



Asahi Kasei Therapeutics Compliance Program

THE ASAHI KASEI THERAPEUTICS, INC. ETHICS AND COMPLIANCE PROGRAM

The ethics and compliance program of Asahi Kasei Therapeutics, Inc. ("AKTX" or the "Company") is designed to assist the Company in preventing, detecting, and responding to illegal, improper, and unethical conduct. The program is designed to serve as a procedural framework for enhancing and monitoring compliance with applicable laws, regulations, the Code of Conduct, the Employee Handbook, and the Company's policies and procedures. The program is based on the elements of an effective compliance program set forth in the Federal Sentencing Guidelines Manual and applicable Department of Health and Human Services Office of Inspector General ("OIG") guidance and the PhRMA Code on Interactions with Healthcare Professionals ("PhRMA Code").

The ethics and compliance program is designed, implemented, and maintained to:

1. Comply with all applicable laws and regulations, including but not limited to the Anti-kickback Statute, False Claims Act, Food Drug and Cosmetic Act, Physician Payments Sunshine Act and applicable state laws.
2. Establish a culture that promotes prevention, detection, and resolution of instances of conduct that does not conform to all applicable laws, regulations, the Code of Conduct, or the Company's policies and procedures;
3. Communicate and demonstrate AKTX' commitment to compliance;
4. Guide management and employees in efficient management and operations;
5. Provide ethical leadership and install systems to facilitate ethical and legal conduct; and
6. Provide information, guidance, and education regarding ethics, regulatory requirements, and standards of practices.

The ethics and compliance program has the following key elements:

1. Written standards of conduct, including the Code of Conduct and Company policies and procedures;
2. Designation of a Compliance Officer and Compliance Committee;
3. Regular, effective education and training;
4. Reporting channels to field compliance questions, concerns, and to report complaints, anonymously, if preferred, and without fear of retaliation;
5. Monitoring and auditing activities;
6. Publicized disciplinary guidelines to enforce the Company's compliance standards; and
7. A mechanism to respond promptly to detected offenses and develop corrective action as necessary.

WRITTEN STANDARDS OF CONDUCT, INCLUDING THE CODE OF CONDUCT AND COMPANY POLICIES AND PROCEDURES

As part of the ethics and compliance program, to further the Company's commitment to compliance, AKTX has implemented the Code of Conduct, as well as specific policies and procedures to address those regulatory issues and standards likely to be of most consequence to the Company's operations. Under the Code of Conduct, all AKTX directors, officers and employees and, when applicable, subcontractors and agents are expected to abide by all the Company's policies and procedures.

All AKTX directors, officers, and employees must annually certify that they have received, read, understood, and agree to abide by the Code of Conduct. New employees shall receive a copy of the Code of Conduct and shall complete the required certification upon hire.

AKTX employees can find all AKTX policies and procedures on the Company's intranet or within the Veeva system.

ETHICS AND COMPLIANCE PROGRAM OVERSIGHT

The Chief Ethics & Compliance Officer and Ethics and Compliance team administers the AKTX ethics and compliance program

Specifically, the Chief Ethics & Compliance Officer and Ethics & Compliance Team:

- Reviews and addresses legal, regulatory, and other compliance-related issues facing AKTX and consults with AKTX' internal and outside counsel as needed to add in such review;
- Oversees and assists efforts to monitor adherence to the ethics and compliance program, applicable law, regulation, OIG guidance, and the Company's standards of business conduct, as set forth in Company Code of Conduct and policies and procedures;
- In consultation with internal and/or outside counsel, analyzes the legal and regulatory environment in which AKTX operates and specific risk areas or compliance-related issues facing AKTX;
- Assists in the development of the Code of Conduct and compliance-related policies and procedures;
- Assists in the development and updating of compliance training programs for employees, directors and, where applicable, subcontractors and agents;
- Periodically reviews and approves the Code of Conduct and compliance-related policies and procedures;
- Develops and undertakes activities designed to monitor and audit AKTX's compliance with applicable law, regulation, OIG guidance, PhRMA Code guidance, Code of Conduct and the Company's policies and procedures;
- Conducts compliance investigations, and oversees monitoring and auditing activities;
- Develops, implements and monitors corrective action plans, including the development of new or amended Company policies and procedures;

- Provides compliance education and training for Company directors, employees and, where applicable, subcontractors and agents;
- Recommends disciplinary and corrective action related to violations of law, regulation, OIG guidance, PhRMA Code guidance, Code of Conduct and the Company's policies and procedures;
- Conducts an annual assessment of the ethics and compliance program effectiveness and potential compliance risks;
- Periodically revises the ethics and compliance program considering the Company's needs, changes in law, OIG guidance or instances of noncompliance; and
- Performs such other duties and responsibilities as may be requested by the AKTX Board of Directors.

The Chief Ethics & Compliance Officer may employ outside consultants or counsel and/or may consult or leverage Company senior leadership to assist in the administration of the ethics and compliance program.

ETHICS AND COMPLIANCE COMMITTEE / BOARD COMPLIANCE COMMITTEE

AKTX has established the Ethics & Compliance Committee that is comprised of executive/senior leadership representing business functions across the organization. Chaired by the Ethics & Compliance Officer, the Ethics & Compliance Committee supports the evolution of the ethics and compliance program and collaborates on risk identification, management, and mitigation strategies. The Committee meets no less than four (4) times annually.

AKTX has established the Board Compliance Committee that is comprised of the AKTX Board of Directors. The Board Compliance Committee supports the evolution of the ethics and compliance program, inclusive of oversight of the Ethics & Compliance Committee to assess ongoing effectiveness. The Board Compliance Committee meets with the Chief Ethics & Compliance Officer no less than four (4) times annually.

REGULAR, EFFECTIVE EDUCATION AND TRAINING

It is the Company's goal to provide its directors, officers, employees, and, where appropriate, subcontractors and agents with the information and education they need to fully understand and comply with all applicable laws, regulations, OIG guidance, and the Company's policies and procedures. The Ethics and Compliance team is responsible for designing compliance training programs appropriate for directors, employees and, where applicable, subcontractors and agents. Methodologies for the dissemination of information include, but are not limited to, email bulletins, list-serves, web-based training programs, memos, and live lectures.

All employees are required to complete compliance training promptly after hire and annually thereafter. Such compliance training includes a review of potential fraud, waste and abuse concerns, laws and regulations applicable to AKTX, including the Anti-Kickback Statute, Office of Inspector General guidance applicable to pharmaceutical manufacturers, and general business ethics. **Failure to complete compliance training in a timely manner violates the Code of Conduct and may lead to disciplinary action up to and**

including termination. The Ethics and Compliance team is responsible for maintaining logs and other documentation of such compliance training programs and will provide copies of the logs and other documentation to Human Resources.

In addition to annual compliance training, the Chief Ethics & Compliance Officer may mandate additional compliance training for some or all directors, officers, employees and, where applicable, subcontractors and agents in the event any instance of non-compliance or a concern regarding a compliance issue arises. Furthermore, the Chief Ethics & Compliance Officer in collaboration with Senior Leadership may distribute periodic updates, via e-mail or other similar distribution channel, explaining or highlighting changes in compliance requirements or appropriate industry standards, and other information relevant to the Company's compliance responsibilities.

The Board of Directors will receive compliance training on an annual basis. The Chief Ethics & Compliance Officer is responsible for arranging/conducting such training in a timely manner and the Ethics & Compliance team maintains documentation of such Board of Director compliance training.

REPORTING CHANNELS

All Company directors, officers, employees and, where applicable, subcontractors and agents, have a duty to report any suspected violation of law, regulation, OIG guidance, PhRMA Code guidance, or Company policies and procedures to AKTX. Failure to report suspected violations of law, regulation, OIG guidance, PhRMA Code, or Company policies and procedures violates the Code of Conduct and may lead to disciplinary action up to and including termination. Such suspicions may be reported to the Chief Ethics & Compliance Officer in person or confidentially and anonymously through the Ethics and Compliance Helpline as set forth below.

To anonymously report a suspected violation of law or Company policy:

Call: 1-833-214-6429

Email: standard-reports@mitratech.com (include "AKTX" in subject line)

Web Portal: <https://report.syntrio.com/aktx>

All reports should contain as much detail as possible so that a thorough investigation may be conducted. This is especially important if reports are made anonymously since the identity of the reporter would not be available if the investigator(s) need additional information or have any questions. Reports of suspected violations should include, at a minimum, the following information:

- The date(s), time(s) and place(s) where the violation took place;
- The person(s) involved, including any witnesses;
- The nature of the violation(s);
- Details of the action(s) or activity (ies) surrounding the violation; and
- If the reporter desires a response to his or her complaint, or to be contacted for questions or additional information, the reporter's name, phone number and /or address.

All reports of suspected violations of law, the Code of Conduct, or Company policies and procedures are logged and shall remain confidential, to the extent possible.

The Chief Ethics & Compliance Officer will ensure that training and educational materials include information on how suspected violations of law, the Code of Conduct, or Company policies and procedures may be reported.

Managers who receive reports of suspected violation of law, the Code of Conduct, or Company policies and procedures must report these suspicions to the Chief Ethics & Compliance Officer immediately.

AKTX will not tolerate any form of retaliation for reporting, in good faith, a perceived instance of such fraud, waste, or abuse or suspected violation of law, regulation, OIG guidance, PhRMA Code guidance, the Code of Conduct or the Company's policies and procedures. Any such retaliation will be investigated and, upon substantiation, met with disciplinary action up to and including termination. All Company directors, officers, employees, subcontractors and agents are protected from retaliation related to the good faith reporting of potential fraud, waste, or abuse or a suspected violation of law, regulation, OIG guidance, PhRMA Code guidance, the Code of Conduct or the Company's policies and procedures.

MONITORING AND AUDITING

The Chief Ethics & Compliance Officer and Ethics and Compliance team with assistance from Company Senior Management will develop activities designed to monitor and audit AKTX's compliance with applicable laws, regulations, OIG guidance, PhRMA Code guidance, the Code of Conduct and the Company's policies and procedures. Such activities may be "informally" conducted by the various AKTX operational departments as ongoing monitoring or they may be more formalized reviews of Company functions and operations in the form of audits.

On an annual basis, AKTX will develop an audit plan, which will be subject to the approval of the Board of Directors. Such audit plan will include two external audits: (1) an annual financial audit conducted by an independent certified public accountant and (2) an annual compliance audit aimed at ensuring compliance with OIG guidance, as well as Company policies and procedures conducted by an independent third party review organization. In addition, such audit work plan may include at least one internal audit designed to audit compliance with applicable laws, OIG guidance, as well as Company policies and procedures. The results of all audits will be shared by the Chief Ethics & Compliance Officer with the Board of Directors.

The Chief Ethics & Compliance Officer shall make recommendations to improve compliance, quality, business efficiency, and effectiveness. Depending on the circumstances, the Board of Directors may appoint an attorney to conduct a legal investigation.

On an annual basis, the Chief Ethics & Compliance Officer will assess the effectiveness of the ethics and compliance program. The program will be updated as needed to reflect changes in applicable law, regulation, OIG guidance, PhRMA Code guidance, the Code of Conduct, the Company's policies and procedures or Company practices.

PUBLICIZED DISCIPLINARY GUIDELINES

Company officers, employees, and, where applicable, subcontractors and agents are expected to abide by the standards set forth in the Code of Conduct and applicable Company policies and procedures. On an annual basis, all Company directors, officers, and employees must certify their compliance with the Code of Conduct. Compliance with the Code of Conduct and Company policies and procedures may contribute to an employee's promotion and increased compensation, as compliant and ethical behavior is an important element in annual performance reviews.

Company employees are subject to disciplinary action up to and including termination for violating the Code of Conduct or applicable Company policies and procedures. Disciplinary action depends on the nature of the violation. AKTX is not obligated to take any particular disciplinary action, but any discipline imposed may include: oral or written warning; probation; demotion; suspension; and termination of employment. Some of the factors that may be taken into account when determining the proper disciplinary action include: the nature and seriousness of the violation; damage caused by the violation; whether the violation was committed knowingly; the impact on the Company; and the individual's history of compliance with the Code of Conduct/Company's policies and procedures.

Subcontractors and agents, where applicable, can be subject to AKTX-imposed corrective action or contract termination in the event of a violation of the Code of Conduct and applicable Company policies and procedures.

Failure to comply with applicable law, regulations and Company policies and procedures could subject individuals, as well as AKTX, to civil liability, including the imposition of fines, criminal liability (including penalties and imprisonment), as well as other sanctions such as exclusion from participation in federal health care programs.

While all Company employees and, where applicable, subcontractors and agents must follow the Code of Conduct, each Company manager must be an example for those under his or her leadership. They must know the Code of Conduct, and all Company policies and procedures relevant to their area of responsibility. Managers must create and maintain a workplace where all employees and, where applicable, subcontractors and agents under their leadership know that ethical and legal behavior is expected of them.

RESPONSE TO DETECTED OFFENSES

The Ethics and Compliance team will log all reports of suspected violations of law, regulation, OIG guidance, the Code of Conduct or the Company's policies and procedures received and will investigate all such reports.

All employees, subcontractors and agents are obligated to cooperate with AKTX, including the disclosure of all information and records relevant to the investigation, in the investigation of suspected violations of law, regulation, OIG guidance, PhRMA Code guidance, the Code of Conduct or the Company's policies and procedures.

Whenever a compliance issue has been identified, the Chief Ethics & Compliance Officer will develop a written corrective action plan designed to not only address the specific compliance issue identified but also with the intent of preventing similar compliance-oriented issues in the future in other areas or departments. Corrective action may include a recommendation that a sanction or disciplinary action be imposed on the offending employee(s), subcontractor(s) or agent(s).

Whenever the Chief Ethics & Compliance Officer has credible evidence of misconduct from any source, whether learned through an investigation, audit or otherwise, and the Chief Ethics & Compliance Officer believes that such misconduct may violate criminal, civil or administrative law, the Chief Ethics & Compliance Officer shall promptly report such matter to the AKTX Chief Executive Officer and Board of Directors.

CALIFORNIA ANNUAL CAP ON THE PROVISION OF ITEMS OF VALUE TO COVERED HCPs

In compliance with the requirements of California Health and Safety Code Sections §§ 119400 - 119402, AKTX has established an annual, aggregate limit of three thousand dollars (\$3,000) on the educational items, promotional materials, and meals associated with an informational presentation that may be provided to an individual "medical or health care professional" defined as a:

- Person licensed by California law to prescribe drugs for human patients;
- Medical student in California; or
- Member of a drug formulary committee in California.

The annual limit of \$3,000 is not a goal and does not represent a typical amount provided to a covered medical or health care professional. The annual limit does not apply to:

- Fair market value payments provided pursuant to fee-for-service written agreements with covered medical or health care professionals for legitimate bona fide professional services;
- Financial support for continuing medical education; or
- Financial support for investigator-initiated research grants.

In addition, AKTX policy prohibits the provision of gifts or entertainment to all HCPs including covered medical or health care professionals.

The Company reviews the established limit on an annual basis and may adopt revisions resulting from its review. In accordance with Section 119402(e) of the Statute, AKTX posts an Annual Declaration of Compliance on its corporate website each calendar year.

REQUEST A COPY

A copy of this ethics and compliance program summary and the California Annual Declaration of Compliance is publicly available on the AKTX corporate website at www.aktx.com/en or by calling +1 (833) 214-6429.