Key Principles Guide

working better, building trust

Healthcare Law Compliance

"As you interact with patients, customers, physicians, and the general public, remember, you are the face of Pfizer. ... And while we live and work in a complicated world, in the end, our ethics will be a source of strength and success. I trust that each of you will accept the personal responsibility to live up to the Pfizer Values ..."

– Hank McKinnell

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Introduction

Introduction

Integrity is a core Pfizer value and the foundation of the way we do business. Compliance with the U.S. healthcare laws and rules that govern our interactions with customers and our communications about our products demonstrates our commitment to integrity. Compliance also builds trust with patients, healthcare professionals, institutional purchasers, and the government.

Using the Guide

The Guide offers an overview of the laws, rules and company policies related to healthcare law compliance. The Guide also provides a common reference for understanding:

- ***How our work environment is regulated***
- ***How healthcare compliance laws apply to our activities***
- ***Which activities may raise potential concerns***
- ***What we must do to comply with the healthcare laws***

Pfizer employees are expected to meet ethical standards as well as legal and regulatory requirements. Unethical conduct violates Pfizer's Values and Leader Behaviors. It is not acceptable under any circumstances.

Compliance not only protects you and Pfizer, it also protects our customers, who are subject to many of the same laws and rules that apply to us.

If you have a question about how a policy applies to you, refer to the relevant Chapter in this Guide or consult with your manager or your team's legal counsel.

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Introduction

Why is the government so concerned about healthcare law compliance? Two reasons: (1) To deter false or unnecessary billing. In this regard, the federal government's share of overall U.S. healthcare dollars is about 48%, of which over 10% covers the cost of prescription medicine; and (2) To promote medically sound care. The healthcare laws help ensure that medical decisions are not inappropriately influenced by financial incentives.

This Guide provides an overview of various healthcare laws, rules and Pfizer policies that are designed to:

- *Protect patients and improve the quality of healthcare services*
- *Protect medical decision-making from undue influence (e.g., improper financial incentives)*
- *Protect federal healthcare programs, non-governmental healthcare programs supported with public monies, and private healthcare programs from the potential for fraud and abuse (the misuse of healthcare funds)*
- *Protect taxpayers by reducing medically unnecessary healthcare costs*

All Pfizer employees, particularly those who interact and communicate with patients, providers, government officials, advocacy groups and the media (among others), are expected to have a basic understanding of the healthcare laws and rules that apply to our business, including:

- *The Federal Anti-kickback Law*
- *The Federal False Claims Act*
- *The Medicaid "Best Price" Law*
- *FDA Laws and Regulations*
- *Federal Privacy Laws*
- *State Anti-kickback, Privacy and Consumer Protection Laws*
- *The PhRMA Code on Interactions with Healthcare Professionals*

Overview of Applicable Laws & Codes

Improper activities can violate several laws and can result in both criminal and civil penalties. Some pharmaceutical companies have paid hundreds of millions of dollars in fines, seen employees criminally prosecuted, and submitted to government oversight of their marketing programs. With the unprecedented growth in government funding of prescription drug benefits, it is virtually guaranteed that investigations and scrutiny of industry practices will increase substantially over the next few years.

"Pharmaceutical manufacturers and their employees and agents should be aware that the anti-kickback statute prohibits in the healthcare industry some practices that are common in other business sectors. In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal healthcare program business."
– April 2003
OIG Pharma Guidance

Anti-kickback Law

OVERVIEW

The federal anti-kickback law provides that anyone who knowingly and willfully pays or receives anything of value to influence the referral of federal healthcare program business can be charged with a felony. As it applies to the pharmaceutical industry, the law prohibits ***payments*** that are intended to induce someone to purchase, prescribe or even endorse or recommend a product that is reimbursed under a federal healthcare program. For example, the law prohibits the following:

- *Providing a gift to a doctor or a pharmacist to influence the selection of our products*
- *Providing a grant to a managed care organization conditioned expressly or implicitly on the purchase of Pfizer products*
- *Purchasing services (e.g., consulting services) from a healthcare provider at a fee significantly above the reasonable, fair market value for such services*

A healthcare provider's decisions about the treatment of his or her patients must not be tainted by motives of personal gain or enrichment. The federal and state anti-kickback laws, also referred to as the "fraud and abuse" laws, seek to protect government healthcare programs and patients from improper influence on healthcare decisions.

Overview of Applicable Laws & Codes

Bear in mind that often the healthcare decision maker (e.g., the provider, provider institution or managed care organization) is not paying for the recommended healthcare products or services. As you probably know, prescription drugs may be paid for through Medicaid, Medicare, other federal and state agencies and programs, private insurers and/or managed care organizations. Not all healthcare providers participate in government programs, ***but Pfizer treats all healthcare customers as if they are subject to the anti-kickback laws.***

In the ***PhRMA Code*** and ***Selected Risk Areas*** sections of this Guide, you will learn more about what constitutes an improper inducement. ***No Pfizer employee may offer a customer an improper inducement to influence prescribing behavior or formulary decisions.***

SAFE HARBORS

"Safe harbors" are government-recognized exceptions to the federal anti-kickback law. Some safe harbors allow certain discounts and the hiring of physicians for bona-fide consulting services. Compliance with the PhRMA Code is not a safe harbor.

The federal anti-kickback law is so broad that, read literally, it could apply to many marketing activities and even to many non-promotional activities. Since the law is so broad, certain ***"safe harbors"*** have been defined by the Inspector General of the Department of Health and Human Services ***(OIG)***. "Safe harbors" are government-recognized guidelines for activities that are deemed to be acceptable. These "safe harbors" permit legitimate marketing and promotional activities, as well as *bona fide* service arrangements with prescribers and other customers.

A number of safe harbors are relevant to our business activities, but three are especially important. The first is the ***"Discount" safe harbor***, which permits Pfizer to discount the price of a product to make it competitive with other products, if the discount is properly reported to the government and complies with other safe harbor requirements. The second is the ***"Managed Care" safe harbor***, which permits the Company to provide a wide array of discounted items or services to certain eligible managed care organizations under specified circumstances. The third is the ***"Personal Services" safe harbor***, which protects legitimate service arrangements (e.g., consulting agreements) with healthcare providers and customers.

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Compliance with this safe harbor requires a written agreement and compensation determined in advance on a fair-market-value basis.

Pfizer's healthcare law ***policies*** help ensure that our business arrangements fall within safe harbors or are otherwise permissible. Should the application of a policy be unclear, discuss the situation with your manager or legal counsel.

The PhRMA Code

OVERVIEW

The PhRMA Code was developed and adopted by the country's leading research-based pharmaceutical and biotechnology companies to govern relationships with physicians and other healthcare professionals.

Key points of the Code may be summarized as follows:

General Interaction. Interaction should focus on providing healthcare professionals with scientific and educational information, and on supporting scientific and medical research and education to maximize patient benefit.

Meals & Entertainment. Informational interactions may not include entertainment (e.g., golf, theater, sporting events, etc.). On occasion, however, it may be appropriate to conduct an informational detail over a modest meal. Such an interaction should occur at a venue conducive to providing scientific or educational information.

"In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirement....The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's knowledge and experience."
– PhRMA Code on Interactions with Healthcare Professionals

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Overview of Applicable Laws & Codes

"Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education."
– PhRMA Code on Interactions with Healthcare Professionals

Continuing Education & CME. Companies may provide support to a medical conference sponsor, but should not underwrite individual attendees' expenses. This means that a company should not pay an individual's tuition, but could provide tuition support to the event sponsor. That sponsor could reduce the registration fee for all attendees or provide stipends to make it possible for individuals to participate.

Consultants. Legitimate consulting or advisory arrangements are appropriate, but token consulting arrangements should not be used to justify payments to healthcare professionals. Characteristics of legitimate consulting arrangements include a documented need for services, retaining professionals to provide those services based on their expertise (not as a reward or improper inducement for prescribing), retaining no more consultants than needed for the specific business purpose, and obtaining a deliverable from the consulting work that is used by the business.

EDUCATIONAL AND HEALTHCARE PRACTICE-RELATED ITEMS ("PREMIUMS")

Educational and healthcare practice-related items may be provided occasionally to healthcare professionals. Such items should be for the healthcare benefit of patients and not of substantial value ($100 or less). Items for the personal benefit of the healthcare professional must not be offered or distributed. In short, nothing should be offered or provided that could interfere – or could be seen as interfering – with the independence of the healthcare professional's prescribing practices. Any gift to a physician that does not meet these criteria could constitute an improper inducement.

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THE LINK BETWEEN THE PHRMA CODE & THE ANTI-KICK-BACK LAWS

Both the PhRMA Code and the anti-kickback laws are intended to protect patients from the undue influence of money on quality healthcare decisions. The PhRMA Code builds on the anti-kick-back laws by focusing on specific relationships between industry and physicians and other healthcare professionals (and not on government healthcare programs). While compliance with the PhRMA Code does not technically provide immunity from prosecution, actions taken in compliance with the Code are, in general, appropriate. Pfizer has endorsed the PhRMA Code and it is embedded in our policies.

False Claims and Best Price

OVERVIEW

The federal government, through its healthcare programs, is a large purchaser and reimburser of prescription drug products. The Medicaid and Medicare programs cover prescription drug purchases in different contexts. In the case of ***Medicaid***, the government reimburses patient purchases of prescription medicines, which usually means that the government pays the pharmacy that fills the prescription. Historically, the ***Medicare program*** typically has reimbursed doctors and institutions for prescription drug products that are dispensed in doctors' offices or institutional settings. ***Beginning in January 2006, the Medicare program will include an outpatient prescription drug benefit as well.***

Generally, Medicaid covers medical care for the needy, including outpatient drugs. Medicare historically has covered medical care for the elderly, and primarily inpatient drugs.

MEDICAID BEST PRICE

Federal law states that the Medicaid program is entitled to quarterly rebates based usually on the lowest price that a pharmaceutical company offers on a product to any customer (subject to certain exceptions for federal customers and certain other customers serving special populations). This is generally described as our "best price" for the product. There are other laws that govern

The Medicaid Drug laws seek to ensure that state Medicaid agencies receive the best price available to other customers.

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prices paid by other federal agencies (e.g., the ***Department of Veterans' Affairs***). Pfizer is responsible for calculating and reporting to the government our ***"best price"*** for each of our products on a quarterly basis.

When Pfizer reports a ***"best price"*** it must take the following into consideration:

- ***All discounts***
- ***Free goods that are contingent on any purchase requirement***
- ***Volume discounts and rebates (not included in the Medicaid rebate program itself)***
- ***Non-price concessions that are offered in connection with a sale***

"Given the importance of the Medicaid Rebate Program... manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs. In sum, pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes."
–April 2003
OIG Pharma Guidance

Failure to accurately account for discounts or other price concessions could result in inaccurate price reporting. This, in turn, could result in overpayment by the Medicaid program for its purchases of a particular drug. Inaccurate price reporting can result in the imposition of significant penalties and operating restrictions on a pharmaceutical company.

FALSE CLAIMS

While government healthcare programs have different formulas for reimbursing prescription drugs, the federal government demands that we calculate and use sound and accurate ***pricing data*** for reimbursement of prescription drug products.

A number of federal criminal and civil laws prohibit individuals and organizations from submitting false information or false claims for payment to the government or other third party payers (e.g., insurance companies).

For example, if a pharmaceutical company, in submitting pricing information to the government, or even to a third-party price reporting service (e.g., First DataBank or the Red Book), deliberately omits certain product discounts from its price calculations, the company may be violating the ***Federal False Claims Act.***

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The False Claims Act also applies to a ***third party*** who assists someone else in making a false claim to the government. This means that a pharmaceutical company that helps, encourages or causes a customer to make a false claim for reimbursement can also be liable for the customer's false claim. The government has criminally prosecuted pharmaceutical companies for encouraging physicians to bill the government for free samples of prescription drug products supplied by the companies.

The boundaries of prosecutions under the healthcare laws are not fixed. Any improper motive or intention may make an otherwise appropriate program subject to federal or state sanctions. Thus, our policies try to minimize such exposure by ensuring ***compliance with FDA laws and regulations*** as well as the healthcare laws.

FDA Laws

OVERVIEW

FDA's mission is to protect the health and safety of the American people by approving new medicinal products and regulating how they are manufactured, marketed and sold. The FDA thus regulates many facets of our business, from research and development to manufacturing and distribution to sales and marketing; in short, almost everything about our products and what we say about them.

OVERVIEW OF APPLICABLE LAWS & REGULATIONS

FDA regulation of product advertising and promotion directly affects our customer relationships. Therefore, each employee must understand the basic rules we follow to help ensure compliance with FDA law and regulations.

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LABELING

FDA regulates the U.S. labeling of all prescription drug products that Pfizer markets for sale in the United States. The "*labeling*" includes:

- *All information on the drug package/label*
- *The prescribing information (package insert or "PI")*
- *Other written, printed, or graphic materials provided by the manufacturer about the drug*

Any materials we use to promote our products – including all media advertising, brochures, detail aids, promotional programs and third party materials – must be consistent with labeling. In addition, the FDA requires that all promotional materials be:

- *Truthful and not misleading*
- *Presented with a fair balance of benefits and risks*
- *Inclusive of full prescribing information or a brief summary of labeling, depending on the type of promotional material*

Overview of Applicable Laws & Codes

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PROMOTION

The FDA offers guidance on how to meet regulatory obligations in promotion. There are FDA regulations and guidance that address questions such as:

- *When can a pharmaceutical company make a superiority claim or compare products?*
- *How may we advertise directly to consumers?*

In order to help ensure that Pfizer meets the FDA advertising and promotion requirements, we take a multidisciplinary approach to reviewing materials related to all promotional activities. Pfizer has a *Review Committee ("RC")* for each actively marketed product. RCs are comprised of representatives from Marketing, Medical, Regulatory and Legal. Review Committees evaluate and approve all promotional materials prior to use. *Pfizer representatives may only use promotional materials approved by a RC.* Any alteration of approved material – even something as seemingly innocuous as a handwritten note – transforms an approved piece into a "*homemade*" piece that does not comply with FDA regulations or Pfizer policy.

After RC approval, promotional materials must be filed with the FDA prior to their anticipated date of first use.

OFF-LABEL USE

It is important to understand that FDA approves a drug product for use only as described in the approved package insert (e.g., to treat specific diseases or specific patient populations). Any other use is considered "*off-label*". As a general rule, healthcare providers can prescribe products for off-label uses in the exercise of their professional judgment and in accordance with professional standards. However, *pharmaceutical companies may not solicit, encourage, or promote unapproved uses of a product.*

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While manufacturers are not permitted to promote unapproved uses of their products, the FDA recognizes that a company that develops and/or markets a drug is usually one of the best-informed sources of information about the product. Therefore, ***pharmaceutical companies are permitted to provide truthful and non-misleading scientific information about unapproved products or unapproved uses in certain limited circumstances (e.g., in response to unsolicited requests for such information from a healthcare provider).***

As a general rule, when an unsolicited off-label question is posed to a ***Medical*** colleague, a brief and medically accurate response is provided. ***Pfizer employees and anyone retained to speak on behalf of Pfizer cannot proactively offer off-label information in a promotional manner, nor can they solicit questions about off-label uses.***

Many pharmaceutical companies, including Pfizer, distribute reprints of scientific articles that contain information beyond the scope of a product's FDA-approved labeling, but that meet specific standards. Teams may submit reprints of peer-reviewed published articles containing "off-label" information for RC evaluation. ***If approved***, Field Force representatives may distribute such reprints. However, representatives may not discuss these reprints with customers. Requests for information about potential off-label uses of our products must be directed to the ***Global Medical Information Department*** (800-438-1985).

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STARTERS (SAMPLES)

The ***Prescription Drug Marketing Act of 1987 (PDMA)*** prohibits the sale, purchase or trade of drug samples (called "starters" at Pfizer), and the offer to sell, purchase or trade drug samples. It is also illegal for a physician to sell (or seek reimbursement for) a free sample. Individuals who engage in such conduct or encourage such conduct are subject to criminal prosecution.

PDMA requires the maintenance of extensive documentation regarding the distribution of drug samples. These requirements are captured in policies contained in our SOPs and in the ***Starter Administration Compliance Manual.*** In addition, drug samples, particularly samples of more expensive drugs, may be viewed as "remuneration" under the anti-kickback laws. As such, ***they should not be distributed with an intent to benefit the physician or used as a "quid" (i.e., incentive) to induce the purchase or prescription of our products based on anything other than patient need.***

Privacy

OVERVIEW

Both Pfizer and firms working for us (e.g., advertising and promotion agencies and other vendors) collect, process and transmit various types of personal data. We are responsible for ensuring that the data are handled carefully and in compliance with applicable privacy laws and regulations.

Mishandling personal data can expose Pfizer to significant legal liability. If the confidentiality of an individual's personal data is breached, the individual could be exposed to embarrassment, stigmatization, harassment or discrimination in insurance coverage or employment.

Pfizer's Interdivisional Policy on Protection of Personal Data (ID-REG09) provides broad guidance on Company standards for preserving privacy. The policy is posted on the Pfizer Web site at: http://privacy.pfizer.com

Overview of Applicable Laws & Codes

The greater the likelihood that individuals or personal facts about them can be identified from their data, the greater the need for safeguards and special handling. Accordingly, ***it is Pfizer's practice to utilize a third party to receive data and shield it from disclosure. When Pfizer does receive data, it does so in "de-identified" form.***

When the use of ***de-identified*** or ***aggregated*** data is not feasible (e.g., if contact information is being collected from individuals enrolling in a disease management program), each ***individual's consent*** to the collection, use or disclosure of personal data must be obtained and documented. In those instances where obtaining individual consent is not feasible, there must be careful review of the legal basis for the collection and use of such personal data.

PRIVACY LAWS, REGULATIONS AND POLICY

Many federal and state laws and regulations protect personal data. Relevant provisions may be found in:

- ***Medical confidentiality or medical records laws, including HIPAA privacy regulations***
- ***Public health laws***
- ***Laws regulating healthcare products or services***
- ***Laws regulating human experimentation***
- ***Broad personal data protection laws***
- ***Case law***

At the federal level, the Department of Health and Human Services has enacted comprehensive privacy regulations under the ***Health Insurance Portability and Accountability Act of 1996 ("HIPAA")***.

Overview of Applicable Laws & Codes

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HIPAA is part of the growing body of law relating to information privacy, which focuses on two equally important concerns: (i) inappropriate disclosure and (ii) unauthorized use of personal information. The data user must maintain the confidentiality of sensitive or nonpublic information, and use personal information only as authorized by the individual. For example, under HIPAA, health insurers, pharmacies and other healthcare providers may not use their patients' health information to make certain marketing communications on their own behalf or on behalf of third parties, unless they have obtained individualized authorizations that comply with federal standards.

ELEMENTS OF COMPLIANCE WITH PRIVACY RULES

Pfizer's policies on data privacy address the following central elements of compliance:

- ***Ability to identify the individual, directly or indirectly***
- ***Source of data (e.g., patient, healthcare provider, vendor)***
- ***Consent of data subject***
- ***Approval by research ethics boards/committees***
- ***Scope of internal access to, and use of, data***
- ***Transfer and disclosure of data to third parties***
- ***Reuse of data***
- ***Data subject rights***
- ***Security***

Pfizer's privacy policy principles apply to all clinical investigators, contract research organizations (CROs), consultants and other contracted collaborators who gather or handle personal data on Pfizer's behalf. Our contracts and other cooperative arrangements with these individuals and organizations must require compliance with these principles.

More information about privacy can be found in the Protecting Personal Data brochure, which is posted on the Pfizer Web site at: http://privacy.pfizer.com

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State Laws

Many states have laws that apply to marketing and sales practices and to privacy. It is important to be aware of and act in accordance with applicable state laws. For example, ***virtually all states have broad laws prohibiting "unfair" or "deceptive" trade practices***. Some state Attorneys General contend that those laws encompass off-label promotion. Any questions regarding state laws should be directed to your manager or legal counsel.

Healthcare fines involving pharmaceutical companies exceeded $1.6 billion in 2002 and $998 million in 2003. Prosecutors have publicly acknowledged that healthcare law compliance is a "growth area" for them, both in civil and criminal contexts.

Violations and Penalties

Both the Office of Inspector General (***OIG***) of the Department of Health and Human Services and the Department of Justice aggressively enforce the **anti-kickback law** and ***False Claims Act***. Each violation of each law can be criminally prosecuted as a ***felony*** and punished by a fine and/or imprisonment, as well as by imposition of civil monetary penalties. Conviction of a pharmaceutical company under these laws can result in ***exclusion*** of that company from participation in federal healthcare programs for five years, as well as ***imprisonment*** of officers and/or employees responsible for each violation.

FDA laws and regulations are also enforced through both the civil and the criminal justice systems. Failure to adhere to FDA advertising and promotion standards can result in a requirement to run corrective advertising or "pre-clear" future promotional materials. These enforcement tools can result in major business disruptions. Violations of the ***PDMA*** and/or ***FDCA,*** including failure to follow sample management requirements or restrictions of promotion may result in criminal sanctions, including imprisonment.

Overview of Applicable Laws & Codes

Overview of Applicable Laws & Codes

The consequences of violating individuals' privacy rights can include civil liability for damages, legal action by the Federal Trade Commission (or similar state agencies) for unfair trade practices, and/or federal prosecution for HIPAA violations.

Privacy is not the only area where an activity may raise issues under multiple laws. For example, the government could characterize an undisclosed offer of free goods by a manufacturer that is contingent on a separate purchase as:

- ***Improperly inducing customers to purchase products (a kickback)***
- ***Attempting to circumvent Medicaid "best price" price reporting and rebate requirements through failure to report the free goods as a discount***
- ***Causing the submission of false pricing information to the government***
- ***Leading customers to submit false claims for reimbursement***

Penalties are based on each incident. The government could consider the same kickback offered to 1,000 physicians as 1,000 violations of the anti-kickback law. Thus, fines can quickly run into millions of dollars.

Penalties for infractions of healthcare laws, civil or criminal, may be imposed on both the Company and individual employees.

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Selected Risk Areas

"In assessing potential risk areas, ask the following questions…

- *Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Is the information complete, accurate, and not misleading?*
- *Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees? Does the arrangement or practice have the potential to be a disguised discount?*
- *Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?*
- *Does the arrangement or practice raise patient safety or quality of care concerns?"*

– April 2003
OIG Pharma Guidance

Certain activities are especially likely to receive heightened government scrutiny. Most higher-risk activities are ***those in which we provide funds to a physician or other customer***, either for doing work for us (e.g., as a speaker, consultant, investigator, mentor, or preceptor) or through a grant, fellowship, charitable contribution or other payment. Other activities also have been deemed particularly suspect by the Office of Inspector General ***(OIG)*** of the Department of Health and Human Services and by federal and state prosecutors.

The government is targeting these activities because of past abuses by a few companies and because of their perceived potential to affect patient care (e.g., by influencing prescribing decisions). The propriety or impropriety of specific situations will depend on the surrounding facts and circumstances. ***Generally, however, providing remuneration to customers is illegal under the anti-kickback laws if the purpose of the payment is to increase the prescribing or use of our drugs.*** For this reason, particular care needs to be taken with regard to activities within the following risk areas.

Off-label Information

While physicians and scientists may engage in scientific exchange of information not contained in approved product labeling, any ***plan*** or ***strategy*** to use Medical colleagues or third party physicians to ***promote*** off-label use of products is generally considered to be illegal. When evaluating putatively off-label statements by physicians or scientists about the use of our products, a major factor the government will consider is ***whether and to what extent the company was involved in encouraging the comments or in directly influencing the statements.*** The government may also try to ascertain if the intent was to "promote" off-label use of the product. For this reason, all employees need to be careful to avoid statements that would be construed as promoting the off-label use of our products or encouraging others to do so. Unsolicited requests for off-label information should be referred to Pfizer's ***Global Medical Information Department*** (800-438-1985).

Selected Risk Areas

"When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines."
– PhRMA Code on Interactions with Healthcare Professionals

Educational Grants & Fellowships

Educational grants and fellowships must be used solely to support ***bona-fide educational programs.*** Use of educational grants or fellowships for any other reason is improper. When evaluating the award of an educational grant or fellowship to a customer, the government will consider a number of factors, including the extent of sales or marketing colleagues' involvement in the decision to provide the grant, ***whether the grant was being used primarily or in large part to build sales or marketing relationships***, and whether the grant was made for bona-fide educational purposes. This is especially critical in the case of grants made to a customer. Making a grant at or around the time of a pending or expected formulary or other business decision affecting Pfizer also will increase the risk that the government will view the offer and/or acceptance of such monies as an illegal inducement.

Research Grants

Independent research grants must be awarded by Medical solely to support scientifically compelling research. Use of independent research grants to establish or build relationships with a healthcare professional or institution to achieve marketing or sales objectives, rather than to support bona-fide research, is likely to be considered illegal. When evaluating an independent research grant the government will consider ***whether and to what extent sales or marketing colleagues were involved in the decision to provide the grant to the customer.*** As with educational grants, making a research grant at or around the time of a pending formulary or other business decision affecting the company can also increase the risk that the government will view the offer and acceptance of such a grant as an illegal inducement.

For more information about independent research grants see http://ig.pfizer.com

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Charitable Contributions & Goodwill Programs

Charitable funds must be used solely to support truly charitable or public interest activities. If a charitable contribution is made for the purpose of increasing the recipient's prescribing or use of our products, such a contribution is likely to be deemed to be illegal. When evaluating a charitable contribution, the government is likely to consider ***whether and to what extent sales or marketing colleagues were involved in the decision to make the contribution and whether the contribution was made to enhance a relationship with a customer rather than to further the charitable or public-interest activities of the recipient.*** Making a charitable contribution to a customer at or around the time of a pending formulary or other business decision affecting Pfizer can increase the risk that the government will view the offer and acceptance of such a contribution as an illegal inducement. Similarly, goodwill programs and other educational services provided by Pfizer must be given without any conditions, express or implied, related to the recipient's use of Pfizer products. ***Using a goodwill program as a reward for past patronage from a favored customer (or to induce future prescribing) is inappropriate and can make an otherwise acceptable program illegal.***

"Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices."
– PhRMA Code on Interactions with Healthcare Professionals

Selected Risk Areas

Consultant/Speaker/Mentor/Preceptor Compensation

Teams may retain and pay qualified physicians and other experts to provide services, such as speaking at sales presentations and training company employees through mentorships and preceptorships. However, care must be taken to ensure that that only those services that are ***actually needed*** are purchased. Using a consulting arrangement or service arrangement to pay a customer and thereby establish or build a sales or marketing relationship is inappropriate and suspect. Specifically, if a speaker is solicited or chosen to increase or influence his prescription of Pfizer products, such an engagement is likely to be illegal. When evaluating a service arrangement with a consultant, speaker, mentor or preceptor, the government will consider ***whether and to what extent any sales or marketing goals involving the proposed service provider, or his or her prescribing, were considered in selecting that provider.*** The government also will consider whether there was a legitimate business need for the consultant's services, whether the consultant was qualified to provide the contracted services, and whether the services resulted in a deliverable that was used by the business. Extensive use of a "key opinion leader" as a consultant or speaker, especially where the individual is involved in policy or formulary decisions about a pharmaceutical company's products, or where the remuneration exceeds a reasonable market rate, may cause the government to question the propriety of the arrangement. All compensation of external physicians and healthcare professionals must be based on the reasonable, fair market value of the services and the services must be "bona-fide" (i.e., legitimate and necessary).

"Compensating physicians as "consultants" when they are expected to attend meetings or conferences primarily in a passive capacity is suspect."
– April 2003 OIG Pharma Guidance

Publication Activities

Significant involvement by ***"technical writers"*** (or other ***non-authors***) in drafting a third-party scientific article, particularly where such involvement includes subjective assessments of the performance of Pfizer products and/or competing products, could be regarded as highly suspect. This is especially true if payments by Pfizer could be correlated to favorable statements about Pfizer products in the article. In evaluating company involvement in third party articles, a pivotal factor is ***whether and to what extent a technical writer and/or his or her company (and/or other contributors) is/are identified in the article in accordance with the published criteria used by the major medical journals.*** Additionally, the government may consider excessive input by or on behalf of a pharmaceutical company or pressure on an author to change a scientific opinion to be evidence of illegal conduct.

For more information about "authorship" refer to Pfizer Global Medical & Regulatory SOP, CT 20, and the Uniform Journal Requirements of the ICMJE.

Clinical Trials

Reasonable compensation of clinical investigators for research services is appropriate as long as the trial is designed and implemented in accordance with professional standards and undertaken to obtain bona-fide scientific data. ***Funding a clinical trial to encourage a group of investigators to prescribe a specific drug or to collect data that are not scientifically significant is likely to be viewed as illegal.*** Studies must be clinically and statistically meaningful. In the case of a pilot study, the investigation must be adequately designed to provide significant information that would usefully support a follow-up study. Additionally, for U.S. studies, the ***failure to file an IND (Investigational New Drug Application)*** for any study that is not exempt from the FDA's IND requirements is illegal.

"Studies of prescription products when the studies are of questionable scientific value and require little or no scientific pursuit, [and] offer substantial benefits based solely on the use of a product." are considered improper under the anti-kickback law. – OIG Special Fraud Alert

Evaluating Financial ROIs of Non-Promotional Activities

Assessing changes in a physician's or healthcare professional's prescribing practices after that physician or professional has received a goodwill program, grant, or service agreement is improper. Such ROI (return on investment) assessments may be construed as a sign that a goodwill program, grant, or service agreement was offered to influence professional judgment. When undertaking to evaluate a company's efforts to measure the usefulness of a goodwill program, grant, or service agreement, a pivotal factor is ***whether and to what extent the analysis focused on particular recipients' prescribing.*** A retrospective measurement of the effect of a non-promotional activity on the prescribing practices of recipients of a goodwill program, grant, or service agreement is improper and can be illegal.

Assessing financial ROIs on non-promotional programs, such as CME, is improper.

Switching programs

It is illegal to induce or pay a physician or other healthcare professional to change his or her prescribing practices or to recommend a particular product that is reimbursed under a federal healthcare program. While companies can encourage a physician or patients to use a different drug through education about the drug's safety and efficacy profiles, any ***offer of payment in association with such a proposal can violate the anti-kickback laws.*** "Switching programs" that involve remuneration are therefore likely to constitute an illegal inducement. Teams can provide medically relevant and accurate information about our products. At the same time, they need to be very careful to avoid encouraging doctors to switch patients from a third-party medication, especially if a change in therapy is likely to entail significant medical risk without a clear, demonstrated benefit.

Pfizer does not pay providers or healthcare professionals to "switch" patients under any circumstances.

Selected Risk Areas

Samples (Starters)

Drug samples (called "starters" at Pfizer) may only be given out, in accordance with the ***Pfizer Starter Administration Manual***, for the benefit of patients. Giving starters to healthcare professionals for their personal use or as a ***"quid"*** to reward their prescribing will subject you and Pfizer to liability under the anti-kickback laws. It is also illegal to seek reimbursement for drug samples or to facilitate or encourage others to do so. Finally, under no circumstances may Pfizer employees sell or trade starters, as such conduct constitutes a violation of the ***Prescription Drug Marketing Act ("PDMA")***.

Addressing Compliance Issues

Reporting Compliance Issues

Pfizer seeks to create an environment in which all employees are comfortable consulting with legal counsel about ongoing and proposed programs and in reporting, without fear of retaliation, conduct that they reasonably believe violates applicable laws, regulations, or Pfizer policies.

If you have a question about the legality or propriety of a proposed or ongoing program, you should always feel free to consult the lawyer who advises your business unit or team, or any other Company attorney. Additionally, under our ***"Open Door"*** policy, employees are encouraged to candidly report concerns, questions, problems or suggestions. Open Door matters can be raised directly with a supervisor or any other manager. ***If you become aware of or reasonably believe that there has been a potential or actual violation of a law, regulation, policy or procedure, you have an obligation to report it to your manager or legal counsel, or to the Corporate Compliance Officer.***

The Corporate Compliance Officer may be contacted through the Corporate Compliance Group (see below). All investigations of compliance matters must be conducted by, and under the supervision of, the Corporate Compliance Officer. Neither you nor your supervisor should conduct any preliminary investigation of any matter. Reports of a violation, possible violation, or general compliance concern may be made by telephone, in person, or in writing:

Pfizer Inc
Corporate Compliance Group
5th Floor
150 East 42nd Street
New York, New York 10017-5755
Telephone: 212.733.3026

If you have reported an actual or possible violation to your supervisor or manager, and do not believe that the supervisor or manager has taken appropriate action, you must contact the Corporate Compliance Officer, and you may do so through the Corporate Compliance Group.

Addressing Compliance Issues

While you are encouraged to first speak with your supervisor, legal counsel, or the Corporate Compliance Group under the Open Door policy, the Pfizer Compliance Hotline provides an additional level of support to colleagues who may not feel comfortable using such reporting channels or who prefer to remain anonymous. The hotline is available to all colleagues, 24 hours a day, seven days a week, 365 days a year, with services offered in 70 languages:

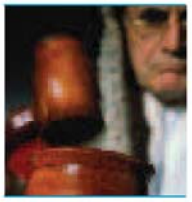
Pfizer Compliance Hotline (U.S. toll-free number):

866-866-PFIZ or 866-866-7349

For more information about the hotline, visit ***http://hotline.pfizer.com***

All persons making reports to the Corporate Compliance Officer or Compliance Hotline are assured that such reports will be treated as confidential, consistent with the Company's need to investigate the conduct alleged. Any issue will be discussed only with those individuals who have a "need to know." Additionally, Pfizer's policy strictly prohibits any adverse action against persons making reports of actual or potential compliance issues in good faith, whether or not the reports ultimately prove to be well founded.

Sanctions



Sanctions for noncompliance with healthcare law requirements may include oral or written warning, disciplinary probation, suspension, reduced compensation, demotion, or dismissal from employment. Any Pfizer employee who materially or repeatedly violates healthcare law requirements will be required, at a minimum, to participate in a remediation program developed at the direction of the Corporate Compliance Officer in coordination with the employee's management. Additional sanctions for behavior that violates Pfizer policies and procedures are assessed on a case-by-case basis.

These disciplinary actions also may be applied to a manager who directs or approves improper actions, is aware of those actions but does not act appropriately to correct them, or otherwise fails to exercise appropriate supervision.

Working Better, Building Trust

Pfizer Corporate Graphic Design
22609 3/2004 CON

In•tég•ri•ty, n.

[L. Integ´ritas. Wholeness, soundness from *integer;* untouched, whole, entire.]
1. Having sound moral principles; uprightness, honesty and sincerity.

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Pfizer Key Principles Guide
www.pfizer.com/download/healthcarelawcompliance.pdf
This manual is not legal advice, and does not replace the advice of counsel.
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