



Continuing Education

Ethical business practices

Learning Objectives

Explain how incentive systems and systems for handling critical information promote ethical behavior.

Describe the tools available to manage business ethics.

Describe the components of an ethical work environment and how ethical behavior is fostered among healthcare representatives.

Describe the ethical issues related to interaction with customers.

Explain how the FDA regulates and monitors pharmaceutical advertising.

This final article in a three-part series discusses aspects of ethical business practices. Topics include: business systems that promote ethical behavior, tools for managing ethics, developing an ethical work environment, interaction with customers and the regulation of advertising.

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Managers and executives at pharmaceutical companies should ensure that their companies promote ethical conduct by providing ethical incentive systems and sharing critical information.

Incentive systems. The business with an ethical incentive system rewards its employees in proportion to their contributions to the goals of the business. For example, ethical systems critically review the past performance of candidates for promotion rather than relying on favoritism or irrelevant factors (such as age or length of tenure). They ask questions such as the following about each candidate:

- What has this individual done to improve the fundamentals of the business?
- What has he or she contributed to product, staff or capital development?
- Did this individual create long-term problems for the company while achieving short-term gains?
- Did his or her actions reflect the values and mission of the company?

One expert recommends promoting employees according to how ethically they handle business issues and deal with their staff and managers.

Incentive systems must foster an environment in which employees are encouraged to admit their mis-

takes so they can be dealt with before they escalate into issues that can seriously hurt business. Employees must not be penalized for coming forward and being honest. In addition, executives should not be exempt from the system.

Systems for handling critical information. Critical information systems must ensure that managers, directors and owners have access to all critical information, even uncomfortable facts. Information obtained should be used as a management resource, allowing problems to be addressed constructively before the business loses control of the situation, the media or the law become involved, and repercussions and expenses escalate.

One such system, called the open book management system, provides employees with the company's financial information on a regular and frequent basis. The belief is that with complete information and the proper incentive, employees will behave responsibly. This helps avoid the abuse of power that may occur when only management possesses vital financial information. In addition, this system gives decision-making authority to those whose performance drives the numbers and ties rewards to company, group and individual performance. It teaches employees to act like owners rather than hired hands. It also respects

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About the CMR Institute:

The Certified Medical Representatives Institute is an independent non-profit educational organization established in 1966 to provide a source of professional development and certification for pharmaceutical representatives. The Institute provides an up-to-date, approved continuing education curriculum designed to expand and enhance internal company training and development in a cost-effective manner. The curriculum concentrates on providing a general knowledge base and avoids such areas as selling skills and specific product education.

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Pharmaceutical company compliance program guidelines

Implement written policies and procedures.

Designate a compliance officer and compliance committee.

Develop effective lines of communication.

Conduct effective training and education.

Conduct internal monitoring and auditing of the program.

Enforce standards through well-publicized disciplinary guidelines.

Respond promptly to fraud problems and undertake corrective action.

the autonomy of individuals, enhances employee self-respect and makes deception difficult when companies find it necessary to lay off employees.

Tools for managing business ethics

The following tools assist managers in promoting ethical business behavior.

Codes of ethics and codes of conduct. In general, codes of conduct specify actions, while codes of ethics offer guidelines for making decisions about those actions. Business codes of ethics usually describe the highest values to which a company aspires and specify the ethical rules of operation. Publishing formal codes can verify an organization's commitment to conducting business in an upright and ethical manner. Also, by sensitizing employees to ethical values, codes of ethics and codes of conduct may help avoid ethical dilemmas.

Policies and procedures. Written policies and procedures avoid ambiguity, informing all personnel of desired behaviors and requirements for all aspects of the business. These guidelines may begin with a statement of the values and mission of the company; they should then spell out in detail what is expected of employees and what the company policies are regarding areas such as: standards of business ethics, approval and verification of expenses, incentive programs, development of business plans, contract procedures, company benefits, and community outreach programs.

Ethical audits. An ethical audit assesses a company's structures, policies, procedures and systems and measures them against the principles of maximizing owner value, distributive justice and ordinary decency. It measures the extent to which actual business activities are consistent with the company's defined criteria. The ethical audit not only enables shareholders to evaluate the performance of directors but also allows directors to assess the conduct of the other stakeholders.

Documented methods for addressing ethical dilemmas. Some businesses may have structured forms and methods that can assist individuals and

groups in resolving dilemmas, including formal checklists of steps that should be taken or questions that should be answered as each situation arises. Key questions might include:

- Could the action or decision harm anyone?
- Will the decision be valid over a long period of time?
- Can the decision or action be openly discussed with the CEO or board of directors?
- Is the decision based on the principles and standards valued by the company and consistent with the company's vision?

The ethical work environment

A work environment conducive to appropriate ethical behavior requires three major components:

Commitment to ethical values by management and top executives. Leaders within a company serve as role models and should be honest, candid and timely when communicating with employees. When they make business mistakes, leaders may benefit in the long term from openly admitting this to employees and shareholders. Through their behavior and their written documentation, managers and top executives in the company should make it clear to all employees that they value ethical principles.

Reinforcement of values and discipline. Management should clearly deliver the message that all employees will be held accountable to the company's code of ethics and conduct. Periodically, they may require employees to sign a statement acknowledging their understanding of and commitment to following the code. The consequences of violations should be clearly established and communicated to all employees.

Compliance programs. Compliance programs for pharmaceutical companies must ensure adherence to all important legal and professional guidelines (see sidebar).

Managers at pharmaceutical companies must ensure that their healthcare representatives are trained on and knowledgeable about the products they are promoting, the disease states treated by their products and the status of competitive products. Equally important is training on ethical issues related to presenting products to the physicians and other healthcare providers they call on. Healthcare representatives should be trained to set challenging objectives and compete aggressively to win new customers and maintain established customers without compromising values. In doing so, they must represent products honestly and fairly, making sure that statements are accurate and consistent with labeling. They should respond to customer inquiries with accurate, complete and current information and be prepared to support product claims with data from clinical studies. Physicians and other healthcare providers want honesty and integrity as well as knowledge. They appreciate courteous, respectful, honest and caring healthcare representatives.

Interaction with customers

There are ethical issues related to the ways in which pharmaceutical companies and their healthcare representatives interact with customers as calls are made to current and potential prescribers. Areas of concern include:

Drug samples and related issues. There have been many cases of unethical and illegal uses of samples by both physicians and pharmaceutical company healthcare representatives. These include billing Medicaid for free samples provided by pharmaceutical companies, using samples to treat family members or office staff, and selling deeply discounted drugs to hospitals and other healthcare facilities.

Compliance with the Prescription Drug Marketing Act (PDMA). The PDMA is a law that governs interactions between pharmaceutical company representatives and healthcare providers. Enacted in 1988, it bans the sale, purchase or trade of prescription drug samples and coupons.

Pharmaceutical companies, healthcare representatives and managers must be fully cognizant of the PDMA regulations concerning sample accountability. Healthcare representatives must maintain an accurate record-keeping system, comply with their company's requirements for the transfer of all samples and make certain that they obtain all of the required signatures for each transaction.

Gift-giving practices. Giving physicians expensive personal gifts to win loyalty to brand-name pharmaceutical products is both unethical and illegal. The gifts do not provide benefits for patients and may do harm if the physician is persuaded to prescribe a product that is less effective or safe than a competing product. There has been concern in recent years over extravagant educational seminars, lectures and meetings held by pharmaceutical companies in entertainment venues such as restaurants. The balance between the need to provide these types of activities and the need to conform to guidelines must be carefully considered.

The Washington-based Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals, a voluntary marketing code adopted in 2002, states that physicians may be given inexpensive items associated with their practices, such as notepads and pens with company or product logos. It also stipulates that continuing medical education should be held at appropriate locations and that its primary purpose should be educating participants on scientific topics. District managers are the primary enforcers of this code within their companies and are responsible for ensuring that their healthcare representatives are trained on and comply with the PhRMA code requirements as well as their individual company's standards and practices. DMs will need to coach their representatives as they encounter ethical dilemmas while also seeing that they achieve their sales goals.

Regulation of advertising

The Food and Drug Administration serves as an ethics watchdog over pharmaceutical advertising. The FDA's Federal Food, Drug and Cosmetic Act is the overarching law regulating pharmaceuticals. It has two key provisions regarding pharmaceutical labeling:

- A drug may be deemed misbranded if its labeling is "false or misleading in any particular way."
- The drug's labeling must include "such information in brief summary relating to adverse effects, contraindications and effectiveness."

Advertising of prescription drugs is generally deemed false or misleading if it:

- Misrepresents or falsely reports data.
- Declares or insinuates superiority to a competitor without supportive scientific data.
- Suggests the drug can be used for conditions not approved by the FDA (called "off-label" uses).
- Describes its product's benefits and risks in lan-

Article Summary

- **Managers and executives at pharmaceutical companies should ensure that their companies promote ethical conduct by providing ethical incentive systems and sharing critical information.**
 - The business with an ethical incentive system rewards its employees in proportion to their contributions to the goals of the business.
 - Critical information systems must ensure that managers, directors and owners have access to all critical information, even uncomfortable facts.
- **Tools for managing business ethics include:**
 - Codes of ethics and codes of conduct.
 - Policies and procedures.
 - Ethical audits.
 - Documented methods for addressing ethical dilemmas.
- **A work environment conducive to appropriate ethical behavior requires:**
 - Commitment to ethical values by management and top executives.
 - Reinforcement of values and discipline.
 - Compliance programs.
- **There are ethical issues related to the ways in which pharmaceutical companies and their healthcare representatives interact with customers. Areas of concern include:**
 - Appropriate use of drug samples and related issues.
 - Compliance with the Prescription Drug Marketing Act.
 - Representation of products and gift giving.
- **The FDA regulates and monitors ethical advertising of pharmaceutical products.**
 - Drug labels must include a brief summary of the adverse effects, contraindications and effectiveness and must not be false or misleading.
 - DTC advertising must include a brief summary (or adequate provision), fair balance of information and a major statement of risks.

guage that is difficult for most consumers to understand.

The Division of Drug Marketing, Advertising and Communications (DDMAC) is the FDA division that regulates medical advertising. The fundamental ethical question for every advertisement DDMAC monitors is: Does this advertisement empower the consumer by providing clear, accurate and complete product information, or does it create confusion and the possibility of harm to consumers?

The FDA's regulations for direct-to-consumer pharmaceutical advertising include the following elements:

- Brief summary – the summary states the drug's adverse effects, contraindications, warnings, precautions and indications.
- Fair balance of information – benefits and risks of the drug must be described in equal detail and readability.
- Major statement – broadcast advertisements must include information on the major risks of the drug within the main part of the advertisement itself.

In 1997, the FDA issued a draft guidance (finalized in 1999) permitting pharmaceutical companies to advertise their products on television by product name. In addition, the rule allows pharmaceutical broadcast advertisements (radio and television) to make "adequate provision" of further product labeling information rather than the brief summary required in print advertising. This can be accomplished by providing a toll-free telephone number, a Web site address, a reference to a concurrent print advertisement or access to healthcare professionals.

The next series of articles will focus on the formulary process.