UNDERSTANDING THE
Healthcare Laws
That Govern
Our Industry

REGENERON
Introduction

Integrity is a core value at Regeneron and lies at the heart of everything we do. We believe that our employees want to do the right thing. However, we work in a highly-regulated, highly-scrutinized industry where identifying the right thing is not always easy. This Guide is intended to provide you with important background information on the laws, rules and company policies related to healthcare law compliance.

Through this Guide, you will gain an understanding of:

- How healthcare laws apply to our activities
- Which activities may raise potential concerns
- What we must do to comply with the healthcare laws
- How you can help in maintaining healthcare law compliance

As a company, we are growing and expanding into new areas. With the launch of our first product and the initiation of company-sponsored clinical trials in foreign countries, we have entered territory that we had not previously navigated. That territory carries with it new laws, regulations, responsibilities and risks that we all must be aware of. For many of you, this Guide is the first step in gaining that awareness.

There are many legal and regulatory regimes that apply to our conduct. We must manufacture our products in accordance with Good Manufacturing Practices. Our research is guided by both Good Laboratory Practices and Good Clinical Practices. Environmental laws, labor laws and securities laws all impact the way we conduct our business. Every applicable legal or regulatory framework is important and demands the utmost integrity and compliance. This Guide provides an introduction to one of those regimes – the United States Healthcare laws.

If you have any questions about the material in this Guide or how the laws, regulations or company policies apply to you, contact our Chief Compliance Officer, Beth Levine or our General Counsel, Joe LaRosa.
Overview of Applicable Laws & Codes

There are many different legal and regulatory regimes that govern our conduct as we engage in the commercialization of our pharmaceutical products. Even inadvertent violations of these laws can result in both criminal and civil penalties for Regeneron. A growing number of pharmaceutical companies have paid hundreds of millions (and even billions) of dollars in fines, seen their employees criminally prosecuted and been forced to accept ongoing government scrutiny of their activities. With the expansion of government funding for prescription drugs, the government has become one of the largest purchasers of prescription drugs. As a result, we can expect the government to closely scrutinize our practices in the years to come.

Anti-Kickback Law

The federal Anti-Kickback Law prohibits payments or any form of remuneration that is intended to reward past prescribing or induce someone to purchase, prescribe or recommend a product that is reimbursed under a federal healthcare program (such as Medicare and Medicaid). The Anti-Kickback Law is based on the notion that a healthcare provider’s decision about their patient’s treatment must not be influenced by motives of personal gain. While the Anti-Kickback law is a federal statute, many states have enacted similar state laws. The federal and state anti-kickback laws, which are also known as the “fraud and abuse” laws, seek to protect government healthcare programs and patients from improper influence on prescribing decisions.

For example, the laws prohibit the following:

- Providing a gift to a healthcare professional to influence the selection of our products
- Awarding a research grant to a physician because he or she is a high potential prescriber
- Purchasing services from a healthcare provider (e.g., for clinical trials or consulting) at a fee that is greater than the reasonable, fair market value for such services
The Anti-Kickback Law also contains certain “safe harbors” that have been defined by the Inspector General of the Department of Health and Human Services (“OIG”) as acceptable. **Conduct that falls within the guidance of a safe harbor is less likely to be considered a violation of the law.** There are safe harbors relating to discounts, managed care contracting and personal services agreements (such as consulting and clinical trial arrangements) that enable us to engage in common business practices without violating the law.

**Regeneron’s policies and practices are designed to ensure that our business conduct falls within one of these safe harbors or is otherwise legally permissible.** Each situation is largely driven by its own unique facts and circumstances. Generally, however, providing something of value to our customers is illegal under the anti-kickback laws if a purpose of the payment is to increase prescribing or use of our drugs. If you’re unsure about whether an activity is permissible, contact the Law Department.
The PhRMA Code

The PhRMA Code is a voluntary, self-regulatory guideline published by the Pharmaceutical Research and Manufacturers of America (“PhRMA”) to govern the relationships between industry and physicians and other healthcare providers. **Regeneron has adopted the PhRMA Code and has agreed to adopt the following principles in its interactions with healthcare professionals (“HCPs”).**

**Meals and Entertainment.** Informational interactions with HCPs may not include entertainment (e.g., theater, sporting events, golf, etc.). On occasion, however, it may be appropriate to provide a modest meal to an HCP in conjunction with a meeting or informational interaction. Any such meals must be modest in cost, must not occur more than occasionally and must be in a location conducive to providing scientific or educational information.

**Gifts or Reminder Items.** The PhRMA code prohibits the distribution of non-educational and practice-related items, such as pens, pads, clipboards, etc. The code also prohibits gifts to HCPs for their personal benefit. Items of educational value to the patient or the HCP, such as anatomical models, medical textbooks, etc., may be provided. However, these items must not be of substantial value and must not have a value to the HCP outside of the HCP’s medical practice.

**Continuing Medical Education.** Companies may provide financial support for continuing medical education (“CME”) programs that are consistent with guidelines that are published by the Accreditation Council for Continuing Medical Education (“ACCME”). Financial support for such programs must be provided directly to the CME provider. It is not appropriate to pay for individual attendees’ expenses. In order for a program to comply with ACCME guidelines, Regeneron may not design the program, develop the agenda, select the speakers or influence the content in any way.
Consultants. Legitimate consulting arrangements with HCPs are appropriate. However, token consulting arrangements must not be used to justify payments to HCPs. Characteristics of legitimate consulting arrangements include a documented need for services, selection of consultants based on their expertise (not as a reward or inducement for prescribing behavior), retaining no more consultants than are needed for the identified business purpose and obtaining a deliverable from the consultant that is subsequently used by the company. All payments for consultants must be based on fair market value and the arrangement must be embodied in an appropriate consulting agreement.

Consultant Meetings. It is appropriate and often necessary to hold meetings for our clinical trial investigators or members of our advisory boards or other consultants. However, the venue and agenda for such meetings must be thoughtfully considered to ensure that the meeting does not appear to be an improper inducement to prescribe our drugs. Resort locations are not appropriate venues for such HCP meetings because the surroundings detract from the business purpose of the meeting. The agenda for such meetings should be robust and the hotel stays should be limited to the minimum number of nights necessary for the meeting. Moreover, while reimbursement for travel and lodging expenses is permitted, it is not appropriate to pay an honorarium to non-faculty attendees at such meetings. Speakers and meeting chairpersons, however, can be compensated for any additional work that their roles require. It is also important to remember that spouses should not be invited to attend company-sponsored meetings and if they do attend, the company cannot pay for any of their expenses.

For example, a winter meeting in a beach resort location over a weekend with meeting times only in the mornings would not be appropriate.
Congress also enacted Open Payments (the Sunshine Act), effective August 1, 2013, which also requires the tracking and reporting of such expenses.

State Disclosure Laws

In recent years, many states have enacted laws that require pharmaceutical companies to track and report meal expenses, gifts and other financial relationships with HCPs in their states. As a result, it is important for all Regeneron employees who interact with HCPs to classify appropriately in their expense report any expenses associated with those interactions (such as meal expenses or other transfers of value).

Best Price and False Claims Act

The federal government is one of the largest purchasers of prescription drugs through such programs as Medicare and Medicaid. Federal law states that certain federal healthcare programs are entitled to rebates based on the lowest price that a pharmaceutical company offers to any customer (subject to certain exceptions). This is known as the company’s “best price” for the product. Regeneron is responsible for calculating and reporting its best price for each product on a quarterly basis. In calculating best price, we must consider any discounts, rebates or free goods that we provide, and any non-price concessions that are offered in connection with a sale. Failure to properly calculate best price could result in inaccurate price reporting, which can carry significant penalties.

Submission of inaccurate pricing data can also have consequences under the False Claims Act, which makes it a crime to deliberately submit a false claim to the government. The False Claims Act also applies to third parties who assist someone in the submission of a false claim. Thus, a pharmaceutical company that helps, encourages or causes a customer to make a false claim for reimbursement can be liable for the customer’s false claim. For example, the government has criminally prosecuted pharmaceutical companies for encouraging physicians to seek reimbursement for free product samples supplied by the companies.
Food and Drug Laws

Under the Food, Drug and Cosmetic Act, the Food and Drug Administration (“FDA”) is responsible for approving new pharmaceutical products and regulating how they are marketed and sold. Thus, it is important for every employee to have a basic understanding of the rules we follow to ensure compliance with FDA laws and regulations.

Labeling. FDA regulates the labeling of all prescription drug products that are marketed for sale in the U.S. The term “labeling” includes more than just the information on the package label. In addition, the package insert (or prescribing information, or “P.I.”) as well as all other materials that are provided by the manufacturer about the drug are considered “labeling.” Any materials that we use to promote the use of a Regeneron drug product, including advertising in any media (print, TV, internet), brochures, patient education, etc., must be consistent with our FDA-approved labeling.

Promotion. The FDA regulates not just the contents of product labeling, but also the conduct of pharmaceutical companies in promoting their products. Thus, the FDA issues guidance on many different dimensions of product promotion, such as the amount of data necessary to make a comparative claim between different drug products. To ensure that our promotional activities are in compliance with FDA law and regulations, an appropriate Review Committee (“RC”) is charged with reviewing and approving all company promotional materials prior to use. The committee is made up of representatives from Medical Affairs, Commercial, Regulatory and Legal, with participation by relevant individuals from Clinical Sciences.
Any promotional materials prepared by or on behalf of Regeneron about our drug products must:

- Be truthful and not misleading
- Present a fair balance of risks and benefits
- Include the full prescribing information or a brief summary (as the regulations may require)

Off-Label Use. One of the trickiest issues facing the pharmaceutical industry is that of off-label use. When the FDA approves a drug, it does so only for the purposes, or “indications,” that are identified in the approved package insert. Any use of the product that is inconsistent with the approved package insert is considered an “off-label use.” What makes this tricky is that HCPs can prescribe products for off-label uses in the exercise of their professional judgment. However, pharmaceutical companies may not solicit, encourage or promote unapproved uses of a product. When conducting clinical trials on potential new indications for an approved product, we must be careful to avoid suggesting or implying that physicians use the approved product for the unapproved use.

The same principle applies to unapproved products. Pre-approval promotion – promotion of a drug candidate before FDA approval – is strictly prohibited.

While drug developers are not permitted to promote off-label use of their products or engage in pre-approval promotion, the FDA does respect the need for robust, scientific debate about medicinal products and recognizes that the company is often the best source of truthful information about its products. As such, companies are permitted to disseminate truthful, non-misleading scientific information about unapproved drug products or unapproved uses of drug products in response to unsolicited requests for such information from an HCP.
As a general rule, when an unsolicited question is posed to Regeneron, a brief, scientifically accurate response should be provided only by a representative of Regeneron’s Medical Affairs department (such as one of our field-based Regeneron Science Managers or by our Medical Affairs hotline). Neither Regeneron employees nor anyone hired to speak on Regeneron’s behalf may proactively offer off-label information in a promotional context, nor can they solicit HCP questions about off-label use.

Any requests for scientific information about our products should be forwarded to our Medical Affairs department (1-877-REGN-777), who tracks and responds to such requests. Questions related to participation in clinical trials should be forwarded to the clinical trials hotline (1-877-REGN-123).

Companies are also permitted, and often required, to make disclosures to the Securities and Exchange Commission and to their investors about the progress of products in development. These communications must be carefully crafted to avoid FDA concerns related to pre-approval or off-label promotion.
**Adverse Event Reporting.** Along with the privilege of commercializing a pharmaceutical product comes the responsibility of reporting safety information to the FDA and other regulatory authorities in a timely fashion. Each employee or agent of Regeneron is responsible for reporting the safety information on any Regeneron product, marketed or investigational, that comes to his or her attention. Adverse safety information that comes to your attention must be reported immediately to the Regeneron Call Center by phone: 1-877-REGN-777, fax: 1-888-876-2736 or email: medical.information@regeneron.com

**Items that must be reported include:**

- **Adverse events:** an undesired event that occurs with drug use, whether or not the event is related.
- **Lack of effect:** any failure of a drug to work as expected.
- **Quality-related issues:** concerns about problematic particulates in a vial.
- **Other general drug-related issues:** medication error, use during pregnancy, difficulty administering an injection, etc.
**Foreign Corrupt Practices Act**

The Foreign Corrupt Practices Act (“FCPA”) is a federal anti-bribery statute that governs financial relationships with foreign government officials to combat corruption. In general, the FCPA prohibits corrupt payments to foreign officials for the purpose of obtaining or keeping business. Pharmaceutical companies must pay particular attention to the statute because, in many countries, health systems are run by the government and therefore the physicians who work within the foreign country’s health system may be considered government officials. The FCPA also applies to payments made to government officials through a third party, such as a contract research organization or other company vendor. It is important to note that the law applies to more than just cash payments – gifts or anything of value can constitute a payment under the FCPA. All relationships with HCPs outside of the U.S. need to be carefully considered in consultation with the Law Department.
In the work that we do, we often are involved in the collection, handling and transmittal of various types of personal data, including medical records. It is our responsibility to ensure that that personal data is treated with the utmost care and respect in compliance with applicable privacy laws and regulations. Mishandling of personal data can result in serious consequences for the individual and liability for Regeneron. There are many federal, state and foreign laws and regulations that govern the protection of personal health information. The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) is a comprehensive statute that is designed to address both the potential for inappropriate disclosure of personal information and the risk of unauthorized use of such information. For example, under HIPAA, an insurer or a healthcare provider cannot use personal medical information gathered from a patient for any purpose other than the necessary provision of medical treatment or the processing of insurance claims, unless they have obtained individual authorizations from the patients. Similarly, the EU Data Protection Directive imposes very stringent requirements on the use and disclosure of personal data, including data collected in the course of clinical trials. Regeneron employees must always be mindful of the privacy laws that are implicated any time we have access to personal medical information.
Integrity at Regeneron

Regeneron has always placed the highest value on compliance with law, honesty and integrity. We are all a part of an important effort to discover, develop, manufacture and commercialize pharmaceutical products that enhance people’s lives. We pride ourselves on striving to do the right thing, whether or not it’s required by law. As we tackle our daily tasks, we must remain mindful of Regeneron’s commitment to integrity. We must constantly choose the higher ground when faced with difficult decisions. And we must take responsibility for ensuring that our colleagues, vendors and business partners are acting with the same standards of integrity.

If you suspect that someone is not behaving in a way that is consistent with Regeneron’s policies or standards, it is your responsibility to report it. Regeneron has an Open Door Policy. You can, and should, raise any concerns or questions you may have and you can do so directly with any supervisor or manager, or by contacting our head of HR, Sally Paull, or the Chief Compliance Officer, Beth Levine. You can also make anonymous reports through our hotline (877-RGN-ETHX) or website (www.ethicspoint.com). The important thing is that you raise any concerns you may have. By working together and maintaining a collective commitment to doing the right thing, we will continue to be proud of our company and the good work that we do.

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