MERCK

Merck's Ethical Operating Standards Handbook

Business Practices for U.S. Related Activities

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OVERVIEW

At Merck, our ethics and values are the foundation for each employee's conduct in pursuit of Merck's business objectives. Our ethics and values inspire trust and confidence on the part of patients, the medical community, government officials, regulatory agencies, financial markets, and our customers—all of whom are essential to our success.

It is critical that we—the Merck employees—understand how our actions in the United States can affect Merck's standing and reputation. Improper conduct by Merck employees can lead to Merck losing its ability to do business with federal and state governments, as well as jeopardize Merck's standing with commercial partners like other pharmaceutical companies, managed care entities, pharmacy benefit managers, hospitals, and physicians.

Even conduct that is limited to a commercial setting can jeopardize our ability to participate in federal and state government health care programs.

Every Merck employee regardless of position, division, or region has an obligation to follow Merck's policies as well as the U.S. federal and state laws and regulations that apply to Merck's business. Every Merck employee is expected to exhibit Executional Excellence with each activity, every day. Executional excellence will be achieved if we adhere to laws, regulations, and policies.

Everybody is expected to implement with precision the established guidelines, policies, and standards of procedures. It is your responsibility to follow expectations and instructions for every detail, for every activity, every time. Expectations and instructions exist, and following them completely and accurately the first time will help to avoid errors. For example, it is your responsibility to ensure that all required fields are checked for completeness prior to submission or approval of a business activity. In addition, you are responsible to follow all processes completely and accurately. If you have questions, ask your manager or the business activity's subject matter expert.

To make sure we adhere to the laws and regulations that guide our industry, Merck has a robust compliance and training program. This program helps us understand and put into practice Merck's ethics and values and teaches us the process for reporting and investigating allegations of misconduct. Details about compliance training are provided in the "Training and Testing" section of this handbook.

It is your responsibility to safeguard against violations and to take the appropriate action if you suspect that improper business conduct has occurred. Failure to report improper conduct that you are aware of is, in and of itself, a serious violation. Improper business conduct can have serious consequences for you, including disciplinary action up to and including termination, and even criminal and civil penalties. Details about this process are provided in the "Reporting Concerns and Allegations of Misconduct" section of this handbook.

To avoid improper business conduct, you must consistently practice the values and standards that have guided this Company for more than 100 years. Our values and standards are the foundation of our Company and all that we stand for. They are the basis of our success and the way we earn the trust of our customers every day.

PURPOSE

To ensure that we know our ethical and legal obligations, Merck has prepared this handbook setting our Ethical Operating Standards (EOS) for Merck employees. These written standards focus on the need for each of us to comply with U.S. federal and state laws and regulations so that Merck will continue to be in good standing with all, including our government business partners.

Merck has designed an Awareness Training program based on the EOS to ensure that all employees have the information necessary to understand these standards and put them into practice. As required, employees will also continue to receive mandatory training in the Code of Conduct and other ethics directives such as:

- Corporate Policy 5 titled *Prevention of Bribery and Corruption (Ethical Business Practices)* and its subsidiary policies:
  - *Merck Standards Governing Activities Related to Government Health Care Programs*
  - *Merck Standards - Direct Engagement Due Diligence Standard – Doing Business with Non-U.S. Government Officials (Individuals)*
- Merck Guiding Principles
- Headquarters Guidance Documents and Divisional Policies
- Field Policy Letters

In addition, Awareness Training and acknowledgement applies to certain contractors, subcontractors, and agents of Merck.

If you need further guidance, there are a number of resources available to you. In addition to your manager, these resources include:

- Divisional Compliance Departments
- Office of Ethics
- Privacy Office
- Office of General Counsel
- Human Resources Department

U.S. LAWS AND REGULATIONS

Merck is committed to complying with all laws and regulations that apply to its business. These Ethical Operating Standards have been developed to help you comply with these laws and regulations. In many cases, violations could lead to stiff penalties and other serious consequences for you and for Merck. It is vital to adhere to these Ethical Operating Standards to maintain Merck's good reputation and to meet our obligations as a corporate citizen.

FOOD AND DRUG ADMINISTRATION (FDA) REQUIREMENTS

The Federal Food, Drug, and Cosmetic Act (FDCA) is the comprehensive regulatory framework for prescription drugs, covering research and development, manufacturing, and sales and marketing. It is important for you to understand the following key principles under this law.

First, the FDCA prohibits the introduction of unapproved new drugs and the misbranding of approved drugs. Off-label promotion is a departure from FDA-approved labeling and is considered misbranding, so this activity can be a violation of the FDCA. Off-label promotion has caused significant liabilities for some pharmaceutical companies over the last few years.

Second, all promotional communications must fairly balance information about a product's benefits with information about a product's risks and limitations. In addition, these communications should always be truthful and non-misleading.

Third, the Prescription Drug and Marketing Act (PDMA), which is part of the FDCA, prohibits any sale, purchase, or trade—or any offer to do so—of a prescription drug sample, voucher and/or coupon; and the counterfeiting of or offer to counterfeit vouchers and coupons. The PDMA is intended to protect the market from counterfeit, adulterated, misbranded, or expired drugs, and one of the ways it does so is by preventing samples from being introduced into the market for sale.

The consequences of FDCA violations can be significant. Each violation of off-label promotion can result in criminal penalties of up to three years imprisonment for an individual and/or a USD $10,000 fine. Each violation of the PDMA can result in criminal penalties of up to 10 years imprisonment for an individual and/or a USD $250,000 fine.

GOVERNMENT PRICING REQUIREMENTS

U.S. federal and state governments pay Merck significant sums for the purchase and/or reimbursement of Merck products. For that reason, they have a strong interest in enforcing pricing rules governing reimbursement of pharmaceuticals and vaccines. It is essential that manufacturer reports to the governments regarding product pricing are accurate and disclose all required information. Merck is committed to complying with all federal and state health care programs and government price program requirements.

Merck participates both directly and indirectly with various U.S. federal and state drug purchase programs. Each of these programs have distinct rules that govern the prices Merck may charge the government customers, and the rules are complex. Certain programs require payment of statutorily defined rebates, such as Medicaid. Others establish a calculation for price limits, such as

procurements of pharmaceuticals by the Department of Veterans Affairs or the Department of Defense for their beneficiaries, and the Section 340B Drug Pricing Program managed by the Department of Health and Human Services.

Merck's Customer Contract Management group is responsible for collecting the relevant data and performing the calculations required by each of the government programs. Merck employees must recognize that all information provided to or relied on by Customer Contract Management must be accurate and complete. All personnel are expected to report any suspected violations of federal and state healthcare programs.

MEDICAID DRUG REBATE STATUTE AND MEDICARE LAWS

The Medicaid Drug Rebate Statute, administered by the Centers for Medicare and Medicaid Services (CMS), requires manufacturers to enter into an agreement with the Secretary of the Department of Health and Human Services (HHS) to provide rebates for their covered outpatient drugs, to help offset government drug spending. Merck must accurately report prices and pay rebates as required by the Medicaid Drug Rebate Statute to Medicaid.

Under the Medicaid Drug Rebate Statute, a manufacturer must give Medicaid the lowest price that it offers to any purchaser, except some federal customers and some federally designated special programs of care, which may receive a lower price. Manufacturers achieve this through Medicaid rebates. Merck enters into an agreement with the federal government to provide quarterly rebates to state Medicaid programs, in exchange for Medicaid coverage of our products.

Civil penalties for Medicaid drug rebate statue violations can be up to USD $100,000 for each item of false information or the refusal of a verification survey request. Penalties up to USD $10,000 for each day in which timely information is not provided can also be levied for violations of this statute. It is important to be mindful of this statute and its requirements.

Medicare is also administered by CMS. Medicare is the federal health care insurance program for older people, some disabled people and people with end-stage renal disease. Medicare Part A, also known as the Hospital Insurance program, covers inpatient hospital services, skilled nursing facility, home health, and hospice care. Medicare Part A is paid for through payroll deduction during an individual's working life. Medicare Part B, the Supplementary Medical Insurance program, helps pay for physician, outpatient, home health, and preventive services. Part B is funded by general revenues and beneficiary premiums. Medicare Part C, also known as the Medicare Advantage (MA) program, allows beneficiaries to enroll in a private plan where the plan receives payments from Medicare to provide Medicare-covered benefits, including hospital and physician services, and in most cases, prescription drug benefits. Medicare Part D is the outpatient prescription drug benefit, delivered through private plans that contract with Medicare, either stand-alone prescription drug plans or Medicare Advantage prescription drug plans.

Depending on the violation, civil penalties up to USD $100,000 can be imposed. Suspensions of enrollment of Medicare beneficiaries, payment to the MA organization, and marketing activities to Medicare beneficiaries are also possible. The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the violation has been corrected and is not likely to recur.

FEDERAL AND STATE ANTI-KICKBACK LAWS

The federal anti-kickback statute is an important law that impacts many of Merck's activities in the United States every day. This law prohibits offering, paying, soliciting, or receiving any remuneration to induce the purchase or order of any drug that may be paid for by a federal health care program. Remuneration is defined broadly to include payment made directly or indirectly, overtly or covertly, in cash or in kind. This law is enforced to prevent fraud, over-utilization, and excessive costs in Medicare, Medicaid, and other federal health care programs.

Activities that seek to improperly influence the decision making of a health care professional may violate this law. For example, entering into arrangements with physicians for services that are unnecessary, paying for services at above-market value, or offering an educational grant to a physician to switch to that company's drugs are the types of arrangements that may violate this law. Certain arrangements with other stakeholders, such as payments to pharmacists or managed care organizations to market a product, can also violate the anti-kickback law. As a result, you must consider this statute carefully when entering into relationships with health care professionals, hospitals, Pharmacy Benefit Managers (PBMs), and Group Purchasing Organizations (GPOs).

A violation of the anti-kickback statute can carry severe penalties. Civil monetary penalties may be imposed, as may criminal penalties of up to five years imprisonment for an individual and/or a USD $25,000 fine. Any violation of the anti-kickback statute also leads to automatic exclusion from Medicare, Medicaid, and other federal health care programs.

In parallel with federal anti-kickback statutes, many states have adopted their own anti-kickback laws.

FEDERAL AND STATE FALSE CLAIMS ACTS

The Federal False Claims Act (FCA) imposes substantial civil penalties on any corporation or individual who knowingly makes or causes another to make a false claim or a false representation in a claim for approval or payment to the United States government.

A false claim is "knowingly" made if the corporation or individual acts with knowledge of the falsity of the claim or representation, or with reckless disregard or willful blindness to the truth or falsity of the claim or representation made to the government.

The False Claims Act also covers "reverse false claims" in which a corporation or an individual knowingly makes a false representation regarding an obligation it owes to the United States, such as falsifying records reflecting an amount owed to the United States. In addition, a "reverse false claim" is also made if a corporation or an individual knowingly makes a false representation to a contractor or subcontractor of the United States.

The U.S. federal and state governments have recently entered into a number of settlement agreements with pharmaceutical manufacturers regarding allegations that the manufacturers violated the False Claims Act by causing federal and state health care programs to be overcharged. The affected programs include Medicaid, Medicare, TRICARE, the Veterans

Administration Federal Supply Schedule, Section 340B drug pricing programs, the Federal Employee Health Benefit Plans, and Indian health clinics, among others.

The underlying misconduct of these settlements included paying kickbacks to physicians, causing health care providers to seek reimbursement from the government for non-reimbursable, off-label indications, and submitting false claims to the government regarding pricing information, such as Average Manufacturer Price and Best Price under the Medicaid rules. Often, the violation of the other statutes previously discussed, such as the anti-kickback statute, FDCA, or PDMA, can also cause a company to directly submit a false claim or cause another to submit a false claim.

Lastly, the False Claims Act is violated by even the mere submission of a false claim for payment, regardless of whether the claim is paid. For that reason, we must exercise caution in advising health care providers about government reimbursement for Merck pharmaceuticals and vaccines.

A number of states have adopted state false claims act statutes that are largely modeled after the federal statute. It is anticipated that additional states will adopt similar statutes in the future.

Civil penalties for false claims act violations can be up to three times the amount of damages to the United States, plus a fine of USD $5,500 to $11,000 for each false claim. For criminal false claims, the penalty is up to five years imprisonment for the individual and/or a fine. Moreover, violations of the FCA could lead to Merck's exclusion from Medicaid, Medicare, and other government reimbursement programs. Any exclusion would obviously have a significant impact on Merck's financial condition and reputation.

FEDERAL ANTITRUST LAWS

Antitrust laws are concerned with promoting healthy competition within industries and ensuring that no single entity gains undue market power to the detriment of consumers. One key trigger of antitrust scrutiny is agreements between competitors. Any agreement with competitors about the pricing of products or services, or markets in which competitors may sell, is likely to be considered an automatic antitrust violation and must be avoided. Even where there is no explicit agreement between competitors, certain types of activities—such as frequent meetings or communications with competitors, or coordinated market behavior, can support an inference that an agreement has been reached. As a result, Merck employees should avoid all communications with competitors on commercially sensitive topics (like pricing or R&D or marketing strategies), and should be mindful of the need to avoid even creating the impression that improper collusion may have occurred.

Price discrimination is another category of potential antitrust issues. Price discrimination is the act of offering different prices to competing customers for similar goods. Not every pricing differential is an antitrust violation—in fact, there are many circumstances where price discrimination is allowed because it promotes market competition. However, the rules are complex, and instances where price discrimination is being contemplated should be reviewed in advance by Merck counsel.

Compliance with Merck policies, as well as consultation with the Office of General Counsel, is critical to steer clear of potential antitrust violations.

FEDERAL BRIBERY, GRATUITY, AND CONFLICT OF INTEREST STATUTES

The federal bribery statute prohibits offering a bribe or gratuity to a public official. Specifically, it is illegal to directly or indirectly give, offer, or promise anything of value to a public official to influence any official act, any act of fraud on the United States, or any action or omission that violates the lawful duty of that person.

Public officials can include any Member of Congress; any officer, employee, or person acting for or on behalf of the United States or any departments, agencies, or branches of the federal government; any former public official; or any person selected to be a public official. The penalty is a fine of up to three times the amount of the bribe and/or from two to fifteen years of imprisonment.

The federal conflict of interest statute forbids giving, promising, or offering any compensation for representational services to any employee of any branch or agency of the federal government. This includes Members of Congress, Commissioners, Members and Commissioners Elect, and Federal Judges.

The statute relates to any matter in which the United States is a party or has a direct or substantial interest before any government office or agency. It does not include matters that are part of the government employee's proper discharge of lawful duties.

The penalty for violating this statute is imprisonment of an individual for one to five years, and/or a fine of USD $50,000 for each violation or the amount of the compensation offered, whichever is greater.

THE FOREIGN CORRUPT PRACTICES ACT (FCPA)

The U.S. Foreign Corrupt Practices Act (FCPA), which is essentially an anti-bribery statute, applies to U.S.-based companies as well as subsidiaries and agents under their control, whether or not they are in the United States. The FCPA prohibits giving, offering, promising, or paying money or anything of value, directly or indirectly by an intermediary or third party agent, to a foreign official for the purpose of obtaining or retaining business or obtaining an improper advantage.

The FCPA applies to Merck's overseas operations, to its foreign subsidiaries, and to any third parties acting for or on behalf of Merck and its subsidiaries.

The term "foreign officials" under the FCPA includes, but is not limited to, the following:

- Direct employees of foreign governments performing government functions, such as product approvals, pricing, reimbursement, and government purchasing.
- Those engaged by foreign governments to provide advice involving a government function, such as experts, consultants, and members of advisory panels.
- Those employed by foreign government agencies, which includes government-owned or government-controlled businesses that perform a function that in other countries is performed privately, such as physicians and purchasing agents at state-owned hospitals.

- Officers of political parties, candidates for political office, and members of public international organizations, such as the United Nations, World Bank, and World Health Organization (WHO), as well as their staffs, business partners, close associates, and family members.

Merck requires that any payments made or benefits provided to foreign officials be subject to evaluation and fact-finding in accordance with approved standards. Those standards require full and accurate documentation of the appropriateness of providing the payment, and pre-approval of the payment from the appropriate organizations and at the appropriate level of management. Merck also requires the completion of risk-based anti-corruption due diligence on third parties who conduct business on Merck's behalf or who Merck authorizes to engage in certain business activities.

A more complete description of the FCPA and related standards for interacting with foreign officials are set forth in Corporate Policy 5–Prevention of Bribery and Corruption (Ethical Business Practices) and related resources. Any question regarding compliance with the FCPA or related standards may be referred to your manager, the Office of General Counsel, your Divisional Compliance Department, or the Office of Ethics.

Individuals who violate the anti-bribery provisions of the FCPA are subject to civil fines of up to USD $16,000 per offense, as well as criminal penalties of up to USD $250,000 per offense and up to five years in prison. Corporations are subject to civil fines of up to USD $16,000 per offense, and criminal penalties of up to USD $2 million per offense. Penalties may also include fines based upon repayment of the benefit obtained or sought. Moreover, violations of the accounting provisions of the FCPA are subject to separate penalties.

FEDERAL AND STATE EXCLUSION, DEBARMENT, OR SUSPENSION PROVISIONS

To protect the public interest, the federal government can exclude, debar, or suspend individuals or corporations from conducting business with the federal government and/or with parties that conduct business with the federal government. Any alleged or actual violation of the laws discussed in this summary could be grounds for this exclusion, debarment, or suspension.

The implications of exclusion, debarment, or suspension are extensive. If a company is excluded, debarred, or suspended from doing business with the federal government, it cannot participate in Medicare, Medicaid, or other federal health care programs. The company is also precluded from providing any of its products to any other federal government agencies.

For the same reason that the federal government excludes certain individuals and corporations, states have established their own rules covering exclusion, debarment, or suspension.

Merck policy requires employees to notify a manager if the employee becomes excluded, debarred, suspended, or convicted of a health care-related crime. Further, Merck employees are required to report if any other employee or any individual or entity acting on behalf of Merck becomes excluded, debarred, suspended, or convicted of a health care-related crime. Any current or prospective employee or person or entity who acts on behalf of Merck who falls within this definition is considered to be an "ineligible person."

Merck is required to screen all individuals and entities who may work at Merck or act on behalf of Merck pursuant to Divisional procedures to ensure that they are not ineligible persons. Screening will occur before employment begins and on an annual basis. Merck policy precludes the Company from billing a federal health care program for items or services from an ineligible person, and it may not use federal funds to pay for items or services from an ineligible person. Merck policy requires that an ineligible person must be removed from responsibility for, or involvement with, Merck's business operations related to federal health care programs.

Additionally, certain employees are required to certify in the Annual Ethics & Policy Certification that they are not ineligible persons. Furthermore, business areas responsible for contracts and contractors are responsible to ensure the ineligible persons screening is complete. For a more complete description of obligations relative to exclusion, debarment and suspension, refer to the Global Human Resources, Corporate Policy 17.

PRIVACY REQUIREMENTS

Privacy in the context of U.S. law is a broad concept that generally relates to the extent of people's rights to make decisions about themselves, including about how their personal information about them may be shared with others. When they apply, privacy requirements can be triggered in the context of programs and activities that involve information about people and/or interactions with people. Privacy requirements are developed from laws, regulations, legal/ regulatory decisions, and Merck corporate policies related to protecting information about people and controlling the manner in which that information is used and disclosed.

Types of privacy laws and regulations that are relevant to business activities at Merck include health information privacy laws, communications privacy laws, data security laws, and unfair/deceptive trade practice and consumer protection laws.

Health information privacy laws relate to the use and disclosure of individually identifiable health information. These include the Federal Health Insurance Portability and Accountability Act (HIPAA), the Federal Health Information Technology for Economic and Clinical Health Act (HITECH), and various state health information privacy laws. Communication privacy laws impose requirements on the method or channel of communication (e.g., e-mail, telephone, fax, and other online regulations), how and when the channel is used, appropriate recipients, and the content of the communication. Data security laws set requirements to protect the security and confidentiality of certain types of personal information as well as requirements for notification to affected individuals in the event of an unauthorized access to certain types of personal information.

Unfair/deceptive trade practice and consumer protection laws establish minimum requirements for all communications with consumers, and customers and may also set minimum standards for the manner in which personal information is secured, subject to more restrictive requirements established by health information privacy laws, communications privacy laws, and data security laws. The focus of recent enforcement and other regulatory actions has been on privacy and data protection expectations for mobile and other connected devices and for predictive analytics using bit data sets. Merck's privacy values guide us in making ethical decisions about uses of new technology and new methods for using data about customers and patients.

Merck's Privacy Program and policies have been developed to facilitate compliance with applicable privacy laws and regulations. For a more complete description, refer to the new Corporate Policy 13 – Information Management and Protection and Corporate Policy 50 – Global Privacy and Data Protection. For additional guidance, consult with the Merck Privacy Office (http://privacy.merck.com/), other personnel within the Office of General Counsel, and Divisional Compliance.

REGULATORY GUIDANCE AND INDUSTRY STANDARDS

In addition to the laws discussed, there are two important sets of standards that shape how Merck employees should act. Both of these standards have been incorporated into Merck's policies.

In 2003, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) issued guidance for pharmaceutical manufacturers' compliance programs. The OIG is a branch of HHS that is responsible for maintaining the integrity of federal health care programs by conducting, among other activities, a nationwide network of audits, investigations, and inspections. The guidance signaled three areas that OIG is particularly concerned about—namely, the integrity of pricing data provided to the federal government to establish payment amounts, kickbacks and other illegal remuneration to health care professionals, and prescription drug samples, vouchers and/or coupons.

In 2008, the Pharmaceutical Research and Manufacturers of America (PhRMA) updated its voluntary ethical code. This code addresses pharmaceutical manufacturers' relationships with health care professionals and establishes guidance concerning several practices, including informational presentations by pharmaceutical company representatives and meals accompanying such presentations, sponsorship or financial support for third-party educational or professional meetings, consulting relationships with physicians, speaker programs and speaker training meetings, scholarships and education funds, and prohibition of non-educational and practice-related items to include "reminder-items."

Merck's policies and practices have been developed to be consistent with the OIG guidance and the PhRMA code, as well as to comply fully with all relevant laws and regulations. By following Merck's policies and Ethical Operating Standards, you can promote the integrity of Merck's Field-based and Marketing related operations and avoid behavior that can be costly to you and to Merck.

MERCK'S COMPLIANCE PROGRAM

If you find that you have questions about the laws and regulations that apply to Merck's business or the spirit and letter of Merck's policies or concerns about illegal or unethical behavior, you should raise them with your manager or the representatives of the Merck Compliance Program.

PURPOSE AND ORGANIZATION OF OFFICE OF ETHICS AND DIVISIONAL COMPLIANCE DEPARTMENTS

The specific individuals and offices that share the overall responsibilities of maintaining company-wide compliance standards are the Chief Ethics and Compliance Officer who is responsible for

Merck's corporate-wide Office of Ethics and the Divisional Compliance Officers who lead the Divisional Compliance Departments.

The Office of Ethics is responsible for corporate-wide implementation of ethics guidance, the Merck Code of Conduct and ethics training.

GHH Compliance is responsible for partnering with Global Human Health to ensure compliance with the U.S. laws and regulations governing Medicare, Medicaid, and other federal, state, and local health care programs, as well as the design, development, and implementation of business practices and policies guiding U.S. marketing and sales activities and global GHH Headquarters related directed activities. The Merck Research Laboratories (MRL) Compliance Department is responsible for partnering with MRL and the Office of the Chief Medical Officer (CMO) to ensure compliance with the applicable laws and regulations governing research-related activities, as well as the design, development, and implementation of compliance practices and policies guiding these activities.

Personal and Management Accountability

Corporate conduct cannot be separated from individual behavior. Each action we take makes an impression, and it is every employee's responsibility to ensure that the impression we leave reflects positively on our Company and upholds Merck's traditions. By adhering to Merck's ethical business practices, we demonstrate an understanding of and a respect for the laws that regulate our business and the ethical principles that serve as the foundation of those laws.

Every Merck employee must comply with the letter and spirit of Merck policies and Guidance Documents and the federal and state laws and regulations that apply to Merck's business. Compliance and ethics are critical to the success of Merck. Everyone is responsible for compliance and ethics. You are also expected to demonstrate Executional Excellence when conducting every activity. You will be held personally accountable if you fail to comply with Merck policies and Guidance Documents and relevant laws and regulations. In addition, you will be held personally accountable if you fail to report known inappropriate or unethical behavior of other employees and those involved in Merck's business.

This includes your responsibility as a manager and/or an employee to protect Merck assets and operate within the Grants of Authority.

REPORTING CONCERNS AND ALLEGATIONS OF MISCONDUCT

What do you do when you have been asked to engage in conduct that you believe might violate a federal or state law or regulation that applies to Merck's business or a Merck corporate policy or the Code of Conduct? What do you do when you suspect a colleague is violating the law or Merck's policies?

The most important thing when you are unsure about the appropriateness of the conduct is that you ask for help. There are several places you can turn for assistance. The first option is to talk with your manager. If you do not feel comfortable with that course of action, the other resources that you may contact are:

- Divisional Compliance Departments
- Office of Ethics
- Privacy Office
- Office of General Counsel
- Human Resources Department

You may call the Office of Ethics, directly, or you may use either the AdviceLine or the Ombuds Program. Both services are managed by the Office of Ethics.

To contact the Office of Ethics:

- Telephone Numbers:
  - Toll Free Telephone Number: 1-800-990-1146
  - Confidential Fax Number: 1-908-259-3788
- E-mail: maureen.mcgirr@merck.com
- Web site: http://ethics.merck.com

AdviceLine

The AdviceLine is available to employees around the world 24 hours a day, 7 days a week. The AdviceLine is staffed by an outside organization, and you can remain anonymous if you so choose. The operator will not give you direct advice; he or she will relay the information to the Merck Office of Ethics, and provide you with a case number and a call-back date. While questions and concerns raised to the AdviceLine will be forwarded to the Office of Ethics for review, no identifying information will be forwarded without the caller's consent.

To contact the AdviceLine:

- Telephone Numbers:
  - Direct Dial Toll Free Telephone Number: 1-877-319-0273
  - Call collect by contacting your local telephone operator and requesting a connection to 1-704-323-4005
- Internet: www.theadviceline.com

From your device:

Smartphone users can scan the following QR code via a QR Reader app to access the AdviceLine site to submit a concern:

The Ombuds Program

The Ombuds Program is part of the services offered by the Office of Ethics. It promotes the positive and fair treatment of employees and provides an alternative channel for use by employees to address work-related concerns. These concerns can include conduct inconsistent with the Company's policies, practices, values, and standards. The program is designed to provide a "safe haven" where these issues can be addressed in confidence and without fear of retaliation. You may contact the Ombuds by telephone (1-800-990-1146), by e-mail (maureen_mcgirr@merck.com), or in person. Employees may remain anonymous if they choose to do so.

Reporting and Confidentiality

Merck takes all reported concerns seriously, and when appropriate, will investigate to determine if there has been a violation. If you report an alleged violation, Merck will make every reasonable effort to keep your identity confidential while conducting a thorough and fair investigation as required under the law. If you wish, you may remain anonymous when making a report.

In situations where an investigation is appropriate, it is imperative that you refrain from discussing with colleagues or co-workers your contact with the Office of Ethics, Divisional Compliance Department, Office of General Counsel, or Human Resources Department. This discretion will help the Company maintain confidentiality of the investigation and your identity.

To learn more about the AdviceLine and the Ombuds Program, please access the Office of Ethics Web site at: http://ethics.merck.com.

Non-Retaliation

Reporting a concern is hard enough, without having to worry about internal consequences. If you need to report a concern, you can be assured that Merck stands by you. The Company will not tolerate retaliation against any employee for raising a business practices issue in good faith. "Good faith" means that you have made a genuine attempt to provide honest and accurate information even if you are later proven to be mistaken.

The fact that an employee has raised concerns in good faith, or has provided information in an investigation, cannot be a basis for denial of benefits, termination, demotion, suspension, threats, harassment, or discrimination. Similarly, if you are aware that a colleague has raised concerns, you are expected to treat that person in a courteous and respectful manner. Certainly, do not engage in behavior that might alienate or intimidate colleagues.

This protection extends to anyone giving information in relation to an investigation. If you or others have experienced an act of retaliation, report this behavior to your manager, the Office of Ethics, or your Divisional Compliance Department.

For more information, you can review Corporate Policy 15, Reporting and Responding to Misconduct at http://ts1.merck.com/com/policy/Pages/Focus-Areas-Be-Responsible-Reporting.aspx

CONSEQUENCES OF UNETHICAL OR ILLEGAL BEHAVIOR

Violations of the laws and regulations discussed in this handbook and Merck policies not only can have a negative impact on Merck's reputation; they can result in criminal and/or civil penalties to both the Company and the individual employee. Urging employees to report suspected misconduct is a necessary part of Merck's compliance activities. Stopping misconduct before it occurs and addressing misconduct as soon as possible gives Merck the opportunity to limit damage to the business community and its reputation. Early reporting also helps Merck work with law enforcement authorities to ensure that the responsible parties are held accountable.

In addition to criminal and civil penalties, failure to comply with Merck standards and to report suspected misconduct can have serious employment consequences, up to and including termination from employment at Merck.

Remember the Merck Code of Conduct Decision Test for assessing whether conduct can lead to violation of laws, regulations, or Merck policies. The Code of Conduct Decision Test asks every employee to consider:

- Is the action legal?
- Does it comply with the letter of our standards and policies?
- Does it comply with the spirit of our standards and policies?
- How would it look in the newspaper? Would it appear to be improper or make you feel embarrassed?

Once you answer these questions, if you are still unsure about what to do, contact your manager, the Office of Ethics, the Divisional Compliance Officer, or the Office of General Counsel.

TRAINING AND TESTING

The laws and regulations governing Merck business and Merck's policies and Guidance Documents are too important to rely on informal communications. Merck recognizes training is critical, and Merck employees in the United States who are involved in the sales and marketing of pharmaceutical products, as well as Merck employees with certain cross-functional responsibilities, will receive training and testing in the laws and regulations discussed in this handbook and other relevant Merck policy documents, including the Code of Conduct and certain Merck corporate policies.

Thorough, engaging training programs will ensure employees are equipped with the knowledge to define, explain, and apply the rules regarding the regulated environment in which Merck operates.

Training Levels

Merck employees, as well as certain contractors, subcontractors, and agents of Merck must complete annual web-based Awareness Training, the most fundamental level of training. Employees who take Awareness Training will be expected to review the training materials, acknowledge their understanding of the materials, and complete a certification test.

Awareness Training provides key information regarding Merck's Ethical Operating Standards. This includes the laws and regulations governing our industry, Merck's Compliance Program, the Guiding Principles governing our activities as well as Merck's obligations under the Corporate Integrity Agreement.

Knowledge Training provides a broad overview of how the Guiding Principles apply to specific activities. The training describes these activities, associated risks, and high-level roles and expectations. Employees who engage in certain activities involving U.S. health care professionals (HCPs), customers, or institutions are required to take Knowledge Training. It is not intended to provide details about the execution of particular activities. Those details are provided in the Mastery Training level.

Mastery Training is the most comprehensive level of training. Mastery Training is focused on implementation excellence and provides in-depth training on the processes, procedures, check-lists, and other requirements for executing specific activities. All employees who execute and direct activities must complete Mastery Training on the activity before they can direct or execute that activity. First-line managers of employees who direct or execute an activity must complete Mastery Training on the activity before they can provide oversight on the activity. The activity leader listed at the top of each Guidance Document will instruct you regarding your Mastery Training requirements for the activity.

Training Requirements

All current employees described above must participate in annual Awareness, Knowledge, and Mastery Training, as appropriate. If you receive new responsibilities following the annual training cycle, you must complete all relevant training prior to assuming the new responsibilities. Managers must ensure their employees complete all training prior to beginning any new responsibilities. You and your manager are responsible for closely overseeing your training to ensure it is consistent with your new responsibilities.

MERCK'S INTERNAL REVIEW PROCEDURES

Merck's Compliance Program is the subject of regular internal reviews and reporting, and, in some instances, external reviews. Those reviews include:

- **Management Reports** for existing activities. These reports are distributed to responsible managers for follow-up on matters identified in the reports. The manager will ensure activities are assessed and appropriate action is taken.
- **Policy Investigation Violation Reports** that provide information about any investigations into potential violations of Merck policy. These reports will be provided to the Divisional Compliance Officer.
- **Corporate Audits** performed by Merck Corporate Audit & Assurance Services (Merck Corporate Audit). In addition to providing the audit findings to the relevant line management and Divisional Compliance, they will be reported directly to the Audit Committee of the Merck Board of Directors and administratively to Merck's Chief Financial Officer.
- **Grant Activity Reports** that review, track, and oversee all grant programs.

Additionally, Merck will continue to prepare Government Pricing Reports reflecting compliance with all federal and state laws and regulations regarding reporting of our product prices. The government pricing group within Customer Contract Management is responsible for all price reporting.

MERCK'S WRITTEN POLICIES AND GUIDANCE

Regardless of how general or detailed the discussion of the laws and regulations that apply to Merck's business may be, this handbook cannot possibly anticipate all the challenges you may face on the job. That is why there are additional resources we can use when we have questions about business conduct.

MERCK'S WRITTEN GUIDANCE ESTABLISHING ETHICAL BEHAVIOR

Merck has developed an extensive collection of resource materials that establish Company expectations for ethical behavior. These materials are prepared by various departments at Merck in connection with the responsibilities of those departments. It is important that you familiarize yourself with the materials that apply to all employees at Merck as well as those that apply to your specific department. Bear in mind that these are evolving materials and will change or grow over time. The specific materials described below will be required for review on a regular basis.

Code of Conduct

Merck's code of conduct, *Our Values and Standards,* is our universal statement of the values, standards, and ethical principles that guide our daily operations. The code of conduct applies to everyone conducting business on behalf of Merck, and stresses the need to be truthful in our relationships with our business partners, the public and applicable government agencies. All new employees are required to review the code of conduct. You can review the code of conduct:

- Online: http://one.merck.com/pub/org/ethics/Pages/ovs.aspx

- From your device: Mobile App: www.merckcode.com

  Smartphone users can scan the following QR code via a QR Reader app to access the Merck Code of Conduct mobile app:

Corporate Policies

Corporate policies apply to all employees and establish Merck's standards of conduct. Be sure to familiarize yourself with the corporate policies relevant to your responsibilities. These policies can be found on Merck's intranet at http://policy.merck.com/

Policies include, but are not limited to:

- Customer Facing, Marketing and Business Practices (Corporate Policy 4)
- Prevention of Bribery and Corruption (Ethical Business Practices) (Corporate Policy 5)
  - Merck Standards - Direct Engagement Due Diligence Standard - Doing Business with Non-U.S. Government Officials (Individuals)
  - Merck Standards Governing Activities Related to Government Health Care Programs
- Procurement and Supplier Relations (Corporate Policy 6)
- Information Management and Protection (Corporate Policy 13)
  - Global Privacy and Data Protection (former Corporate Policy 50)
- Reporting and Responding to Potential Compliance Violations (Corporate Policy 15)
- Global Human Resources (Corporate Policy 17)
  - Effect of Exclusions, Debarments, Suspensions and Healthcare-Related Criminal Convictions; Reporting and Screening (former Corporate Policy 62)

Information and resources pertaining to Grants of Authority can be found on the Merck intranet.

Headquarters Guidance Documents and Divisional Policies

Merck related activities must comply with Merck policy and federal and state laws and regulations. Headquarters Guidance Documents and Divisional Policies have been written to help Merck employees who participate in these activities. These documents provide employees with the direction they need to perform activities that comply with both the letter and the spirit of applicable laws and regulations. It is your responsibility to familiarize yourself with any applicable guidance and adhere to the stated laws and regulations while performing covered activities. You can review Headquarter Guidance Documents on the Merck intranet at http://ts1.merck.com/com/ghh_us_compliance/Pages/HQ/HQ.aspx

Field Policy Letters

U.S. Field Policy Letters describe applicable legal and regulatory requirements for Field-based employees. These letters reflect the commitment of the Global Human Health Field-based organizations to a high level of ethical conduct when working with health care professionals and customers.

Merck Field-based employees are responsible for knowing and acting in accordance with the content of the Field Policy Letters. Contact your manager if you have any questions about the policy letters, or review the letters on the Merck intranet at http://ts1.merck.com/com/ghh_us_compliance/Pages/Field/FieldPolicyLetters.aspx

Keep in mind that all discussions by Field-based employees are considered promotion and are closely regulated.

Guiding Principles for Business Practices

Merck's Guiding Principles for Business Practices build a bridge that connects applicable laws, regulations, Merck's Corporate and Divisional Policies, and other guidance provided by Merck. The Guiding Principles exist to ensure that all activities have a well-articulated business purpose, are implemented to the highest standards of ethics and integrity, are consistent with Company policies and applicable industry laws and regulations, and have the utmost regard for patient health and safety.

The Guiding Principles are as follows:

Principle 1. Focus interactions with the medical and scientific community on business and scientific objectives that support the Company's mission of Putting Patients First.

Principle 2. For Company-sponsored or supported activities, comply with all applicable laws, regulations, and industry or professional Codes of Conduct of both the host country and the resident country of individual participants or organizations.

Principle 3. Compensate for services at fair market value, purchasing only those services that are required to address the business issue/need at hand.

Principle 4. Ensure that offering something of value to members of the medical and scientific community does not have the appearance or the intent of influencing regulatory, formulary, pricing, or reimbursement decisions or inducing or rewarding the referral, recommendation, utilization, or prescribing of Merck products.

Principle 5. Maintain a business-like atmosphere for all interactions with the medical and scientific community, avoiding lavishness or extravagance, as well as the appearance of such.

Principle 6. Ensure that decision making regarding activities associated with grants, payments for services to the medical and scientific community, and the generation and reporting of clinical information is free of any inappropriate commercial or other influences (that is, influences that are not aligned with the stated objective of the activity).

Principle 7. Apply good business judgment to all communications and documentation involving our interaction with the medical and scientific community, and ensure proper implementation of activities (e.g., training, documentation, tracking, reporting, and follow-up).

Principle 8. Conduct activities and interactions with the medical and scientific community in a manner that protects our intellectual property and respects that of others.

Principle 9. Ensure that all communications shared with the medical and scientific community are based on accurate and balanced scientific information.

Principle 10. Ensure that selection of members from the medical and scientific community is based on their areas of expertise, experience, and other appropriate, objective criteria aligned with the stated purposes of the activity.

Corporate Integrity Agreement Obligations

Effective November 22, 2011, Merck entered into a Corporate Integrity Agreement (“CIA”) with the Office of the Inspector General ("OIG") of the United States Department of Health and Human Services. The purpose of the CIA is to promote compliance with laws and regulations relating to Federal health care program requirements and FDA requirements. The CIA incorporates many of the compliance program and other activities that Merck had previously implemented and will further contribute to Merck's robust ethics and compliance program. Every Merck employee is responsible for compliance with the CIA, applicable laws, and Merck policies.

The following is an explanation of Merck's requirements and obligations under the CIA:

- Maintain a Compliance Officer, a Compliance Committee, and an Ethics Officer.

- Maintain a Code of Conduct, the Ethical Operating Standards, and Policies and Guidance Documents designed to promote compliance with all applicable U.S. laws and regulations. Employees must continue to perform their responsibilities consistent with these written standards. Merck must review the standards annually and report any changes to the OIG.

- Maintain a training program consisting of Awareness and Knowledge training for certain categories of employees engaged in or having responsibilities relating to what are defined as "Covered Functions" in the CIA. Certain contractors and vendors who perform Covered Functions are also required to receive training. In general, Covered Functions include: marketing and promotional activities; government price reporting; interactions with state Medicaid personnel; preparing and distributing non-promotional product information; contracting with HCPs for post-marketing studies; authorship and publication of product-related articles or study results; and submission of product information to drug compendia.

- Obtain certifications from certain management personnel regarding compliance obligations and adherence to applicable laws, policies and CIA requirements.

- Obtain a resolution adopted by a subcommittee of the Board of Directors regarding Merck's compliance program and Merck's ability to meet applicable laws and CIA requirements.

- Conduct ongoing monitoring and auditing of field force and headquarter activities covered by the CIA.

- Engage an independent review organization to evaluate Merck's compliance systems, processes, and policies as well as sample transactions covered by the CIA.

- Maintain its Disclosure Program, including Merck's AdviceLine and Ombudsman Program, where employees can raise concerns related to potential unethical or illegal behavior associated with Merck policies as well as all U.S. federal and state laws and regulations that apply to our business. Merck will maintain its emphasis on confidentiality and its non- retaliation policy.

- Post payments and other transfers of value made to U.S. physicians.

- Maintain transparency initiatives in the areas of grants, charitable contributions, consultant and author relationships, and registration of clinical studies.

- Ensure that employees, contractors and vendors do not appear on government lists of individuals and entities excluded from participation in federal healthcare programs.

- Notify the OIG of government investigations, FDA communications regarding alleged potential improper promotion, and probable violations of applicable healthcare laws.

- Submit annual reports to the OIG detailing compliance efforts and certifying to compliance with the requirements of the CIA.

- Maintain for inspection all documents and records relating to reimbursement from the Federal Health Care programs and to compliance with this CIA for 6 years (or longer if otherwise required by law) from the effective date.

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