



Code of Conduct and Compliance Program Summary



*January 2009
Rev 2*



An important message from the President of Luitpold Pharmaceuticals, Inc.

The primary mission of Luitpold Pharmaceuticals, Inc. ("Luitpold") is to provide safe, effective, high quality pharmaceutical products meeting all Local, State and Federal regulations in conformance with Luitpold's stringent internal quality standards. We have remained true to this mission for many years and will continue to do so. Consistent with this mission, Luitpold is committed to ethical business practices and compliance with applicable Federal and State laws and regulations.

As such, Luitpold has prepared a comprehensive Code of Conduct and policies and procedures implementing its Compliance Program. These materials, along with various other materials, form the framework for Luitpold's Compliance Program. The Code of Conduct and Compliance Program policies and procedures are designed to reinforce your understanding of Luitpold's Compliance Program, and to assist you in navigating the various compliance obligations of the highly regulated industry in which we do business. By adhering to the standards and principles within this Code of Conduct, you enable Luitpold to continue to achieve its goal of providing excellent service to our customers in a legal and ethical fashion. Each employee will be given a copy of the Code of Conduct and Compliance Program Summary, and will be required to review and become familiar with their contents. The Compliance Program policies and procedures will be available to all employees for their review. They will be located in the office of the Compliance Officer in the Regulatory Affairs Department. Luitpold will provide you with training regarding the Code of Conduct and its Compliance Program. You will be required to annually certify that you have read and understand the contents of the Code of Conduct. This is important.

The Compliance Officer will be in charge of Luitpold's regulatory compliance efforts, and will chair Luitpold's Compliance Committee, which includes members from Luitpold's senior leadership team from various different departments. The Compliance Officer will be a resource for employees with respect to compliance matters, and will be available to address any employee questions.

I am very excited about these enhancements to our Compliance Program and look forward to working with each of you to ensure we operate in a compliant and ethical manner. Please join me in reaffirming Luitpold's ongoing commitment to compliance.

Mary Jane Helenek
President & CEO



Luitpold's Commitment to Compliance Code of Conduct

Luitpold Pharmaceuticals, Inc. (hereinafter "Luitpold" or the "Company") is committed to conducting its business with integrity and in compliance with applicable federal and state laws and regulations. Luitpold can meet its commitment to compliance only through the efforts of its managers and employees (collectively referred to as "employees"), each of whom must perform his or her duties on behalf of Luitpold with honesty and integrity. Although each individual ultimately is responsible for his or her own conduct, Luitpold is committed to maintaining a working environment that fosters conduct consistent with these ideals and that permits Luitpold to meet the highest ethical standards in conducting its business. ***WE WANT YOU TO ASK QUESTIONS WHEN IN DOUBT AS WE STRIVE ALWAYS TO DO THE RIGHT THING!***

To this end, Luitpold has adopted this Code of Conduct to describe the standards its employees must meet. As part of Luitpold's commitment to its Code of Conduct, each Luitpold employee must certify that he or she (1) has read, understands and will comply with the Code of Conduct and Compliance Program Summary, and (2) will retain a copy of this Code of Conduct and Compliance Program Summary for future guidance. These certifications must be renewed by each employee on an annual basis.



Code of Conduct Principles

The Code of Conduct provides a high-level overview of the expectations that Luitpold has for its employees. Because employees will be responsible for complying with this Code, Luitpold has put together the following Code of Conduct Principles that outline and summarize the basic concepts underlying Luitpold's Code of Conduct and its Compliance Program.

Compliance with the Law and High Ethical Business Standards

Luitpold operates in a heavily regulated industry and is subject to a large number of federal and state civil and criminal laws and regulations. Violation of these laws and regulations can result in harm to the public, severe financial penalties, exclusion from participation in government health care programs (such as Medicare and Medicaid) and - in some cases- criminal fines and/or imprisonment. Luitpold's Code of Conduct and Compliance Program are designed to prevent and detect such violations.

Employees of the Company shall adhere to the high standards of business ethics as set forth in the Code of Conduct and in the Compliance Program policies and procedures, and acknowledge that such compliance is a condition of employment and is a factor that will be considered in his or her performance evaluation.



Compliance with Law and Regulations

Luitpold does not expect any of its employees to become experts in these areas. For precisely this reason, where an employee is not sure whether a particular activity or practice violates the law (or any of the Compliance Program policies and procedures), the employee should not - under any circumstances - "guess" as to the correct answer. Instead, the employee should seek appropriate guidance from his or her supervisor or the Company's Compliance Officer.

Accuracy and Integrity of Books and Records

The Company must keep accurate books, records, and accounts and must accurately reflect the nature of transactions and payments

No undisclosed or unrecorded fund or asset shall be established in any amount for any purpose. No false or artificial entries shall be made for any purpose.

The Company records and reports facts accurately, honestly, and objectively and does not hide or fail to record any funds, assets, or transactions. Employees are accurate and honest in reporting or recording our business expenses, time worked, research test results, production data, expense reports, and all other business-related activities.



Confidential Business Information

The Company safeguards confidential and proprietary information regarding its business and scientific operations. Employees understand that the disclosure of the Company's confidential business information, whether intentional or accidental, may adversely affect the financial stability and competitive position of the Company and their job security as employees.

Employees who learn confidential business information about the Company, or other companies or persons with whom the Company does business, shall not disclose that information to third parties, including family or friends.

Employees shall promptly report to their immediate supervisor or the Compliance Officer any attempt by outsiders to obtain confidential information or any unauthorized use or disclosure of confidential information by other employees.





Fair Competition and Antitrust

Luitpold is committed to the ideals of free, open, and competitive enterprise. There should be no artificial restraints in the marketplace such as price-fixing, illegal monopolies, boycotts, improper bundling, or tie-ins. The Company avoids situations that could violate the principles of fair competition, and therefore we do not discuss the following with competitors: prices or pricing policies (past, present and/or future), bids, discounts, rebates, chargebacks, promotions, costs, profits, customers, territorial markets, production capacities or plans, distribution or selling strategies, pending research, and the like. We do not engage in unfair or deceptive acts or practices, including false or misleading advertising, or any other form of misrepresentation.

Conflicts of Interest

Conflicts of interest can come up when our personal interests or outside activities influence an employee's ability to act in the best interests of the Company.

In general, employees must seek to avoid entering into arrangements that cause conflicts of interest, which may include: (1) doing business with family members; (2) having a significant and/or direct financial interest in a competing company, supplier, or customer; (3) having a personal financial or other interest in any transaction involving or made on behalf of the Company; and (4) serving, without the approval of Luitpold's President & CEO, on the board of directors of a customer or competitor.

Contracts with Third Parties

Luitpold sometimes engages the assistance of outside people or organizations to help conduct the Company's business. Vendors and subcontractors shall be selected only on the basis of objective criteria such as quality, cost, experience and service. We expect our agents and representatives to observe the same high standards of business conduct as the Company does.

Gifts and Entertainment

Employees shall not seek, accept, offer, promise, or give any inappropriate payments, fees, loans, services or gifts from or to any person or firm as a condition or result of doing business with the Company. Luitpold's business ethics policies however, permit field-based employees to provide gifts or items of reasonable value intended solely to benefit patients, or to provide modest "in-office" or "in-hospital" meals to healthcare professionals for a legitimate business or educational function. Non-field based employees may provide modest business meals outside the office or hospital setting. Gifts shall not be of substantial monetary value and shall not be offered to influence inappropriately future behavior or conduct. Office trinkets or other promotional items shall not be distributed. All sales employees will receive detailed training on these policies.





Compliance with Medicare/Medicaid Fraud and Abuse Laws and Prohibition against Bribes, Kickbacks, Unlawful Payments

“Anti-Kickback” Laws and Regulations. Federal and state laws prohibit payments (in cash or in kind) that are intended to induce the recipient to: (1) refer patients to the individual or entity offering such payment; (2) order, purchase, or lease items or services from the payor; or (3) arrange for, or recommend that others order, purchase or lease items or services from the payor.

Inappropriate educational or clinical research grants also may have potential fraud and abuse law implications. The penalties for violating such Anti-Kickback laws are severe and may include criminal prosecution, incarceration, substantial fines, and exclusion (debarment) from participation in federal health care programs.

To this end, all Company products are sold solely on the basis of quality, service, and price. Employees shall not offer, make, or authorize or receive payment of money or anything of value, directly or indirectly, with improper intent to:

- Illegally influence the judgment or conduct, or create a desired outcome or action by, any individual customer, company or company representative; or
- Gain an improper business advantage involving items reimbursed by a government health care program.

False Claims Act. The Federal False Claims Act is a civil law that prohibits submission, or causing the submission, of fraudulent claims to Medicare/Medicaid, and other federal and state programs. False claims that are submitted to a federal health care program intentionally or with reckless disregard or deliberate indifference can subject the Company or individuals to significant penalties. Employees must ensure that all statements, submissions, and other communications - whether oral or written - with our customers, prospective customers, suppliers and other persons and entities are truthful, accurate, and complete.



Compliance with Food and Drug Laws and Regulations

Luitpold employees shall comply with all applicable laws and regulations, including, but not limited to, the Food, Drug, and Cosmetic Act and the regulations of the Food and Drug Administration ("FDA"), and the Prescription Drug Marketing Act, as well as the statutory and regulatory equivalents in jurisdictions around the world. When dealing with the FDA or other government representatives both inside and outside the United States, employees shall be truthful and accurate in all statements that they make.



Violations, Anonymity, and Non-Retaliation

All employees are required as a condition of employment to report suspected misconduct. Reports of suspected misconduct may be made to a manager or the Compliance Officer in writing or verbally. If a report is made in writing, the report need not include the identity of the person making the report. However, each employee should understand that often it is easier to assess the issues or concerns raised in a report when there is an ability to ask the reporting employee follow-up questions.

In all instances when requested, Luitpold will strive to maintain the anonymity of any reporting employee. It must be understood, however, that there may come a point in time when a reporting employee's identity may become known or may have to be revealed (e.g., if government authorities become involved in the investigation).





Compliance Responsibilities

All employees have a responsibility to comply with the Code of Conduct and Compliance Program policies and procedures. When trying to make a decision or determine an appropriate course of action, employees should always ask themselves:

- Is my action honest and truthful?
- Is my action ethical and legal?
- Does my action comply with the Company's Code of Conduct, as well as with the spirit of the Code?
- How would my action look in the newspaper or on television? Would it appear to be improper, or make me feel embarrassed?

If an employee reasonably believes that another employee has violated or may violate a law, regulation, or specific Compliance Program policy or procedure, the information must be reported immediately to a manager or supervisor, the Human Resources Director, or for more serious potential violations, directly to the Compliance Officer.

This is an important step, because non-compliance can pose very serious risks for the Company and all of its employees.

Disciplinary and Remedial Action

Employees will be subject to disciplinary action, ranging from verbal warnings to termination of employment regardless of his or her level or position, if they fail to comply with these Code of Conduct, Compliance Program policies and procedures or applicable laws and regulations. The severity of the disciplinary action will depend on a variety of factors, including, but not limited to (1) the severity of the violation, (2) whether the violation was committed intentionally, recklessly, negligently or accidentally, (3) whether the employee has committed any other violations in the past, (4) whether the employee self-reported his or her misconduct, and (5) whether (and the extent to which) the employee cooperated with Luitpold in connection with its investigation of the misconduct. Any employee who intentionally files a false report of misconduct will be subject to disciplinary action pursuant to this Principle.

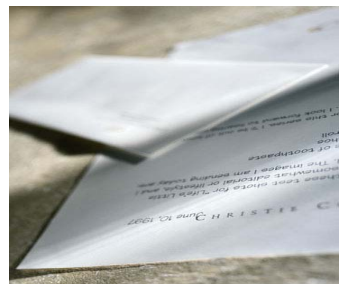


Compliance Program Summary

The Compliance Program is designed to implement the Code of Conduct and prevent violations of applicable laws and regulations and, where such violations occur, to promote their early and accurate detection and prompt resolution through education, monitoring, disciplinary action, and other appropriate remedial measures.

Luitpold's Compliance Program consists of the following core components:

- Written policies and procedures addressing the Company's commitment to compliance and specific policies and procedures addressing areas of potential fraud and abuse.
- Luitpold has appointed a Compliance Officer who will be responsible for maintaining the Code of Conduct and Compliance Program policies and procedures.
- The Luitpold Compliance Officer will chair a Compliance Committee that is responsible for developing, maintaining, and monitoring the Compliance Program.
- Luitpold will provide its employees with compliance education and training with respect to the Compliance Program
- Luitpold has established procedures that permit (and indeed encourage) Luitpold employees to raise questions or concerns
- Luitpold has established procedures for (1) receiving reports concerning possible violations of relevant laws and regulations, and Compliance Program policies and procedures, (2) protecting the anonymity of the reporting party, and (3) protecting the reporting party from retaliation.
- Luitpold will monitor compliance on a regular basis through the use of periodic reviews, audits, and other practices.
- Luitpold has established procedures for responding to and investigating possible violations of relevant laws and regulations and for appropriate remedial and corrective actions, if applicable.
- Luitpold has established procedures to avoid employing, contracting with, or retaining individuals or entities that have been excluded or are otherwise debarred from participation in federal health care programs.





Implementation of the Compliance Program

Compliance Officer

The Compliance Officer is responsible for the oversight and implementation of the requisite elements of the Company's Compliance Program, including the Code of Conduct.

Compliance Committee

The Compliance Committee is chaired by the Compliance Officer and is comprised of senior managers of the following departments: Human Resources, Marketing & Professional Services, Contracts & Chargebacks, and Compliance.



Employee Responsibilities

Each employee is responsible for his or her own daily business conduct. Employees shall conduct themselves with integrity and abide by the Code of Conduct. Employees shall seek to do what is right, not just what is required. Employees shall seek advice from the management team if they have questions or doubt.

Questions Regarding the Code of Conduct

Employees who have questions regarding the applicability or interpretation of the Code of Conduct, should direct their questions to:

- their manager or supervisor;
- another management employee;
- a member of the Compliance Committee; or
- the Compliance Officer



Reporting of Violations

If an employee knows of a violation or possible violation of the Code of Conduct, such employee shall immediately report it to one or more of the above or also to:

- the Compliance Hotline

Anyone who receives such a compliance report must advise the Compliance Officer as soon as possible by telephone or in writing. Written reports to the Compliance Officer should be addressed to:

Luitpold Pharmaceuticals, Inc.
One Luitpold Drive, P.O. Box 9001
Shirley, New York 11967

and should be marked "CONFIDENTIAL - TO BE OPENED BY THE COMPLIANCE OFFICER ONLY."



Telephone reports should be made either directly to the Compliance Officer or to the Compliance Hotline.

There shall be no retaliation for good faith reporting of actual or possible violations of the Code, laws, or Company Policies.

Compliance Hotline Access

Employees may call the Compliance Hotline, which is available 24 hours a day, 7 days a week. Telephone reports to the Compliance Hotline should be directed to

1-800-398-1496.

Reports to the Compliance Hotline may be made on an anonymous basis if callers prefer.

Investigation of Violations

All reported violations of the Code of Conduct, laws or Company Policies related to Compliance Program issues will be promptly reviewed and investigated, as appropriate, by the Compliance Officer or an appropriate designee and will be treated confidentially to the extent possible and consistent with the Company's legal obligations.



Discipline for Violations

Disciplinary actions shall be taken as appropriate for:

- Authorization or participation in actions that violate the Code of Conduct, law, or Company Policies;
- Failure to report a violation of the Code of Conduct, law, or Company Policies
- Refusal to cooperate in the investigation of a potential violation;
- Failure by a violator's supervisor(s) to detect and report a compliance violation, if such failure reflects inadequate supervision or lack of oversight;
- Retaliation against an individual for reporting a compliance violation

Disciplinary action shall be appropriate to the misconduct and, when appropriate, may include dismissal.

LUITPOLD'S COMPLIANCE HOTLINE

1-800-398-1496

Available 24 hours a day, 7 days a week.

Reports to the Compliance Hotline may be made on an anonymous basis.

The primary mission of Luitpold Pharmaceuticals, Inc. is to provide safe, effective, high quality pharmaceutical products. Consistent with this mission, Luitpold is committed to ethical business practices and compliance with all applicable Federal and State laws and regulations.

The Code of Conduct and Compliance Program policies and procedures are designed to enable you to continue to achieve Luitpold's goal of providing excellent service to our customers in a legal and ethical fashion.

Any questions? Call Jean Poulos, Compliance Officer at ext. 168.

Luitpold Pharmaceuticals, Inc.