ENCYCLOPEDIA OF
BIOETHICS

3RD EDITION

EDITED BY
STEPHEN G. POST

VOLUME
I
A - C

MACMILLAN
REFERENCE
USA™

THOMSON
GALE

New York • Detroit • San Diego • San Francisco • Cleveland • New Haven, Conn. • Waterville, Maine • London • Munich

Encyclopedia of Bioethics, 3rd edition

Stephen G. Post

Editor in Chief

For more information, contact
Macmillan Reference USA
300 Park Avenue South, 9th Floor
New York, NY 10010
Or you can visit our Internet site at
http://www.gale.com

Library of Congress Cataloging-in-Publication Data

Encyclopedia of bioethics / Stephen G. Post, editor in chief.— 3rd ed.
p. cm.
Includes bibliographical references and index.
ISBN 0-02-865774-8 (set : hardcover : alk. paper) — ISBN 0-02-865775-6 (vol. 1) — ISBN 0-02-865776-4 (vol. 2) — ISBN 0-02-865777-2 (vol. 3) — ISBN 0-02-865778-0 (vol. 4) — ISBN 0-02-865779-9 (vol. 5)
1. Bioethics—Encyclopedias. 2. Medical ethics—Encyclopedias. I. Post, Stephen Garrard, 1951-
QH332.E52 2003
174'.957'03—dc22

2003015694

This title is also available as an e-book.
ISBN 0-02-865916-3 (set)
Contact your Gale sales representative for ordering information.

Printed in the United States of America
10 9 8 7 6 5 4 3 2 1

Front cover photos (from left to right): Custom Medical Stock; Photo Researchers; Photodisc; Photodisc; AP/Worldwide Photos.

immunization, benefit from the immunization program, the costs of the immunization program should be born by the public. The full series of childhood immunizations costs more than $500 and is not always covered by insurance. Charging individuals the cost of vaccines has a negative effect on immunization rates by offering a financial disincentive to vaccinate. At the same time, it allows "free riders" to avoid the financial costs of a program that benefits them. For those reasons, a strong argument can be made to fund immunization programs for all citizens through a tax-based system into which all citizens contribute (Diekema and Marcuse).

Public health interventions benefit all citizens. The harm principle justifies restrictions on individual liberty when individual decisions or actions put others at risk, when harm can be prevented by restricting individual liberty, and when no less restrictive alternative would be equally effective at preventing the harm. Justice requires that the burdens and benefits of public health intervention be shared equally across the population.

DOUGLAS S. DIEKEMA

SEE ALSO: *Abuse, Interpersonal; Autonomy; Beneficence; Blood Transfusion; Children; Healthcare Resources, Allocation of; Health Screening and Testing in the Public Health Context; Infants; Informed Consent*

BIBLIOGRAPHY

Anderson, Roy, and May, Robert. 1982. "The Logic of Vaccination." *New Scientist* 96(1332): 410–415.

Diekema, Douglas S., and Marcuse, Edgar K. 1998. "Ethical Issues in the Vaccination of Children." In *Primum non nocere Today,* 2nd edition, ed. G. Roberto Burgio and John D. Lantos. Amsterdam: Elsevier.

Dover, Thomas E. 1979. "An Evaluation of Immunization Regulations in Light of Religious Objections and the Developing Right of Privacy." *University of Dayton Law Review* 4(2): 401–424.

Feinberg, Joel. 1986. *Harm to Self: The Moral Limits of the Criminal Law.* New York: Oxford University Press.

Gelfand, Henry M. 1977. "Vaccination: An Acceptable Risk?" *Science* 195(4280): 728–29.

Mill, John Stuart. 1956. *On Liberty.* Indianapolis: Bobbs-Merrill.

Noah, Norman D. 1987. "Immunisation Before School Entry: Should There Be a Law?" *British Medical Journal* 294: 1270–1271.

Rogers, Anne; Pilgrim, David; Gust, Ian D.; et al. 1995. "The Pros and Cons of Immunisation." *Health Care Analysis* 3: 99–115.

Ross, Lainie Friedman, and Aspinwall, Timothy J. 1997. "Religious Exemptions to the Immunization Statutes: Balancing Public Health and Religious Freedom." *Journal of Law, Medicine & Ethics* 25: 202–209.

Veatch, Robert M. 1987. "The Ethics of Promoting Herd Immunity." *Family & Community Health* 10(1): 44–53.

Wilson, Christopher B., and Marcuse, Edgar K. 2001. "Vaccine Safety—Vaccine Benefits: Science and the Public's Perception." *Nature Reviews Immunology* 1: 160–165.

Wing, Kenneth R. 1990. *The Law and the Public's Health.* Ann Arbor, MI: Health Administration Press.

PHARMACEUTICAL INDUSTRY

• • •

In the public media and in discussions of healthcare ethics significant questions have been raised about some of the practices of the pharmaceutical industry in the early years of the twenty-first century. The increase in expenditures for medications in the United States appears to be one of the reasons for this attention. The expansion of direct-to-consumer advertising of prescription drugs, particularly on television, and the manner in which industry sales representatives relate to physicians are among the other factors that have focused attention on the industry.

Pharmaceutical companies are in the healthcare business. It therefore is not surprising that much of the interest in the ethics of the industry relates to the potential impact of company practices on the quality and cost of healthcare, access to healthcare, and the integrity of healthcare professionals. This entry discusses some of the major and recurring issues in studies of and commentaries on ethics and the pharmaceutical industry.

Relationships between Industry Representatives and Healthcare Professionals

Representatives of the pharmaceutical industry relate to healthcare professionals in a variety of ways, including personal visits with physicians, exhibits at professional meetings, industry-sponsored education on products, financial support for nonindustry educational programs, and employment of professionals as consultants. The general ethical concerns related to these relationships are whether the

interactions are in the best interests of patients and the way the relationships should be managed or structured to prevent a negative impact on healthcare.

It has long been recognized in business ethics that when gifts are given by vendors or suppliers to purchasers, there is a serious risk of undermining the objectivity of the purchasers. Most corporate codes of ethics limit the kinds of gifts that may be offered and accepted to those of minimal or nominal value. Although physicians may not be purchasers as that term sometimes is understood, their decisions are directly related to the purchase of pharmaceutical products. As could be expected, therefore, the issue of gift giving has received particular attention in the context of efforts to prevent or limit inappropriate industry influence on healthcare professionals.

Studies consistently report that the acceptance of gifts or samples from pharmaceutical representatives is associated with the rapid prescription of a new drug, the prescription of fewer generic drugs, the use of more newer medications, and formulary requests for medications (Wazana). Although some healthcare professionals state that gifts and personal relationships do not influence their professional judgment about what is best for patients, research raises serious doubt about the validity of that assertion.

The responsibility to avoid practices that result in unnecessary conflicts of interest rests with both the industry and healthcare professionals. Professional healthcare providers have a responsibility to prevent other interests from compromising their ability to exercise independent objective judgment in their work, in other words, a responsibility to subordinate other interests to their commitment to provide good medical care. A pharmaceutical company, as a healthcare business, has a responsibility to interact with physicians and other healthcare professionals only in ways that do not lead to harm of patients or undermine the professionalism of medical practice.

By 2002 healthcare professionals, healthcare organizations, the pharmaceutical industry, and the federal government had begun major efforts to reform the interactions of company representatives with physicians in response to the concerns that have been identified here. Many hospitals developed policies clarifying and restricting the activities of industry representatives while on the hospital campus. The American Medical Association (AMA) undertook a major initiative to communicate its ethical guidelines on gifts to physicians, and the Ethics and Human Rights Committee of the American College of Physicians, and the American Society of Internal Medicine issued a position paper titled "Physician-Industry Relations" (Coyle). The industry trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), published its voluntary "Code on Interactions with Healthcare Professionals" (Pharmaceutical Research and Manufacturers of America). The U.S. Department of Health and Human Services (2002) drafted standards for pharmaceutical companies, the first of this kind, for marketing products to healthcare professionals.

Although there were differences among these efforts, they all were designed to limit abuses without prohibiting all interaction between the industry and healthcare professionals. There is a widespread belief that continued interactions are valuable and benefit patients, especially through the information that is provided to healthcare professionals by the industry about new products and the risks and benefits of these products. It remains to be seen whether these reforms will prevent undue industry influence on doctors' prescribing behavior.

It also remains to be seen whether a system that permits drug companies to function as a significant source of physician education despite the fact that those companies have an organizational self-interest in selling their drugs (especially their most profitable drugs) will continue to be accepted as reasonable and ethically supportable. For many observers it is irresponsible to expect unbiased information about their own products from drug companies. Although pharmaceutical companies have an interest in promoting good healthcare, their marketing practices are designed to sell their products.

Industry Sponsorship of Research

Another issue that has received significant attention in healthcare ethics is sponsorship of medical research by the pharmaceutical industry. As in the issue of the relationship between doctors and the pharmaceutical industry, the concern is whether the nature of the relationship undermines professionalism and scientific objectivity, a concern expressed most frequently about clinical trials. The way a trial is designed and/or the relationship of the clinical researcher to the sponsor may result in research that is neither good science nor in the public interest.

Much attention has been paid to financial conflicts of interest that result from the relationship of investigators to the companies that manufacture the medication and/or sponsor their research. When investigators are paid consultants to or regularly receive speaker honoraria from a company, when they have significant personal funds invested in company stock, or when the research compensation arrangement is such that they personally benefit significantly, their scientific and professional objectivity and independence may be compromised. In these situations there is an incentive to avoid reporting findings that make it less likely that

the company will do well selling the product or continue to hire the investigator.

Ethical reflection on conflicts of interest has indicated that in most instances actual conflicts of interest are unrecognized and/or unintentional. That is, professionals do not choose deliberately to go against their primary responsibility. Instead, the nature of the context inclines one to other interests, often without conscious awareness. Most efforts to prevent or mitigate the potential negative effects of conflicts of interest therefore go beyond appeals to individual ethical integrity. Policies, procedures, and other safeguards have to be put in place.

One response to the growing concern about the financial interest of investigators was a decision made by several major medical journals in 2001 to revise and strengthen their policies regarding financial disclosure by authors. Authors are required to disclose the sponsorship of their studies and any relevant financial associations. Editors can use that information in making decisions about publication and to inform readers of potential bias if an article is published.

Another response to concern about conflicts of interest was a task force report approved in 2001 by the Executive Council of the Association of American Medical Colleges (AAMC). The AAMC Taskforce on Financial Conflicts of Interest in Clinical Research developed guidelines for medical school policies on financial conflicts of interest. In addition to requirements for reporting and monitoring, the task force recommended that institutional policies assume that an individual who has a significant financial interest in a study involving human subjects should not do that research. This assumption may be overcome in individual cases, but the researcher should have to persuade an institutional committee that his or her involvement is in the best interests of the subjects.

Although most of the emphasis has been on the responsibility of investigators to avoid conflicts of interest, there is a concomitant responsibility on the part of companies that sponsor research to avoid such conflicts. Companies have a responsibility to ensure that trials assessing the safety and efficacy of their medications are scientifically sound. They can do this by adopting policies and practices designed to prevent obstacles to the independence and objectivity of investigators. In addition to avoiding conflicts of interest for the investigators, companies need to avoid the other reported threats to scientific independence, such as industry control over or delay of publication of study results. The ethical burden of doing good research falls on both the sponsors and the clinical investigators.

Direct-to-Consumer Advertising of Prescription Drugs

At the beginning of the twenty-first century the only countries that permitted direct-to-consumer (DTC) advertising of prescription drugs were the United States and New Zealand. In 1997 the U.S. Food and Drug Administration (FDA) adopted more permissive rules on mass media advertising of prescription drugs, and in the following years DTC advertising increased significantly in the United States. The 1997 regulations permitted advertisements for prescription drugs without detailed medical information on risks and side effects. The question of whether such advertising is ethically and socially responsible is widely debated.

The Institute of Medicine (1998) described problems with healthcare quality as including underuse (failure to provide proven effective medicine), overuse (unnecessary interventions or treatments not indicated by symptoms), and misuse (interventions causing preventable complications). The primary criticism of DTC advertising of prescription drugs is that it may contribute to overuse or misuse because patients demand and sometimes get prescriptions for medications that are not appropriate in their circumstances. This leads to poor-quality care. The unnecessary use of brand-name drugs also leads to unjustified increases in healthcare costs with all the implications for healthcare access that follow from rises in those costs. The primary ethical argument for DTC advertising is that it improves the quality of healthcare because patients, through their informed questions about specific medications, assist physicians in avoiding underuse or misuse. In addition, some argue that it gives patients a much more active role in their healthcare.

Other concerns have been raised about the impact of DTC advertising. One is whether such advertising more commonly contributes to valuable interaction or puts an undue strain on the patient–physician relationship. There is also serious concern about whether specific advertisements educate consumers or mislead them and oversimplify. There is also the question of whether in a culture in which such advertising is common the result will be a heightened expectation that physicians can and should prescribe pills to cure all ills.

One study found that prescription drugs that were advertised heavily accounted for a significant proportion of the increase in pharmaceutical spending in the year studied. The same study found that the number of prescriptions for the most heavily advertised drugs grew at a rate several times higher than that of prescriptions for other drugs (National Institute for Health Care Management). This study did not try to determine whether the public health benefited from or

was harmed by the growth in prescriptions of the heavily advertised drugs. There appears to be evidence that DTC advertising leads to increased use of the drugs advertised in most cases, but it is not clear whether that use is medically appropriate and cost-effective and how the patient–doctor relationship is affected.

The controversy about whether DTC advertising is good for public health and healthcare is related to other questions about the nature of a good healthcare system. Those who advocate a more rigorous evidence-based foundation for decisions about medical treatment are not likely to welcome the influence of popular marketing tactics and techniques or that of patients who expect to get specific brand-name medications. The same thing is true of those who are seeking the most effective allocation of limited healthcare resources. In contrast, those who believe that patients are best served by a consumer-driven model of healthcare are likely to welcome the contribution of advertising to consumer initiative in interactions with professionals.

Many healthcare professionals have not accepted the claim that DTC advertising contributes to improved patient care. Patients who demand a particular brand-name drug are not necessarily better-informed patients. Some advertising does not even indicate the condition or symptoms a medication is designed to address; little if any of it describers the success rate of a drug or the necessary duration of use. Furthermore, there is often no independent evidence that a more expensive brand-name product (the type that typically is advertised) is sufficiently superior to generic medications to justify the use of limited healthcare resources.

The basic question may be whether medicines are enough like other commodities that it is appropriate to advertise them in a similar manner. One major difference is that unlike consumer products, they have to be prescribed by a licensed professional. If the objective of DTC prescription drug advertising is a better-informed public, the informational nature of the marketing will be of central importance. If the objective is to contribute to improvement in the quality of healthcare, the advertising will be designed to prevent misuse and overuse as well as underuse.

Other Issues

Whereas the three issues discussed above have received the most attention in the literature on healthcare ethics, several other questions have been raised about the practices and standards of the pharmaceutical industry. Three additional concerns are noted below as examples of those issues.

MISUSE OF THE PATENT SYSTEM. Pharmaceutical companies have been accused of "gaming the drug patent system." (*New York Times*) The concern here is that drug companies are using questionable methods to extend the life of their most profitable patents. At least some of those methods are legal, taking advantage of existing interpretations of the law. One such method is to sue a generic company for infringing on patents for packaging or dosing schedules. Those suits automatically delay the introduction of the generic version into the marketplace for thirty months even if the suit is frivolous. Extending patent life may prove financially beneficial to the company but may be detrimental to public health by increasing healthcare costs and placing an unnecessary burden on available healthcare resources. The question is whether this is an ethically defensible practice for a health-related business even when it is legal.

PRICING. A related issue concerns pricing. The effort at the beginning of the twenty-first century to extend Medicare benefits to cover prescription drugs was driven in large part by the high cost of prescription drugs for many citizens over age sixty-five. The fact that the same drugs can be purchased in a neighboring country at a much lower price raises the question of whether the price in the United States is unnecessarily high. In addition, because the prices of pharmaceuticals are different for group purchasers from what they are in retail pharmacies, those who must purchase their prescription drugs at a local retail pharmacy pay the highest prices. This is a part of the bigger issue of equitable access to healthcare in the United States, but it also raises a serious question for the pharmaceutical industry: What constitutes fair pricing for prescription medicines?

RESEACH AND DEVELOPMENT. Pharmaceutical companies also have also been challenged in terms of their research and development agenda. There are two parts to this criticism: (1) that many of the drugs being developed are "me-too" medications, or prescription drugs that are slightly different formulations of existing drugs; and (2) that the new medications developed by the (multinational) industry are more likely to be lifestyle drugs for the wealthy world than drugs for serious diseases commonly found in poorer countries. Research programs in pharmaceutical companies on male impotence (Silverstein) and on baldness, for example, may have many more resources put into them than research programs on malaria. Because the industry both is a for-profit industry and accounts for a significant part of international efforts to meet the real healthcare needs of people, what is a responsible agenda for research and development?

Conclusion

A review of some of the ethical concerns about the pharmaceutical industry must focus on criticisms and questions

related to industry practices. This focus does not deny that the industry has made significant contributions to public health through the development and marketing of important medications.

The concept of the stakeholder has come to occupy a central place in reflection on business ethics. Businesses have responsibilities to various stakeholders: all those who are affected significantly by company decisions and practices, including employees, investors, customers, suppliers, and the larger community. Although it is not always possible to satisfy the concerns and legitimate interests of all stakeholders all the time, it is not satisfactory to say that a company has only one key responsibility: to benefit the shareholders. Making the right decisions and keeping priorities straight when there have to be trade-offs in regard to different stakeholders is the hard work of business ethics.

Establishing the right priorities among stakeholder interests depends somewhat on the nature of the industry. Businesses in the healthcare industry, whether for-profit or not-for-profit, have a high-priority responsibility to protect public health and the integrity of the healthcare system. When specific practices of a health-related business appear to be placing the public health at unnecessary risk or to be undermining the public commitment to a good healthcare system, it is reasonable to question the ethical appropriateness of those practices. The variety and seriousness of the questions asked about practices of the pharmaceutical industry appear to indicate that for many people some industry practices mean unnecessarily risks for health and healthcare despite the industry's contributions to healthcare.

LEONARD J. WEBER

SEE ALSO: *Advertising; Commercialism in Scientific Research; Corporate Compliance; Pharmaceutics, Issues in Prescribing*

BIBLIOGRAPHY

Angell, Marcia. 2000a. "Is Academic Medicine for Sale?" *New England Journal of Medicine* 342: 1516–1518.

Angell, Marcia. 2000b. "The Pharmaceutical Industry—To Whom Is It Accountable?" *New England Journal of Medicine* 342: 1902–1904.

Blackett, Tom, and Robins, Rebecca, eds. 2001. *Brand Medicine: The Role of Branding in the Pharmaceutical Industry.* New York: Palgrave.

Bodenheimer, Thomas. 2000. "Uneasy Alliance—Clinical Investigators and the Pharmaceutical Industry." *New England Journal of Medicine* 342: 1539–1544.

Coyle, Susan L. (for the Ethics and Human Rights Committee, American College of Physicians, American Society of Internal Medicine). 2002. "Physician-Industry Relations." *Annals of Internal Medicine* 136: 396–406.

Holmer, Alan F. 2002. "Direct-to-Consumer Advertising—Strengthening Our Health Care System." *New England Journal of Medicine* 346: 526–528.

Institute of Medicine National Roundtable on Healthcare Quality. 1998. "The Urgent Need to Improve Health Care Quality." *Journal of the American Medical Association* 280: 1000–1005.

Kelch, Robert P. 2002. "Maintaining the Public Trust in Clinical Research." *New England Journal of Medicine* 346: 285–287.

New York Times. 2002. "Gaming the Drug Patent System." June 10, editorial, p. A24.

Silverstein, Ken. 1999. "Millions for Viagra, Pennies for Diseases of the Poor." *The Nation,* July 19, pp. 13–19.

U.S. Department of Health and Human Services, Office of Inspector General. 2002. "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers." *Federal Register* 67: 62057–62067.

Wazana, Ashley. 2000. "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *Journal of the American Medical Association* 283: 373–380.

Wolfe, Sidney M. 2002. "Direct-to-Consumer Advertising—Education or Emotion Promotion?" *New England Journal of Medicine* 346: 524–526.

INTERNET RESOURCES

American Medical Association. 1990. "Gifts to Physicians from Industry." Updated 1998. Available from <http://www.ama-assn.org>.

National Institute for Health Care Management. 2001. "Prescription Drugs and Mass Media Advertising, 2001." Available from <http://www.nihcm.org>.

Pharmaceutical Research and Manufacturers of America. 2002. "PhRMA Code on Interactions with Healthcare Professionals." <http://www.phrma.org>.

PHARMACEUTICS, ISSUES IN PRESCRIBING

• • •

During much of the fourth quarter of the twentieth century, discussions of ethics in prescribing tended to focus on the physician–patient relationship, the quality of patient care, and on patient rights. By the turn of the century, another set