



US STANDARDS OF BUSINESS CONDUCT

Daiichi Sankyo, Inc. • American Regent, Inc.



US STANDARDS OF BUSINESS CONDUCT

We believe in cultivating an in-office and virtual work environment that contributes to our employees success. Key to this is treating all employees with respect and dignity and providing equal employment and advancement opportunities for all qualified personnel.

These Standards of Business Conduct are the fundamental principles by which every Company Employee is expected to work. These Standards are written in accordance with our Global Values of Innovation, Integrity, and Accountability.

Every Company employee is accountable for adhering to our commitment to conduct our business fairly, honestly, and with integrity. It is our Company policy to comply with all applicable laws and regulations including, but not limited to, all Federal Healthcare Program and FDA requirements. No officer, executive, director, or supervisor has authority to violate any law or these standards or to direct another employee or any other person to violate any law or these standards on behalf of the Company or any partner or affiliate of our Company.

It is important that each employee understands the global Daiichi Sankyo values described below and strives to uphold these values in all work-related activities:

Innovation is our imperative, as well as a fundamental requirement in our ongoing pursuit of creating innovative, world-class drugs. Every employee should share this spirit of innovation. What does innovation look like in action?

- Scientific curiosity leading to new methods of discovery and clinical research
- Not being satisfied with the status quo
- Improving processes, out of the box thinking, and developing new ways to achieve business results

Integrity is our strength and an integral part of our character. We always strive to do the right thing and to improve patients' health and well-being. We are an ethical, trusted, and respectful partner. We provide the highest quality medical information and provide a stable supply of quality pharmaceutical Products.

What does integrity look like in action?

- Doing the right thing even when nobody is looking
- Acting responsibly and with respect for others
- Providing balanced and scientifically accurate information

Accountability is our culture. We enthusiastically embrace our responsibilities, and we honor our commitments to all those who are dependent on our work to provide innovative drugs to people around the world. What does accountability look like in action?

- Taking ownership of success and failure
- Being responsible for one's actions and performance
- Clearly understanding one's role in the organization and fulfilling that role with excellence

As a Company employee, you must review these Standards of Business Conduct at least annually. If you have questions or concerns after reviewing this document, speak with your supervisor, Senior Management, Human Resources, Legal Affairs, or the Compliance Department, including the Chief Ethics & Compliance Officer.

Note: For the purposes of this Standards of Business Conduct document the term "Compliance" shall refer to, collectively, the Compliance Department and the Chief Ethics & Compliance Officer.

If you have a concern that the Standards of Business Conduct has been violated, please contact the appropriate Compliance Department via the contact information provided in the Resources for Employees to Ask Questions or Raise Concerns section of this document.

Who do the Standards of Business Conduct apply to?

The Standards of Business Conduct apply to Daiichi Sankyo, Inc. and American Regent, Inc. ("American Regent"). "Daiichi Sankyo, Inc." as that term is used herein shall include employees within Daiichi Sankyo Pharma Development ("DSPD") Division, Daiichi Sankyo U.S. Business ("DSUSB") Division, and the U.S. Corporate Division ("USCD"), including, without limitation, global functions within those divisions. Daiichi Sankyo, Inc. and American Regent may be referred to, collectively, as the "Companies" or as the "Company." The Standards of Business Conduct apply to all employees of the Companies ("Company employees").

We are proud of our growth, and our continued success depends on every employee's lawful and ethical conduct to maintain our integrity and good reputation.

Thank you for your commitment to integrity.

The Company's Standards of Business Conduct contain an overview of various policies, procedures, and requirements applicable to Company employees. These summaries are not intended to be all-inclusive or limiting in any way. Company employees are responsible for reviewing and adhering to their respective Company's policies and procedures.

Neither this Standards of Business Conduct document nor any other Company policy constitutes a contract of employment. This means that no promise of any kind is created or intended. The Company may change or withdraw any policy as well as any other condition of employment (including those related to wages and benefits) without anyone's agreement.

Nothing in this document should be construed as changing the "At Will" employment relationship between the Company and its employees. **This means the employee may terminate the employment relationship at any time, with or without notice, reason or cause. Similarly, the Company may terminate the employment relationship at any time, with or without notice, reason or cause.** This also means that you are not guaranteed employment for any specific amount of time. Verbal agreements or promises cannot change this at-will employment relationship. All Company employees are employed by the Company on an at-will basis, unless otherwise agreed in a written agreement signed by both parties and specifically signed on behalf of the Company by an authorized Officer or Board Member of that Company.

RESOURCES FOR EMPLOYEES TO ASK QUESTIONS OR RAISE CONCERNS

Remember, all Company employees are required to promptly report any suspected violations of these Standards of Business Conduct or any Company policy, procedure, or law, or any retaliation by any employee or Agent of the Company to management, Compliance, Legal Affairs, Human Resources, or the Company's Compliance Hotline:

1 (877) 48ALERT (1-877-482-5378) or [dsi.alertline.com](https://www.daiichisankyo.com/dsi/alertline)

ANYONE WHO, IN GOOD FAITH, RAISES A CONCERN ABOUT A POSSIBLE COMPLIANCE VIOLATION WILL NOT BE SUBJECT TO ANY FORM OF RETALIATION. ANY ACT OR THREAT OF RETALIATION AGAINST ANYONE REPORTING A SUSPECTED VIOLATION WILL BE CONSIDERED A SERIOUS VIOLATION OF THESE STANDARDS SUBJECT TO DISCIPLINARY ACTION UP TO AND INCLUDING TERMINATION.

You may at some time be faced with a situation that appears to violate the Company's Standards of Business Conduct or one of its policies. Everyone has an obligation to report any suspected violation promptly. There are a variety of means by which individuals can report their concerns or seek answers to their policy questions.

Supervisor or Senior Management

In general, you should begin by consulting your Manager or supervisor, since he or she best understands your area of responsibility. You may also consult with Senior Management of your Company. If you believe these options are not appropriate, uncomfortable, or unhelpful, there are several other resources available to you.

Human Resources

For employee-related issues, such as concerns involving interpersonal conflict with, or performance of management and/or other employees, you should contact your site's Human Resources representative.

Legal Affairs

You may contact an attorney in the Legal Affairs Department with questions or concerns about any aspect of the Standards of Business Conduct, or to report a possible violation. The Legal Affairs Department can provide specialized guidance by answering questions concerning laws, regulations, industry, and acceptable business practices. There are lawyers assigned to each business area.

Note: For American Regent employees, a form is available on the Human Resources and Legal Department intranet sites, which may be used to report possible harassment and discrimination violations.

Compliance

There may be situations when you would prefer to discuss your questions or concerns about our policies or Standards of Business Conduct with someone outside your group or location. Compliance is a valuable resource available to you to answer questions or address concerns. You are encouraged to contact Compliance, at any time, for any issue or question that relates to our policies or Standards of Business Conduct, or to discuss concerns about possible policy violations. Any employee, Agent or third party who raises, in good faith, a concern of a possible violation will be protected from retaliation. "Agents" includes all Company Vendors, contractors, Contingent Workers, partners, or other Agents engaged to act on behalf of the Company. This protection also extends to anyone providing information in connection with an Investigation.

To Contact Compliance at Daiichi Sankyo, Inc.:

- Direct Dial Telephone: 1-908-992-6651
- E-mail: DSICompliance@DSI.com or contact at [dsi.alertline.com](https://www.daiichisankyo.com/dsi/alertline.com)
- Direct Postal Mail: Attn: Compliance Department, Daiichi Sankyo, Inc., 211 Mt. Airy Road, Basking Ridge, New Jersey 07920

To Contact Corporate Compliance at American Regent:

- E-mail: Compliance@americanregent.com
- Direct Postal Mail: Corporate Compliance Department, American Regent, Inc., P.O. Box 9001, 5 Ramsey Road, Shirley, NY 11967

Compliance Hotlines

The Company also provides confidential compliance hotlines where suspected policy violations or potential retaliation can be reported (and can be reported anonymously if you wish).

- DSI Compliance Hotline: 1 (877) 48ALERT (1-877-482-5378) or [dsi.alertline.com](https://www.daiichisankyo.com/dsi/alertline.com)
- American Regent, Inc. Compliance Hotline: 1-877-482-5378 or [ari.ethicspoint.com](https://www.americanregent.com/ari/ethicspoint.com)

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WORK ENVIRONMENT

EMPLOYEE CONDUCT IN THE WORKPLACE

We believe in cultivating an in-office and virtual work environment that contributes to our [Employees](#) success. Key to this is treating all employees with respect and dignity and providing equal employment and advancement opportunities for all qualified personnel.

The following types of behavior will not be tolerated by the Company:

Prohibited discrimination is described as unlawful discrimination in hiring, terminations, promotions, demotions, transfers, and selection for training based on race, color, religion, gender, sexual orientation, national origin, ancestry, culture, ethnicity, age, disability, pregnancy, veteran status, citizenship status, marital status, genetic information, or other categories protected by law.

Workplace harassment is any action that inappropriately or unreasonably creates an intimidating, hostile, or offensive work environment based on categories protected by law. This type of unlawful harassment may be based on a person's race, color, religion, gender, sexual orientation, national origin, ancestry, culture, ethnicity, age, disability, pregnancy, veteran status, citizenship status, marital status, genetic information, or other categories protected by law.

Examples of prohibited workplace conduct include racial, ethnic, suggestive, or inappropriate sexual comments, foul language, unwanted physical contact and sexual advances, offensive jokes and slurs (where the subject matter involves, for example, race, ethnicity, religion, age, or sex), and making or threatening reprisals as a result of reporting harassment.

Prohibited intimidation and bullying is described as repeated mistreatment of one or more people by one or more perpetrators. It is abusive conduct that includes threatening, humiliating or intimidating behaviors; work interference/sabotage that prevents work from getting done; and verbal abuse. Examples of behavior that may constitute or contribute to evidence of bullying and/or intimidation in the workplace include, but are not limited to: persistent singling out of one person; shouting or raising one's voice at an individual in public or in private; personal insults and use of offensive nicknames; public humiliation in any form; constant criticism on matters unrelated, or minimally related, to the person's job performance or description; public reprimands; repeatedly accusing someone of errors that cannot be documented; and spreading rumors and gossip about an individual.

WE WILL NOT TOLERATE ANY FORM OF UNLAWFUL DISCRIMINATION OR HARASSMENT AGAINST EMPLOYEES BY OTHER EMPLOYEES, SUPERVISORS, MANAGERS, CONTRACTORS, OR CUSTOMERS.

A colleague in a different department works with me on a regular basis. About a month ago, she told me she had feelings toward me and asked me to dinner. I said no, but, since then, she has been asking me to dinner or drinks almost every day. I just want her to stop. Should I report her?

Even though this involves an employee in a different department, the Standards of Business Conduct apply. While asking a co-worker out for dinner once might not be a violation of policy, persistence in asking could be. This conduct should be reported to your supervisor, Senior Management, Compliance, Legal Affairs, HR, or the Company's Compliance Hotline. American Regent employees may also report incidents of workplace harassment or discrimination using the "Complaint Form for Reporting of Discrimination or Harassment" available through Human Resources or the Legal Department.



Sexual harassment is another form of workplace harassment that affects the dignity of men and women at work. Sexual harassment will not be tolerated under any circumstances. Basing promotions, raises, or desirable job assignments on submission to sexual advances or requests for sexual favors is an example of prohibited conduct that constitutes sexual harassment.

Reporting: If you believe that you have been subjected to workplace harassment or discrimination, or that such activities have occurred, you must promptly report the incident. You may report the incident to your supervisor, Senior Management, Human Resources (HR), Compliance, Legal Affairs or the Company's Compliance Hotline. For ARI employees, a form is available on the Human Resources and Legal Affairs intranet sites, which may be used to report possible harassment and discrimination violations.

Please see the [Resources for Employees to Ask Questions or Raise Concerns](#) section in this document for additional ways to report suspected violations of these Standards of Business Conduct, Company policies, procedures, the law, or regulations.

Q&A

One of the managers in my region told a sexual joke at a dinner event during a sales meeting. We were all having fun; I think he might have just had too much to drink, so I don't want to get him in trouble. Do I really need to report him?

Yes. Any conduct that could violate the Company's Workplace Harassment Policy should be reported. As a Company employee, you have an obligation to report such conduct.

One of my key Customers is a physician who keeps making unwelcome sexual advances towards me. Is this something I can report to the Company, or is this between my Customer and me, since he doesn't work for the Company?

Even though this involves a Customer and not a co-worker, the Company's intention is to provide a harassment-free workplace; thus, the Standards of Business Conduct apply. Report your concerns to your supervisor, Senior Management, HR, Compliance or Legal Affairs, who will work with you to find an acceptable solution. You may also make a confidential report to the Company's Compliance Hotline. American Regent employees may also use the "Complaint Form for Reporting of Discrimination or Harassment."



WORKPLACE SAFETY AND HEALTH

One of our greatest priorities is to promote the safety and health of our employees.

Each of us is responsible for preventing accidents, following safety rules and procedures, participating in safety training, and complying with all applicable federal, state, and local health and safety laws. All of us must be familiar with and follow all Company and facility-specific health, safety, and security policies and requirements applicable to our jobs.

If you sustain a work-related injury:

- Seek emergency or other medical treatment, if needed. Be sure to indicate that your injury or illness is work related.
- Please refer to your local Company Policy for more guidance on workplace safety and health.
- For Daiichi Sankyo, Inc. employees:
 - Call the phone number assigned by the Benefits Department within 24 hours, or as soon thereafter as possible, to report your workers' compensation claim. Employees at the Basking Ridge location must also notify their supervisor.
 - Call the Company's designated disability insurer to initiate the appropriate leave/attendance process if you will miss time from work.

WE MUST EACH DO OUR PART TO MAINTAIN A SAFE, HEALTHY AND SECURE WORKPLACE. WE CONDUCT OUR OPERATIONS WITH THE HIGHEST REGARD FOR THE SAFETY AND HEALTH OF OUR EMPLOYEES, CONTRACTORS, VISITORS AND THE GENERAL PUBLIC. WE MUST ALL CONTRIBUTE TO THIS COMMITMENT TO MAINTAIN A SAFE WORKPLACE.

- For American Regent employees:
 - Immediately report occupational injury/illness to your supervisor, regardless of how slight.
 - Home office employees at the Shirley, NY site should contact Security at extension 109 in the event of an emergency.



Is it necessary to report even minor injuries that occur while working?

Yes. Employees must immediately report any injury, even if it is minor, to a supervisor, facility associate, or HR representative consistent with the guidelines outlined above. Reporting even minor injuries helps the Company identify possible safety hazards and opportunities to improve our safety rules, procedures, and training. It also ensures that employees receive the help needed to deal with injuries.

DRUGS AND ALCOHOL IN THE WORKPLACE

The use of illegal drugs, the illegal use of legal drugs, and alcohol abuse can create serious health and safety risks in the workplace.

To foster a drug-free environment, the Company tests individuals for use of illegal drugs and controlled substances prior to employment at the Company, as permitted by law. Employees may also be tested whenever there is reasonable suspicion that an employee may have used drugs or alcohol in violation of Company policy.

Prior to and during operation of a Company vehicle, employees may not ingest alcohol or any drug in a manner or amount that impairs his or her ability to operate the vehicle in a safe and lawful manner.

WE DO NOT PERMIT THE USE, PURCHASE, SALE, TRANSFER, OR POSSESSION OF ILLEGAL DRUGS OR THE ILLEGAL USE OF LEGAL DRUGS, AT ANY TIME ON COMPANY PREMISES, IN A COMPANY VEHICLE, OR ANY TIME WHILE ON COMPANY BUSINESS. WE ALSO DO NOT PERMIT BEING IMPAIRED OR UNDER THE INFLUENCE OF ANY DRUGS OR ALCOHOL DURING WORK TIME, WHILE ON COMPANY BUSINESS, ON COMPANY PREMISES, OR WHEN OPERATING A COMPANY VEHICLE.



In a meeting one of my colleagues was making comments that were incomprehensible. As I was walking past him after the meeting, I noticed a strong odor of alcohol. Am I required to report him?

Yes. To provide a safe and drug-free environment, suspected inappropriate use of drugs or alcohol must be reported to your supervisor, Senior Management, Human Resources, Legal Affairs, Compliance, or the Company's Compliance Hotline.

WORKPLACE VIOLENCE

The Company strives to foster a safe and secure working environment free from violence and threats of violence.

Unless otherwise expressly allowed by local statute, possession, transfer, or use of [Weapons](#) by any individual on Company premises, including any of the Company parking lots, is prohibited. This includes a Company-issued vehicle while you are working or on any Company-related business. A weapon includes, without limitation, any implement or object intended to or that may be used in a manner to inflict injury on a person or damage to property, including but not limited to firearms, knives, clubs, incendiary devices, ammunition, and explosives, regardless of whether the person is licensed to carry the weapon.

Unless otherwise expressly allowed by local statute, possession, transfer, or use of weapons by any individual on Company premises, including any of the Company parking lots, is prohibited. This includes a Company-issued vehicle while you are working or on any Company-related business. A weapon includes, without limitation, any implement or object intended to or that may be used in a manner to inflict injury on a person or damage to property, including but not limited to firearms, knives, clubs, incendiary devices, ammunition, and explosives, regardless of whether the person is licensed to carry the weapon.

THE COMPANY WILL NOT TOLERATE VIOLENCE IN THE WORKPLACE, INCLUDING BUT NOT LIMITED TO PHYSICAL ASSAULTS, THREATENING COMMENTS OR ACTS, INTIMIDATION, AND THE INTENTIONAL DESTRUCTION OF COMPANY OR EMPLOYEE PROPERTY. ANY COMMENTS OR BEHAVIOR THAT REASONABLY COULD BE INTERPRETED AS INTENT TO DO HARM TO EMPLOYEES OR PROPERTY WILL BE CONSIDERED A THREAT.

I'm an avid hunter. During hunting season, I carry my gun in my trunk so that I can get in an hour of hunting after work before it gets dark. If I can't keep my gun in my car, I won't be able to do this. Is this the intention of the policy?

The intention of the Company is to provide a safe work environment for all employees, contractors, and vendors. Thus, it would be a violation of Company policy to have a gun or other weapon on Company property. This would include, for example, inside your car while parked in one of the Company's parking lots or at a Customer's place of business. It would also be a violation of this policy to have a weapon in your Company car while working or on any business-related activity.

I had a business-related disagreement with one of my co-workers yesterday, and he ended the conversation with the statement that he was "going to get me." He hasn't actually done anything to me, but, based on his comment, I have the feeling that I am now in physical danger. What should I do?

You should immediately report the situation to any or all of the following: your supervisor, Senior Management, Human Resources, Legal Affairs, or Compliance. Also, if you believe that your personal safety is at issue or in an emergency, you should contact local law enforcement.



USE OF E-MAIL, VOICE MAIL, AND OTHER COMPANY SYSTEMS

Access to the internet, e-mail, and voice mail systems is provided for Company business purposes and to facilitate business communications.

Employees may not use these systems or equipment to violate any law, Company policy, or rule. This means, for example, that employees may not transmit, access or receive any inappropriate or offensive material, including pornographic or obscene material.

Monitoring of Company-owned technology systems:

Company-owned technology systems used for e-mail, internet, and other communications are monitored by the Company. The Company may audit all usage of these systems and equipment consistent with applicable Company policies and procedures. We may access, review, and disclose any Company equipment or system—as well as any content on them—without employee knowledge, for [Investigation](#), audit, litigation, or other authorized purposes. Content can also include personal messages, files, and documents or individual use of a personal nature that might be on Company equipment (even if the content is sent and/or retrieved from third-party, password-protected sites).

Use of personal e-mail: No Company business may be sent to or conducted over your personal e-mail accounts; this includes any business-related items as well as any [Confidential Information](#) of the Company. Confidential information includes but is not limited to: Company private information, financial information, corporate strategies, competitor-sensitive information, trade secrets, specifications, customer lists, research data, network architectures, or anything covered by a nondisclosure agreement.

COMPANY PROPERTY AND EQUIPMENT ARE TO BE USED FOR BUSINESS PURPOSES. REASONABLE, LIMITED PERSONAL USE OF INTERNET, E-MAIL, COMPUTER SYSTEMS, AND EQUIPMENT IS PERMISSIBLE TO THE EXTENT IT IS ALLOWED BY COMPANY POLICY, BUT SUCH USE IS NOT PRIVATE, AND EMPLOYEES SHOULD HAVE NO EXPECTATION OF PRIVACY WHEN DOING SO. EMPLOYEES MAY NOT USE THE COMPANY'S CORPORATE OR PRODUCT LOGOS, TRADEMARKS, OR COPYRIGHTED MATERIAL FOR PERSONAL USE. BUSINESS USE OF COMPANY-OWNED OR LICENSED LOGOS, TRADEMARKS, AND COPYRIGHTED MATERIALS MUST FOLLOW APPLICABLE POLICIES FOR USE.



Does the Company monitor my e-mail and internet use?

The Company monitors Company-owned technology systems used for e-mail, internet, and other communications. We may audit and access all usage of these systems and equipment and investigate inappropriate and unauthorized use.

Can I use my Company laptop or iPad to check my personal e-mail?

Yes. Reasonable, limited personal use of internet, e-mail, computer systems, and equipment is permissible. However, remember that under appropriate circumstances, the Company may access, review, and disclose such information, even if the third-party site is protected by a personal password. Employees may not use these systems or equipment for any illegal purpose or to transmit or receive any inappropriate or offensive material, including pornographic or obscene material, or to excessively conduct personal business.

Can I put the Company logo on my social networks (e.g., Facebook, LinkedIn, Instagram, etc.)?

While you may identify yourself as an employee of the Company in your profile, you may not use any Company or product logos, trademarks, or Company-copyrighted material.

RECORDINGS OF MEETINGS AND CONVERSATIONS

It is critical to Company business that the sharing of information during in-person and virtual business meetings flows freely and is not encumbered by concerns of privacy, intimidation, or retaliation.

No audio or visual recordings of any Company business meetings or personal conversations are permitted without approval of management after consulting with Legal Affairs, as appropriate.

Individuals must be notified that they are being recorded, and in the case where individuals are not Company employees, a signed release must be obtained.

For recording of employees at large group business meetings, such as national managers meetings, notice of recording is sufficient.

TO ENSURE THE CANDID, FREE FLOW OF INFORMATION, YOU WILL NOT RECORD (E.G., VIDEO OR AUDIO-RECORD, SCREEN SHOT/CAPTURE) ANY PERSONAL OR TELEPHONIC BUSINESS CONVERSATIONS OR MEETINGS AT ANY LOCATION WITHOUT THE PRIOR APPROVAL OF YOUR MANAGEMENT AND ALL PARTICIPANTS IN THE CONVERSATION OR MEETING.

All recordings made must follow appropriate retention schedules and are subject to requirements of any legal holds.



I am having a guest speaker at my National Sales Meeting (NSM), and I would like to record his presentation so those who were absent may view it. May I record the presentation?

Yes, provided you obtained prior approval and you have a signed release from the presenter indicating that he is okay with being recorded. The release should state how the recording will be used.

I am conducting an advisory board and would like to record the session so the discussion can be transcribed. May the advisory board sessions be recorded?

Yes, provided you obtained the prior approval and you have a signed release from the advisory board participants indicating that they are okay with being recorded. The release should state how the recording will be used.

PRIVACY OF EMPLOYEE INFORMATION

The Company respects the privacy of our employees' personal information and safeguards the confidentiality of employee records.

Limited use of personal information: We collect, retain, and disclose personal information needed to support functions such as benefits, compensation, and payroll, as well as for other legally required reasons.

THE COMPANY PRESERVES THE CONFIDENTIALITY OF EMPLOYEE INFORMATION AND RECORDS CONSISTENT WITH LAW AND USES IT ONLY FOR AUTHORIZED AND LEGALLY PERMITTED BUSINESS PURPOSES.

Disclosure of employee information: Human Resources, Legal Affairs, and Finance/Accounting, as applicable and in accordance with Company policy, are the only departments that may release or authorize the release of personal information about our employees. Absent legal process (such as a subpoena or court order), it is prohibited for any employee to reveal or divulge such information to another individual outside the Company or within the Company if such individual does not have the business need to know such information. Such prohibited disclosures include unauthorized disclosure of salary information of other employees as well as references for current or former employees.

Reference:

- [Use of E-mail, Voicemail, and Other Company Systems](#)

Q&A

For what purpose may the Company use my personal information?

The Company may collect and retain personal information needed to support functions such as benefits, compensation, and payroll, as well as for other legally required reasons. For instance, the Company uses certain personal information for purposes of required government reporting. We collect and provide information to our benefits and insurance vendors so that they can process your benefits coverage and claims. We also, at times, are legally required to produce information in our possession about our employees in connection with litigation or government requests. Any such disclosures are done only by the authorized Company department with the approvals required by Company policy.



COMPANY PREMISES FREE FROM SOLICITATION

The Company wants a workplace that is focused on Company business, free of interference and distraction from employees' personal business. Our workplace must also be free of pressure or coercion to participate in non-Company activities.

Prohibited activities: The following activities are not permitted in the workplace or when utilizing Company e-mail or other systems:

- Selling commercial goods or services (for example, clothing, jewelry, real estate, vacation planning, financial planning, etc.)
- Distributing literature or electronic or printed materials for commercial enterprises or other activities not related to an employee's work

Permitted activities: Employees may, using good judgment, inform co-workers of the opportunity to contribute to or support charitable fund raising events such as:

- Selling items of minimal value, such as Girl Scout cookies, candy bars, wrapping paper, cookie dough
- Supporting runs/walks for charity

Unless written permission is granted by management, persons not employed by the Company are not allowed to distribute material or solicit employees on the Company's premises at any time.

No coercion: Even in cases where solicitation is permitted, employees, [Vendors](#), and others should not be pressured to contribute or participate. Such solicitations should not be disruptive of Company business.

TO AVOID THE PERCEPTION OF COERCION, EMPLOYEES MAY, IN LIMITED CIRCUMSTANCES, AND AS APPROVED BY THE COMPANY, INFORM THEIR COLLEAGUES THAT THEY ARE INVOLVED IN A FUNDRAISING ACTIVITY. REQUESTS FOR SUPPORT OF THESE ACTIVITIES MUST BE VOLUNTARY AND WITHOUT THE PERCEPTION OF COERCION.



I am running a marathon to raise money for the Leukemia and Lymphoma Society. May I ask co-workers to sponsor me?

For Daiichi Sankyo, Inc. and American Regent, you may inform co-workers that you are involved in a fundraising activity and indicate how they may contribute if they desire to do so. You may not coerce or pressure any employee into contributing (for example, sending multiple requests or reminders). Under no circumstances may any solicitation be done in a manner that negatively impacts an employee who chooses not to participate.

DISCLOSURE OF DEBARMENT AND CRIMINAL CONVICTIONS

We work in a highly regulated industry in which the law requires companies to ensure that their employees and [Agents](#) are not debarred or excluded from participating in [Federal Healthcare Programs](#).

As part of the hiring process, all employees must complete a certification of non-debarment and must disclose criminal convictions, to the extent permitted by applicable law, prior to commencement of employment.

THE COMPANY DOES NOT EMPLOY OR DO BUSINESS WITH INDIVIDUALS WHO ARE DEBARRED, EXCLUDED, OR OTHERWISE INELIGIBLE TO PARTICIPATE IN A STATE OR FEDERAL HEALTHCARE PROGRAM.

Ongoing disclosure: Following the commencement of employment, the Company requires the ongoing immediate disclosure of all criminal convictions (including, among others, any conviction where an appeal is pending, where you are fined, or where you are awaiting sentencing) and debarments, exclusions, or debarment proceedings. This includes any conviction relating to illegal drugs/illegal use of legal drugs, and/or operating a vehicle while impaired/under the influence.

The Company has adopted procedures to ensure that it does not utilize the services of Agents who are debarred or excluded.

The Company will not hire and will remove from all call lists or service agreements any [Healthcare Professionals \(HCPs\)](#) or Customers who have been debarred.

I'm a manager and just found out that one of my employees pled guilty to a minor drug charge. His sentence is to do 100 hours of community service. He told me that he is innocent and pled guilty to avoid jail time. Is this something I have to report?

Yes. The Company requires the ongoing disclosure of all criminal convictions (including, among others, any conviction where an appeal is pending) and debarments, exclusions, or debarment proceedings.





CONFLICTS OF INTEREST

DSI Compliance Hotline: 1 (877) 48ALERT (1-877-482-5378) or [dsi.alertline.com](https://www.dsi.alertline.com)

CONFLICTS OF INTEREST PRINCIPLES

A [Conflict of Interest](#) may arise in any situation in which an [Employee](#)'s loyalties are divided between business interests that, to some degree, are incompatible with the interests of the Company. Employees must avoid any situation where personal interests (or those of [Relatives](#), friends, or associates) might conflict, or even appear to conflict, with the best interests of the Company. Employees should not place themselves in situations that might force them to choose between their own personal or financial interests and the interests of the Company. These general principles on conflicts of interest apply to all of the subjects mentioned in these Standards of Business Conduct, as well as any issues encountered by employees that may not be mentioned here specifically.

Should an actual or potential conflict of interest arise, before acting, the employee must report it to the appropriate local senior management member or as otherwise set forth in local company policies and procedures, for direction on how to proceed in accordance with local laws, regulations, business customs and local company policies and procedure. Always err on the side of reporting a situation that may appear to be a conflict of interest. Often, just disclosing the potential conflict to the Company is the only action required. If you are not sure if you are involved in a situation that has the potential for a conflict of interest, discuss the situation with Human Resources (HR).

EMPLOYEES HAVE AN OBLIGATION TO PUT THE INTERESTS OF THE COMPANY AHEAD OF THEIR PERSONAL OR FINANCIAL INTERESTS. EMPLOYEES ARE REQUIRED TO REPORT ANY ACTUAL OR PERCEIVED CONFLICT OF INTEREST.

It is often difficult to know if an actual conflict of interest exists. The following are some examples of situations that would necessitate further evaluation:

- Running for elected office
- Board membership for any healthcare organization or any for-profit corporation
- Family members or significant others working for [Customers](#), [Competitors](#), [Vendors](#) or for the Company
- Outside employment or a consulting role
- A volunteer position in a healthcare-related field

References:

- [Employment of Relatives](#)
- [Outside Employment and Activities](#)

I work for the Market Research Department, and I am occasionally asked to do some consulting in market research for other companies. Does this Standard mean I can't be involved in that work anymore outside of the Company?

Maybe. For example, you cannot do this kind of work while you are employed by the Company if it will interfere with your commitments to the Company, if you will be exposed to confidential information of a competitor as a result of your research, or if you are asked to interpret research findings that involve Company products. The proposed consulting arrangement must be brought to the attention of your manager for review and discussion with Human Resources (HR) and Legal Affairs. American Regent employees must bring the proposed arrangement to the attention of HR, Legal Department, and Compliance.



CONFLICTS WITH VENDORS

A conflict of interest can be created when employees use or recommend the use of vendors in which they have a significant financial interest or with whom they have a personal relationship, including the relationship employees have with a family member, significant other, or friend.

Employees are required to disclose any personal or family relationships that they may have with vendors that they are in a position to recommend, refer, or influence the Company or its vendors to hire.

Employees may not recommend or hire any vendor in which they have an ownership interest (unless that interest is in a publicly traded security and the employee owns less than 5 percent of any outstanding class of securities), and may not earn any commission from or otherwise profit from any vendor's business with the Company.

At no time should an employee who is referring or recommending a vendor with whom they have an ownership interest or a personal relationship communicate an expectation or exert pressure on a colleague to consider for hire or to hire the vendor being referred. As mentioned above, when making a recommendation all such relationships must be disclosed.

EMPLOYEES MAY NOT ENGAGE VENDORS TO DO WORK FOR THE COMPANY IF THERE IS A CONFLICT OF INTEREST OR THE POTENTIAL FOR A CONFLICT OF INTEREST.

Any questions should be referred to your management or Human Resources.

A manager in Clinical Operations has a personal friend who has extensive experience as a clinical research associate. The manager has a project that requires this expertise. Can the manager contract with this individual for the assignment if he discloses the fact that they are friends?

Yes. If the individual is assessed objectively, based on required skills, expertise, competitive rates, and would be hired regardless of the friendship, then the friend may be hired if there is also clear disclosure in writing with management approval. The pool of potential candidates genuinely considered for the role should not be limited to the employee's friend.



GIVING AND RECEIVING OF GIFTS

[Gifts](#) have the potential to inappropriately influence behavior or may give the appearance of inappropriate influence.

Ethical relationships with [Healthcare Professionals \(HCPs\)](#) are critical to our mission of helping patients by developing and marketing new medicines. The giving or exchange of gifts with HCPs, Customers, or vendors may create the appearance of a conflict of interest or kickback and is prohibited by the Company.

Ethical relationships with our vendors are also critical to ensuring that Company resources are utilized only to pay for necessary, qualified vendors free from personal interest of individual Company employees.

In addition, the work environment should not be inappropriately influenced by gift giving among employees, and Company funds should only be used for employee gifts under limited circumstances.

To prevent actual conflicts of interest or the appearance of conflicts, Company policies may place limitations on gifts to employees from vendors, from our own Company, and from other employees.

- Employees are prohibited from soliciting and/or otherwise requesting any gift from any vendor, HCP, and/or Customer.
- Giving personal gifts to HCPs or Customers is strictly prohibited, whether Company or personal funds are used.

The acceptance of nonmonetary gifts or business courtesies from vendors, suppliers, or consultants who are not Customers or HCPs is acceptable in very limited circumstances that do not create the appearance of a conflict of interest.

ANY GIFT, WHETHER GIVEN OR RECEIVED, THAT CREATES AN APPEARANCE OF COMPROMISING THE EMPLOYEE'S JUDGMENT OR THE INTEGRITY OF THE COMPANY, OR THAT INTERFERES WITH JOB RESPONSIBILITIES IS PROHIBITED.

EMPLOYEES MAY NOT ACCEPT OR GIVE ANY MONEY, GRATUITIES, OR ANY OTHER PERSONAL GIFTS OR BENEFITS EITHER FROM OR TO CUSTOMERS OR HCPs UNDER ANY CIRCUMSTANCES.

Applicable Company policies must be consulted before accepting any gift. Employees may not accept goods or services from vendors for less than market value.

- Gifts to Company employees from the Company or other employees may be limited by policy.
- Items designed primarily for the education of patients or HCPs, as well as items designed for use by patients to assist in the administration or management of their condition, may be provided under limited circumstances: prior approval as required by Company processes; if the item is not of substantial value (\$100 or less); the items do not have value to an HCP outside of his or her professional responsibilities and are consistent with the PhRMA Code on Interactions with Healthcare Professionals and all applicable Company policies. Other items of value, not in compliance with these requirements, may not be provided to HCPs.



I was talking to the account manager from our ad agency about how hard it is to get good tickets to the big new hit on Broadway. She said she has connections and can get me two tickets. May I accept the tickets?

No. The Company prohibits employees from soliciting or requesting gifts from vendors.

EMPLOYMENT OF RELATIVES

The employment of relatives, [Co-Habitants](#), or significant others may cause serious conflicts, perceptions of favoritism, and problems with employee morale. As a result the employment of such persons is limited by the Company.

The Company requires employees to disclose, to Human Resources (HR), that a relative, significant other, or co-habitant is employed by, or seeking employment with, the Company. In some cases where a conflict exists, the employee(s) may be transferred to another location or position, or one or both employees may have to seek other employment.

The Company may require employees to disclose to HR any relative, significant other, or co-habitant who is employed by a Company vendor, a competitor, or providing services to a competitor of the Company.

THE COMPANY WILL NOT EMPLOY THE RELATIVES, CO-HABITANTS, OR SIGNIFICANT OTHERS OF AN EMPLOYEE IN POSITIONS WHERE A CONFLICT OF INTEREST MAY EXIST GIVEN THE NATURE OF THE EMPLOYEE'S ROLE OR WHERE ONE SUPERVISES OR CAN DIRECTLY OR INDIRECTLY INFLUENCE THE TERMS AND CONDITIONS OF EMPLOYMENT OF THE OTHER.

THE COMPANY MAY, BY POLICY, ALSO PLACE ADDITIONAL LIMITATIONS OR PROHIBITIONS ON EMPLOYMENT OF RELATIVES, CO-HABITANTS, OR SIGNIFICANT OTHERS OF EMPLOYEES BASED ON THE EMPLOYEE'S TITLE, LEVEL, ROLE, OR POSITION IN THE COMPANY.

Relatives means persons who are related to one another by birth, marriage, by registered domestic/civil union partnership, or by legal guardianship or adoption.

Co-habitants means persons who share a primary residence with one another, regardless of whether they are relatives or are involved in an intimate personal/romantic relationship.

Significant others means persons who are in an intimate personal/romantic relationship with one another but who are not married or in a registered domestic/civil union partnership with one another.

Competitors means companies whose product directly competes with a Company-marketed product (for example, products used to treat the same medical condition or in the same product class) and/or who has a [Product](#) in Phase II of clinical research or beyond that will compete with a currently marketed product by the Company or will compete with a Company pipeline product.

Services to a Competitor means services whereby the individual would have access to competitive messages and/or strategies (for example, ad agencies, print services, consulting services, etc.).

I am a Sales Representative. My sister recently lost her job at another pharmaceutical company. I know we have an opening in clinical development that she would be perfect for. May I send her resume to the hiring manager?

Since the open position would not be reporting to you, you may submit her resume, but in all respects her application for employment must follow the normal application and screening process.



OUTSIDE EMPLOYMENT AND ACTIVITIES

The Company limits outside employment and activities but does not prohibit employees from engaging in lawful off-hour activities, provided that the activities do not create a perceived or real conflict of interest with the Company's interests or interfere with job performance.

Employees are required to disclose and obtain Company approval before participating in certain outside employment and activities. More specifically, employees shall notify their Human Resources representative (who may thereafter engage other departments at the Company, such as Legal Affairs and Compliance, as well as the employee's management depending on the circumstances and Company policy) if the employee plans to:

- Pursue or hold local, county, state or federal public office;
- Serve on the board of directors or as an officer of any for-profit entity, any healthcare-related not-for-profit entity or any healthcare-related professional association;
- Engage in any healthcare-related employment or consulting activities; and/or
- Engage in any activities that may conflict, or be perceived to conflict, with the Company's business interests.

EMPLOYEES ARE REQUIRED TO DISCLOSE, IN ADVANCE, ANY PROPOSED OUTSIDE ACTIVITIES OR EMPLOYMENT THAT MAY POTENTIALLY INTERFERE WITH JOB PERFORMANCE OR THAT MAY CONFLICT, OR APPEAR TO CONFLICT, WITH THE COMPANY'S INTERESTS.

It is important to remember that any such outside employment and activities must occur on the employee's own time and not during normal business hours. The use of Company property, systems, resources, and/or facilities during the course of such outside employment or activities is not permitted.

Company policy does not prohibit an employee from engaging in lawful off-hour activities, or employment that does not create, or appear to create, a conflict of interest with the Company's business interests or interfere with the employee's job performance.

I have been asked to take a position on the board of my local chapter of the Visiting Nurse Association. Do I have to get permission from the Company, even if it's a not-for-profit organization?

Yes. You must notify Human Resources of the request and get approval from your manager, Senior Management, and the head of Human Resources before taking the position on the board. If you are a Daiichi Sankyo, Inc. or American Regent employee, you also must also get the approval of Legal Affairs or the Legal Department.

I am a pharmacist and would like to work in one of my local retail pharmacies one weekend each month. Is that allowed?

We do have some employees who "moonlight" as pharmacists. However, the answer to whether this is a conflict may depend on your role here at the Company and the specific retail pharmacy involved. So, you should let your manager know and then work with Human Resources, your manager, and Senior Management to determine if it would be acceptable. Daiichi Sankyo, Inc. employees must also consult with Legal Affairs, and American Regent employees must also consult with the Legal Department. If approved, the Company will outline any requirements or limitations on the outside role to help avoid a conflict or the appearance of a conflict.

I work in the Finance Department as an accountant, and I would like to work the late shift and weekends at a local home improvement store to help pay for my daughter's college tuition. Do I need permission from the Company?

No, as long as your second job does not interfere with your ability to do your Company job.





CONDUCTING OUR BUSINESS

PROMOTIONAL AND ADVERTISING INFORMATION

The Company is committed to providing truthful, accurate, and fairly balanced promotional messages for its [Products](#), regardless of the medium of delivery.

- All promotional materials for the Company’s products must be approved through the Company committee responsible for reviewing all [Advertising and Promotional Materials](#) (e.g., [Product Material Review Team \(PMRT\)](#)). Employees may not change, alter, modify, or create their own promotional materials or use them outside of the scope of approval.
- Promotion of [Off-Label](#) uses for a product is prohibited.
- When promoting Company products, employees must provide a fair balance of safety (including side effects and contraindications) and effectiveness information.
- The Company does not disparage or make false statements about [Competitor](#) products.
- Any promotional presentations by a Company employee must be consistent with the content approved by the Company committee responsible for reviewing all advertising and promotional materials (e.g., PMRT).

THE COMPANY PROMOTES ITS PRODUCTS IN A TRUTHFUL, ACCURATE, AND NONMISLEADING MANNER CONSISTENT WITH US FOOD AND DRUG ADMINISTRATION (FDA)—APPROVED LABELING (PRODUCT PRESCRIBING INFORMATION, OR “PI”).

PROACTIVE COMMUNICATION ABOUT COMPANY PRODUCTS BY ANY EMPLOYEE IS SUBJECT TO FDA REGULATIONS. THESE REGULATIONS REQUIRE THAT ALL PROMOTIONAL PRODUCT DISCUSSIONS BE CONSISTENT WITH THE PI, NOT BE MISLEADING, AND INCLUDE A FAIR BALANCE BETWEEN THE RISKS AND BENEFITS OF THE PRODUCT.

THE COMPANY HAS ADOPTED AND ADHERES TO THE PhRMA CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (JANUARY 2022) AND THE PhRMA DIRECT TO CONSUMER ADVERTISING PRINCIPLES (OCTOBER 2018).

I am a Sales Representative and found a study in the New England Journal of Medicine that has positive evidence for one of our products. Can I show this study to healthcare professionals (HCPs)?

No. Field-based employees may only use materials that have been approved for use by the Company committee responsible for reviewing all advertising and promotional materials (e.g., PMRT), so the piece may only be shown to an HCP if specifically approved for that use, and in such case, only if presented consistently with all accompanying training materials or direction provided by the Company as approved by such committee. Never use material, even if it is consistent with the product label, unless it has been approved by PMRT or other such review committee. If you are unsure if a piece of material is approved, contact your manager.

The sales organization just received new data on our product, which is very exciting. May I copy messages verbatim from the Master Visual Aid and put it in a text message to key Customers or HCPs?

No. Promotional messages are approved by the Company committee responsible for reviewing all advertising and promotional materials (e.g., PMRT) in the context of the communication vehicle. A text message, a written note, or communication via any other vehicle would not be considered approved even if the communication was verbatim, because the context has changed. Only pieces that have been approved by such committee may be used by Field Sales.

I am a Medical Science Liaison (MSL), and I am going to spend an hour with an HCP whom I have known for several years and who is a paid promotional speaker for the Company. My plan for today’s visit is to discuss with her a new Phase IV study about one of our products that shows good efficacy for a use that is not included in current product labeling. Can I discuss this as a professional medical colleague as part of “scientific exchange”?

No. Even if you are an MSL and a member of Medical Affairs, you cannot initiate a discussion with an HCP about off-label data in this context, even if the HCP is a paid consultant for the Company.

OFF-LABEL INFORMATION

The Company will only promote its pharmaceutical products that have been given marketing approval by the FDA. Any promotion will be consistent with the FDA's approved uses for such products and consistent with the Company's policies and procedures. Off-label promotion is prohibited.

Off-label information is information about marketed Company products that is not consistent with the FDA approved labeling (product Prescribing Information, or "PI"), including information about a use outside of the FDA approved indication for a product, or a use at a dosage or in a population not approved in a product PI. However, there are specific and limited circumstances when authorized Company employees may appropriately provide off-label information to HCPs, [Customers](#), and the public.

The Company may engage contracted HCPs or other third-party advisers for a legitimate business purpose, such as [Advisory Boards](#) or [Clinical Investigator](#) meetings. In the context of such meetings, it may be appropriate to proactively provide off-label information to such advisers, if necessary, to gain their opinion, feedback, advice, on scientific, clinical, or business subjects. Any such disclosures may only occur as part of an event that is reviewed and approved under Company policies and procedures that are designed to require that such disclosures are not in fact for purposes of promoting products off-label.

In certain circumstances the Company may proactively provide off-label information about Company products to the public or the media via press releases or other public announcements or presentations, consistent with law and regulation and when approved under applicable Company policies and procedures. Any such disclosures of information — by authorized Company personnel only — must be truthful, accurate, scientifically valid and balanced, and complete.

The Company may respond to unsolicited requests for off-label information about the Company's products. Company employees may not suggest or prompt a request for off-label information. The response to such a request must only be made by authorized Company personnel, must be limited to the information requested, and must be truthful, accurate, scientifically valid and balanced, and complete.

OFF-LABEL INFORMATION MAY BE PROVIDED ONLY BY AUTHORIZED COMPANY PERSONNEL, IN A MANNER THAT IS CONSISTENT WITH APPLICABLE LAW AND REGULATION, ACCORDING TO APPLICABLE COMPANY POLICIES AND PROCEDURES. ANY SUCH OFF-LABEL INFORMATION MUST BE TRUTHFUL, ACCURATE, SCIENTIFICALLY VALID AND BALANCED, AND COMPLETE.

As a sponsor of a [Clinical Study](#), the Company has a responsibility to provide investigators with the information they need to conduct an [Investigation](#) properly and ensure that investigators are properly informed of significant new adverse effects or risks with respect to the drug. This may include proactively providing off-label information about a currently marketed product.

I work on a clinical development team, and we are conducting an investigators' meeting. I need to provide an investigator brochure and new unpublished data on an investigational use of our product. Is this permitted under Company policy?

Yes. The Company has a responsibility to provide investigators with the information they need to properly conduct a clinical study and ensure that the investigators are properly informed of significant new adverse events or risks with respect to the drug.

I am a Product Manager who is getting ready to launch a new indication for one of our marketed products. As this is a new indication for a product for which the Company does not currently have sufficient expertise or experience, I would like to convene an advisory board with 12 knowable physicians in this area. They can provide feedback in several specific areas where there is a documented need. May I conduct this advisory board and provide the relevant off-label data and anticipated new use to these experts before the product is approved?

Yes. You have a legitimate business need to engage outside experts to provide direction and advice in the specific areas where feedback is required. It is appropriate to share off-label information that is relevant to the specific areas requiring feedback with the experts to answer the questions that you have documented. The advisory board must be approved by the Programs and Grants Committee. The experts must be contracted with in advance and paid no more than fair market value for their services.

I am a Sales Representative. I mentioned to one of my physicians that there are data published in JAMA today to demonstrate the safety and efficacy of a new use for one of our products. She asked for the data, and I referred her to the Call Center to get the information from Medical Affairs. Did I handle this correctly?

No. You must not discuss new off-label information with HCPs, even if it is published widely. Your discussion could constitute off-label promotion. In addition, since you prompted the physician's request for the off-label data, the physician's request is not "unsolicited," and the physician should not have been referred to the Call Center.

PROVIDING PAYMENTS OR ITEMS OF VALUE

The Company's relationships with [Healthcare Professionals \(HCPs\)](#) and Customers are intended to enhance the practice of medicine. Interactions should be focused on informing HCPs and Customers about products, providing scientific and educational information, and supporting medical research and education.

The Company only compensates HCPs and Customers for Company-requested bona fide services. The Company does not pay HCPs or Customers to incentivize them to prescribe, order, purchase, or recommend any product, or as a reward for having done so. The Company's relationships with healthcare professionals (HCPs) and Customers are intended to enhance the practice of medicine. Interactions should be focused on informing HCPs and Customers about products, providing scientific and educational information, and supporting medical research and education.

The Company only compensates HCPs and Customers for Company-requested bona fide services. The Company does not pay HCPs or Customers to incentivize them to prescribe, order, purchase, or recommend any product, or as a reward for having done so.

Generally, business arrangements with HCPs and Customers may take different forms; some may be for promotional services, others medical or purely scientific. However, each arrangement must be documented by a contract; compensation must always be based on [Fair Market Value \(FMV\)](#); the engagement must be approved through the applicable Company processes (e.g., [Programs and Grants Committee "PGC"](#)); and all payments must be recorded by the Company.

THE COMPANY DOES NOT PAY OR PROVIDE ITEMS OF VALUE TO HCPs OR CUSTOMERS WITH THE INTENT TO INDUCE THEM TO PRESCRIBE, PROMOTE, RECOMMEND, OR GAIN A FAVORABLE FORMULARY POSITION FOR ANY COMPANY PRODUCTS AND ONLY RETAINS THEIR SERVICES AT FMV FOR LEGITIMATE AND NEEDED BUSINESS REASONS.

The Company will not take into account the volume or value of any referrals or business involving Company products or services that have been, are, or may be generated by the HCP or Customer when the Company is considering entering into a business arrangement. Also, the Company will not pay an HCP or Customer more than FMV for actual services rendered. FMV includes both monetary compensation that is provided by check, as well as compensation in kind (for example, textbooks, electronic medical information subscription).

Any financial arrangements, meals, or any items of value provided to HCPs will comply with the PhRMA Code on Interactions With Healthcare Professionals (January 2009).

Company decision-making processes ensure that financial support (e.g., [Grants](#) and business arrangements) to entities such as professional organizations, patient advocacy groups, and other similar organizations, are free of any inappropriate influences.

All HCP payments, items of educational value, grants, and contributions must be approved in advance through formal Company processes.

We are holding an advisory board meeting of physicians about one of our marketed products in a few months in order to obtain feedback on Phase IV study design. Most attendees are flying in from out of town. We would like to provide all attendees with a gift to thank them for coming such a long way: a leather travel kit valued at \$75. Is this permitted?

No. The PhRMA Code on Interactions With Healthcare Professionals precludes the provision of items of value to HCPs, unless the items are specifically intended for use in educating HCPs and/or their patients, do not have value to the HCP outside of his/her professional responsibilities, and are not of substantial value (\$100 or less). As such, the leather travel kit does not comply with the PhRMA Code and would not be appropriate, even though it has a value of less than \$100, because it is a personal gift unrelated to educating HCPs or patients.



USE OF PRESCRIBER DATA AND OTHER MARKET DATA

[Prescriber](#) data and other market information that the Company obtains or purchases is the Company's confidential information and must be treated as such. Prescriber data and other market information that the Company obtains or purchases is the Company's [Confidential Information](#) and must be treated as such.

The Company complies with state laws on use of prescriber data and the American Medical Association Physician Data Restriction Program (PDRP). The PDRP offers physicians the option of withholding their prescriber data from pharmaceutical sales representatives and their immediate supervisors.

THE COMPANY TREATS PRESCRIBER DATA AS SENSITIVE TO THE PRESCRIBER AND WILL NOT SHARE THE DATA WITH THE PRESCRIBER, OTHER PRESCRIBERS, COMPETITORS, AND/OR ANY OTHER THIRD PARTIES IN ANY MANNER INCONSISTENT WITH THE APPLICABLE PURCHASE AGREEMENT, STATE LAW, AND/OR THE AMERICAN MEDICAL ASSOCIATION PDRP.



When looking at my prescriber data report, I noticed that a physician in my territory has not prescribed one of my products for the last two months. Is it okay for me to ask him why?

It is not appropriate for you to share prescriber data or to reference your specific knowledge of such data with your physician, even if it is about that physician herself. For example, it would not be appropriate to say, "Doctor, based on the prescriber data we get, I am aware that you have not been writing our product for the last two months."

FAIR COMPETITION AND ANTITRUST

Antitrust laws protect free enterprise. In general, these laws prohibit business activities that restrict free trade and competition, such as agreements between competitors to fix prices or reduce availability of a product.

To comply with antitrust laws, employees may not have any discussions with competitors concerning confidential Company or competitor information, including without limitation:

- Past, present, or future prices
- Pricing policies
- Price trends
- Bids
- Discounts
- Promotions
- Terms or conditions of sales
- Customers
- Profits
- Market shares
- Territories in which products are sold

Employees may not deal or contract with suppliers and Customers in a manner that unfairly restricts trade or excludes competitors from the marketplace.

Additionally, employees may not work with other third parties to boycott certain Customers, Healthcare Professionals, or [Vendors](#).

Any business decision related to the selection, termination, restriction, or significant modification of the Company's relationship with Customers or competitors, pricing determinations, use of competitor information, as well as potential mergers and acquisitions requires consultation with legal counsel and approval through formal Company processes.

THE COMPANY COMPETES VIGOROUSLY, INDEPENDENTLY, AND IN STRICT COMPLIANCE WITH THE ANTITRUST LAWS OF THE UNITED STATES.

As a Marketing Manager, I am planning on attending a trade association meeting that includes some of our competitors and have been invited to participate in a roundtable event. Are there any rules I should be aware of?

Yes. These meetings pose certain risks because they bring together competitors to discuss matters of mutual concern. You should consult applicable Company policies and/or get advice from Legal Affairs before participating in such a meeting.

If you have any questions about antitrust compliance, you should contact the Legal Affairs Department.



COMPETITIVE BUSINESS INTELLIGENCE

The Company respects the confidential and proprietary information of other companies. The gathering of publicly available competitive information is necessary to compete in business and is generally permitted. When employees are involved in the gathering of publicly available competitive information, however, they must do so in accordance with applicable laws and confidentiality agreements.

It is permissible to gather information on competitors from public sources such as websites, press briefings, publications, and public presentations by competitors or Customers. However, employees may not request or acquire confidential or proprietary information belonging to competitors or other persons.

The use of research vendors to obtain publicly available information is permissible. However, the vendor may only obtain information in a legal and ethical manner in compliance with all laws, Company policies, and confidentiality agreements. A vendor may never be used to obtain information that is confidential or proprietary to other companies. Employees looking to collect or hire a vendor to collect competitive information must first consult with the Legal Affairs Department.

THE COMPANY DOES NOT ACCEPT OR SOLICIT CONFIDENTIAL OR PROPRIETARY INFORMATION BELONGING TO THIRD PARTIES OR COMPETITORS.

- The Company will not ask Company employees to disclose confidential information from prior employment, and employees should not solicit confidential information from prior employers.
- If exposed to confidential information of another company, our employees should not distribute or use the information and should immediately forward the information to Legal Affairs.
- The Company will not put current or former employees of other companies in a position to violate their own confidentiality obligations by asking them to provide our Company with proprietary or confidential information.

I just joined the organization as a Manager in Managed Care and came from one of the Company's primary competitors. One of my colleagues was asking me about how my former employer plans to deal with the evolving managed care environment. Is it okay to answer the question?

No. You should never disclose the confidential and proprietary information of any of your prior employers or companies with whom you have had prior business dealings. If anyone at the Company suggests that you disclose such information, you should contact the Legal Affairs Department or Compliance.

My manager asked me to reach out to some colleagues at the clinical research organization I used to work for to find out details of the new study they are doing with one of our competitors. Is this okay?

No. You may not reach out to employees at another organization to collect confidential information.

I was in a doctor's office today, and the office staff asked if I wanted a copy of our competitor's new detail piece. Is it okay for me to accept?

Yes. It is okay to accept publicly available information. Never ask for or accept any material that is identified as confidential.



BRIBERY AND CORRUPTION

Employees and anyone acting on our behalf are prohibited from directly or indirectly paying or providing anything of value to [Government Officials](#) to improperly influence or gain unfair business advantage.

As a leading developer of innovative new pharmaceuticals, the Company must be particularly sensitive to bribery and corruption issues because governments and government employees are often both the regulators of our products and Customers.

THE COMPANY MAINTAINS HIGH ETHICAL STANDARDS AND WILL NOT SEEK BUSINESS ADVANTAGES THROUGH UNETHICAL OR ILLEGAL MEANS.

Also, many of the healthcare professionals (HCPs) and scientists with whom we interact are employees of public institutions and may be considered government officials. For this reason, no employee should ever make a payment or provide a benefit in any form that is intended to improperly influence, or even appears to improperly influence, a government official's actions.

Company employees may not offer or provide any form of [Gift](#) or payment to HCPs or Customers to induce them to prescribe, recommend, or place in a favorable formulary position any Company products.

- Employees are prohibited from directly or indirectly paying, giving, promising, gifting, authorizing, or offering money or anything of value to any domestic or foreign public official or other third parties, on behalf of the company, to obtain commercial benefit or advantage.

- Employees must also not commit such acts using third parties who provide services to the Company.
- The Company's interactions with HCPs should be focused on informing them about our products, providing scientific and educational information, supporting medical research, and education.
- The Company has issued a [Global Anti-Bribery & Anti-Corruption \(ABAC\) Policy](#), which is positioned as a supplement to the Daiichi Sankyo Group Corporate Conduct Charter and the Daiichi Sankyo Employee Code of Conduct, and that applies to all executives, employees and [Contingent Workers](#) of all Daiichi Sankyo Group Companies. This global policy establishes the minimum standards of global anti-bribery and anti-corruption rules and principles to promote ethical business conduct and ensure compliance with anti-bribery and anti-corruption laws and regulations across the entire Daiichi Sankyo Group. All executives, employees and contingent workers must maintain high ethical standards by adhering to all applicable laws and industry codes, and internal policies, procedures and conduct codes of the Company, which may impose more stringent requirements than the Global ABAC Policy. In addition, Daiichi Sankyo, Inc. and American Regent have each issued ABAC policies that apply to executives, employees and contingent workers of each respective company.

Are facilitation payments to non-US government officials allowed (for example, payment to facilitate visas or provide mail services)?

No. Facilitation payments may never be used, even where otherwise permitted by law.



INTERNATIONAL TRADE

International trade is fundamental to maintaining a global economy but requires awareness and diligence by organizations to ensure their business associations are with appropriate countries, individuals, and organizations.

Antiboycott laws are adopted to encourage and, in some cases, require US companies to refuse to participate in foreign boycotts that the United States does not sanction. They have the effect of preventing US companies from being used to implement foreign policies of other nations that run counter to US policy. The Arab League boycott of Israel is the principal foreign economic boycott that US companies must be concerned with today. The antiboycott laws, however, apply to all boycotts imposed by foreign countries that are not sanctioned by the United States. The types of activities prohibited under antiboycott laws include:

- Agreements to refuse or actual refusal to do business with or in Israel
- Agreements to discriminate or actual discrimination against other persons based on race, religion, sex, national origin, or nationality
- Agreements to furnish or actual furnishing of information about race, religion, sex, or national origin of another person
- Implementing letters of credit containing prohibited boycott terms or conditions

WE DO NOT SUPPORT OR CONDUCT OUR BUSINESS WITH NATIONS, ENTITIES, GROUPS, OR INDIVIDUALS WITH WHOM THE UNITED STATES PROHIBITS TRADE, NOR DO WE PARTICIPATE IN PROHIBITED BOYCOTTS.

Import/export controls: The Company will not knowingly import from or export to countries against which there is a US embargo or individuals or organizations with which contact is prohibited by the US government.

The Office of Foreign Assets Control (OFAC) of the US Department of the Treasury administers and enforces economic and trade sanctions based on US foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, those engaged in activities related to the proliferation of weapons of mass destruction, and other threats to the national security, foreign policy, or economy of the United States.

- OFAC maintains a list of sanctioned countries. Depending on the country, OFAC may freeze assets of embargoed countries, prohibit payment of funds to individuals and countries on the embargo list, prohibit provision of services to countries subject to US sanctions or provide other sanctions. Currently, sanctioned regions and countries include the Balkans, Belarus, Burundi, Central African Republic, Cuba, Democratic Republic of Congo, Iran, Iraq, Lebanon, Libya, Mali, Nicaragua, North Korea, Somalia, Sudan and Darfur, Syria, Ukraine/Russia, Venezuela, Yemen, and Zimbabwe. The list of sanctioned countries is updated periodically. Any employee conducting business in these regions, or any country on an OFAC sanction program, must consult with the Legal Affairs Department before engaging in such activity
- “Exports” include not only the shipment of physical goods, but also the transfer of services or technology through methods such as e-mail, conferences, meetings, and site visits
- The Company will not do business with any individuals or companies owned or controlled by, or acting for or on behalf of, countries identified by OFAC. OFAC also lists individuals, groups, and entities, such as terrorists and narcotics traffickers designated under programs that are not country-specific. Such individuals and companies are called “Specially Designated Nationals” or “SDNs.” Their assets are blocked and US companies and the Company are generally prohibited from dealing with them



If you have any questions about compliance with the antiboycott laws or import/export control laws, you should contact the Legal Affairs Department.

TRANSPARENCY AND REPORTING REQUIREMENTS

The Company is committed to the timely public disclosure of information about its financial relationships with healthcare professionals (HCPs), as required by law.

Employees are responsible for accurately recording and reporting all reportable expenses required under applicable federal and state laws, including, but not limited to:

- Payments or items of value (for example, meals and travel) to teaching institutions and physicians
- Payments to clinical investigators
- Payments to [Consultants](#) and [Speakers](#) in conjunction with promotional programs, fee-for-service arrangements, or other engagements permitted by law and by Company policies

THE COMPANY COMPLIES WITH ALL STATE AND FEDERAL LAWS REGARDING TRACKING AND REPORTING IN CONNECTION WITH PAYMENTS OR TRANSFERS OF VALUE TO HCPs.



PATIENT SAFETY AND ADVERSE EVENT REPORTING

The safety of patients using our products is paramount, and the safe participation of clinical trial subjects is critical to the development of compounds developed by the Company. We conduct clinical studies in a manner that recognizes the importance of safety and respects research subjects, and we take precautions established to protect both research subjects and patients who use our marketed products.

Adverse Event reporting for marketed products: An adverse event includes any unintended experience associated with the use of a drug, any unanticipated exposure, overdose, abuse, misuse, medication error, product defect, or product quality complaint.

All Daiichi Sankyo, Inc. employees must report any and all adverse events within twenty-four (24) hours of first becoming aware of any adverse event associated with a marketed Daiichi Sankyo product to the Contact Center at 877-4-DS-PROD (877-437-7763). All American Regent employees and [Agents](#) must report any and all adverse events associated with American Regent products within twenty-four (24) hours to American Regent's Pharmacovigilance Department at 800-734-9236 or via e-mail at pv@americanregent.com. Adverse events must be reported whether or not the event is considered to be drug related.

All Company employees must report adverse events regardless of where, when, or how the information was received.

Examples include information:

- Learned during an in-office or virtual presentation, during a meeting with a vendor, healthcare professional (HCP), and Customer
- Brought to a Company employee's attention by friends, neighbors, acquaintances, or competitors
- Learned at work or in non-work situations
- Discovered spontaneously
- Communicated in person or remotely (for example, electronically)

WE ARE COMMITTED TO THE SAFETY OF SUBJECTS WHO PARTICIPATE IN OUR CLINICAL TRIALS AND PATIENTS WHO USE OUR PRODUCTS, AS WELL AS THE ACCURATE AND TIMELY REPORTING OF ADVERSE EVENTS FOR BOTH MARKETED PRODUCTS AND DEVELOPMENT COMPOUNDS.

Adverse event reporting for clinical studies: Adverse event reporting for products in clinical studies shall follow the requirements as outlined in the clinical study protocol.

What information do I need to report an adverse event?

Always call with whatever information you have, even if it is incomplete. Ideally, though, try to obtain the following:

1. Reporter information, including contact details (phone number, mailing address, etc.). The reporter may be a patient, another consumer, an HCP, or anyone else with knowledge of the adverse event;
2. If the reporter is not the treating HCP, obtain the contact information, including phone number(s), for the treating HCP;
3. The name of the product and information regarding how the product was used (indication, dosage, duration of use, etc.);
4. Patient information, including age, patient identifier (e.g., patient initials or other description), gender, medical history, and contact information;
5. A brief description of the adverse event using as many of the actual words in the original communication as was initially communicated to the employee;
6. The date that the adverse event was communicated to the employee or the date he/she first became aware of the adverse event;
7. When available, the lot number of the product the patient used; and
8. In case the adverse event relates to a clinical study, follow all other requirements as set forth in the study protocol.

TRANSPARENCY OF CLINICAL DATA

The Company is committed to the transparency of clinical trials that it sponsors. We recognize there are important public health benefits that result from making appropriate clinical trial information widely available to healthcare professionals (HCPs), patients, and the public. Our disclosures, however, maintain protections for patient privacy, Company intellectual property, and contract rights, as well as comply with legislative requirements and patent law practices. As sponsors, we verify data from all study sites, and we ensure the accuracy and integrity of our study database.

The Company has adopted procedures by which its sponsored clinical trials are registered, and results are disclosed for public viewing on [ClinicalTrials.gov](https://clinicaltrials.gov), the databank administered by the US National Library of Medicine. Disclosing information about clinical trials sponsored by the Company in a public portal helps achieve the Company policy of transparency regarding clinical trials, and also achieves compliance with US federal and state regulations regarding clinical trial disclosure.

THE COMPANY DISCLOSES AND COMMUNICATES ITS SCIENTIFIC DATA AND RESULTS IN AN ACCURATE AND TIMELY MANNER, INCLUDING THE LISTING OF OUR CLINICAL TRIAL PROTOCOLS ON [CLINICALTRIALS.GOV](https://clinicaltrials.gov).

THE COMPANY HAS ADOPTED AND ADHERES TO [PHARMA PRINCIPLES ON CONDUCT OF CLINICAL TRIALS AND COMMUNICATION OF CLINICAL TRIAL RESULTS \(JUNE 2015\)](#).

Do we have to post ALL clinical results on clinicaltrials.gov? For example, do we have to post the results from a post hoc analysis of clinical data that looks at data and results that weren't in the original protocol and/or statistical analysis plan? What about results that are not positive?

The regulations require the reporting of clinical results, regardless of whether they are positive or negative.

Does the data posted on [ClinicalTrials.gov](https://clinicaltrials.gov) and in the clinical study report have to match exactly?

Clinicaltrials.gov sometimes requires data that are not included in the clinical study report. For example, we may need to post demographic information on the entire study population, which is not included in the clinical study report.



PRIVACY OF PATIENT INFORMATION IN CLINICAL STUDIES

Respecting the privacy of subjects in our sponsored clinical studies is critically important to the Company. There are times when legitimate research activity may necessitate the review of a patient's medical record or the collection of personal information.

We employ procedures to prevent such personal information from being released to Company employees and provide education on how to appropriately handle this information should it be inappropriately released into our possession.

We ensure that clinical research organizations (CROs) and investigators receive training to inform them of the importance of not releasing personal subject information to the Company as the sponsor.

We ensure that informed consent forms (ICFs) for sponsored studies contain appropriate wording under the [Health Information Privacy and Accountability Act \(HIPAA\)](#) legislation and European Data Protection legislation, and other country-specific laws and regulations informing subjects of their rights and what will happen to their data.

THE COMPANY WILL HOLD CONFIDENTIAL ANY PATIENT-IDENTIFYING DATA WE COME IN CONTACT WITH DURING THE NORMAL COURSE OF BUSINESS AND USE IT ONLY FOR THE PURPOSES FOR WHICH PERMISSION WAS GRANTED.

Q&A

I received some clinical data with a patient's name included. What should I do?

Contact your manager, as well as Legal Affairs, to determine whether there are any notification requirements and other requirements that need to be implemented in order to address the privacy breach.



CONDUCT OF CLINICAL TRIALS

The rights, safety, and well-being of study subjects are the most important considerations when conducting clinical studies. It is Company policy to comply with all applicable research-related policies and guidances. We design and conduct our clinical trials in an ethical, scientifically rigorous manner, to study the benefits, risks, and value of our pharmaceutical products.

The Company prides itself on providing beneficial, safe, and reliable pharmaceuticals to patients. Our clinical research is conducted under the direction of qualified medical and scientific personnel and according to applicable standards of medical and clinical ethics. We educate all employees engaged in research and development to ensure that they adhere to ethical standards in their research and development activities. We conduct our clinical trials in compliance with the Declaration of Helsinki, the Guideline for Good Clinical Practice of the International Conference on Harmonisation (ICH), the [PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results \(June 2015\)](#), and all applicable local laws and regulations, including the disclosure obligations of the Food and Drug Administration Amendments Act (2007).

Company responsibilities in conducting clinical trials include the management and oversight of study activities to ensure the rights and well-being of human subjects are protected, the reported study data are accurate and complete, the inventory of investigational product is managed, and the conduct of the trial is in compliance with the currently approved protocol and relevant legal and regulatory requirements.

The Company continuously monitors for any new regulations to ensure clinical practices are current with applicable regulations.

WE CONDUCT OUR CLINICAL STUDIES IN AN ETHICAL AND COMPLIANT MANNER, IN ACCORDANCE WITH INTERNATIONAL STANDARDS INCLUDING THE GUIDELINE FOR GOOD CLINICAL PRACTICE OF THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH), THE [PHRMA PRINCIPLES ON CONDUCT OF CLINICAL TRIALS AND COMMUNICATION OF CLINICAL TRIAL RESULTS \(JUNE 2015\)](#), AND OTHER COUNTRY-SPECIFIC LAWS, REGULATIONS, AND INTERNAL PROCEDURES.



ANIMAL WELFARE

The use of animals in the conduct of preclinical trials for the advancement of human pharmaceuticals is, at times, necessary to determine efficacy in an indication, pharmacokinetic (PK) properties, and to ensure the safety of a drug when no other means is acceptable or available, and is done in compliance with health authority regulations. When the use of research animals is needed, the Company is committed to the humane and respectful treatment of them at all times.

The Company thoroughly evaluates all planned animal studies to minimize the use of research animals by seeking alternatives wherever feasible.

While the Company does not conduct any animal research directly, the Company ensures that any third party who conducts such preclinical studies on its behalf, abides by generally accepted standards of animal care and is required to comply with all laws and regulations, whether federal, state, or local.

To the extent possible, this means we avoid or minimize the distress or discomfort to animals, minimize the number of animals to obtain valid results, and only use them if their use is relevant or required by regulatory health authorities for the study of human health or for the advancement of scientific knowledge.

All employees who are involved in the design and conduct of studies involving animals must be properly qualified and trained. They must follow all Company standards as well as all applicable laws and regulations. The Company thoroughly evaluates all planned animal studies to minimize the use of research animals by seeking alternatives wherever feasible.

While the Company does not conduct any animal research directly, the Company ensures that any third party who conducts such preclinical studies on its behalf, abides by generally accepted standards of animal care and is required to comply with all laws and regulations, whether federal, state, or local.

THE COMPANY IS COMMITTED TO CONDUCTING ALL PRECLINICAL ANIMAL RESEARCH IN AN ETHICAL AND RESPONSIBLE MANNER.

To the extent possible, this means we avoid or minimize the distress or discomfort to animals, minimize the number of animals to obtain valid results, and only use them if their use is relevant or required by regulatory health authorities for the study of human health or for the advancement of scientific knowledge.

All employees who are involved in the design and conduct of studies involving animals must be properly qualified and trained. They must follow all Company standards as well as all applicable laws and regulations.





COMPANY INFORMATION AND RESOURCES

PROTECTION OF COMPANY INFORMATION

Information is a valuable corporate asset, and much information about our business activities is confidential or proprietary. [Confidential Information](#) is information that the Company considers private and that is not common knowledge outside the Company. Proprietary information is information the Company owns, develops, pays to have developed, or to which it has an exclusive right. Because the disclosure of such information could seriously damage the Company's interests, safeguarding this information is the responsibility of all our [Employees](#). Protection of confidential and proprietary Company information, including trade secrets, is critical to our continued growth and ability to compete.

- Employees may not disclose confidential or proprietary information without having an authorized and fully executed Confidential Disclosure Agreement (CDA) in place with third parties including current or potential [Vendors](#), partners, contractors, etc.
- Employees will not share proprietary information with anyone including spouses, other family members, and friends not entitled to know for a legitimate business reason.
- To avoid inadvertent disclosure of such information, employees will avoid discussions of Company information in public places such as elevators, airplanes, or restaurants.
- Employees may never include or share confidential or proprietary information in [Social Media](#) or other public forums.
- Confidential and proprietary information may only be disclosed to other Company employees who need to know it.
- Once employees are entrusted with confidential information of third parties, they must protect it as they would protect confidential information of the Company.
- Employees may not share confidential and proprietary information for their own benefit or for the benefit of anyone outside the Company.
- An employee's obligation to protect the Company's confidential and proprietary information continues even after he or she leaves the Company.

EMPLOYEES ARE REQUIRED TO KEEP ALL CONFIDENTIAL, PROPRIETARY, AND TRADE SECRET INFORMATION IN CONFIDENCE AT ALL TIMES. EMPLOYEES MUST COMPLY WITH THE TERMS OF THEIR EMPLOYEE OBLIGATION AGREEMENT.

As a manager at American Regent's production facility in Shirley, NY, I am always looking at different ways to improve or streamline our production process. I am thinking about using a neighbor as a consultant. He is a retired process engineer from another large pharmaceutical company. Can I bring him in for a tour so that he can provide some recommendations?

No, not until there is a fully executed CDA in place. There may be additional conflict of interest issues associated with hiring a neighbor as a consultant, if that is your plan. In addition, you may not ask him to disclose confidential or proprietary information of his prior employer(s).



MEDIA INQUIRIES AND EXTERNAL COMMUNICATIONS

Any form of external communication can potentially have a significant impact on the share price or reputation of the Companies. It is critical that all Company information released to the public be accurate and truthful.

Only Company-authorized spokespersons may give press and media interviews or make presentations to the financial community.

All external presentations about the Company, its [Products](#), and its business, whether to the public, HCPs, [Customers](#) or other third parties, must be limited to Company-approved content, even if the presentation would not be a disclosure of confidential and proprietary information.

ONLY COMPANY-AUTHORIZED SPOKESPERSONS MAY RESPOND TO INQUIRIES FROM THE MEDIA, THE FINANCIAL COMMUNITY, OR OTHER OUTSIDE ENTITIES ABOUT THE COMPANY.

Because there may be opportunities for employees to present in public settings such as trade association meetings or to author articles, employees must have their external presentations and articles authorized by your immediate [Manager](#) and reviewed in advance by Senior Management, Intellectual Property, and/or Legal Affairs as applicable.

Company employees may not discuss Company-related business in public forums, including social media networks, unless properly authorized by the Company.

I work in Clinical Development, and we just unblinded one of our pivotal Phase III trials. I got a call from a science editor at the Wall Street Journal asking about the results. May I share what I know?

No. All media contacts need to be directed as follows: For Daiichi Sankyo, Inc., to the Public Affairs Department; for American Regent, to the Legal Department.

I was recently promoted to Executive Director. My local newspaper wants to do a quick interview to talk about my promotion and to get some background on the Company, and our products. I plan to limit my comments to publicly available information, and my boss said he thinks this will be great local exposure for our department. Can I do the interview?

Even though you do not plan to disclose any confidential or proprietary information, you may not give the interview without prior authorization from the Public Affairs Department for Daiichi Sankyo, Inc.; or from the Human Resources Department, in consultation with the Legal Department, for American Regent. Similarly, any media contacts that are received must also be directed to the entities described in the preceding sentence.



SECURITIES LAWS AND INSIDER TRADING

In the course of performing work for the Company, employees may learn information about the Company or other companies before it is made public. All employees have an obligation not to use such information for their personal advantage or to share it with others. Serious legal obligations apply to trading in the stock of our parent company, Daiichi Sankyo, Co., Ltd., which is publicly traded in Japan as well as in the United States through American Depository Receipts (ADRs). Similar obligations apply to other companies that we do business with and to our [Competitors](#).

Inside information includes, but is not limited to:

- Contracts or proposed contracts with Customers, suppliers, or business partners
 - Proposed acquisitions, joint ventures, or divestitures
 - New products or services and regulatory approvals or disapprovals
 - Financial performance
 - Insider trading is the buying or selling of stock or securities of any company while aware of information about the company that is both material and nonpublic. It is illegal.
- The same rules against using inside information apply when an employee gives that information other than in the necessary course of business to someone else, such as a friend or family member, because he or she may profit from that information by trading in stock or other securities.
 - If employees are uncertain about the legal rules involving purchase or sale of any stock or securities in Daiichi Sankyo, Co., Ltd., its current or potential competitors, partners, vendors, or other companies that they are familiar with by virtue of their work for the Company, they should consult with Legal Affairs before making any such purchase or sale.
 - Other companies that may be affected by inside information include our Company's or our parent company's competitors, development and commercialization partners, and vendors. Such confidential nonpublic information is considered "material" if it is important enough to affect a reasonable investor's decision to buy or sell shares of any company's stock. This includes nonpublic material information about other entities that you may learn through your work at the Company.

EMPLOYEES MUST NEVER USE CONFIDENTIAL OR PROPRIETARY COMPANY INFORMATION OR THAT OF ANOTHER PARTY ENTRUSTED TO THE COMPANY AS A BASIS FOR PURCHASING OR SELLING STOCK OR SECURITIES IN OUR PARENT COMPANY, DAIICHI SANKYO, CO., LTD., OR THE STOCK OR SECURITIES OF OTHER COMPANIES THAT MAY BE AFFECTED BY SUCH KNOWLEDGE.



I've heard some rumors in the hallway that Daiichi Sankyo, might acquire a small biotech company. Is it okay for me to tell my brother-in-law that the biotech company is "one to watch"?

No. Recommending or buying stock with knowledge of a potential financial deal that is material and not publicly available would be considered insider trading, and is illegal.

THEFT OF COMPANY PROPERTY

Company assets and property are provided to Company employees for them to conduct business and perform work on behalf of the Company.

As a general rule, Company property, equipment, or funds may not be used for personal reasons except for the limited use of communication tools found in [Use of E-mail, Voice Mail, and Other Company Systems](#).

Theft, whether directly (for example, the permanent and intentional removal of Company equipment) or indirectly (for example, seeking reimbursement for expenses not related to Company business), will result in disciplinary action up to and including termination and may be a criminal act.

THEFT OR MISUSE OF ANY COMPANY EQUIPMENT, PROPERTY, FACILITY, OR FUNDS, INCLUDING, WITHOUT LIMITATION, THE SUBMISSION OF INAPPROPRIATE OR FRAUDULENT PAYROLL TIME SHEETS OR REQUESTS FOR REIMBURSEMENT OF EXPENSES, WILL NOT BE TOLERATED.



RECORDS MANAGEMENT

Proper storage, management, retention, and disposal of Company records are important to the Company's business; in addition, they satisfy various legal and regulatory requirements.

Consistent with good business practices and good judgment, we will retain records for as long as required and in the manner required to meet legal, regulatory, administrative, and operational requirements, after which they may be disposed of according to Company procedures.

Records relating to actual or threatened litigation or government investigations must be kept under a "legal hold" until the Legal Affairs Department communicates otherwise in writing. Legal holds can apply to any classification of records under Company policy or program involving records management. Requirements outlined in legal holds supersede the records retention policy and schedule. If you are uncertain whether records under your control should be preserved because they might relate to a lawsuit or [Investigation](#), contact Legal Affairs. American Regent employees should contact the Legal Department.

OFFICIAL RECORDS MUST BE APPROPRIATELY SAFEGUARDED BY ALL COMPANY EMPLOYEES. ALL OFFICIAL RECORDS MUST BE APPROPRIATELY STORED, MANAGED, AND DISPOSED OF.

Official Record: A record that is the complete and final version that provides evidence of the Company's operations (for example, organization, business functions, policies, decisions, procedures, or internal or external transactions). Official records typically commit the organization or a third party to an action or document an action, obligation, or responsibility. These records are often required to be retained for business, regulatory, and/or legal reasons.

Q&A

Legal Affairs just put a legal hold in place for all documents relating to the clinical development of one of our marketed products. I was on the clinical study team, and it has always been my personal policy to delete e-mail on any project more than a year old. Can I delete such e-mail?

No. You must follow the legal hold. Also, you must follow Company and department policies about the retention of e-mail, rather than any "personal policies" or work habits; this includes items not subject to a legal hold. Contact Legal Affairs to review your specific situation if you have any questions about any of the directions provided in the legal hold.



ACCURATE BOOKS AND RECORDS

Accurate reporting of corporate activities and processes, from financial information to results of research and development activities, has received significant attention both globally and in the United States. Serious ramifications, including fines, reputational harm, and other sanctions, exist for knowingly reporting inaccurate information or creating or falsifying information and records. The accurate reporting of data and information is important to the Company and critical to our success.

The integrity of the Company's accounting records is critical to maintaining credibility with our Customers, suppliers, and regulators. All business and financial information must be reported accurately and completely by all employees as required by Company policy and/or federal, state, or local authorities.

THE COMPANY IS COMMITTED TO ACCURATE REPORTING OF ALL INFORMATION, INCLUDING FINANCIAL, CLINICAL RESEARCH, PRODUCTION AND QUALITY DATA, AND OTHER COMPANY INFORMATION THAT IS RELEASED TO THE PUBLIC, THE GOVERNMENT, AND ANY OTHER ENTITIES. COOPERATION WITH INTERNAL AND EXTERNAL AUDITORS IS EXPECTED OF ALL EMPLOYEES. FALSIFICATION OR INACCURATE REPRESENTATIONS OF ANY BOOKS, RECORDS, REPORTS, MANUFACTURING, OR PRECLINICAL DATA OR CLINICAL TRIAL RESULTS WILL NOT BE TOLERATED.

Preclinical and clinical research data must be accurately recorded and reported as required by local, state, federal, or international laws and regulations.

Accurate recordkeeping and reporting are equally important in all areas of our business, including our internal recordkeeping. For example, employees are responsible for the accuracy and completeness of environmental and safety reports and records, drug sampling records and call reports, shipping and purchasing data, commercial contracts, invoices, costs and expenses, and payroll, benefits, and employment records.

I have responsibility for signing off on a Finance Department report that is due tomorrow morning. I am not 100% sure of the accuracy of some of the information. What should I do?

Discuss the issue with your manager and take steps to ensure that the report accurately reflects Company operations and data. If you cannot ensure accuracy by the time the report is due, either do not submit it or submit it with a clearly written explanation of your concerns regarding its accuracy.





CORPORATE RESPONSIBILITY

DSI Compliance Hotline: 1 (877) 48ALERT (1-877-482-5378) or [dsi.alertline.com](https://www.dsi.alertline.com)

ACCESS TO MEDICINES

As part of its desire to address health issues, Daiichi Sankyo continually evaluates its US and global programs to assist patients who face obstacles (whether financial or medical) to receiving drug treatment.

Daiichi Sankyo seeks to strike an equitable balance between the public interest in securing the approval of a new drug and allowing extended access to certain investigational products that may be necessary to treat seriously ill patients who cannot be satisfactorily treated with commercially available products, in the Company's discretion.

A GLOBAL MISSION OF DAIICHI SANKYO IS TO EXPLORE AND PURSUE DIFFERENT APPROACHES AIMED AT INCREASING ACCESS TO LIFE-CHANGING AND LIFE-SAVING MEDICINES THAT WE HAVE THE PRIVILEGE TO MARKET.

Daiichi Sankyo believes that improving access to medicines can help solve an important part of the global health problem.

The Daiichi Sankyo PAP Foundation, Daiichi Sankyo Access Central resource, and American Regent PAP Program sponsor a patient assistance program to provide certain DSI products for free to qualified patients with demonstrated medical and financial need. Daiichi Sankyo assists qualified patients who are prescribed [Products](#) covered by these programs and who lack insurance coverage or alternative payment sources. Daiichi Sankyo strives to provide free product to uninsured patients who qualify and for whom no alternative source of reimbursement can be identified.



PHARMACEUTICAL PRODUCT PRICING

The Company is committed to pricing its products fairly and appropriately, and acts independently when setting prices, by factoring in costs, market conditions, customer responses, and the state of competition.

The Company is committed to vigorous competition. This position stems from the belief that competition, in a fair, free, and open marketplace, promotes innovation and market efficiency.

At times, the Company does change the prices of some of its medicines in consideration of changes in costs, investments in R&D and manufacturing, and other factors. The Company strives to ensure that the pricing of its product does not prevent affordable access to treatment. The final cost of any prescription medication to a patient depends on a number of factors, from the Wholesale Acquisition Cost (the initial list price set by a manufacturer) and patient insurance status, to the insurer's co-pay and deductible policy.

THE COMPANY'S REVENUE ALLOWS IT TO CONTINUE THE RESEARCH, DEVELOPMENT AND COMMERCIALIZATION OF NEW AND INNOVATIVE THERAPIES AND FULFILL ITS MISSION TO CONTRIBUTE TO THE ENRICHMENT OF QUALITY OF LIFE AROUND THE WORLD AND ADDRESS DIVERSE MEDICAL NEEDS.

The Company works diligently to help secure lower out-of-pocket costs for the people who are prescribed our medications. This is achieved primarily through discounts and rebates.

Additionally, Daiichi Sankyo and ARI offer their own Patient Assistance Programs, found in [Access to Medicines](#), for individuals who meet certain financial criteria. These programs are intended to ensure that patients of limited means and for whom no alternative source of reimbursement can be identified, have access to needed therapy.

Price and access to medicines is just one part of the larger healthcare system, and it is important to consider pricing data within this broader context. For example, when taken appropriately, medicines reduce other healthcare-related costs.

As the healthcare market continues to evolve, the Company will continue to prioritize patient-focused policies to address costs holistically across the continuum of care.



ENVIRONMENTAL STEWARDSHIP

Concern for environmental factors such as the water we drink, the air we breathe, and the carbon footprint we create is critical to each of us as individuals and as [Employees](#) of the Company. The Company works to identify initiatives to protect our environment now and for future generations.

The Company:

- Contributes to the reduction and remediation of environmental issues affecting our stakeholders and our world;
- Encourages conservation and environmentally sustainable practices by using natural resources and energy wisely and efficiently. The Company values employee efforts to consider the environmental impact when making business decisions and planning and developing new products; and
- Encourages recycling at all of its facilities by providing appropriate receptacles to meet these objectives.

THE COMPANY IS COMMITTED TO THE PRESERVATION OF OUR ENVIRONMENT AND TO FULL COMPLIANCE WITH ALL APPLICABLE LOCAL, STATE, AND FEDERAL ENVIRONMENTAL LAWS AND REGULATIONS.





COMPLIANCE WITH THE STANDARDS OF BUSINESS CONDUCT

STANDARDS OF BUSINESS CONDUCT

All [Employees](#) have a responsibility to follow these Standards of Business Conduct. The Company is committed to conducting all business activities in an ethical manner consistent with industry standards and legal requirements. These Standards of Business Conduct reflect general standards to guide employees in making ethical decisions. They are not intended to address every specific situation. The Company strongly encourages dialogue between employees and their supervisors or with Human Resources to discuss ethical dilemmas, ask questions related to Company policies and procedures, and discuss acceptable ways of handling challenging situations.

- The Company has no tolerance for retaliatory action taken against an employee because he or she reports suspected violations or participates in an [Investigation](#). Anyone who is found to be engaged in such retaliation will be subject to disciplinary action, up to and including termination.
- There is no penalty for an employee who in good faith reports an actual or alleged violation.
- Following the review of a report, the Company will begin a confidential inquiry and take corrective action where appropriate. It may be determined that further investigation, including interviews and the review of relevant documents, is warranted.
- To the extent appropriate in each case, confidentiality will be expected for all those participating in an investigation. Additionally, the Company will attempt to treat all employee reports confidentially, disclosing information on a need-to-know basis only, and will seek to protect an employee's identity to the maximum extent possible.
- All employees, including the reporting employee, are required to cooperate in an investigation, if requested and provide timely, truthful, and accurate information in response to investigation requests, including those for interviews and documents.
- Violations of these Standards of Business Conduct, any Company policy, procedure, practice, regulation, rule, or law or any retaliation may result in discipline ranging from warnings and reprimand to termination. All disciplinary decisions will be made in accordance with HR practices and policies.
- Nothing prohibits or restricts the Company from taking any disciplinary action on any matters pertaining to employee conduct, whether or not they are expressly discussed in this document.
- The Company may revise, change, or amend these Standards of Business Conduct, policies, procedures, or practices at any time.

INDIVIDUALS WHO BELIEVE THAT THEY HAVE BEEN SUBJECTED TO CONDUCT THAT VIOLATES THE COMPANY'S POLICY PROHIBITING DISCRIMINATION OR WORKPLACE HARASSMENT ARE ENCOURAGED TO REPORT SUCH VIOLATIONS PROMPTLY. MANAGEMENT, HUMAN RESOURCES (HR), LEGAL AFFAIRS, COMPLIANCE OR THE DAIICHI SANKYO OR AMERICAN REGENT COMPLIANCE HOTLINE SHOULD BE NOTIFIED.

ALL INDIVIDUALS ARE REQUIRED TO PROMPTLY REPORT TO MANAGEMENT, HR, LEGAL AFFAIRS, COMPLIANCE OR THE DAIICHI SANKYO OR AMERICAN REGENT COMPLIANCE HOTLINE ANY SUSPECTED VIOLATIONS OF THESE STANDARDS OF BUSINESS CONDUCT, ANY COMPANY POLICY, PROCEDURE, PRACTICE, REGULATION, RULE, OR LAW OR ANY RETALIATION BY ANY EMPLOYEE OR AGENT OF THE COMPANY.

Why is it a requirement to report observed or suspected violations of the Standards of Business Conduct or any other Company policies?

To provide all patients, Customer and Agents, and employees the protections outlined in these Standards and maintain the values and ethical goals of the Company, it is incumbent on all stakeholders listed to support these Standards by reporting any violations or suspected violations of these Standards or any other Company policies.

Reference:

- [Employee Conduct in the Workplace](#)



DAIICHI SANKYO GROUP CORPORATE CONDUCT CHARTER

The Daiichi Sankyo US Standards of Business Conduct represent those core values by which we conduct our business here in the United States. These Standards are consistent and aligned with the Daiichi Sankyo Group Corporate Conduct Charter and Employee Code of Conduct. We have included these documents here as the foundation on which the US Standards of Business Conduct are based.

Foreword

The DAIICHI SANKYO Group fulfills its mission “To contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs.” We comply with laws, regulations and rules regarding global corporate activities, and act with the highest ethical standards and a good social conscience based on the following 10 principles of this Charter.

In order to actively respond to an ever-changing society, we address social issues and business in an integrated manner. It will enhance our corporate value, fulfill our social responsibilities and contribute to the realization of a sustainable society.

Article 1: Contribution to Healthcare

We diligently address medical needs by providing beneficial, safe, and reliable pharmaceuticals and services.

Article 2: Fair Business Practices

We respect international norms, diverse cultures and customs, conduct business in a fair manner through free and fair competition, and conduct responsible procurement by complying with laws and regulations in each country and region in which we do business. We maintain productive, positive and professional relationships with our stakeholders, which include medical professionals and governments.

Article 3: Fair Disclosure of Information and Constructive Dialogue with Stakeholders

We actively, effectively and fairly disclose corporate information to the public and engage in an open and constructive dialogue with a wide range of stakeholders.

Article 4: Respect For Human Rights

We conduct business that respects the human rights of all persons.

Article 5: Enhancement of Workplace Environment and Human Resource Development

We respect the diversity of our employees, and seek to include a diversity of thought in our daily work.

We are committed to ensuring a healthy and safe working environment and do not tolerate harassment and discrimination. We provide employees the opportunity to develop their skills and abilities for the mutual growth of the individual employee and the corporation.

Article 6: Information Management

We take necessary measures to manage and protect personal information, business partner information as well as other confidential information of Daiichi Sankyo and others.

Article 7: Engagement in Environmental Issues

Environmental challenges are universally critical to all of mankind. We responsibly manage the environmental impact of our operations and include our efforts for a better environment in our corporate activities and our very survival.

Article 8: Involvement in Community and Contribution to its Development

We are actively involved in community activities and contribute to its development as a good corporate citizen.

Article 9: Thorough Crisis and Emergency Management

We adhere to crisis and emergency management in the face of actions by antisocial forces, terrorism, cyber-attacks, natural disasters, pandemics and other significant issues that may threaten the order or safety of civil society and the corporate activity.

Article 10: Role of Executives and Implementation of this Charter

Executives of the DAIICHI SANKYO Group actively build and maintain effective governance systems to implement this Charter, ensure it is understood by all Group companies, and encourage behavior based on the principles of this Charter to the business partners of Daiichi Sankyo Group. If the Charter is violated, executives of DAIICHI SANKYO Group Companies take responsibility to respond by determining the cause of infringement, taking corrective action as necessary and making efforts to prevent similar violations in the future.

DAIICHI SANKYO GROUP EMPLOYEE CODE OF CONDUCT

The Daiichi Sankyo US Standards of Business Conduct represent those core values by which we conduct our business here in the United States. These Standards are consistent and aligned with the Daiichi Sankyo Group Corporate Conduct Charter and Employee Code of Conduct. We have included these documents here as the foundation on which the US Standards of Business Conduct are based.

Introduction

The purpose of the Code is to establish uniform standards of fairness, ethics and integrity, by which all Executives and Employees will operate. The Code applies to executives, directors, officers, employees, temporary workers (whether full-time or part-time), and any individual hired or contracted by Daiichi Sankyo Group companies (collectively, “Executives and Employees” or “We”). In this Code, references to “Daiichi Sankyo” or the “Company” include Daiichi Sankyo Company, Limited, and all its affiliates worldwide. In addition to the principles contained in our Business Partner Code of Conduct, we encourage our business partners to adhere to the principles outlined in this Code. The Code further requires Executives and Employees to conduct our business according to the framework established in this Code as well as our Core Values of Innovation, Integrity and Accountability, while abiding by applicable laws, regulations, industry codes, and our global, regional and local Company policies and procedures. This requirement applies equally to our interactions with stakeholders such as patients, [Healthcare Professionals](#), business partners, shareholders and society.

PATIENTS:

Aspiring to Improve Patient Quality of Life

We research, develop, manufacture and provide [Products](#) aimed to deliver value to our patients and improve their quality of life.

Patient Safety & Adverse Event Reporting

We collect, review and evaluate safety information on our drug products in a timely manner. We also report this information to regulatory authorities, as required, and promote proper use of our drug products.

Product Quality

In delivering value to patients, we research, develop, manufacture and provide products that meet strict quality and regulatory requirements.

Access to Healthcare

Pharmaceutical products only have meaning if they are accessible to patients. We continually evaluate our global programs to assist patients who face access barriers caused by social factors such as public health and income inequality, geographic, and financial factors, when receiving or in need of treatment. We believe that improving access to healthcare can help solve an important part of the global health crisis.

Relationships with Patients & Patient Organizations

We are committed to maintaining appropriate, transparent and fair relationships with patients and patient organizations.

Conduct of Clinical Trials/Studies

We conduct clinical trials/studies in an ethical and compliant manner in accordance with international standards including the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human use (ICH) guidelines. We conduct clinical trials/studies in a manner that recognizes the importance of safety and respects research participants, and we commit to maintaining the confidentiality of patient-identifiable data.

Access to Clinical Trial/Study Information & Transparency

We recognize the public health benefits that result from making appropriate clinical trial/study information widely available to patients, healthcare professionals, researchers, academicians and others, while maintaining patient privacy and confidentiality. We disclose our clinical trial/study information in an accurate, appropriate and timely manner.

Continued >

SOCIETY:

Sustainability

We believe in creating and maximizing long-term economic, social and environmental value. We do this in order to diligently address medical needs by delivering beneficial, safe and reliable medicines and services, while responsibly minimizing the negative environmental impact of our business operations.

Human Rights

We are committed to respecting the human rights of all people and upholding high labor standards.

Environmental Stewardship

We believe environmental management is the fundamental measure of sustainability and enhances our good corporate citizenship. We are committed to protecting our environment.

Animal Welfare

We minimize the use of animals for research by seeking alternatives wherever feasible. When the use of animals for research is needed, we are committed to their humane and respectful treatment.

Ethical Engagements

We do not support or conduct business with antisocial forces, prohibited entities or groups that may threaten the order or safety of society.

Involvement in Community & Social Contribution

We actively engage in community activities and philanthropic programs focused on social causes.

Stakeholder Relations & Social Media

We actively, effectively and fairly disclose Company information to the public and engage in an open and constructive dialogue with a wide range of stakeholders. We appropriately use [Social Media](#) to enhance our corporate value for the distribution of accurate and truthful Company information.

HEALTHCARE PROFESSIONALS & BUSINESS PARTNERS:

Appropriate Partners

We are committed to doing business with those healthcare professionals and business partners who comply with applicable laws, regulations, industry codes and contractual terms, including those related to human rights, workplace safety, the environment, child or forced labor, money laundering and bribes. We do not employ, nor do business with, individuals, companies or other entities who are debarred, excluded, or otherwise ruled ineligible by applicable laws and regulations.

Interactions with Healthcare Professionals

In various ways, we interact with healthcare professionals; including when we exchange medical information, conduct promotional activities, and engage in research and educational efforts. When engaging in such activities, we are committed to the highest standards of integrity.

Promotion & Advertising

We are committed to providing truthful, accurate and fairly balanced promotional messages for our products and disease awareness information, regardless of the medium of delivery. We do not permit or condone false or disparaging statements against our competitors or their products.

Anti-Bribery & Anti-Corruption

We do not provide or accept any money, [Gifts](#) or other benefits, to or from any [Government Official](#) or private party, for the purpose of securing an illicit or inappropriate business advantage.

STAKEHOLDER RELIABILITY:

Accurate Books & Records

We believe that the integrity of our Company information and data, such as accounting records and our preclinical and clinical research data, is critical to maintaining credibility with our patients, healthcare professionals, business partners, shareholders, and regulators. We are committed to accurately reporting all information, including financial, clinical research, production and quality data and any other Company data that is released to the public, the government, shareholders, or any other entities.

Anti-Trust & Fair Competition

Antitrust and competition laws promote fair competition and ensure our businesses compete based on quality, price and service. We compete vigorously, independently, and in compliance with the antitrust and competition laws of those countries in which we do business.

Insider Trading

We do not permit the use of material and non-public Company information, or that of business partners, as a basis for trading stock or securities in Daiichi Sankyo Company, Limited, or the stock or securities of other companies. This includes a prohibition on sharing material and non-public information with others (including family members, friends, or significant others).

Conflicts of Interest

We prioritize Company interests over our own business or financial interests and avoid situations in which our personal interests conflict with Company interests. If a potential conflict of interest arises, we require it be reported according to Company policies and procedures. If a potential conflict of interest exists, before acting, employees must seek direction on how to proceed in accordance with Company policies and procedures.

Continued >

Information Security

We maintain in confidence all proprietary and confidential information and trade secrets, whether belonging to the Company or any third party with which we do business.

Business Intelligence

We respect the confidential and proprietary information of third parties. We do not accept or solicit confidential and/or proprietary information belonging to third parties without their consent.

Privacy

We are committed to maintaining the confidentiality of protected personal information of patients, clinical trial/study subjects, healthcare professionals, business partners, shareholders and employees, and appropriately treat their personal information.

Safeguarding Corporate Assets

We properly use and maintain Company assets and ensure that they are protected from misuse, loss, theft and unnecessary waste. We appropriately maintain and protect Company intellectual property.

EXECUTIVES & EMPLOYEES:

Conduct in the Workplace

Our commitment is to support diversity in our workforce and in our leadership. We treat Executives and Employees with respect, fairness and dignity. We respect and value our Executives and Employees' individual characteristics, perspectives, and their distinctive backgrounds.

Discrimination & Harassment

We are committed to maintaining a work environment free from intimidation, violence or threats of violence. We do not tolerate discrimination or harassment against Executives and Employees by other Executives and Employees, supervisors, managers, business partners or healthcare professionals. We prohibit bullying including abusing one's position or role to harass another.

Workplace Safety

We maintain a safe working environment that protects the health and welfare of our Executives and Employees.

Growth & Development

We provide equal employment and advancement opportunities for all Executives and Employees according to each person's qualifications. Our work environment allows for the development of an individual's skills and abilities, which enables the individual Executive or Employee to grow within the Company.

REPORTING OF VIOLATIONS OF THIS CODE:

If any Executive or Employee discovers any actual or potential violation of this Code, the person must promptly report the matter to the responsible function(s) designated by each Company (such as Compliance, Legal or Human Resources), or to the person's [Manager](#), or via other mechanisms established on a local/ regional level. By reporting actual or potential problems, you are contributing to the Company's ethical culture. There is no penalty for reporting in good faith something that turns out not to be a problem. Daiichi Sankyo Group strictly prohibits retaliation against Executives or Employees who report actual or potential violation(s) of this Code in good faith and/or Executives or Employees who assist in the investigation of misconduct.

REPORTING INFORMATION

You are required to report incidents related to violation of the Standards of Business Conduct to your supervisor, Senior Management, Human Resources, Compliance, or Legal Affairs.

Please see the [Resources for employees to ask questions or raise concerns](#) section in this document for additional ways to report suspected violations of the Company's Standards of Business Conduct, policies, or procedures.

By reporting actual or potential problems, you are contributing to the Company's ethical culture, and, remember, there is no penalty for reporting in good faith something that turns out not to be a problem! Also, you will be protected by the Company's nonretaliation policy discussed previously in this document.

Daiichi Sankyo's Compliance Hotline:

1 (877) 48ALERT (1-877-482-5378) or
[dsi.alertline.com](https://www.dsi.alertline.com)

or

American Regent, Inc. Compliance Hotline:

1-877-482-5378 or
[ari.ethicspoint.com](https://www.ari.ethicspoint.com)



COMPLIANCE
PROGRAM

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Adverse Event	<p>Any unexpected medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unexpected and or unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. any unintended experience associated with the use of a drug in humans whether or not the event is considered drug related. Thus, any unanticipated exposures to the drug, with or without associated adverse effects, such as use during pregnancy or breastfeeding, should be reported even if no immediate adverse outcome was reported. Other examples of at risk exposures to a drug include drug overdose, abuse, or misuse, and medication error or inappropriate administration of the drug.</p>
Advertising and Promotional Material	<p>(a) All materials relating to Products, including without limitation any materials, which are a display of written, printed, graphic, visual or audio matter, broadcast material, internet postings (including links to any internet content prepared by a third party), or delivered by any other medium, promoting the use of such Products which constitute labeling or advertising pursuant to applicable laws, regulations, guidance documents and decisional law including without limitation brochures, booklets, mail pieces, file cards, price lists, catalogs, exhibits, literature and reprints, published references (e.g., PDR), formulary cards, flashcards, journal /magazine advertisements, slide kits, videotapes, CDROMs/ DVDs, notices, letters, signs, stickers, buttons, posters, display panels, press releases, meeting invitations, formulary committee presentations, etc.; (b) Sales force training materials created by any home office department or any sales region, district, etc. including manuals, slide presentations, memoranda, backgrounders, sales call algorithms, etc. (even though such items are not allowed to be distributed by Health Care Professionals), and promotional speaker training materials (slides, etc.); (c) Any item or material that pictures, names or discusses a prescription drug or device and is used in detailing or for dissemination to HCPs, Customers or consumers; (d) The dissemination by DS to HCPs, Customers or consumers of any article, magazine, book, pamphlet, etc. published by either DS or an independent third party that mentions any Product marketed by DS. (e) Advertising and Promotional Material as described in this section may also be referred to, collectively, as “Materials” for purposes of this policy.</p>

Advisory Board	<p>A meeting of HCP Consultants or Customers implemented for a legitimate business purpose to gain feedback and advice from the HCPs contracted to participate in the meeting so the Company may develop and market its products/compounds.</p>
Agent	<p>“Agent” as that term is used herein shall include all contractors, subcontractors, agents and other persons of Daiichi Sankyo, Inc. who create Advertising and Promotional Material for Products.”</p>
Clinical Investigator	<p>Individuals who actually conduct clinical studies at a study site.</p>
Clinical Study	<p>Research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies.</p>
Co-habitants	<p>Persons who share a primary residence with one another, regardless of whether they are relatives or are involved in an intimate personal/ romantic relationship.</p>
Competitors	<p>Companies whose product directly competes with a Company-marketed product (for example, products used to treat the same medical condition or in the same product class) and/or who has a product in Phase II of clinical research or beyond that will compete with a currently marketed product by the Company or will compete with a Company pipeline product.</p>
Confidential Information	<p>Confidential information is information that is intended, by the information owner, for a particular audience. This information is for use solely within the company or by its designated partners, and it is limited to those with a “need to know.” Confidential information includes but are not limited to: company private information, confidential employee information, financial information, corporate strategies, competitor sensitive information, trade secrets, specifications, customer lists, and research data, and network architectures, or anything covered by a non-disclosure agreement.</p>

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Conflict of Interest	For purposes of this Policy, the term “Conflict” or “Conflict of Interest” whether actual or perceived, shall have the meaning of the term “Conflict of Interest” as described in the DSI Standards of Business Conduct. A Conflict of Interest may arise in any situation in which an employee’s loyalties are divided between business interests that, to some degree, are incompatible with the interests of the Company. Employees must avoid any situation where personal interests (or those of relatives, friends, or associates) might conflict, or even appear to conflict, with the best interests of the Company. An “actual” Conflict of Interest is a situation in which a Member who is in a position of trust, has a competing professional or personal interest, in the outcome of a matter or could impair the ability of the Member to perform his or her duties and responsibilities objectively. A Conflict of Interest exists even if no unethical or improper act results. A “perceived” Conflict or Conflict of Interest is an appearance of impropriety that can undermine confidence in the Member by others.
Consultant (HCP)	All medical professionals including, but not limited to, physicians, medical students, nurses, nurse practitioners, physician assistants, pharmacists and medical technicians. “HCP” also includes other employees or staff involved in purchasing or prescribing decisions including, but not limited to, formulary and P&T committee members who are contracted by the Company to provide services.
Contingent Worker	All individuals who provide services to the company subject to a contingency. Typically, the contingency is a temporary need for services for a limited period of time, a select service, or a specific result/outcome. Contingent workers include agency temporary workers, independent contractors, consultants, vendors, contract workers and fellows.
Customer	Any entity involved in the purchasing, prescribing or reviewing for the purchasing or prescribing of a Company product including, but not limited to, purchasing groups, hospitals, medical schools, nursing homes, pharmacies, risk and non-risk bearing payers (e.g., PBMs, HMOs, PPOs, ACOs, etc.), physician groups, integrated health systems, drug wholesalers and distributors (primary or secondary), and federal and state government entities (e.g., CMS, VA, DOD, Federal Health Insurance Exchanges, etc.). “Customer” also includes any employees or staff of such entities involved in decisions related to purchasing, prescribing or review of Company products.

Employee	An individual hired directly by the Company and paid through the Company payroll as an employee for an ongoing, indefinite period to perform work for the Company on a weekly schedule.
Fair Market Value	The commercially reasonable amount of compensation that would be paid, directly or indirectly, in an arm’s length transaction, to an HCP Consultant, Customer, or its agent for the provision of legitimate Services.
Federal Healthcare Program	Any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5); or any State health care program receiving federal funds, including State child health plans.
Gift	Any and all items of value, including but not limited to: (a) cash (as well as any other cash equivalents); (b) gift certificates, gift cards and/or credits (as well as any other equivalents such as vouchers or passes for free hotel stays or services such as massages); (c) any tangible items such as greeting cards, flowers, gift baskets, food baskets, free or complimentary meals, clothing, etc.; (d) tickets (as well as any other equivalents) for sporting events, concerts, theater and/or related entertainment events; (e) donations made to a charity or memorial fund on behalf of a family member; (f) any similar item(s) that may have a personal benefit purchased using personal funds.
Government Official	A member of an agency, instrumentality, subdivision or other body of any national, state or local government, including hospitals and other health facilities owned or operated by a government; regulatory agencies; and government-controlled businesses, corporations, and societies.
Grant	An unsolicited request for financial support from Company to a Professional or Patient Organization or Healthcare I institution for support of a specific bona fide medical or scientific, or educational objective that is described in an agreement between Company and the organization and in which Company does not have control over intent, presenter, attendees (in the case of a research grant, any scientific protocol) and does not receive any tangible benefit. Examples: <ul style="list-style-type: none"> • Certified Continuing Medical Education Grants (CME) • Non-CME Educational program Grants • Fellowships, Scholarships and Similar Educational Opportunities • Other grants for research (non-clinical) or public policy initiatives.

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Health Insurance Portability and Accountability Act (HIPAA)	A Privacy Rule enforced by the Office for Civil Rights, which protects the privacy of individually identifiable health information.
Healthcare Professional (HCP)	All medical professionals including, but not limited to, physicians, medical students, nurses, nurse practitioners, physician assistants, pharmacists and medical technicians. “HCP” also includes other employees or staff involved in purchasing or prescribing decisions including, but not limited to, formulary and P&T committee members.
Investigation	The process undertaken in response to an alleged violation of law, regulation, Company policies, SOBC, or other misconduct to collect facts regarding the nature and Subject of the allegations, and which may include, without limitation, an internal review of data, documents, emails, or other materials (collectively, “records”); and/or an Employee being asked to provide assistance in gathering such records, as well conducting of interview(s) of any witnesses, the Subject, and other persons of interest.
Manager	An Employee, regardless of band level, who has one or more direct reports who are Employees.
Official Record	A record that is the complete and final version that provides evidence of DSI’s operations (e.g., organization; business functions; policies; decisions; procedures; or internal or external transactions). Official Records typically commit the organization or a third-party to an action or document an action, obligation or responsibility. These records are often required to be retained for business, regulatory and/or legal reasons and are listed in the Records Retention Schedule set forth in IT-AOP-001.1.
Off-Label	Unapproved indications or uses for products currently on the market or products that have not yet been approved by the FDA.
Payment	Any offer, payment, promise to pay, or authorization of payment of any money, or offer, gift, promise to give, or authorization of the giving, of anything of value.
Prescriber	HCPs licensed by state law to prescribe drugs to patients.

Prescribing Information (PI)	Any materials which are a display of written, printed or graphic matter upon the immediate container of or accompanying pharmaceutical products or medical devices marketed by Daiichi Sankyo in the United States including the product package insert.
Product Material Review Team (PMRT)	The team of DSI Employees or Contingent Workers responsible for the review and approval of materials (internal and external) related to applicable products.
Product or Products	Any pharmaceutical products or medical devices marketed, distributed and/or promoted by DS in the United States (including Puerto Rico), as well as those products pending registration.
Program and Grants Committee (PGC)	The committee which reviews commercial programs requests and other arrangements involving payments to HCPs and/or Customers, Independent Educational Grants and certain Charitable Contributions.
Prohibited Discrimination	Unlawful discrimination in hiring, terminations, promotions, demotions, transfers, and selection for training based on race, color, religion, gender, sexual orientation, national origin, ancestry, culture, ethnicity, age, disability, pregnancy, veteran status, citizenship status, marital status, genetic information, or other categories protected by law.
Relative	Persons who are related to one another by birth, marriage, by registered domestic/civil union partnership, or by legal guardianship or adoption.
Services to a Competitor	Services whereby the individual would have access to competitive messages and/or strategies (for example, ad agencies, print services, consulting services, etc.).
Sexual Harassment	Another form of workplace harassment that affects the dignity of men and women at work. Sexual harassment will not be tolerated under any circumstances. Basing promotions, raises, or desirable job assignments on submission to sexual advances or requests for sexual favors is an example of prohibited conduct that constitutes sexual harassment.

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Social Media	Daiichi Sankyo defines Social Media (SM) as the application of mobile and web-based technologies to turn communication into interactive or bi-directional (e.g., two-way) dialogue. SM data consists of any user-generated content that is either a) propagated by a single user or b) the product of interaction between one or more users/contributors. SM data exists in various formats such written information, photos, videos, and audio files. SM exchange includes all forms of online publishing, digital media sharing and online discussions in Social Networks, Collaborative Forums, Social Communities and other bi-directional social interaction technologies, including but not limited to blogs, micro-blogs, wikis, user-generated video, location-based applications, and audio.
Speaker	HCP Consultants engaged to speak on behalf of the Company using PMRT-approved slide decks after completing Speaker Training on those slides.

Vendor	An individual or entity who is engaged by the Company to provide service(s) or product(s) to the Company.
Weapon	Any implement or object intended to or that may be used in a manner to inflict injury on a person or damage to property, including but not limited to firearms, knives, clubs, incendiary devices, ammunition, and explosives, regardless of whether the person is licensed to carry the weapon.
Workplace Harassment	Repeated mistreatment of one or more people by one or more perpetrators. It is abusive conduct that includes threatening, humiliating, or intimidating behaviors; work interference/sabotage that prevents work from getting done; and verbal abuse.

US STANDARDS OF BUSINESS CONDUCT

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