCM1000003256f70aSTFL&ei=oGY1VJ-5OaaM8QH91YCwCw&usg=AFQjCNGxNiALDys_IFGPjjcLIfpwQGq4Gw&bvm=bv.76943099,d.b2U

Dolcera. (2011). OTC vs. prescription drugs market study & trends. Retrieved December 4, 2014, from http://pharmamarketresearchconference.com/files/OTC_vs_Prescription_Drugs_Market_Study_and_Trends.pdf

EMIS. (2013). Pharmaceutical sector Brazil. Retrieved December 4, 2014, from www.securities.com/emis/sites/default/files/EMIS%20Insight%20-%20Brazil%20Pharmaceutical%20Sector.pdf

equitymaster.com. (2014). Pharmaceutical sector analysis report. Retrieved December 4, 2014, from www.equitymaster.com/research-it/sector-info/pharma/Pharmaceuticals-Sector-Analysis-Report.asp

Flannery, R. (2013). China's top pharmaceutical companies in 2012 (List). Retrieved October 8, 2014, from www.forbes.com/sites/russellflannery/2013/07/24/chinas-top-pharmaceutical-companies-in-2012-list/

Graham, J. (2014). Indian patients suffer from India's weak pharmaceutical patents. Retrieved October 8, 2014, from www.forbes.com/sites/theapothecary/2014/09/09/indian-patients-suffer-from-indias-weak-pharmaceutical-patents/

Harrington, P., & Shepherd, M.D. (2002). Analysis of the movement of prescription drugs to over-the-counter status. *Journal of Managed Care Pharmacy: JMCP*, *8*(6), 499–508; quiz 509–511.

Heakal, R. (2014). What is an emerging market economy? Retrieved October 8, 2014, from www.investopedia.com/articles/03/073003.asp

Henson, S., Cranfield, J., & Herath, D. (2010). Understanding consumer receptivity towards foods and non-prescription pills containing phytosterols as a means to offset the risk of cardiovascular disease: an application of protection motivation theory. *International Journal of Consumer Studies*, *34*(1), 28–37. doi:10.1111/j.1470-6431.2009.00829.x

Hill, R., & Chui, M. (2009). A new world of revenue growth is just breaking the horizon. Here's a first view of tomorrow's pharma. *Pharmaceutical Executive*, (July), 44–52. Retrieved December 4, 2014, from www.imshealth.com/imshealth/Global/Content/Document/IMS%20in%20the%20News%20Documents/Pharmerging_Markets.pdf

Hirschler, B., & Siddiqui, Z. (2014). Big pharma still betting on 'messed up' Indian drugs market. Retrieved December 4, 2014, from http://in.reuters.com/article/2014/03/12/india-bigpharma-patent-idINDEEA2B09220140312

Hollmer, M. (2012). Fierce's 5 drug delivery companies to watch. Retrieved October 7, 2014, from www.fiercedrug-delivery.com/special-reports/fierce-5-drug-delivery-companies-watch

IBEF. (2014). Indian pharmaceutical industry. Retrieved December 4, 2014, from www.ibef.org/industry/pharmaceutical-india.aspx

IHS. (2014). Russian pharmaceutical market value grows 14% in 2013. Retrieved December 4, 2014, from www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065985325

IMAP. (2011). Pharmaceuticals & biotech industry global report – 2011. Retrieved December 4, 2014, from www.kurmannpartners.com/fileadmin/user_upload/Industry_Reports/IMAP_Global_Pharma_and_Biotech_Report_2011.pdf

IMS. (2010). Pharmerging shake-up. Retrieved December 4, 2014, from www.imshealth.com/imshealth/Global/Content/IMS%20Institute/Documents/Pharmerging_Shakeup.pdf

Karnani, A. (2006). Misfortune at the bottom of the pyramid. Retrieved December 4, 2014, from http://responsiblebop.com/BOP%20Database/misfortune-at-the-bottom-of-the-pyramid-2/

Karnani, A. (2007). The mirage of marketing to the bottom of the pyramid: how the private sector can help alleviate poverty. Retrieved December 4, 2014, from http://economicsandpeace.org/the-mirage-of-marketing-to-the-bottom-of-the-pyramid-how-the-private-sector-can-help-alleviate-poverty

Kelly, L. (2013). Growing demand in Brazil beckons big pharma. Retrieved October 8, 2014, from http://social.eyeforpharma.com/market-access/growing-demand-brazil-beckons-big-pharma

Khan, Y., Gupta, P., Goswami, D., Bihari, B., & Verma, K.V. (2013). A review on marketing of OTC drugs. *Asian Journal of Research in Pharmaceutical Sciences*, *3*(2), 72–78.

London, T., & Hart, S.L. (2004). Reinventing strategies for emerging markets: beyond the transnational model. *Journal of International Business Studies*, *35*(5), 350–370. doi:10.1057/palgrave.jibs.8400099

McKinsey. (2010). India pharma 2020 propelling access and acceptance, realising true potential. Retrieved December 4, 2014, from http://online.wsj.com/public/resources/documents/McKinseyPharma2020ExecutiveSummary.pdf

Mooraj, H. (2013). Emerging markets – a $284 billion opportunity for pharma companies? Retrieved December 4, 2014, from www.accenture.com/us-en/blogs/life-sciences-blog/archive/2013/12/10/emerging-markets-a-284-billion-opportunity.aspx

NCK Pharma. (2014). India OTC drugs market growing at a rate of 23%. Retrieved September 19, 2014, from http://hosted.comm100.com/knowledgebase/article_print.aspx?id=151&siteid=95439

Nguyen-Quang, T. (2012). Accelerated registration pathways in the consumer healthcare market: an overview of the global non-prescription regulatory landscape (unpublished research paper). Concordia University, Montreal, Canada.

NovaMedica. (2014). Healthcare industry: Russia over-the-counter (OTC) drugs industry research report. Retrieved October 7, 2014, from http://novamedica.com/media/theme_news/p/952

Osec. (2010). Brazil's pharmaceutical industry, opportunities for Swiss suppliers. Retrieved October 8, 2014, from www.s-ge.com/en/blog/brazil%E2%80%99s-pharmaceutical-industry-opportunities-swiss-suppliers

Panin, A. (2014). Government undercutting its own drive to localize pharmaceuticals production. Retrieved October 8, 2014, from www.themoscowtimes.com/business/article/government-undercutting-its-own-drive-to-localize-pharmaceuticals-production/507825.html

Pharmaceutical Drug Manufacturers. (2014). Top pharmaceutical companies in India. Retrieved December 4, 2014, from www.pharmaceutical-drug-manufacturers.com/articles/top-10-pharmaceutical-companies-in-india.html

Pharmastandard. (2011). Pharmastandard – leading Russian pharmaceutical company. Retrieved December 4, 2014, from http://pharmstd.com/news3files/_sales_2011._10.02.12.pdf

PMLive. (2012, January 5). Country report: the healthcare market in China [text]. Retrieved December 11, 2014, from www.pmlive.com/pharma_intelligence/country_report_the_healthcare_market_in_china_400599

PMLive. (2013, April 7). A tailored approach to the BRIC markets [text]. Retrieved December 11, 2014, from www.pmlive.com/pharma_intelligence/a_tailored_approach_to_the_bric_markets_485646

Prahalad, C.K., & Hart, S.L. (2002). The fortune at the bottom of the pyramid. Retrieved December 4, 2014, from www.cs.berkeley.edu/~brewer/ict4b/Fortune-BoP.pdf

Puentes, J., & Cahill, J. (2012, April 7). Country report: the healthcare market in Brazil [text]. Retrieved October 8, 2014, from www.pmlive.com/pharma_intelligence/country_report_the_healthcare_market_in_brazil_409950

Puzakova, M., Kwak, H., & Andras, T. (2010). Mitigating consumer ethnocentrism via advertising and media consumption in a transitional market: a study from Russia. *International Journal of Advertising*, *29*(5), 727–764.

Railean, L. (2012). Russia 2012: the pharmaceutical market & new legislation – building for growth in a fast changing marketplace. Retrieved December 4, 2014, from http://crm.cegedim.com/Docs_Whitepaper/Marketing/Cegedim%20-%20Russia%20Pharma%20Market%20-%20Aug%202012.pdf

Rao, P. M. (2008). The emergence of the pharmaceutical industry in the developing world and its implications for multinational enterprise strategies. *International Journal of Pharmaceutical and Healthcare Marketing*, *2*(2), 103–116. doi:10.1108/17506120810887907

Saboo, A. (2013a). AstraZeneca. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/astrazeneca-top-10-drugmakers-emerging-markets

Saboo, A. (2013b). Bayer HealthCare. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/bayer-healthcare-top-10-drugmakers-emerging-markets

Saboo, A. (2013c). GlaxoSmithKline. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/glaxosmithkline-top-10-drugmakers-emerging-markets

Saboo, A. (2013d). Johnson & Johnson. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/johnson-johnson-top-10-drugmakers-emerging-markets

Saboo, A. (2013e). Novartis. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/novartis-top-10-drugmakers-emerging-markets

Saboo, A. (2013f). Novo Nordisk. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/novo-nordisk-top-10-drugmakers-emerging-markets

Saboo, A. (2013g). Pfizer. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/pfizer-0

Saboo, A. (2013h). Roche. Retrieved October 8, 2014, from www.fiercepharma.com/special-reports/roche-top-10-drugmakers-emerging-markets

Saha, P.G. (2013). Indian OTC drug market: opportunities and challenges. *Global Research Analysis*, 2(10), 61–63.

Sharma, K.E. (2013). Niche drugs key to growth of pharma industry in 2014. Retrieved December 4, 2014, from http://businesstoday.intoday.in/story/niche-drugs-key-to-growth-for-pharma-industry-in-2014/1/201927.html

Sheth, J.N. (2011). Impact of emerging markets on marketing: rethinking existing perspectives and practices. *Journal of Marketing*, *75*(4), 166–182. doi:10.1509/jmkg.75.4.166

Sloan, E. (2011). Getting ahead of the curve: diabetes & sugar management. *Nutraceuticals World*, December, 16–17.

Spigarelli, F., & Wei, H. (2014). The Chinese pharmaceutical market: driving forces and emerging trend. Retrieved December 4, 2014, from www.chetch.eu/cms/index.php/dissemination/events/cat_view/2-events.html

Staton, T. (2013). Top 10 drugmakers in emerging markets. *FiercePharma*. Retrieved from www.fiercepharma.com/node/111899/print

The Economic Times. (2010, June 21). Indian biotech industry grew 17 percent in 2009–10: survey. Retrieved October 7, 2014, from http://articles.economictimes.indiatimes.com/2010–06–21/news/27618981_1_biotech-industry-biospectrum-bio-tech-industry

The Economist. (2014). Physician, heal thyself. Retrieved December 4, 2014, from www.economist.com/news/china/21595431-medicines-are-over-prescribed-and-overpriced-physician-heal-thyself

Tisman, A. (2010). The rising tide of OTC in Europe. Retrieved December 4, 2014, from www.imshealth.com/deployedfiles/imshealth/Global/Content/Healthcare/Healthcare%20Solutions/Consumers/The_Rising_Tide_Of_OTC_Europe.pdf

Van Arnum, P. (2014a). Gauging the potential of Russia's pharmaceutical market. Retrieved December 4, 2014, from http://connect.dcat.org/blogs/patricia-van-arnum/2014/05/27/gauging-the-potential-of-russias-pharmaceutical-market#.VDVkihZeXaI

Van Arnum, P. (2014b). IMS offers a subdued outlook for the global pharmaceutical industry at DCAT week' 14. Retrieved December 4, 2014, from http://connect.dcat.org/blogs/patricia-van-arnum/2014/03/25/ims-offers-a-subdued-outlook-for-the-global-pharmaceutical-industry#.VDWIdBZeXaI

Visiongain. (2014). 'The global over-the-counter pharmaceuticals market will reach $106.3bn in 2017' predicts new visiongain report. Retrieved December 4, 2014, from www.visiongain.com/Press_Release/493/The-global-over-the-counter-pharmaceuticals-market-will-reach-106–3bn-in-2017-predicts-new-visiongain-report

Volkov, M. (2014). Challenges for pharmaceutical companies in Russia. Retrieved December 4, 2014, from http://corruptioncrimecompliance.com/2014/06/challenges-for-pharmaceutical-companies-in-russia/

Yeh, L., & Gladers, M. (2008). China may have second largest market for over the counter drugs by 2010, *Business-ForumChina*. Retrieved December 4, 2014, from www.businessforum-china.com/article_detail.html?articleid=353

12 The Industry's Declining Reputation

A Prescription for Change

Regrettably, the public's perception of the pharmaceutical industry is the lowest it has been in recent history. An independent survey of 600 international patient groups from 56 countries (72 percent of these in Europe) reported that their overall evaluation of the industry's reputation declined from 42 percent (a good or excellent rating) in 2011 to 34 percent in 2012. Approximately half of these survey respondents evaluated the industry's record as poor based on its unfair pricing policies and lack of transparency (PatientView, 2014). The most significant areas of concern were the management of adverse events; brand marketing; and the industry's relationship with the media. This reputational decline has been developing for some time—for example, a 2008 Kaiser Family foundation study reported that only 27 percent of the US population feels 'very confident' that the drugs on the market are safe (Silverman, 2008a).

These data represent a continuous and downward slide in reputation for a once highly regarded industry. Despite this decline, there are still many contributions to the world's health made by this important industry, as millions of individuals would not be alive today without the scientific advances made by pharmaceutical companies. Consider that Merck was *Fortune Magazine*'s most admired company in the US for seven consecutive years (1986–1993) and this record has never been duplicated (Hawthorne, 2006). Ironically, Merck was also the marketer of Vioxx, a product that experienced one of the most well-publicized drug recalls in history due to the failure of Merck, as well as the FDA and the NIH (National Institutes of Health) to report the known adverse effects of the drug to physicians and the public (see Hill et al., 2008; Cahana & Mauron, 2006; Tong et al., 2009; Olsen & Whalen, 2009; Lofstedt, 2007; and Krumholz et al., 2007 for a complete discussion of the Vioxx case; and Stuart & Willyard, 2013 for a detailed analysis of the crisis management response from Merck and the FDA). Pharmaceutical companies still appear on *Fortune*'s list, but not with the same frequency as before.

Areas of controversy such as marketing and lack of transparency are described in several books that outline the role of industry marketers in what is called disease mongering and the overmedicalization of consumers (these include Moynihan & Cassels, 2005; and Petersen, 2008). Magazines such as *Forbes* have devoted stories calling the industry "pill pushers" and detailing how they "abandoned science for salesmanship" (Langreth & Herper, 2006). Other books detail questionable post-marketing clinical trials, off-label marketing, ghostwriting, and the potential bias of medical journals such as the *New England Journal of Medicine* as a consequence of industry funding (Goldacre, 2013). In December, 2014, *Newsweek* published a cover story entitled "Bad Medicine," which outlines specific examples of the lack of transparency in clinical trials due to the selective publication of clinical trials with favorable results to the company (Wolford, 2014). Transparency International (2011) reported that the pharmaceutical and health care industry ranked seventh out of 19 industries that use bribery to speed up administrative processes in 30 countries around the world. For example, recent bribery accusations in China

have been brought against GlaxoSmithKline and the firm is also facing charges in the UK for domestic bribery with respect to the Chinese charges (Helfand, 2014a–c; and Staton, 2014a–c). GlaxoSmithKline is not alone: Novartis has also been accused of kickbacks to pharmacies in the US (Palmer, 2014).

One contributing factor to the industry's negative reputation appears to be a certain disregard to criticism about some of its marketing practices and seemingly little interest in changing these practices. This attitude is somewhat reflected in the highly public settlements levied against it in the US since 2004 for violations that include off-label promotion, physician and pharmacist kickbacks, and monopolistic practices. The highest awards were levied against GlaxoSmithKline (US$3 billion; the largest award in history and the largest paid by a pharmaceutical company on both criminal and civil charges) for ten different drugs including Avandia and Advair (Department of Justice, 2012); Pfizer ($2.3 billion) for four different drugs including Lyrica (The United States Department of Justice, 2009a, 2009b); Abbott ($1.5 billion) for Depakote (The United States Department of Justice, 2012); and Eli Lilly ($1.4 billion) for Zyprexa (The United States Department of Justice, 2009a, 2009b). Almashat and Waterman (2010) have compiled a database of all criminal and civil monetary penalties levied against the industry. (For readers interested in content research, DIDA—the Drug Industry Document Archive—is available at http://dida.library.ucsf.edu/queryform.jsp. This resource contains internal company documents from major pharmaceutical companies in regards to their marketing practices that include clinical trial study results, physician relationships, CME, and pricing, among other topics.)

One may ask why these companies continue to withhold critical safety information from the public, such as the recent accusation that Boehringer Ingelheim failed to disclose the importance of monitoring anticoagulant activity in the use of its drug Pradaxa (dabigatran) for stroke prevention (Lee, 2014). An attorney whose firm represented GSK on certain aspects of the $3 billion criminal and civil case mentioned earlier was quoted as follows: "GSK simply considers this the cost of doing business" (Thomas, 2013, p. 4). One may also ask what the industry is doing to improve its reputation. The results of a recent industry survey indicate that 23 percent of firms do not even know how to address their reputational problem, and believe that no collective and cohesive program can be developed to fix it (Coleman, 2014). Staton (2014d) provides another perspective: the benefit to repairing the industry's reputation may not be worth the financial risk—in other words, as long as firms continue to earn profits and their stock price remains high, there is no compelling reason for the industry to take action.

That said, the purpose of this chapter is not to enumerate the industry's legal and ethical violations, as there is already more than enough written on this subject by others. A more nuanced approach may be required to understand the dynamic of pharmaceutical advertising and promotion that has contributed to the industry's current state of affairs. *It is not the marketing of prescription drugs in and of itself that is the problem, but rather, the execution of industry marketing strategies that has resulted in a general lack of public trust.* This chapter will examine several factors relating to marketing that have contributed to the industry's negative reputation, and then, will propose a framework and process for evaluating the appropriateness of future marketing programs. (Issues related to clinical research, such as outsourced clinical trials, ghostwriting, and Phase IV trials, are beyond the scope of this book.) There are many benefits to the industry, including financial ones, in ensuring the quality and accuracy of prescription drug advertising and promotion.

Factors Associated with Reputational Damage

Why does the industry seem unwilling or unable to change given its reliance, in part, on the public's trust? Part of the answer to this question is found in the internal structure of the industry, and the other, in the industry's external environment. The contributing factors are listed below, and this list is followed by a detailed

discussion of each. This is not intended to be an exhaustive list of factors, but rather, those that directly relate to marketing in some way. These factors include:

1) An industry described as inward-looking and resistant to change with self-reinforcing beliefs about its marketing practices;
2) Inexperienced marketing managers who manage brands and learn their skills on-the-job without sufficient formal training;
3) A lack of accuracy and balance in the presentation of marketing messages and the effects of this message repetition in multiple communication channels;
4) The use of DTCA and the way it trivializes drug therapy;
5) The belief that if a particular marketing activity is legal, then by definition, it must also be appropriate;
6) The perception of high drug prices as a consequence of sizeable marketing budgets;
7) The effects of physician engagement with the industry resulting in potential bias toward the drugs prescribed;
8) The inaccurate reporting of medical news and the blurred lines between legitimate news and marketing messages;
9) The perceived industry agenda setting in the determination of disease treatment policies; and
10) The public distrust of the industry as a result of the negative publicity given to off-label drug marketing.

Inward Looking and Resistant to Change

The industry suffers from its insular and inward looking nature, as well its resistance to change. The pharmaceutical industry tends to hire from within and prefers marketing managers who originate either directly from their sales forces or from other pharmaceutical companies. A feedback loop exists which perpetuates the same ideas within one company and then, the loop continues as managers move elsewhere to other firms. This leads to the repetition and perpetuation of inappropriate marketing strategies that contribute to a negative industry reputation. Internal industry conversation tends to be self-reinforcing and self-justifying: the industry believes it is different from others because its primary customers are a professional, scientific audience and, therefore, no one else can understand how it works. Coleman (2014) sheds some light on this phenomenon: she reports that only 1 percent of current industry employees want to leave the industry, and as a result, they experience "linear" careers.

The pharmaceutical industry is not the only one that is highly regulated and reaches both professional and consumer audiences; or, that has multiple constituencies requiring specialized training on the part of sales and marketing personnel. Further, the available research suggests that while pharmaceutical marketing managers may spend more time on different aspects of their job (sales oriented versus brand oriented), in other respects, marketing managers have similar day-to-day responsibilities as those in other industries. The linearity of industry careers may lead marketers to ignore outside influences that might provide them with new points of view as well as new and more appropriate marketing skills.

One example of this difficulty in the acceptance of outside ideas may be seen in the various industry reports on the use of multichannel marketing in digital media; the use of value-added services as part of the brand offering ('beyond the pill' strategies); and, finally, the use of closed loop and multichannel marketing. Despite the widespread acceptance of these practices in other industries, these marketing tools are seen as revolutionary by the industry. While there are limited and anonymous examples of their use in the public domain, many firms are unsure where to begin the process of such significant structural change. It is unclear that the

industry can even implement strategies such as 'beyond the pill' services, despite its belief that they may provide a desirable future direction—it appears heavily wedded to 'pill' focused operations because of its current structure. The industry appears to behave conservatively when it comes to adopting internal mechanisms that might improve its operational abilities, but not sufficiently so in its execution of marketing communication strategies, which in turn, contributes to its negative reputation.

Inexperienced Marketers with the Need for Training

Based on existing research, little has changed in the marketing organization with respect to those who are employed as brand managers in many pharmaceutical companies. Professional sales representatives, who may be excellent salespeople, are promoted into brand management positions, for which they are likely both inexperienced and untrained. Much of the training they are given is in-house and takes place on the job. These same brand managers are then promoted into the highest ranks of the company. While some on-the-job training is necessary, additional formalized training in marketing and brand management is essential. Further, the tenure of most brand managers is very short: two to three years. This turnover also results in lack of continuity and the need for additional training.

This lack of training has led to some inappropriate choices of marketing strategies. These choices included excessive detailing, oversampling, and off-label marketing to physicians, as well as lack of understanding about the appropriate use of consumer marketing communication tools. Sales force shrinkage and fines for off-label marketing are the final outcomes of inappropriate physician marketing. An example of ill-conceived DTCA that comes to mind is the Gardasil vaccine campaign, in which teenagers were provided with Gardasil beach towels and a specialty line of Gardasil bracelets (Silverman, 2008b). While these strategies may be appropriate in a consumer goods campaign, they are totally unsuitable for a teenage audience which is highly impressionable and lacks the ability to make critical decisions about its health.

Lack of Accuracy and Balance

Many industry critics are concerned about the accuracy and balance of benefit and risk information presented to both physicians and consumers. Further, it is the augmented effect of the different types of communication media used simultaneously that reinforce brand messages to both physicians and consumers. These messages may be problematic if accurate information is not presented in a balanced way because this information appears repeatedly to target audiences in multiple media channels. Based on research presented earlier in this book, this concern may be the result of the industry's failure to follow both its formal regulations with respect to off-label marketing and its own self-regulatory guidelines in its marketing activities.

The Use of Direct to Consumer Advertising

Some of the research presented in this book suggests that patients have increased control over their health care decisions, actively seek out health care information online via websites and online patient groups, and even ask their physicians directly for specific drugs as a consequence of DTCA. However, most patients have neither the expertise to evaluate this information nor to determine whether the information is accurate or unbiased. While many consumers seem to understand that much of this information is advertising and designed to influence them, the dual nature of this information may also lead to inappropriate drug requests to physicians.

This happens because DTCA and eDTCA present an idealized view of drug therapy outcomes, with consumers focused on drug benefits and not the risks. Consequently, this type of communication results in a lack of respect and trivialization for the serious nature of the drug being advertised, as the ads appear in the same communication channels next to snack foods and cars. Cognitive dissonance may occur when patients experience serious side effects after they request a prescription, or read about these side effects on the Internet or in the media, thus creating negative views of both the advertised brand and the industry.

Health care information which is inaccurate or difficult to understand may also lead to negative impressions about the industry. Recent research suggests that many health care websites contain information that is hard for an expert to parse in terms of its accuracy, much less a consumer. For example, Yi et al. (2014) reviewed online patient education materials and determined that most major sources of this material are written at a higher level than the average patient is able to understand. In general, DTCA and eDTCA have contributed to the negative image of health care companies in general.

If Legal, Then Appropriate

The industry has a 'no apologies' approach with respect to its marketing activities, and believes that its legal right to market its products does not prevent it from behaving in a way that invites critical examination. Langreth and Herper (2006) reported that industry executives reject criticisms that their marketing is inappropriate despite numerous lawsuits that document the contrary. The authors report that companies provided excuses for the deaths of patients due to their drugs (either they had pre-existing illnesses or were taking other drugs) rather than accepting responsibility. This defensive position may be explained from a legal liability perspective; however, it may contribute to the negative impression of the industry and is not necessarily acceptable behavior to the public at large. Silverman (2014) reported that the industry believes its "questionable marketing practices, in particular, have largely receded in response to the public scolding that has followed so many settlements." Further, there is disbelief that some industry insiders express at how their industry is portrayed because of "how people in it [the industry] feel the way they do"—in other words, they sincerely believe they are helping the public (Langreth & Herper, 2006). There appears to be a disconnect between what the industry believes and what the public perceives.

Perception of High Prices

The public in general, as well as many payers, believes that prescription drug prices are overly high. The public, in particular, believes that companies spend more on marketing than on research to develop new drugs and that this marketing activity results in higher prices. This perception should not be an unexpected one, as the media widely reports that marketing budgets significantly exceed R&D expenditures in some companies. GlobalData recently reported that Johnson & Johnson, Pfizer, and Novartis are spending almost double their R&D expenses on marketing, with others such as Roche and Lilly spending almost equal amounts on both (Anderson, 2014). In addition, there is a perception that the industry is not transparent in its pricing policies and companies do not report how they calculate their drug prices. This leads to some mistrust about the fairness of drug prices, particularly in light of the press about marketing budgets.

This perception of unfairness is described in a detailed analysis of the HIV crisis by Trullen and Stevenson (2006). The authors show that while the industry was influenced by the pressure from the media and interested activist groups, it only took action by announcing price cuts when the pressure became sufficiently strong

to threaten it economically. Drug prices were cut slowly in order to protect profits and to create a barrier to entry to generic firms at the same time. In other words, pharmaceutical companies act only when there is an economic reason to do so, but also lose goodwill in the meantime. In a recent survey of 26 countries, it was found that this very issue regarding access to life-saving drugs contributes to the industry's poor reputation (GlobeScan, 2014).

Industry Relationships with Physicians

Some research suggests that physicians have their own interests in engaging with the industry and have, in part, contributed to its poor reputation. Kassirer (2005) implies that physicians are in collusion with the pharmaceutical industry because of the financial benefits it provides, and thus, doctors are accused of endangering the public's health because of these relationships. Typically, the marketing department in a given company supplies these benefits. In a national survey of 3,167 physicians, Campbell et al. (2007) support Kassirer's findings, and in addition, these authors reported that 94 percent of physicians have relationships with the pharmaceutical industry, largely in the form of free food in their offices (83 percent). Twenty-eight percent of physician respondents received consulting fees for lectures or clinical trial recruiting and 35 percent received reimbursement for attending CME or professional meetings. Even at the prestigious Harvard Medical School, there were concerns that its professors were too closely tied to the industry as a result of their consultant work and did not present information about drugs in an objective fashion when teaching their medical students (Wilson, 2009). Fugh-Berman and Ahari (2007) recount eight 'categories' of physicians used to help pharmaceutical sales representatives sell to physicians based on their receptivity to different marketing messages (this information is based on court documents from various trials). These categorizations suggest a close relationship between the industry and certain groups of physicians (who are described as "friendly," "mercenary," and "high prescribers," among others).

It is interesting to note that the public does not negatively evaluate physicians for their relationships with the pharmaceutical industry, even though it is the industry supplying the financial support. The public does not see physicians as part of the problem. A recent Maclean's poll reported that 92 percent of Canadian respondents generally hold their physicians "in high esteem," even though they feel their doctors care less for their patients and that they are somewhat less honest than they were ten years ago (Gillis et al., 2010). The reputation of physicians in the US and the UK also remains high: Ipsos MORI (2011) reported that physicians were ranked as the 'most trusted profession' in the UK, and in the US, 70 percent rated their physicians as 'high' or 'very high' (the highest since 1990 when the rating was 52 percent) with respect to their ethics and honesty (Gallup Poll as cited by Sanger-Katz, 2012). Most physician associations have made a concerted effort to address this problem in their professional codes; however, the recent revelations from the Sunshine laws enacted in various countries suggest that financial compensation to physicians may require rethinking on the part of physicians and their professional associations.

Inaccurate Information from the Mass Media

The media, in some part, is also responsible for the negative image of the industry as a participant in its marketing activities. Mechanic (2005) states that "there is great intermixture of purpose [in the media], often making it difficult to separate objective information from advertising and promotion." He outlines several reasons why the media play such a major role in the public perceptions of medical issues that include: 1)

the need to generate interesting and exciting content to generate revenue; combined with 2) the reporting of unrepresentative but interesting anecdotes from patients to draw in readers. Cassels (2007) suggests that the media overemphasizes the benefits of new drug therapies through the inadequate reporting of side effects; the overemphasis on rare side effects, thus depriving patients of appropriate medication; the potential of influence by commercial sources; and the overreporting of weak positive evidence of the effects of drugs.

It should be no surprise, therefore, that the media have only a slightly better reputation than the pharmaceutical industry, with Mendes (2013) reporting that 44 percent of the public have a "great deal or fair amount of trust or confidence in the mass media" (p. 1). This level of trust has continuously declined from a high of 55 percent in 1999. This lack of public trust in the media may have also 'infected' the industry as a result of exaggerated reporting about prescription drug therapy.

Political Agenda Setting in the Treatment of Disease

There is a perception among members of the public as well as those in health care professions that the industry places undue influence on health and governmental agencies in the determination of treatment modalities; this lobbying effort by public relations agencies is a form of marketing. There are questions about the appropriateness of an individual company's involvement in the setting of public policy when there is a clear conflict of interest (Tomljenovic & Shaw, 2012). This influence combined with a delay in policy announcements allows a firm to pursue its own interests at the expense of others. If this influence and resulting treatment guideline changes are not seen as being in the best interests of the public, it negatively affects the perception of the industry; some examples are presented below.

Gosden and Beder (2001) analyzed the political agenda-setting in the treatment of mental health through advocacy coalitions (that include consumer groups supported by the industry and public relations firms), government initiatives, and inside access from policy communities for changes that positively affect the industry using the example of schizophrenia. Changes in treatment policy were achieved through the use of all three methods to the change of the guidelines for disease treatment that included: the period where symptoms were identified prior to the onset of the disease; weakening the civil liberties laws to ease the involuntary treatment of the sick; and using the media to present the potential 'dangers' of untreated schizophrenia to the public. These outcomes were criticized as not in the best interests of the public. Finally, in a detailed case study of Gardasil, Tomljenovic and Shaw (2012) discuss how Merck stopped its lobbying of state governments for mandatory coverage of the vaccine's costs when confronted by parent groups questioning the need for such an overarching program and religious groups concerned about promiscuity and the resulting negative publicity about the drug.

Off-Label Marketing

The court cases that have resulted from the use of off-label marketing have been a key factor in the industry's reputational decline. Off-label marketing is defined as the prescribing of a drug outside its approved labelling as determined by a regulatory body such as the FDA and the approach to off-label drug use varies in different countries. There is often confusion about off-label use of drugs because different rules apply for physicians and pharmaceutical companies. Physicians may prescribe drugs as they see fit for various medical conditions, and the drug itself does not have to have a specific indication for its use. This is often the case because certain drugs may not be tested in certain populations such as children and adolescents due to ethical guidelines, but may have therapeutic benefits (Neville et al., 2014).

However, in the US, a pharmaceutical company may not advertise or sell a drug for any indication that is not included in its package labelling (or insert). There are certain sources in which information about the off-label use of drugs is permitted: compendia and drug references; CME; journal articles; medical and graduate education; medical liaisons in pharmaceutical companies; websites; and sales representatives (who may only provide peer-reviewed journal articles but may not use these articles to promote company products and must refer the physician to the medical liaison) (Ventola, 2009). Based on the number of lawsuits brought against companies who engaged in off-label promotion mentioned earlier, it is clear that governments are taking a hard-line approach to this activity and the resulting publicity is extremely unfavorable to the industry. In response to these legal challenges, a recent whistleblower lawsuit against Millennium Pharmaceuticals in the US has raised the issue of protection of free speech; in other words, the industry is arguing that it should be allowed to discuss off-label drug use with physicians as along as the discussion is truthful (Staton, 2014a–e). Time will tell whether or not the court will find this a valid argument.

Fairbairn et al. (2011) provide an overview of off-label medications in Europe and this information is summarized here. In Europe, there is little control over off-label drug use; however, a drug may not be advertised for claims that have not been approved by a regulatory body. In certain European countries, physicians are allowed to prescribe off-label drugs due to the threat of lawsuits from patients who might be denied the necessary treatment; however, full disclosure to the patient is required including the fact that the cost of the drug for that use might not be covered. Pharmaceutical companies are still not allowed to promote off-label use and product liability claims brought by patients against pharmaceutical companies are a distinct possibility. In China, Ma and Lou (2013) report that physicians may prescribe off-label if there is scientific evidence to support the drug's use and they may rely on their medical judgment. However, as in Europe and the US, there is always the possibility of liability lawsuits. Advertising drugs off-label is prohibited; however, the definition of advertising is not well defined and is a grey area with unclear guidelines.

There are two diametrically opposing viewpoints with respect to off-label use and these are summarized here (Ventola, 2009). The view in favor of off-label marketing is that it provides "transparency regarding treatment choices" (p. 431). Some arguments that support off-label marketing include: more data available to physicians leads to potentially better treatment; access to off-label clinical trials might provide information missed by a busy physician, particularly in the areas of oncology, psychiatry, and pediatrics; off-label indications support 'innovation' in a physician's practice, particularly with respect to orphan diseases; and finally, new information is rapidly disseminated that would otherwise not be available.

The opposing view suggests that these unapproved uses pose a "significant risk to public health and well-being" (p. 431). Arguments against off-label drug prescribing include: peer review does not guarantee that the information is of high quality (drug companies may only publish positive results and ghostwriting); lack of physician time to verify claims made in clinical studies; lowering of the quality of the peer-review process by allowing companies to have control over off-label clinical trials; journals do not know if an article is ghostwritten or not; and the difficulty of determining reimbursement and insurance for off-label use.

One example of the positive effects of off-label drug use is provided by Michels et al. (2009). The authors examined the off-label use of Avastin in ophthalmology and determined that the use of this drug off-label in Germany resulted in lower prices charged for the approved indications of the drug, as well as for other drugs used to treat the same condition. The data suggest a potential pricing disadvantage for the pharmaceutical company and a potential benefit of unapproved labelling to the government agencies that reimburse drug costs. The authors caution that this finding may be limited to this particular situation. In addition, while the price effects of off-label marketing may be favorable in certain circumstances, the

potential unmonitored use of drugs for unapproved indications may lead to serious health problems that may increase health care costs.

Despite these two conflicting views, off-label drug promotion generates negative publicity and is not viewed favorably by the public and regulatory authorities as a result of the publicity given to the serious side effects attributed to off-label use. Unless there is some change in the laws regarding off-label drugs, this type of drug use will continue to contribute to the negative reputation of the industry, particularly if it contributes to patient harm with new court actions and unfavorable publicity.

Why Change Is Needed

Many references sourced for this book provided policy recommendations that involve specific regulatory changes, such as the prohibition of DTCA and increased oversight of marketing activity through pre-clearance of all advertising and promotional materials by a regulatory agency; and also, greater financial penalties for violating the law. Others called for stronger sanctions by self-regulatory groups for firms that violate their agreements with stiffer financial penalties and other non-monetary sanctions for non-compliant firms.

Some of these recommendations may be appropriate; however, these types of initiatives will take time to gain approval and additional funding to implement. Unfortunately, it is not clear that the political will exists to do this in many countries and the ethical and legal problems that currently exist will continue while remedies are sought. While additional regulation should be pursued if deemed appropriate, changes must be made in the interim to address these important concerns. The answer will not be found by developing additional marketing or issues management programs to 'massage' existing industry communication. It may be developed through fundamental changes in values at the firm level, which then must be supported by global and national industry organizations.

Some in the industry believe that reputational change is not possible, and state that they do not know where to begin the change process. This feeling arises from the belief that the problem is so deep that change must be dramatic in order to have impact. There are no quick fixes or easy solutions for reputational problems—marketers understand very well that it takes much longer to change existing attitudes than to create new ones. Change does not have to be dramatic—however, it must be meaningful, systematic, and implementable at the firm level with accountability for this implementation. This change must then be supported at the industry level if it is to be lasting. This type of fundamental change requires a strong commitment and must become a key part of the firm's value set which is then communicated both internally to employees and externally to its stakeholders. However, the change must be implemented by employees with visible results before communication to the public begins.

Changes to compliance training appear to be required for both regulatory requirements and voluntary guidelines. Recent research suggests that the industry frequently violates formal regulations and its own voluntary codes in many countries—clearly, current compliance strategies are not effective. It seems evident that while companies provide compliance training, either its content is not well-understood or it is not properly applied to the development of marketing materials. Legal counsel which represent these companies may advise them of the legality of marketing activities, but not their suitability, which results in a poor reputation.

This is an unfortunate state of affairs, as there is now evidence to suggest that regulatory compliance has a direct effect on shareholder returns. PA Consulting Group has developed a "regulatory effectiveness score" and the development of this metric is summarized here (Silverman, 2014). This score measures how well firms manage the regulatory process within their firms over a ten-year period and whether or not they have a specific

individual or compliance group to handle this responsibility. The score consists of 15 variables that include (among others) the size of fines paid, the number of warning letters sent, the existence of corporate integrity agreements, and references to these items in annual reports. Silverman (2014) states that "drug makers might do themselves—and their shareholders—a favor if they were to no longer consider it a cost of doing business to pay large fines for imbroglios." The report lists Gilead and Novo Nordisk tied with the highest scores and Eli Lilly with the lowest score.

Implementing Change: A Behavioral Framework

While neither a novel approach nor a cure for all the industry's problems, the use of an ethical framework may be one way to change its behavior in order to improve its reputation, and there are various ethical frameworks to choose from that may provide guidance to pharmaceutical firms. Ferrell et al. (1989) discuss several of these frameworks, but ultimately conclude that situational factors and organizational culture are the most important determinants of ethical behavior in an organization: *in fact, they suggest that in a corporate setting, the influence of one's peers and top management is even more important than one's own personal belief system*. First, it is up to the CEO to set the tone and provide common values for the entire organization—and it is a responsibility they should act upon immediately if they hope to improve the reputation of their own firms as well as the industry as a whole. Second, an internal structure needs to be established within the firm to ensure that these values are well understood and become part of the way the firm does business. Values training should take place *in addition to* compliance training, not only for new employees, but for all employees on a regular basis. In addition, there should be a monitoring and reward system for implementing these values for all employees, but particularly for marketers. This is because company marketers are the public face of the company and their work is visible to the public (penalties for violating these values should also be developed). Given the importance of peer influence in the organization, it would make sense that peers take responsibility for each other to make certain that the firm's values are upheld when developing their marketing materials; some mechanism for encouraging peer consultation should be put in place.

The next issue to be addressed is the content of these company values. The TARES Test (Baker & Martinson, 2001, as cited by Wand, 2012) provides a useful framework for establishing values and measuring whether or not they are followed with the use of some basic questions. This framework and test are summarized below. While this framework was developed specifically for marketing and advertising, the general principles may be applied to any organization. The TARES framework provides a view of ethics in a "macroethical" context versus a "microethical" context (Baker & Martinson, 2001, p. 156). Rather than looking at whether one particular piece of advertising or type of communication (referred to as persuasion) is unethical (the microethical), a company must examine the macroethical, which is the total effect of all its communication (persuasion) on the "persuadee" (target audience). According to the authors, it is the macroethical context that is the primary cause of unethical persuasion. This notion reinforces one of the points made earlier in this chapter: marketing messages are augmented when used in multiple channels (within and across audiences) and have effects when used together, so this holistic approach makes sense when evaluating advertising and promotion activities in the industry.

Baker and Martinson (2001) ask what elements of today's working culture contribute to the acceptance of unethical behavior and why it is so prevalent in many organizations. While some marketers claim that they engage in unethical means because without them they cannot reach their goals, the authors posit that this is an excuse rather than an explanation. Clearly, there are personal and financial benefits to engaging

in unethical acts, or their incidence would not be so prevalent. In the words of the authors, "persuasive communication . . . must center around respect for the individual to whom the particular persuasive effort is directed" (p. 153). Marketers must put the interests of their target audience before their own 'narrowly defined' self-interest (which might be increased sales or market share, as an example). This behavior must be modelled at the top of the organization and then implemented by peers at the lower organizational levels, as supported by Ferrell et al. (1989)—it does not work if it is limited to one department in a company. The TARES Test is one way for CEOs to choose meaningful and fair values, and for marketers to evaluate their own behavior with respect to the interests of their persuadees (target audiences).

The TARES Test is composed of five principles, hence the acronym: Truthfulness, Authenticity, Respect, Equity, and Social Responsibility. Truthfulness means that the message must be "not only true, but truthful" (p. 159). This is an important distinction because one can be deceptive without telling an out-and-out lie. One example of this would be the reporting of clinical trial results in percentages rather than in absolute numbers. A 50 percent improvement might be the equivalent to one or two patients; while the percentage reported is true, the magnitude of the effect as expressed by the percentage is misleading. Authenticity consists of integrity and personal virtue, sincerity and genuineness, and loyalty and independence. These mean that one must have a "virtuous" (p. 162) goal in one's work; a strong belief in the product; and to determine whether the loyalty requested by one's employer is appropriately placed and does not violate the rights of others. Respect means that the persuadees' dignity and human rights are not violated in the pursuit of self-interest or exclusively for the benefit of the company. According to the authors, this principle is the most important of TARES and forms the foundation for all other principles. Equity dictates that both the content of the communication and its ability to persuade are fair to the persuadee, and do not manipulate them. This principle assumes equality between the persuader and the persuadee, so that both have the same information on which to base their decisions. The authors also suggest the application of the Golden Rule, a concept which is generally well-understood, as the foundation for their principle of Equity. Finally, Social Responsibility emphasizes the need to be concerned about the greater good and public interest. As pharmaceutical companies are responsible in some part for the health and well-being of the general public, their actions must meet the standard of being good citizens. Table 12.1 provides selected questions from the TARES Test that may be considered by the readers of this book when identifying company values and evaluating their marketing programs.

Table 12.1 Selected Questions from the TARES Test

Truthfulness
1) Is communication true and truthful?
2) Have I presented selected information?
3) Have I withheld information needed to make an informed decision?
4) Have I distorted information by using improper comparisons?
Authenticity
1) Does this action affect my integrity?
2) Would I recommend this product to my loved ones without reservation?
3) Are my motives self-serving or do they benefit others?
4) Would I be proud if others were to find out about my behavior?

Respect

1) Do my actions respect the rights and dignity of others?
2) Have I provided enough information to meet the needs of physicians and patients?
3) Will physicians and patients benefit from following the advice in my communication?
4) How can I be more responsible in my behavior towards physicians and patients?

Equity

1) Have I targeted vulnerable audiences based on the content of my communication?
2) Are my persuaders able to assess the claims I make in my communication fully and rationally?
3) Does the audience know that I am persuading them rather than informing them?
4) Should I engage in this type of persuasion?

Social Responsibility

1) Do I respect the welfare of all?
2) Do I harm individuals with any actions?
3) Do I encourage public dialogue based on truthful information?
4) How can I serve the interests of society?

Source: Adapted from Baker & Martinson, 2001

Implications and Conclusions

The worldwide reputation of the pharmaceutical industry is poor and shows no signs of immediate improvement. This is an unfortunate situation, because the industry is an important contributor to the well-being of society. It has a responsibility as a member of the global community to address its problems for the benefit of its employees, its shareholders, and the public at large. While many in the industry acknowledge the current situation, they appear to be either unwilling or unable to address the problem. Key contributors to the industry's declining reputation addressed by the research presented in this book include, in part, the execution of marketing strategies, providing balance for drug benefits and risks, the industry's insular nature, the inexperience of marketing managers, perception of overly large marketing budgets contributing to high drug prices, and the use of off-label marketing. Many of the problems mentioned above have solutions—companies must decide how they may be best addressed.

In addition, the research suggests that the industry generally does not comply well with either formal regulation or voluntary guidelines, and this is also a contributing factor to its negative reputation. New research suggests that this lack of compliance results in lower stock share prices, so it may be in the industry's self-interest to find a way to improve this important reputational element, even if other non-financial issues are deemed unimportant.

However, more than improved compliance will be needed to change the industry's reputation in a fundamental and meaningful way. Companies must change their values, communicate them to their employees throughout the organization, implement them, and then monitor their implementation. This change in individual company values must then be reflected at the broader industry level. This type of change is neither easy nor quick, but it is doable and must be undertaken for the future health of the industry and society. The TARES Test with its five core principles is one suggested framework for companies to develop a set of meaningful values, and for marketers, in particular, to then apply these values to the development of future marketing programs and materials.

References

Almashat, S., & Waterman, T. (2010). Rapidly increasing criminal and civil monetary penalties against the pharmaceutical industry: 1991 to 2010. Retrieved December 10, 2014, from www.citizen.org/hrg1924

Anderson, R. (2014). Pharmaceutical industry gets high on fat profits. Retrieved December 10, 2014, from www.bbc.com/news/business-28212223

Baker, S., & Martinson, D.L. (2001). The TARES Test: five principles for ethical persuasion. *Journal of Mass Media Ethics*, *16*(2–3), 148–175. doi:10.1080/08900523.2001.9679610

Cahana, A., & Mauron, A. (2006). The story of Vioxx—no pain and a lot of gain: ethical concerns regarding conduct of the pharmaceutical industry. *Journal of Anesthesia*, *20*(4), 348–351. doi:10.1007/s00540-006-0432-7

Campbell, E.G., Gruen, R.L., Mountford, J., Miller, L.G., Cleary, P.D., & Blumenthal, D. (2007). A national survey of physician–industry relationships. *New England Journal of Medicine*, *356*(17), 1742–1750. doi:10.1056/NEJMsa064508

Cassels, A.K. (2007). The media–medicine mix: quality concerns in medical reporting. *Open Medicine*, *1*(1), 52–54.

Coleman, D. (2014). First industry healthcheck. Retrieved December 10, 2014, from http://social.eyeforpharma.com/market-access/time-rip-your-list-competitors-and-start-again

Department of Justice (2012). www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

Fairbairn, D., Izzard, C., & Holtorf, M. (2011). Promotion and use of off-label pharmaceuticals in Europe, the US and China. Retrieved December 10, 2014, from www.cliffordchance.com/briefings/2012/03/promotion_and_useofoff-labelpharmaceuticalsi.html

Ferrell, O.C., Gresham, L.G., & Fraedrich, J. (1989). A synthesis of ethical decision models for marketing. *Journal of Macromarketing*, *9*(2), 55–64. doi:10.1177/027614678900900207

Fugh-Berman, A., & Ahari, S. (2007). Following the script: how drug reps make friends and influence doctors. *PLoS Med*, *4*(4), e150. doi:10.1371/journal.pmed.0040150

Gillis, C., Belluz, J., & Dehaas, J. (2010). Do you trust your doctor? Retrieved December 10, 2014, from www.macleans.ca/news/canada/do-you-trust-your-doctor/

GlobeScan. (2014). CSR reputation pharmaceutical industry |2013 In a fast-changing world, context is everything. Retrieved December 10, 2014, from www.globescan.com/component/edocman/?view=document&id=148&Itemid=591

Goldacre, B. (2013). *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients* (reprint edition). New York: Faber & Faber.

Gosden, R., & Beder, S. (2001). Pharmaceutical industry agenda setting in mental health policies. *Ethical Human Sciences and Services*, *3*(3), 147–159.

Hawthorne, F. (2006). Merck's fall from grace. *The Scientist*. Retrieved from www.the-scientist.com/?articles.view/articleNo/23978/title/Merk-s-Fall-from-Grace/

Helfand, C. (2014a). GlaxoSmithKline's Chinese reps demand to be repaid for bribes, FT reports. Retrieved September 19, 2014, from www.fiercepharmamarketing.com/story/glaxosmithklines-chinese-reps-demand-be-repaid-bribes-ft-reports/2014–06–03

Helfand, C. (2014b). GSK can't deep-clean its image overnight. But it can revamp its websites. Retrieved September 19, 2014, from www.fiercepharmamarketing.com/story/gsk-cant-deep-clean-its-image-overnight-it-can-revamp-its-websites/2014–09–03

Helfand, C. (2014c). GSK trims Witty's bonus in face of China probe. Retrieved September 19, 2014, from www.fiercepharma.com/story/gsk-trims-wittys-bonus-face-china-probe/2014–02–27

Hill, K.P., Ross, J.S., Egilman, D.S., & Krumholz, H.M. (2008). The advantage seeding trial: a review of internal documents. *Annals of Internal Medicine*, *149*(4), 251–258. doi:10.7326/0003-4819-149-4-200808190-00006

Ipsos MORI (2011). Doctors are most trusted profession – politicians least trusted. Trust in professions 2011. Retrieved December 10, 2014, from www.ipsos-mori.com/researchpublications/researcharchive/2818/Doctors-are-most-trusted-profession-politicians-least-trusted.aspx

Kassirer, J.P. (2005). *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health*. Oxford; New York: Oxford University Press.

Krumholz, H.M., Ross, J.S., Presler, A.H., & Egilman, D.S. (2007). What have we learnt from Vioxx? *British Medical Journal*, *334*(7585), 120–123. doi:10.1136/bmj.39024.487720.68

Langreth, R., & Herper, M. (2006). Pill pushers. Retrieved September 19, 2014, from www.forbes.com/forbes/2006/0508/094a.html

Lee, R. (2014). Popular blood thinner Pradaxa maker withheld critical safety data. Retrieved September 19, 2014, from www.techtimes.com/articles/11316/20140726/popular-blood-thinner-pradaxa-maker-withheld-important-safety-data.htm

Lofstedt, R. E. (2007). The impact of the cox-2 inhibitor issue on perceptions of the pharmaceutical industry: content analysis and communication implications. *Journal of Health Communication*, *12*(5), 471–491. doi:10.1080/10810730701438724

Ma, F., & Lou, N. (2013). Chinese regulation of off-label use of drugs. *Food and Drug Law Journal*, *68*(2), 189–200, ii.

Mechanic, D. (2005). Media, public perceptions & health, and health policy. *Houston Journal of Health Law & Policy*, *5*, 187.

Mendes, E. (2013). In U.S., trust in media recovers slightly from all-time low. *GALLUP*. Retrieved December 10, 2014, from www.gallup.com/poll/164459/trust-media-recovers-slightly-time-low.aspx

Michels, S., Kurz-Levin, M., & Schmitz, C. (2009). Off-label drug use – price analysis for Avastin® in ophthalmology. *International Journal of Pharmaceutical and Healthcare Marketing*, *3*(1), 59–73. doi:10.1108/17506120910948511

Moynihan, R., & Cassels, A. (2005). *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning Us All into Patients*. New York: Nation Books.

Neville, K. A., Frattarelli, D. A. C., Galinkin, J. L., Green, T. P., Johnson, T. D., Paul, I. M., & Anker, J. N. V. D. (2014). Off-label use of drugs in children. *Pediatrics*, *133*(3), 563–567. doi:10.1542/peds.2013-4060

Olsen, A. K., & Whalen, M. D. (2009). Public perceptions of the pharmaceutical industry and drug safety: implications for the pharmacovigilance professional and the culture of safety. *Drug Safety: An International Journal of Medical Toxicology and Drug Experience*, *32*(10), 805–810. doi:10.2165/11316620-000000000-00000

Palmer, E. (2014). Novartis accused again of kickback tactics in new whistleblower suit. Retrieved September 19, 2014, from www.fiercepharma.com/story/novartis-accused-again-kickback-tactics-new-whistleblower-suit/2014–07–08

PatientView. (2014). Corporate reputation of pharma – the patient perspective. Retrieved December 10, 2014, from http://alexwyke.wordpress.com/2014/02/13/corporate-reputation-of-pharma-the-patient-perspective-february-2014/

Petersen, M. (2008). *Our Daily Meds: How the Pharmaceutical Companies Transformed Themselves into Slick Marketing Machines and Hooked the Nation on Prescription Drugs*. New York: Picador.

Sanger-Katz, M. (2012). Why we trust doctors. Retrieved September 18, 2014, from www.nationaljournal.com/features/restoration-calls/why-we-trust-doctors-20120419

Silverman, E. (2008a). Is too much safety information a bad thing? Retrieved from www.pharmalot.com/2008/12/is-too-much-safety-information-a-bad-thing/

Silverman, E. (2008b). Merck launches a charm offensive for Gardasil. Retrieved December 10, 2014, from www.pharmalot.com/2008/08/merck-launches-a-charm-offensive-for-gardasil/

Silverman, E. (2014). A cost of doing business? How regulatory fines hurt shareholder returns. Retrieved December 10, 2014, from http://blogs.wsj.com/pharmalot/2014/06/18/a-cost-of-doing-business-how-regulatory-fines-hurt-shareholder-returns/tab/print/

Staton, T. (2014a). Free speech, PhRMA? Not in this off-label marketing case, feds say. Retrieved September 19, 2014, from www.fiercepharma.com/story/free-speech-phrma-not-label-marketing-case-feds-say/2014–09–10

Staton, T. (2014b). GlaxoSmithKline steps up bribery probes, eyeing potential violations in 9 Middle Eastern countries. Retrieved September 19, 2014, from www.fiercepharma.com/story/glaxosmithkline-steps-bribery-probes-eyeing-potential-violations-9-middle-e/2014–04–17

Staton, T. (2014c). If Glaxo's CEO wants to be Mr. Clean, he needs to pick up a broom. Retrieved September 19, 2014, from www.fiercepharmamarketing.com/story/if-glaxos-ceo-wants-be-mr-clean-he-needs-pick-broom/2014–04–07

Staton, T. (2014d). Top GSK exec faces life in Chinese prison for alleged 'massive bribery network.' Retrieved September 19, 2014, from www.fiercepharmamarketing.com/story/top-gsk-exec-faces-life-chinese-prison-alleged-massive-bribery-network/2014–05–14

Staton, T. (2014e). Can pharma salvage its tarnished rep? Survey says yes. Retrieved December 10, 2014, from www.fiercepharma.com/story/can-pharma-salvage-its-tarnished-rep/2014–06–19

Stuart, J., & Willyard, J. (2013). Crisis management rhetoric of Merck and the FDA in response to Vioxx. Retrieved December 10, 2014, from http://citation.allacademic.com/meta/p_mla_apa_research_citation/0/9/3/1/3/p93139_index.html?phpsessid=uahsjsm2l7l1uoffoir1hn9lk6

The United States Department of Justice. (2009a). Acting United States attorney Michael L. Loucks district of Massachusetts. Retrieved from www.justice.gov/usao/ma/news/Pfizer/Pfizer%20-%20PR%20%28Final%29.pdf

The United States Department of Justice. (2009b). Eli Lilly and company agrees to pay $1.415 billion to resolve allegations of off-label promotion of Zyprexa. Retrieved September 19, 2014, from www.justice.gov/opa/pr/eli-lilly-and-company-agrees-pay-1415-billion-resolve-allegations-label-promotion-zyprexa

The United States Department of Justice. (2012). GlaxoSmithKline to plead guilty and pay $3 billion to resolve fraud allegations and failure to report safety data. Retrieved September 19, 2014, from www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report

Thomas, C. (2013). The public relations minefield that is Big Pharma. Retrieved December 10, 2014, from http://ethicalnag.org/2013/10/26/pr-for-big-pharma/

Tomljenovic, L., & Shaw, C.A. (2012). Too fast or not too fast: the FDA's approval of Merck's HPV vaccine Gardasil. *The Journal of Law, Medicine & Ethics: A Journal of the American Society of Law, Medicine & Ethics*, *40*(3), 673–681. doi:10.1111/j.1748-720X.2012.00698.x

Tong, C.H., Tong, L., & Tong, J.E. (2009). The Vioxx recall case and comments. *Competitiveness Review*, *19*(2), 114–118. doi:10.1108/10595420910942289

Transparency International. (2011). Bribe payers index 2011. Retrieved December 4, 2014, from www.isn.ethz.ch/Digital-Library/Publications/Detail/?id=134888&lng=en

Trullen, J., & Stevenson, W.B. (2006). Strategy and legitimacy: pharmaceutical companies' reaction to the HIV crisis. *Business & Society*, *45*(2), 178–210. doi:10.1177/0007650306286740

Ventola, C.L. (2009). Off-label drug information. *Pharmacy and Therapeutics*, *34*(8), 428–440.

Wand, E. (2012). DTCA: Web 2.0 evolution (unpublished paper). Concordia University, Montreal, Canada.

Wilson, D. (2009, March 3). Harvard Medical School in ethics quandary. *The New York Times*. Retrieved December 10, 2014, from www.nytimes.com/2009/03/03/business/03medschool.html

Wolford, B. (2014). Bad medicine. *Newsweek*, *163*(20), 28–33.

Yi, P.H., Chang, M.M., Haughom, B.D., & Jawa, A. (2014). Readability of patient education materials from the AAHS. *HAND*, *9*(3), 393–394. doi:10.1007/s11552-014-9643-9

Index

Note: page numbers in **bold** type refer to Tables.

4Ps, of pharmaceutical marketing (physicians, patients, pharmacists and payers) 32, 65

Abbott 10, 68, 155
academic detailing 60 *see also* detailing
account management function 31–2
acquisitions *see* M&As (mergers and acquisitions)
Activis, acquisition of Allergan 11
activist groups 134
Adair, R.F. 85
Adams, S.M. 38
adverse reactions, and social media 120, 122
advertising *see* DTCA (direct to consumer advertising); eDCTA (digital communication to consumers)
Affordable Care Act (ACA), US 20, 31, 37, 134
Agarwal, S. 142
agenda-setting, in health care 160
aging population 17, 141
Agrawal, D.P. 18
Ahari, S. 159
Akannac, C. 32
Albers, S. 86, 106
Alkhateeb, F.M. 94
Allergan, hostile takeover attempt by Valeant 10–11
Almashat, S. 155
alternative therapies 18, 141–2, 148
Amadeo, K. 137
AMARC Enterprises 120
American Health Insurance Plans (AHIP) 44
American Medical Association, Code of Medical Ethics 105
Amin, T. 73
Andersson, M. 26
Angell, M. 45
Angelmar, R. 69
antibiotics 17, 18, 24
apps 99, 100, 116, 121, 122–3, 126
Arndt, M. 60
Arnold, D.G. 129, 133
Asia 24–5
asset swaps 9–10, 12, 147
AstraZeneca 10, 11, 58, 103, **145**
Australia 24, **35,** 36, 109, 111, 133
Authenticity (TARES Test) 163–4, **164,** 165
authorized generics 73–4
Avorn, J. 60

Baker, S. 163–4
Baker, T. 138, 140
Balamurugan, E. 25
Bangladesh 17, 51
Barnes, K. 143
Baron, R.B. 82–3, 87
Bayer 10, 20, **145**
Beck, E. 138, 139, 140
Beder, S. 160
Bednarik, J. 67
'below the line' communication strategies 110
BEUC 134
beyond the pill branding strategy 73, 156
Big Data 16–17
Big Pharma *see* ethical pharmaceutical sector (Big Pharma)
biologics 3, 58 *see also* biotechnology sector
biosimilars ('follow-ons') 4, 5, 138, 143
biotechnology sector 1–2, **3,** 3–4, 6
Biovail 10
Blackett, T. 65
Blauvelt, B.M. 85
blogs 119, 121
Bloor, K. 20

Boeringer Ingelheim 120, 123, 124–5, 155
Boltri, J.M. 85
Bosch, X. 88
Bottles, K. 97–8
boundary spanners 51, 52
brand extension 72–3, 81
brand managers 49, 50, 61; effects of team structure on marketing performance 51–2; functional tasks of 52–3, **53**; performance evaluation of 55; pharmaceutical industry and FMCG industry 54; profile and responsibilities 52; skill sets of 53–4; team structure 51; training of 56, 157
branded generics 73–4, 140
branding 64, 77; brand extensions 72–3, 81; brand personalities 66–8, **67,** 76, 77; case studies of successful strategies 74–6, **75,** 77; corporate branding 68–9, 75, 77; criticisms of 65, 76–7; disease branding 69–70, 75, 77; franchise branding 69, 70, 75; and generic drugs 73–4, 77; historical view of 64–5; niche branding 71–2, 77; reality of 65–6, **66**; value added/beyond the pill strategies 73
brands, and products 49–50
Brazil 17, 18, 37, 57, 148; as an emerging market 139, 140, 141–2 *see also* BRIC (Brazil, Russia, India, and China) countries
Brekke, K.R. 40–1
BRIC (Brazil, Russia, India, and China) countries 18, 27, 46, 148; as emerging markets 137, 139–44
Briscoe, M.E. 23–4
Brody, H. 87
Bucerius, M. 7
Buente, M. 146
Buysse, I.M. 16
Bye, J. 59

Calfee, J.E. 107, 108
Campbell, E.G. 159
Campo, K. 81, 82, 83, 85, 86
Canada 24, 25, **35,** 36, 133, 159; drug reimbursement case study 42–3; and DTCA (direct to consumer advertising) 108–9, 111
CanWest Global 108
Capella, M.L. 106
capitation payment 34
Carmody, D. 89
Carroll, J. 11
Carter, F.J. 57, 58, 81, 94
carve-outs 10, 12
Cassels, A.K. 160
Cegedim Strategic Data 57, 83, 93
Cervero, R. 87
change, in the pharmaceutical industry 156–7, 162–3, 163–4, **164–5**
Charlesworth, A. 34
Chase, J. 85
China 17, 18, 36, 57, 59, 141, 148, 161; as an emerging market 139, 140, 141; corruption 42, 154–5; drug reimbursement case study 42 *see also* BRIC (Brazil, Russia, India, and China) countries
Ching, A.T. 58, 83
Chintagunta, P.K. 57
Chowdhury, N. 51
Chretien, K.C. 98
Chui, M. 140
clinical trial publications, sponsorship of 87–8
closed loop marketing (CLM) 49, 50, 60–1, 62, 93, 95–6, 100, 156
co-payers 32
codes of conduct, voluntary 129, **130–1,** 131–2, 135
Coleman, D. 156
Colyer, W. 65, 66
Comanor, W.S. 6
Comer, B. 84
commercial agreements (CAs) 41
Common Drug Review (CDR), Canada 42, 43
Commonwealth countries, health care system **35,** 36
communication, to physicians 80–1, 89–90; continuing medical education (CME) 86–7, 90, 159; detailing 58, 60, 82–4, 89, 106; digital communication 93–100; e-detailing 58, 61, 82, 93, 94–5, 100; gift-giving 88–9, 90; industry-sponsored clinical trial publications 87–8; journal advertising 85–6, 90; sampling 84–5
complaint process, in voluntary codes of conduct 132
compliance training 162
complimentary franchises 70
Coney, S. 109
consolidation *see* M&As (mergers and acquisitions)
consumerization of health care 19
consumers *see also* DTCA (direct to consumer advertising); eDCTA (digital communication to consumers); patients
continuing medical education (CME) 86–7, 90, 159
Cooper, C.P. 97
Copaxone 72
corporate branding 68–9, 75, 77
corruption 42, 142–3, 154–5
cost savings, and M&As (mergers and acquisitions) 7
counterfeit drugs 21
coverage with evidence development (CED) 41
'cross-price' effect 40–1

customer relationship marketing (CRM) 61, 95 *see also* closed loop marketing (CLM)
Cutrona, S.L. 85

Daiichi-Ranbaxy M&A 7–8
Dana, J. 89
Danone 147
Danzon, P.M. 1, 6–7, 9
Das, L. 147
Datta, D.K. 7
Dave, D.M. 105, 106
David, G. 107, 122
death, leading causes of 18
Dehaas, D. 86
Deloitte 141, 143
Deloitte University Press 119
DeLor, K. 68
Demirbag, M. 8–9
demographic factors in health care 17–19, 141
Denmark 25, 34, **35**
"desperation index", for M&As (mergers and acquisitions) 6
detailing 58, 89, 106; academic detailing 60; effectiveness of 83–4; overview of 82–3 *see also* e-detailing
Dey, E. 5
diagnosis-related group (DRG) based payment 34
Digital Health Coalition 120
digital selling 58
direct to consumer advertising (DTCA) 19, 20, 24, 64–5, 68, 103–4, 76, 110–11, 128, 134, 157–8; consumer profiles 104–5; controversy about 107–8; country-by-country survey 108–10; effects on prescription requests 106–7; overview of research 105–6; perceived risk by consumers 107; physician views on 105 *see also* eDCTA (digital communication to consumers)
discount cards 74
disease awareness advertising (DAA) 103, 108, 109–10, 111
disease branding 69–70, 75, 77
'disease mongering' 70, 108, 154
Dolcera 146
Doran, E. 133
Doucette, W.R. 94
Dr. Reddy 74
Drechsler, D. 37–8
drug reimbursement policies 20, 31, 32, 38–9, **39–40,** 46; Canada case study 42–3; China case study 42; Sovaldi case study 43–5
drugs: counterfeit 21 *see also* generic drugs; patented drugs
DTCA *see* direct to consumer advertising (DTCA)
Duffy, J. 51

e-detailing 58, 61, 82, 93, 94–5, 100 *see also* detailing
e-mail, use by physicians 93, 97
e-physician websites 96–7
e-sampling 84
early adopters, of new drugs 81
economic factors in health care 15–16
eDCTA (digital communication to consumers) 116, 125–6, 158; case studies 123–5; eDTCA 1.0 116–19; eDTCA 2.0 119–22; mHealth 122–3
Edwards, J. 120
efficacy claims 84, 87
Eli Lilly 155, 158, 163
emerging markets 137–9, 149; Brazil 139, 140, 141–2; China 139, 140, 141; India 139, 140, 143–4; pharmerging markets 139–40; Russia 139, 140, 142–3; successful strategies; case studies 144–6, **145**
environmental forces in health care 15–27
episode-based payments 34
Epperly, L. 5
Equity (TARES Test) 163–4, 165, **165**
Ernst & Young 3, 45
Essential Drug List (EDL), China 42
essential drugs, access to 45–6
Ethical Criteria for Medicinal Drug Promotion, WHO 131–2
ethical pharmaceutical sector (Big Pharma) 1, **2,** 2–3, 20
Europe 117, 121–2, 149, 161; and direct to consumer advertising (DTCA) 108, 110, 111; health care systems 34, **35**; OTC (over-the-counter) medicines 148–9
European Federation of Pharmaceutical Industries and Associations (EFPIA) 132
evidence-based medicine (EBM) 41
external reference pricing, patented drugs 39, 41
eye for pharma 55, 59

Facebook 103–4, 119, 121, 124, 125
Faden, M. 61
Fairbairn, D. 161
Farmer, R.G.: 36
Farmindustria (Unit for Supervising Ethical Practices/ USD) 133
fast moving consumer goods (FMCG) industries, brand managers in 54
FDA *see* Food and Drug Administration (FDA)
Feder, J. 34
Federal Trade Commission 99
fee for service payment 34

Ferrell, O.C. 163, 164
financial performance, effect of M&As on 8–9
Fischer, M.A. 60, 86, 106
Five Pillars for Ethics in Public Communication 70
fluoxetine 72
'follow-ons' (biosimilars) 4, 5, 138, 143
Food and Drug Administration (FDA) 25, 64, 86, 99, 105, 108, 122, 144; social media guidelines 94, 97, 120
food companies, and nutraceuticals 147
Forcellina, A. 32
Fosdick, M. 18, 19
France 18, 34, **35,** 41; social media use 18, 121–2; Sunshine laws (Reform de Medicaments/Loi Bertrand) 88, 128, 135
Francer, J. 129
franchise branding 69, 70, 75
Freifeld, C. 122
Fugh-Berman, A. 159
functional foods (nutraceuticals) 147

gabapentin 82–3
Gaffney, A. 120
Ganesh, K. 25
Gardasil 77, 157, 160
gatekeepers 21
gender, and physician consultations 23–4
generic drugs 25; and branding 73–4, 77; in emerging markets 140, 141, 143, 144; internal reference pricing 39, 40–1; price caps 39, 40–1
generic pharmaceutical sector 1, 2, **4,** 4–5, 20, 72
Germany 18, 34, **35,** 121–2
Gettings, J. 86
ghostwriting, of clinical trial publications 88
gift giving, to physicians 88–9, 90 *see also* incentives
Gilead 33, 43–5, 163
Glass, H.E. 81
GlaxoSmithKline (GSK) 103; asset swaps 9, 149; corruption 142–3; and emerging markets **145**; settlements against, in the US 155; and social media 120, 123, 124
Glenn, B. 99
Glick, J.L. 4
global budget payment system 34
global organizations, marketing organization in 50
Gönül, F.F. 57, 58, 81, 83, 85, 94
Gores, M. 59
Gosden, R. 160
government affairs function, of pharmaceutical companies 31
governments: health care policies 20, 21 *see also* drug reimbursement policies
Govette, J. 119
Grabowski, H.G. 72
Grande, D. 89, 135
Green, S. 24
grey markets (parallel imports) 20–1, 27
Gross, A. 42
Groves, K.E.M. 84
GSK (GlaxoSmithKline) *see* GlaxoSmithKline
Gurau, C. 25
Gureje, O. 23

Hack, E.I. 129
Hagemeyer, D. 95–6
Hall, D.V. 69, 70, 109
Harrington, P. 147
Harrison, T. 65
Hart, S.L. 138, 144, 146
Harvard Medical School 159
Hassan, M. 8
Haute Authorite de Sante (HAS), France 34
Hawn, C. 98
He, J. 87
Health Action International 134
health care: citizen satisfaction with 38; consumerization of 19; environmental forces in 15–27
health care professionals 22–6, 23 *see also* pharmacists; physicians
health care systems: global **33,** 33–4; regional/country analysis 34–7, **35**
health technology assessment (HTA) 41
Healthy Skepticism 134
Henson, S. 147
hepatitis C; Gilead's Sovaldi case study 43–5
herbal medications 141–2
Herper, M. 11, 158
Heutschi, R. 94
Higgins, M.J. 6, 8
Hill, R. 140
Hitz, A. 71–2
HIV 158–9
Hollis, A. 74
Hollmer, M. 143
Holmgren, L.R. 85
Honburg, C. 7
Hong Kong 24–5
Hong, S.H. 73
'house of brands' strategy *see* franchise branding
Huh, J. 118
Hurley, M.P. 85
Hutton, G. 18, 19
'hybrids' 5

IMS 121, 123, 139, 147
incentives 94 *see also* gift giving, to physicians
India 17, 18, 20, 41, 95, 133, 148; as an emerging market 139, 140, 143–4; health care system 22, 36–7 *see also* BRIC (Brazil, Russia, India, and China) countries
Indonesia, population 17
Information Practices Committee (NBL) 133
Instagram 124
Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen(IQWiG), Germany 34
insurance companies 21, 31, 37–8, **38** *see also* private health care services
insurance mandate health care systems 33, **33**
intellectual property 19–20, 27, 143, 144 *see also* patent cliffs; patented drugs
interactive detailing 94
internal reference pricing, generic drugs 39, 40–1
International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) 131
international non-proprietary name (INN) 4, 140
international price comparison *see* external reference pricing, patented drugs
Internet 18–19, 54; and branding 64–5; e-physician websites 96–7; use by patients 16, 19, 23, 116–19; use by physicians 16, 19, 93, 96–7, 100
Ishihara, M. 58, 83
Italy **35,** 121–2

Jacobson, R. 85
Januvia 70
Japan 17, 18, **35,** 36, 59; and DTCA (direct to consumer advertising) 109–10; Sunshine laws 128, 135
Jarosławski, S. 41
Johnson & Johnson 72, 121, **145,** 158
Johnson, M. 9
joint ventures 9, 12
Jones, S.C. 69
journal advertising 85–6, 89
Joyce, G.F. 81
Jutting, J. 37–8

Kabir, E.R. 51
Kamtekar, R. 45–6
Kapferer, J.-N. 49, 67, **67**
Karnani, A. 138
Kassirer, J.P. 159
Katsanis, L.P. 49, 51, 52–3, **53,** 55, 56, 67, **67,** 71–2, 89, 109
Kavadas, C. 107
Keselman, A, 23, 117
Kesselheim, A.S. 73, 74
key performance indicators (KPIs) 51–2, 55, 62 *see also* performance evaluation
Kim, J. 97–8
Kipp, O. 5
Kobelak, S. 3
Korenstein, D. 86
Krishnaswamy, K. 22
Kumar, B.D. 22

LAMASIL 69
LaMattina, J.L. 7, 8, 17, 44
Landro, L. 26
Langreth, R. 158
Law, M.R. 106, 109
legal factors: in brand management 53–4; in health care 19–21
Leiding, P. 5
Leo, G. 97
Leonard, E. 49, 67, **67**
Lewis, L.S. 118
Lexchin, J. 86, 88, 107, 108, 129, 133
Liang, B.A. 74, 121
licensing 9, 12
live (video) detailing 94
lobbying 31, 77, 160
Loewenstein, G. 89
Lofgren, H. 133
London, T. 144, 146
lopinavar/ritonavir 73
Lou, N. 161
Luthra, S. 37

M&As (mergers and acquisitions) 1, 12; asset swaps, carve-outs and spin-offs 9–10, 12; and corporate branding 69; effect on financial returns 8–9; effects on physicians and consumers 8, 12; impact on marketing performance and strategy 7–8, 12; licensing and strategic alliances 9, 12; 'megamergers' 9; and product innovation 6–7; rationale for 5; and tax inversions 10–11
Ma, F. 161
Macias, W. 118
Mack, J. 93, 94, 103, 119, 120
Mackey, T.K. 121
Maddox, L. 109, 117
Mali, S.N. 133
Manchanda, P. 57, 83–4
Mangin, D. 107
Manhattan Research 18, 19
Mansfield, P. 89

market access 20, 31–3, 46; and brand management 54; Canada case study 42–3; China case study 42; essential drugs 45–6; global healthcare systems **33,** 33–7, **35**; price cap regulation 40–1; pricing regulation and drug reimbursement policies 38–9, **39–40**; private healthcare services **35,** 37–8, **38**; Sovaldi case study 43–5
marketing organization, structure of 49–50, 61–2; and brand managers 49, 50, 51, 52–6, 61; closed loop marketing 49, 50, 60–1, 62; multichannel marketing 50, 60, 61; and sales representatives 49, 56–60, 61
marketing performance: effects of team structure on 51–2; impact of M&As (mergers and acquisitions) on 7–8, 12
marketing strategy: emerging markets 144–6, b145; impact of M&As (mergers and acquisitions) on 7–8, 12
Martins, M. 122, 123
Martinson, D.L. 163–4
mass media 159–60
Mattioli, D. 10
Maynard, A. 20
McHenry, L. 88
McKinsey & Company 9, 144
Mechanic, D. 159–60
Medecins Sans Frontiers 44
medical education and communications companies (MECCs) 88
medical science liaisons 58
medical students, gift-giving to 89
Medicines Transparency Alliance (MeTA) 134
MedWatcher app 122
Mellor, P. 24
men, and physician consultations 23–4
Mendes, E. 160
Menon, A.M. 107, 117–18
Merck 10, 58, 120, **145,** 147, 154; lobbying 77, 160
mergers and acquisitions *see* M&As (mergers and acquisitions)
Mexico, as an emerging market 140
mHealth 99, 100, 116, 121, 122–3, 126
Michels, S. 161–2
Millennium Pharmaceuticals 161
Miller, Steve 44
Mintzes, B. 107, 108, 109
Mittra, J. 2, 6
Mizik, N. 85
mobile apps 99, 100, 116, 121, 122–3, 126
Mooraj, H. 140
Moore, T. 96
Moretti, U. 110
Moss, G. 65, 66, 68, 70
Mott, D.A. 74
Moynihan, R. 70
Mukherjee, A. 105–6
Mulinari, S. 133
multichannel marketing 50, 60, 61, 93, 96–100, **98,** 156
multinational organizations, marketing organization in 50
Myshko, D. 71

nanotechnology 17
Narayanan, S. 83–4
National Institute for Health and Clinical Excellence (NICE), UK 34
National Rural Health Mission (NRHM), India 36
Nationally Reimbursed Drug List (NRDL), China 42
negotiated price volume agreements, patented drugs 39, 41
Nestle 147
Netherlands 34, **35,** 38
new product development *see* product innovation
New Rural Cooperative Medical System (NRCSM), China 36
New Zealand 24, **35,** 36; and DTCA (direct to consumer advertising) 108, 109, 111
niche branding 71–2, 77
Nigeria, population 17
No Free Lunch 134
non-governmental organizations (NGOs) 38, 134, 139
Norway, health care system 34, **35**
Novartis 20, 104, 120, 142, **145,** 155, 158; asset swaps 9, 10, 147
Novo Nordisk 68–9, 123, 125, **145,** 163
nurses, as sales representatives 60
nutraceuticals (functional foods) 147

O'Connor, L. 18, 19
O'Donnell, M. 98
O'Grady, G. 59
Oakley, J.L. 129, 133
off-label marketing 160–2
Ornaghi, C. 7
Ornstein, C. 134–5
OTC (over-the-counter) medicines 24, 137, 146–9
Othman, N. 86
outcomes (pharmacoeconomic) research 31, 41
overmedicalization 106, 154; and disease branding 69–70, 77

PA Consulting Group, "regulatory effectiveness" score 162–3
Pakistan, population 17

Palmer, E. 72
Pan American Network for Drug Regulatory Harmonization (PANDRH) Ethical Criteria for Promoting, Advertising and Publicizing Pharmaceuticals 132
Pan-Canadian Oncology Drug Review (pCODR), Canada 42, 43
pan-Canadian Pharmaceutical Alliance (pCPA), Canada 43
Pangyrakis, G.G. 54
parallel imports (grey markets) 20–1, 27
parallel paths in product innovation 6, 7
Parry, V. 69
Parsons, P.J. 70
patent cliffs 4, 5, 20
patented drugs: brand extension 72–3; and branding strategies 65; external reference pricing 39, 41; impact of generic drugs on 74; negotiated price volume agreements 39, 41; switching to OTC sales 146–7
Patented Medicine Prices Review Board (PMPRB), Canada 42–3
Patient Assistance Programs (PAPs) 40
patient centricity 73
patients 21; adherence 26, 85; and brand personalities 67, **67,** 68, 76, 77; effects of M&As on 8, 12; empowerment of 19; interactions with health care professionals 22–6; interactions with payers 26; interactions with pharmacists 24–5; interactions with physicians 23–4; perceived risk of DTCA 107; and personalized medicine (PM) 71–2; post-consultation decision making 25; prescription requests 106–7; psychographic profiles 104–5; self-assessment by 22–3; social media/Internet use 16, 19, 23; technological factors affecting 16 *see also* DTCA (direct to consumer advertising); eDCTA (digital communication to consumers)
payment for performance (P4P) programs 34, 41
payments to physicians 134–5, 159
Pendlebury, J.J. 84
performance evaluation, of brand managers 55
Perry, S. 94
Pershing Square Capital Management LP 10
personal data, and privacy 17, 76
personalized medicine (PM) 71–2
Pew 18, 19
Pfizer 10, 68, 74, **145,** 155, 158; and intellectual property rights 1, 2, **4,** 4–5; merger attempt with AstraZeneca 10, 11; Pfizer-Wyeth M&A 7–8, 147
Pharma 2020 policy, Russia 142
Pharmaceutical Advertising Advisory Board (PAAB) 133
Pharmaceutical Executive 74, **75**
pharmaceutical industry 21; behavioral framework for change 163–4, **164–5**; economic factors affecting 15–16; insularity of 156–7; need for change 162–3; relationship with physicians 159; reputation of 154–62; resistance to change 156–7; structure of **2, 3, 4,** 11–12, 105
Pharmaceutical Industry Information Examiner (IGM) 133
Pharmaceutical Manufacturers and Research of America (PhRMA) 133
pharmaceutical marketing, definition of 15
pharmacies 24, 27, 149
pharmacists 21, 24–5, 27, 73
Pharmastandard 142
PharmaVision 2020, India 143
pharmerging markets 139–40
PharmFree 134
Phase III trials 87, 88
Phase IV trials 87, 88, 90
PhRMA (Pharmaceutical Manufacturers and Research of America) 133
physicians 21; and brand personalities 67, **67,** 77; consultation times 23; continuing medical education (CME) 86–7, 90, 159; and DTCA (direct to consumer advertising) 103, 105; effects of M&As on 8, 12; interactions with patients 23–4; payment systems 34; payments to 134–5, 159; and personalized medicine (PM) 71; pharmaceutical industry relationship with 159; prescribing behavior 24, 89; prescribing characteristics 80–1; reputation of 159; and sales representatives 57, 58; social media/Internet use 16, 19; technological factors affecting 16; traditional industry communication to 80–90; wait times 23 *see also* communication, to physicians; detailing; sampling, to physicians
Pines, N. 71
Pinterest 124, 125
Pitta, D.A. 55
political factors in health care 19–21
Polygenis, D. 88
portfolio branding *see* franchise branding
post-marketing surveillance trials (PMS) 87, 88
Prahalad, C.K. 138
prescribing behavior 24, 89, 94, 106–7
Prescription Brand Personality Scale (PBPS) **67,** 67–8
prescriptions 24, 25; and sales representatives 58; unfulfilled 25, 26
price caps 39, 40
price indexing *see* internal reference pricing, generic drugs
PriceWaterhouseCoopers 49–50

pricing of drugs 20, 31, 32, 33, 38–9, **39–40,** 46; and brand extensions 73; and brand management 53–4; and branding 73, 76; Canada case study 42–3; China case study 42; and DTCA (direct to consumer advertising) 106, 110; impact of generic drugs on 74; and pharmaceutical industry reputation 158–9; price cap regulation 39, 40–1; Sovaldi case study 43–5 *see also* drug reimbursement policies
primary health care 22, 23–5
privacy, and personal data 17, 76
private health care services **35,** 37–8, **38** *see also* insurance companies
product evergreening 20, 72
product innovation 6–7, 9, 72
product origin branding 70
products, and brands 49–50
professional sales representatives (PSRs) 49, 50, 56–7, 61; changing role of 58, 61; historical perspective 57; nurses as 60; physicians' refusals to see 82; profile and responsibilities 57–8; training of 59, 61, 157 *see also* detailing
PROZAC 72
psychographic profiles of consumers 104–5
public subsector (SUS), Brazil 37
Puig-Junoy, J. 40, 41
Puzakova, M. 143

Qanadilo, H. 96

R&D (research and development) 6, 7, 9, 10–11
Ranbaxy 7–8, 144
Rangaswamy, A. 61
Rao, P.M. 138
Rao, S.K. 26
rare diseases 71
Rashtriya Swasthya Bima Yojana (RSBY), India 36
Reast, J. 110
Reform de Medicaments/Loi Bertrand, France 88, 128, 135
"regulatory effectiveness" score, PA Consulting 162–3
regulatory factors: advertising and promotion 128; in brand management 53–4; and digital communication 99; in health care 19–21
Reinstein, J.A. 24
Remuzat, C. 41
renaming, of patented drugs 72
reputation, of pharmaceutical industry 154–65
Respect (TARES Test) 163–4, 165, **165**
Reuters 10
Richman, J. 120
ritonavir 73
Rizzo, J.A. 74
Robinson, R. 71
Roche 104, **145,** 158
Rockoff, J.D. 10
Rodale 106, 117
Rodriguez, D. 6, 8
Rosenthal, B. 81
Ross, J. 17
RSS feeds 121
Rubin, J. 68–9
Russia 17, 18, 36; as an emerging market 139, 140, 142–3; OTC (over-the-counter) medicines 142, 148 *see also* BRIC (Brazil, Russia, India, and China) countries
Rx&D 133

Saboo, A. 5, 144, **145**
Saffer, H. 106
sales representatives *see* professional sales representative (PSR)
sampling, to physicians 84–5, 89
sanctions, in voluntary codes of conduct 132, 135
Sanofi-Aventis 58, 142, **145**
SARAFEM 72
satisfaction, with health care 38
Scandinavia, health care system 34, **35**
Scherer, F.M. 6
Schering Plough, merger with Merck 147
Schmukler, M. 94
Schreyögg, J. 41
Schroff, K. 65
Schuiling, I. 68
Schweizer, L. 3
self-assessment, by patients 22–3
self-care 22, 24, 27
self-medication 24, 25
self-regulation, of pharmaceutical industry 128–9, 135; effectiveness of 132–3, 135; industry transparency and Sunshine laws 134–5; and non-governmental activist organizations 134; voluntary codes of conduct 129, **130–1,** 131–2, 135
Shaw, C.A. 160
Sheehan, K.B. 118–19
Shepherd, M.D. 147
Sheppard, A. 5
Sheth, J.N. 138
Shilling, C. 58
Shinghal, M. 5
Siddiqui, U.T. 89
side effects 84, 87

Silverman, E. 158, 162–3
single payer health care systems 33, **33**
Sloan, E. 147
Smith, M.C. 15
social media 18–19, 116; Food and Drug Administration (FDA) guidelines 94, 97, 120; use by patients 16, 119–22; use by physicians 16, 97–8, **98**
Social Media Engagement Index (IMS) 121, 123
Social Responsibility (TARES Test) 163–4, 165, **165**
social/demographic factors in health care 17–19
somatization 23
South Asia 24–5
Spain 98, 121–2, 133
Spigarelli, F. 141
spin-offs 10, 12
sponsorship: of clinical trial publications 87–8; of continuing medical education (CME) 87
Spurling, G.K. 83, 86, 87
Srivastava, R.K. 7–8
'stakeholder marketing' 139
stakeholders, in health care 15, 21–7 *see also* patients; pharmacists; physicians
Stargardt, T. 41
Staton, T. 16, 94
Steinman, M.A. 82–3, 87, 89
Stevenson, W.B. 158–9
Stop Corporate Inversions Act, US 11
strategic alliances 9, 12
Stremersch, S. 83, 84, 85
Sunshine laws 88, 94, 128, 134–5
'super-generics' 5
'superbugs' (antibiotic resistant pathogens) 18
Sweden 34, **35,** 117, 133
Switzerland, health care system **35**

tablets (computers) 82, 93, 95
Takeda 142
TARES (Truthfulness, Authenticity, Respect, Equity, and Social Responsibility) Test 163–4, **164–5,** 165
tax inversions, and M&As (mergers and acquisitions) 10–11
Taylor, N.P. 123
TCM (traditional Chinese medicine) 148
technological factors in health care 16–17
Teva Pharmaceuticals 72, 142
Thailand, alternative therapies 18
therapeutic area portfolio branding *see* franchise branding
therapy franchise groups 70
third-party payers 31, 32 *see also* insurance companies
Thomson, S. 38
Tisman, A. 148–9
Tomljenovic, L. 160
Toop, L. 107
Toumi, M. 41
Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement 1995), WTO 19, 27, 138, 140
traditional Chinese medicine (TCM) 148
training 157; of brand managers 56; compliance training 162; of sales representatives 59, 61; values training 163
transfer pricing 38–9
Transparency International 154
transparency, in the pharmaceutical industry 134–5
Trullen, J. 158–9
Truthfulness (TARES Test) 163–4, **164,** 165
Turner, E.H. 88
Twitter 94, 98, 119, 120, 121, 124, 125
two-tier health care systems 33, **33**

UK 18, 24, 38, 117, 133, 155, 159; and DTCA (direct to consumer advertising) 110; health care system 34, **35**; physician consultations 23–4; social media use 98, 121–2
Unit for Supervising Ethical Practices/USD (Farmindustria) 133
United Nations Report on World Population Aging 17
universal health care systems 31
Urban Employee Basic Medical Insurance (UEBMI), China 36
Urban Resident Basic Medical Insurance (URBMI), China 36
US 17, 24, 25, 38, 149, 155, 159, 161; health care system 31, **35,** 37; self-regulation 133; social media use 18; Sunshine laws 88, 94, 128, 134–5

Valeant Pharmaceuticals, takeover attempt of Allergan 10–11
value added branding strategy 73, 156
values training 163
Van Arnum, P. 139–40, 142
Van Bruggen, G.H. 61
Van den Engh, M. 109
Velo, G. 110
Veloutsou, C.A. 54
Venderbyl, S. 3
Venkataraman, S. 83, 84, 85
Vernaz, N. 73
Vernon, J.M. 72
videoconferencing 94
Vine 124

Vlassov, V.V. 86
voluntary codes of conduct 129, **130–1,** 131–2, 135

Walker, L. 87
Wartenberg, F. 59
Waterman, T. 155
WebMD 120
Wei, H. 141
Wertheimer, A.I. 22
Whalen, J. 58
Whelan, E. 34
WHO, Ethical Criteria for Medicinal Drug Promotion 131–2
Wikipedia 117
Witty, Andrew 9
women, and physician consultations 23–4
Wong-Reiger, D. 107, 109
World Demographics Profile 17
Wyeth, Pfizer-Wyeth M&A 7–8, 149

Yeh, L. 148
Yi, P.H. 158
You, J.H. 24–5
YouTube 119, 121, 124, 125

Zarbees 120
Zeckhauser, R. 74
Zetterqvist, A.V. 133
Zipkin, D.A. 89