

***CODE OF CONDUCT
FOR
SIGMA-TAU PHARMACEUTICALS, INC.***

Sigma-Tau Pharmaceuticals Corporate Code of Conduct

TABLE OF CONTENTS

Introduction	3
Work Environment	3
Workplace Environment.....	4
Safe and Healthy Work Environment.....	4
Company Systems Use.....	4
Conflicts of Interest	5
Financial Integrity	5
Business Records and Information	5
Healthcare Compliance	6
Overview of Applicable Healthcare Compliance Laws and Codes	6
Anti-Kickback Law.....	6
Federal False Claim Act.....	7
Medicaid Drug Rebate Statute.....	8
Medicare Part B ‘ASP’ Pricing and Price Reporting.....	9
Privacy Laws.....	9
Consumer Protection Laws.....	10
The PhRMA Code on Interactions with Healthcare Professionals.....	10
Violations of Healthcare Compliance Laws.....	10
Healthcare Compliance Employee Responsibilities	11
Product Pricing.....	11
Product Information.....	11
Protection of Information.....	12
Political Activities and Donations.....	12
Addressing and reporting Compliance Issues	13
Addressing Compliance Issues.....	14
Non-Compliance with this Code of Conduct.....	14
Training on Standards of Conduct	14



Rare dedication

SIGMA-TAU PHARMACEUTICALS

CODE OF CONDUCT

INTRODUCTION

At Sigma-Tau Pharmaceuticals we have made integrity the core value of our business. We are committed, as a company and as individuals, to conduct our business according to appropriate legal and ethical standards.

Our commitment to comply with all U.S. healthcare laws and policies is demonstrated in our communications regarding our products. Sigma-Tau has adopted and enforces policies designed to prevent and detect unethical activity as well as activity that violates federal, state, local and foreign laws.

In addition to providing an overview of our company policies related to healthcare law and compliance, our Code of Conduct provides guidance on:

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

However, this Code of Conduct does not address every legal or ethical issue that an employee may confront, nor is it a summary of all laws and policies that may apply in any particular situation.

SIGMA-TAU PHARMACEUTICALS WORK ENVIRONMENT

All Sigma-Tau Pharmaceuticals employees are required to follow applicable laws and act in accordance with the highest standards of professional behavior. We expect all employees to behave with integrity, treat others with respect and comply with company policies.

We understand that we are responsible for maintaining our company's reputation and therefore we do not engage in conduct or activity that could raise questions about our integrity or could cause embarrassment to our company.



Workplace Environment

Sigma-Tau Pharmaceuticals promotes an environment that includes a wide variety of backgrounds and experiences. We believe this diversity provides us with a well-rounded source of ideas and information that will assist us in attaining the highest quality results.

We believe that any discriminatory conduct or any harassment that violates our company's policies can affect our ability to work together as a team and contradicts our belief in the importance of respecting all of our co-workers.

To that end, we do not participate and strictly prohibit any unlawful discrimination (including but not limited to any harassment) and expect all of our employees to support and comply with Sigma-Tau's policies of equal employment opportunity and non-harassment of any form. Please see Sigma-Tau's equal employment opportunity and non-harassment policies for a fuller description of these policies including their descriptions of prohibited conduct and required reporting procedures under those policies.

Safe and Healthy Work Environment

Sigma-Tau Pharmaceuticals is committed to providing a safe and healthy environment for staff members and visitors. We encourage all staff members to assure that their work conditions meet safety requirements and to report any concerns about safety.

We are also committed to providing a work environment that is free from substance or alcohol abuse. Sigma-Tau employees are not permitted to be on the company premises, in a company vehicle or perform company-related work if they are under the influence of drugs or alcohol. We do encourage anyone with a substance-related problem to seek appropriate treatment.

We are committed to a workplace free of violence. Violent or threatening behavior is not permitted from any employee or visitor. Offensive, threatening or violent behavior must be reported immediately, whether it is verbal or physical.

Company Systems Use

Company systems that Sigma-Tau provides to you are to be used for company business. These systems and all information and records stored on them are the property of Sigma-Tau. Sigma-Tau may, if it is deemed appropriate, inspect your files and messages or monitor your internet usage without advanced notice or consent. All

company systems, software and equipment are to be returned to Sigma-Tau when employment ends.

All employees are to assure that they do not create, send, display or receive inappropriate, offensive or disruptive material. You must not share your password with others to ensure the protection of sensitive company information located on these systems.

CONFLICTS OF INTEREST

All Sigma-Tau staff members are responsible for acting professionally and making appropriate business decisions in the best interests of Sigma-Tau without any consideration of personal gain. Therefore, you must avoid situations in which personal interests, outside activities, financial interests or relationships interfere or conflict or even appear to interfere or conflict with the interests of Sigma-Tau or could be considered as inappropriately influencing a business decision. Conduct with suppliers, customers or anyone doing business with Sigma-Tau must be objective, professional and fair. It is difficult to identify exhaustively what constitutes a conflict of interest. For this reason, you must avoid any situation in which your independent business judgment might appear to be compromised.

FINANCIAL INTEGRITY

Sigma-Tau has a responsibility to provide various reports and documents to government and regulatory agencies. All staff members involved in these requirements have a responsibility to ensure that our commitments are met.

Employees associated with reporting requirements to government or regulatory agencies are required to maintain appropriate records. Employees are to assure that all reports and documents submitted to these agencies comply with filing requirements. Employees who have interaction with public accountants are to cooperate when requested and are not to coerce, manipulate or mislead them.

BUSINESS RECORDS AND INFORMATION

All staff members are responsible for proper management of business records and information. Proper retention and storage of information assists in making appropriate business decisions, supports our legal, financial, regulatory and contractual obligations and promotes organizational efficiency.

Staff members are required to have knowledge of and follow appropriate record retention schedules. This includes retaining records for the required period of time to

comply with applicable schedules and laws and disposing of documents and information once the applicable retention period has passed. Disposal of records, data or information that is required to be retained under a “hold order” is prohibited. No one is to alter, destroy or create documents with the purpose of interfering with a government or regulatory agency submission or inquiry.

HEALTHCARE COMPLIANCE

All staff members at Sigma-Tau, especially those who interact and communicate with patients, customers, providers, government officials, advocacy groups, the media and our business partners, are expected to have a basic understanding of the healthcare laws and rules that apply to the pharmaceutical business, including:

- The Federal Anti-kickback Statute
- The Federal False Claims Act
- The Medicaid Drug Rebate Statute
- The Medicare Part B “ASP” Law
- Federal Privacy Laws, including the Health Insurance Portability and Accountability Act (“HIPAA”)
- State Anti-kickback, Privacy and Consumer Protection Laws
- The PhRMA Code on Interactions with Healthcare Professionals

OVERVIEW OF APPLICABLE HEALTHCARE COMPLIANCE LAWS AND CODES

Improper activities can violate federal and state laws and can result in both criminal and civil penalties. With the growth in government funding of prescription drug benefits, it is virtually guaranteed that investigation and scrutiny of industry practices will increase.

Anti-kickback Law

The federal anti-kickback law provides that anyone who knowingly and willfully offers, pays, solicits, 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 the offering or giving of anything of value when one purpose is to induce anyone to purchase, prescribe, endorse or recommend a product that is reimbursed under a federal healthcare program.

A healthcare provider’s decisions about the treatment of his or her patients should not be guided by motives of personal gain or enrichment. The federal and state anti-kickback laws seek to protect government healthcare programs and patients from improper influence on healthcare decisions.

At Sigma-Tau, all healthcare customers are treated as if they are subject to the anti-kickback laws regardless of whether the prescription drugs they use are paid for through Medicaid, Medicare or other federal or state agencies and programs. Our policy is

never to provide anything of value as an encouragement or inducement for a healthcare professional to purchase, prescribe the use of, or recommend our products, unless it qualifies for an exception under the law.

Compensation of a healthcare professional for his or her services must be commensurate with the services provided and must reflect fair market value. Make sure you are familiar with the appropriate detailed policies and procedures in this area. Ensure that you follow appropriate procedures when healthcare professionals are performing research activities. These activities must fill a legitimate Sigma-Tau research requirement. If you are unsure, you must confer with the Corporate Compliance Officer before proceeding.

Federal False Claims Act

The federal False Claims Act prohibits the making or causing of false or fraudulent claims for payment to the government. The False Claims Act states, in part:

Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; ...or (7) knowingly makes, uses or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person....

Submission of false claims to the Medicare or Medicaid programs, or causing a third-party to submit false claims to those programs, may create liability under the False Claims Act. A pharmaceutical company potentially may cause a third-party to submit false claims to the federal government in various ways:

1. The company can submit false information to the third-party, e.g., false or inaccurate invoices or reimbursement advice, which causes the third-party to improperly bill the government;
2. The company can give “kickbacks” to a third-party in violation of the federal anti-kickback law, which can cause that third-party to improperly certify its compliance with that law on its claims for Medicare or Medicaid payment; or



Rare dedication

3. The company can give false information to a third party, e.g., price reporting services such as First DataBank or RedBook, that publish data that governments rely on for reimbursement purposes.

Sigma-Tau requires that all communications with government officials, including the Medicare and Medicaid programs, and all communications that are relied upon for reimbursement purposes, be accurate, fair and truthful. Further, Sigma-Tau requires its employees to comply with the anti-kickback statute as well as the Medicare and Medicaid pricing and price reporting laws, discussed below.

Medicaid Drug Rebate Statute

In response to findings that Medicaid was paying more for prescription drugs than other large drug purchasers, Congress passed the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, which requires pharmaceutical companies to pay a rebate to state Medicaid programs in order for their drugs to be covered under the Medicaid program. Specifically, the Medicaid Rebate Statute requires manufacturers to pay the states a rebate on single source drugs and innovator multiple source drugs, which is based on two calculated prices: Average Manufacturer Price (“AMP”) and Best Price.

AMP is generally defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. Best Price is generally defined as the lowest price available from the manufacturer during the rebate period to any customer other than those which are specifically exempted by statute, such as certain government entities. Pharmaceutical companies calculate and report AMP on a monthly and quarterly basis, and Best Price on a quarterly basis, pursuant to regulations and guidance issued by the Centers for Medicare and Medicaid Services (CMS). The reported AMP and Best Price figures are then used to determine pharmaceutical companies’ rebate liability to the Medicaid program.

Sigma-Tau is committed to ensuring that AMP and Best Price are properly calculated and reported to CMS. Because AMP and Best Price are “net” prices inclusive of discounts, rebates and other price concessions, this pricing information must be adequately and accurately documented. Sigma-Tau requires that data and records used to calculate federal pricing be maintained for a period of ten years from the date prices using those records were calculated and submitted to CMS. To ensure that accurate prices are reported to the government, Sigma-Tau requires all employees who

are in a position to affect pricing and price reporting practices consult with the Corporate Compliance Officer before offering pricing or price concessions to customers.

Medicare Part B “ASP” Pricing and Price Reporting

The Medicare Part B program provides coverage for outpatient prescription drugs that are administered by a physician, as well as certain other specified categories of prescription drugs. These drugs are reimbursed on the basis of Average Sales Price or “ASP,” which is generally defined as the weighted average sales price of a drug product to all commercial customers excluding sales exempted from the Medicaid “Best Price” (e.g., government sales). Like AMP and Best Price, ASP is inclusive of discounts, rebates and price concessions.

Pursuant to the Medicare statute, pharmaceutical companies must calculate and report ASP to CMS on a quarterly basis. Accordingly, Sigma-Tau requires that data and records used to calculate ASP be collected and maintained for a period of ten years from the date prices calculated using that data are submitted to CMS. Sigma-Tau is committed to ensuring that ASP is properly calculated and reported to CMS.

Privacy Laws

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

- i. Medical confidentiality or medical records laws, including HIPAA privacy regulations
- ii. Public health laws
- iii. Laws regulating healthcare products or services
- iv. Laws regulating human experimentation
- v. Broad personal data protection laws
- vi. 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”). HIPAA focuses on two important concerns:

- i. Inappropriate disclosure of protected health information, and
- ii. Unauthorized use of protected health information.

There are also state privacy laws that apply to the use and disclosure of personal, financial and health-related information. Employees should be aware of, and act in accordance with, such applicable state laws.

Sigma-Tau is committed to protecting the confidentiality of personal, sensitive, or nonpublic information, including protected health information. Accordingly, employees must maintain and use such information only as authorized by the individual or as



Rare dedication

otherwise required by law. 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 authorization that comply with federal standards.

Further, Sigma-Tau applies privacy laws to all clinical investigators, contract research organizations (CROs), consultants and other contractors who gather or handle personal data on behalf of Sigma-Tau.

Consumer Protection Laws

State laws regulate marketing and sales practices, including practices applicable to pharmaceutical products. For example, virtually all states have broad laws prohibiting "unfair" or "deceptive" trade practices that may be applied to the sale or promotion of pharmaceutical products. Any questions regarding such state laws should be directed to the Corporate Compliance Officer.

The PhRMA Code on Interactions with Healthcare Professionals

The PhRMA Code on Interactions with Healthcare Professionals ("PhRMA Code") is a voluntary code of conduct governing interactions between pharmaceutical companies and healthcare professionals regarding marketed products and related pre-launch activities. Sigma-Tau adheres to the PhRMA Code and has implemented policies and procedures consistent with the PhRMA Code.

Violations of Healthcare Compliance Laws

The Department of Health and Human Services Office of the Inspector General (OIG) and the Department of Justice aggressively enforce healthcare compliance laws. Violations can be criminally prosecuted as felonies and punished by a fine and/or imprisonment in addition to monetary penalties. Conviction under these laws can result in exclusion of a company from participation in federal healthcare programs as well as imprisonment of officers and/or employees responsible for violations.

Furthermore, private individuals may bring civil qui tam, or "whistleblower" actions, on behalf of the government under the False Claims Act (FCA). These whistleblowers share a percentage of any monetary recovery from the False Claims Act litigation.

Many states have enacted state law versions of the Federal False Claims Act, which similarly allow private plaintiffs to bring suit on behalf of state governments for alleged false claims submitted to state programs, such as Medicaid.



Rare dedication

Food and Drug Administration (FDA) laws and regulations are also enforced through both the civil and criminal justice systems. Violations of the Prescription Drug Marketing Act (PDMA) and/or the Food, Drug and Cosmetic Act (FDCA), including failure to follow sample management requirements or laws regarding promotion of Sigma-Tau products, may result in criminal sanctions, including imprisonment.

SIGMA-TAU HEALTHCARE COMPLIANCE EMPLOYEE RESPONSIBILITIES

Sigma-Tau takes its responsibilities for healthcare compliance very seriously and expects employees to adhere to the following:

Product Pricing

Antitrust laws were enacted to assure fair competition. Sigma-Tau will not participate in any activity that violates antitrust and competition laws. To achieve fair pricing and prevent possible violations, all pricing of products must be reviewed by the Corporate Compliance Officer.

Sigma-Tau does not deem it acceptable to discuss or make agreements with any current or potential competitor regarding pricing, discounts, terms of sale or division of the market. Any discussion or agreement with current or potential competitors regarding the sale of our products or theirs is prohibited. You are not permitted to offer inducements to customers or suppliers as a means of helping our business or harming our competitors.

We do not enter into agreements or understandings with distributors regarding the prices the resellers will charge customers. Make sure to avoid any conduct that could possibly be seen as unfair competition or abuse in the market.

Product Information

Sigma-Tau values our relationships with healthcare professionals and patients. We are committed to developing and providing the best products and services possible.

Distribution of labeling, advertising and marketing materials that are false or misleading are clearly prohibited by federal and state laws. Our policy is to provide truthful, balanced and accurate advertising and promotional materials based on facts and documented research.

Sigma-Tau's promotional material and information on products shall be in compliance with the Food, Drug and Cosmetics Act (FDCA) and relevant FDA regulations and guidance. Promotional material and information shall contain an accurate, fair, and non-misleading assessment of the benefits as well as the risks of the product. Further,



Rare dedication

promotional material and information shall be consistent with the FDA-approved labeling and FDA policies on off-label promotion.

Any questions regarding product information, and the promotion of such information, should be directed to the Corporate Compliance Officer.

Protection of Information

Sigma-Tau maintains information about its employees, patients, customers and those with whom we partner. This information is necessary in the operation of our business. The inappropriate disclosure of this information to others is unlawful and could adversely affect our company.

All employees are advised that it is your responsibility to safeguard all company information and to use it for business purposes only. Sharing information with unauthorized individuals is prohibited. You are required to adhere to the specific guidelines that your department may have created to protect information, such as clinical trial information or customer-related information. This includes assuring that all security measures related to protecting information from inappropriate access, destruction, alteration or storage are met.

Political Activities and Donations

Corporate contributions for federal and many state and local elections are illegal. In addition to cash contributions, the donations of goods or services by employers to benefit a campaign are also illegal. Federal law does allow a corporation to administer a political action committee for its employees. Lobbying activities by companies are also regulated by federal, state and local laws. Gifts to federal, state and local officials are often prohibited or regulated regarding the value of the gift. No gift of any kind may be given to a public official unless you have determined in advance that the gift may be legally given. This rule applies whether you pay for the gift with your own money or are reimbursed by the Company.

Sigma-Tau does not permit contributions of any type for a candidate running for public office in exchange for any official action. Compliance with all applicable laws pertaining to lobbying of government entities or personnel is required. You must make sure you understand and follow all appropriate processes for political contributions and grants of other funding to government personnel or entities. If you are uncertain about procedures you must seek legal counsel or consult with our Corporate Compliance Officer.

ADDRESSING AND REPORTING COMPLIANCE ISSUES



Rare dedication

Sigma-Tau strives to create an environment in which all employees are comfortable consulting with the Corporate Compliance Officer regarding ongoing and proposed programs.

If you have a question about the legality or propriety of a proposed or ongoing program, you should always feel free to consult with the Corporate Compliance Officer. 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 the law or Sigma-Tau policies and procedures, you have an obligation to report it as soon as possible to your manager, the Corporate Compliance Officer, or to the Sigma-Tau Compliance Hotline described below. The Corporate Compliance Officer may be contacted through the Corporate Compliance Group (see contact information below). All investigations of compliance matters must be conducted by, and under the supervision of, the Corporate Compliance Officer unless Sigma-Tau determines that the circumstances or nature of the complaint or report suggest that an alternative approach is appropriate. 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 to:

Sigma-Tau Pharmaceuticals, Inc.
Corporate Compliance Group
9841 Washingtonian Boulevard, Suite 500
Gaithersburg, MD 20878
Telephone: (800) 775-8581 (Option 5)

The Sigma-Tau Compliance Hotline provides an additional level of support to anyone who may feel uncomfortable about the “Open Door” policy or who prefers to remain anonymous. The hotline is available to all employees 24 hours a day, seven days a week, 365 days a year. The Compliance Hotline number is (800) 775-8581 (Option 5).

For more information about the hotline visit www.sigma-tau.com.

Addressing Compliance Issues

Anyone making a report to the Corporate Compliance Officer or Compliance Hotline is assured that such reports will be treated as confidential, consistent with the Company’s need to investigate the alleged conduct and take any action it deems appropriate under the circumstances. Any issue will be discussed only with those individuals who have a “need to know.” Sigma-Tau will not retaliate against any employee for reporting in good faith conduct that he or she reasonably believes may violate applicable laws, regulations or Sigma-Tau policies (including this Code of Conduct) or for participating in any investigation of such a report. Additionally, Sigma-Tau’s policy strictly prohibits any



adverse action against persons making reports of actual or potential compliance issues in good faith, whether or not the report ultimately proves to be well founded.

Non-Compliance with this Code of Conduct

Employees who fail to comply with the standards of behavior described in this Code of Conduct, including its healthcare law requirements and reporting procedures, are subject to disciplinary action that may include oral or written warning, disciplinary probation, suspension, reduced compensation, demotion or dismissal from employment. Any manager who directs or approves of actions that he or she knows or should have known are improper and/or is aware of those actions but does not act appropriately to correct them also may be subject to disciplinary action up to and including dismissal from employment.

TRAINING ON STANDARDS OF CONDUCT

To assure that all employees are aware of their continuing responsibilities for compliance, all Sigma-Tau employees will receive annual training on Sigma-Tau's standards of conduct and compliance policies. They will be required to certify that they have read the Corporate Code of Conduct and the Comprehensive Compliance Program (CCP) and agree to comply with Company policies.

The Sigma-Tau Human Resources Department is responsible for assuring that the new employee orientation program includes training with respect to the Code of Conduct and the Comprehensive Compliance Program (CCP) to ensure that each employee is aware of Sigma-Tau's requirements concerning legal compliance. Each employee must sign a Compliance Documentation Certificate stating that the individual has received such

training and that they agree to comply with Sigma-Tau policies. The Compliance Documentation Certificate is attached as Exhibit A. All current employees will also be provided at least one session of formal training each year, and new employees will be provided initial training within 30 days of employment with Sigma-Tau.

Exhibit A

COMPLIANCE DOCUMENTATION



Rare dedication

Your signature below indicates that you have received, read, and understood the principles set out in Sigma-Tau Pharmaceutical's Code of Conduct and the Comprehensive Compliance Program (CCP).

NAME (please print): _____

SIGNATURE: _____ DATE: _____

DEPARTMENT: _____ SITE/FACILITY _____