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978-0-521-68866-6 - Understanding Physician-Pharmaceutical Industry Interactions

Shaili Jain

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Understanding Physician–Pharmaceutical Industry Interactions

Physician–pharmaceutical industry interactions continue to generate heated debate in academic and public domains, both in the United States and abroad. Despite this, recent research suggests that physicians and physicians-in-training remain ignorant of the core issues and are ill-prepared to understand pharmaceutical industry promotion. Furthermore, few medical curricula cover this issue, despite warnings of the imperative need to address this gap in the education of tomorrow’s physicians. There is a vast medical literature on this topic, but no single, concise resource. This book aims to fill that gap by providing a resource that explains the essential elements of this subject. The text makes the reader more aware of the key ethical issues and allows the reader to be a more savvy interpreter of industry promotion, have a heightened awareness of the public and medical legal consequences of some physician–pharmaceutical industry interactions and be better equipped to handle real-life encounters with industry.

Shaili Jain, MD, attended Liverpool Medical School in England and completed her postgraduate training in the United States. She currently works as a General Adult Psychiatrist with Aurora Behavioral Health Services and is also Clinical Assistant Professor of Psychiatry at the Medical College of Wisconsin in Milwaukee.

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Foreword

Understanding Physician–Pharmaceutical Industry Interactions is a long-overdue book summarizing deliberations that have spanned many years. I am a PGY (postgraduate year) 51; Dr. Shaili Jain is a PGY 8. Although two generations apart, we are in complete agreement with the need for coalesced thinking about the conflicts of self-interest in the relationship between the pharmaceutical industry and the profession of medicine. Dr. Jain is to be complimented for undertaking this subject that has undoubtedly caused her consternation as a young physician.

This topic is very important for all health professionals who prescribe medicines or medical devices. Health care now consumes \$2 trillion annually and is approaching 17% of the gross national product. And, as the costs continue to escalate, individuals, families, industry, and businesses and municipal, county, state and federal governments falter economically. Prescribing medical professionals, who are responsible for at least 75% of the annual cost of health care, unfortunately are often unaware of the cost of the drugs, tests, services and supplies they prescribe. The patients, except for their co-payments, are uninterested because of the confusion and complexities of billing, and, after all, a third party is responsible for

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payment. To curtail the rising cost of health care, everyone *must* become cost conscious. No other service or product is purchased so blindly.

Business ethics are different from medical ethics. In the business climate it is common for industry to reward and entice their vendors in order to stimulate sales. The pharmaceutical industry has a similar culture, and at its interface and overlap with the medical profession, what the pharmaceutical industry formally considers normal business behavior, the medical profession considers unethical. It is estimated that the pharmaceutical industry spends \$14 billion per annum in marketing. According to statistics, there is one pharmaceutical representative for every nine physicians. It is a huge force. This, coupled with direct-to-consumer advertising, in which the bottom line is always “ask your doctor if this medicine is good for you,” places the prescriber under increasing pressure. Medical ethics prompt physicians to consider that if current promotional activities such as inviting physicians to expensive dinners, parties, trips, entertainment and even office lunches as well as direct-to-consumer advertising were eliminated, the money saved could be used to lower the cost of drugs to the benefit of our patients. *Understanding Physician–Pharmaceutical Industry Interactions* outlines current thinking and guidelines for accomplishing that goal.

When I studied pharmacology in medical school, it was stressed that physicians should familiarize themselves with selected drugs, learn to understand them well and prescribe as few medicines as expeditiously as possible. Based on experience, we were taught to continue to use those medicines that were therapeutically effective, had a wide margin of safety and were least expensive among their class. These principles hold true today.

The American Medical Association was founded in 1847 for the purpose of developing a code of medical ethics to promote professionalism. Today the AMA’s Council on Ethical and Judicial Affairs (CEJA) is responsible for the AMA’s *Code of Medical Ethics*, a volume updated and published biannually. The current Code includes

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approximately 180 Opinions (www.ama-assn.org/go/ceja). All Opinions relate to the nine time-honored Principles of Medical Ethics. Opinion 8.061, entitled “Gifts to Physicians from Industry” and adopted by the AMA’s House of Delegates in 1990, offers guidelines regarding gifts from the pharmaceutical industry to physicians. Gifts should not be of substantial value, should relate to the physician’s work, should be educational and scholarly and should not involve direct or indirect exchange of currency.

In 1999, a task force entitled the Working Group for Communication of Ethical Guidelines on Gifts to Physicians from Industry was convened. The following organizations were represented: Accreditation Council for Continuing Medical Education; Adva Med, Inc.; Alliance for Continuing Medical Education; American Academy of Family Practice; American Academy of Pediatrics; American College of Obstetricians and Gynecologists; American College of Physicians; American College of Surgeons; American Medical Association; American Medical Association Industry Roundtable Steering Committee; American Osteopathic Association; American Psychiatric Association; American Society of Anesthesiology; AstraZeneca International; Bayer Corporation; Coalition for Healthcare Communication; Council of Medical Specialty Societies; Eli Lilly and Company; GlaxoSmithKline; Merck & Company, Inc.; National Medical Association; Pfizer, Inc.; Pharmaceutical Research and Manufacturers of America; Pharmacia Corporation; Physicians World/Thompson Healthcare; Procter & Gamble Pharmaceuticals; Society for Academic Continuing Medical Education; United States Department of Veterans Affairs and Wyeth-Ayerst Laboratories. After review and meeting for approximately three years, it was agreed and promulgated that CEJA Opinion 8.061 entitled “Gifts to Physicians from Industry” was an acceptable guideline to which all parties would adhere.

In my library I have a copy of William Osler’s volume *Aequanimitas with Other Addresses*, which was a gift to all medical school graduates in 1932 from Eli Lilly and Company and includes a

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letter inscribed by Mr. Eli Lilly, the company president, that reads as follows:

May 1932

Dear Doctor,

Together with congratulations on your attainment of a medical degree, this volume of addresses by Sir William Osler, who adorned your profession in the United States for so many years, is cordially presented.

As the addresses by this master mind of modern medicine are read, may you catch his vision of the almost boundless possibilities of your profession.

May you share with him his "relish of knowledge" and his absorbing love and passionate search for truth.

Above all, may there come to you an inspiration which will enable you to live a rich, a happy and an abundant life.

Sincerely yours,

Eli Lilly and Company

Eli Lilly

President

I consider a gift of this nature to be a thoughtful expression. It is an inexpensive gift, but a valuable and useful reference for a physician's lifetime and beyond.

The achievements in medicine during the 20th century were spectacular. Life expectancy in the United States has nearly doubled in 100 years. In the past 50 years, we have seen the conquest of poliomyelitis and the transplantation of organs, among so many other achievements. Society benefits from brilliant minds in basic science, medicine and pharmacology working collaboratively. It is

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said of the late Dr. Maurice R. Hilleman that he saved many lives with the development of 40 vaccines that have eliminated or significantly reduced the occurrence of many communicable diseases. Dr. Hilleman, who had a PhD degree, worked most of his professional life for Merck & Co.

In order to continue to advance along the road of discovery, the pharmaceutical industry and the medical profession must work in synergy. The relationship must be completely devoid of conflict of self-interest and greed. And the relationship between the prescriber of medicines and the pharmaceutical manufacturers (and their representatives) must not be self-serving for either. It is all about the patient and the betterment of society.

I think every young physician should have the opportunity to tour a pharmaceutical manufacturing company and marvel at and better appreciate the elaborateness and complexities of the drug production process. Bridging the chasm within the framework of science, ethics, service and professionalism will encourage mutual appreciation and respect.

This book, written by a young psychiatrist, brings it all into focus.

It should serve to strengthen the importance of collaboration within the boundaries of ethics and professionalism. Upholding ethics and professionalism will, and should, solidify the matrix of the healing occupations.

Leonard J. Morse, MD
Commissioner of Public Health, City of Worcester,
Massachusetts, USA

Professor of Clinical Medicine,
Family Medicine and Community Health,
University of Massachusetts Medical School.

Past member and Chair, Council on Ethical and Judicial Affairs,
American Medical Association
September 8, 2006

Introduction

Why Write a Book about Physician–Pharmaceutical Industry Interactions (PPIIs)?¹

These interactions have consequences for patients, doctors and the larger society [1]. These interactions are frequent and involve more than just a face-to-face visit with a pharmaceutical company representative (PCR). Moynihan referred to these interactions as “entanglements,” and examples are listed in Figure 0.1. The budgets of the pharmaceutical industry (PI)² support many of the PPIIs, such as paying PCR salaries, providing free gifts for physicians and subsidizing funding for continuing medical education (CME). The marketing expenditure of the U.S. drug industry reached \$15.7 billion in 2000 [2] with nearly one PCR and almost \$100,000 for every eleven practicing physicians in the United States [3]. With the number of new medications coming onto the market only increasing, physicians are finding it hard to keep up to date, and many find that utilizing

¹ This term was first used in the literature by Watkins RS, Kimberly J. *Acad Med* 2004; 79:432–7

² The term *pharmaceutical industry* is interchangeable with *pharmaceutical equipment manufacturers*.

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industry-supplied sources of information can be a convenient and easy way of staying current in their daily practice. As government funds diminish in academic settings and industry investment increases, this subject is likely to remain an important issue for the medical profession to study and understand [2].

Who Should Read This Book?

This book should be read by any physician or medical trainee who has engaged in any of the interactions outlined in Figure 0.1, as well

Forms of Entanglement
<input type="checkbox"/> Face-to-face visits from drug company representatives
<input type="checkbox"/> Acceptance of direct gifts of equipment, travel or accommodation
<input type="checkbox"/> Acceptance of indirect gifts, through sponsorship of software or travel
<input type="checkbox"/> Attendance at sponsored dinners and social or recreational events
<input type="checkbox"/> Attendance at sponsored educational events, continuing medical education, workshops or seminars
<input type="checkbox"/> Attendance at sponsored scientific conferences
<input type="checkbox"/> Ownership of stock or equity holdings
<input type="checkbox"/> Conducting sponsored research
<input type="checkbox"/> Company funding for medical schools, academic chairs, or lecture halls
<input type="checkbox"/> Membership in sponsored professional societies and associations
<input type="checkbox"/> Advising a sponsored disease foundation or patients' group
<input type="checkbox"/> Involvement with or use of sponsored clinical guidelines
<input type="checkbox"/> Undertaking paid consultancy work for companies
<input type="checkbox"/> Membership of company advisory boards of "thought leaders" or "speakers' bureaus"
<input type="checkbox"/> Authoring "ghostwritten" scientific articles
<input type="checkbox"/> Reading medical journals that rely on drug company advertising, company-purchased reprints and sponsored supplements

Figure 0.1

Table taken from "Who pays for the pizza?" Redefining the relationships between doctors and drug companies 1: Entanglement *BMJ* 2003; 326:31. Reprinted with the permission of BMJ Publishing Company.

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as by other health care professionals such as nurses, nurse prescribers, physician assistants and pharmacists who have such interactions with the PI and a significant influence on patient perceptions of prescription medications.

Why Should I Read This Book?

PPIIs on an individual basis are frequent; they begin in medical school and persist through a physician's career.

Outside of one-on-one interactions, the relationship of industry with the medical establishment is extensive: funding of research trials, subsidizing CME and advertisements in major medical journals.

There is considerable empirical data proving that physician judgment and prescribing is compromised and negatively influenced if these physicians are recipients of gifts from the pharmaceutical industry.

This data as well as increasing public scrutiny of these interactions has prompted many medical societies and professional organizations to offer position statements and policies on these issues.

Despite all this, most physicians at various levels of training remain unaware of the data or the policies and uninformed on how to conduct ethical relationships with the PI and PCRs.

The debate about PPIIs is not only a professional debate but also a public one, with much media scrutiny and legal consequences of problematic PPIIs.

This book aims to heighten the reader's awareness about PPIIs, the nature of these interactions and their advantages and disadvantages in a variety of medical settings. The hope is that this will increase the reader's "promotional literacy": that it will fine-tune the reader's ability to separate true science from sophisticated promotion and thus to better serve our patients.

Clinical vignettes revolving around four fictional characters support the material in these chapters. Brenda Balant is a PCR for the company Brown Pharmaceuticals, promoting the new antihypertensive drug Lowpress. Jack Jones is a senior internal medicine

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resident with aspirations to become a cardiologist. Bob Brunswick is a PCR for the company MedCorp and is promoting the new antidepressant Vivre. Jane Jansen is a family practice resident with a special interest in psychiatry.

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