



2010
Pocket Guide to Gilead's
Business Conduct Manual
U.S. Operations

Since Gilead Sciences obtained its first product marketing approval, the Company's employees have worked together to build Gilead's positive reputation in the healthcare community as a company driven by science and dedicated to improving patient care and quality of life. Gilead's commitment to adhere to the highest legal and ethical standards of business conduct is fundamental to that reputation. Adherence to these standards protects patient safety, as well as the Company, its employees, and business customers.

The Gilead Business Conduct Manual builds upon the foundation of Gilead's *Code of Ethics* and governs how Gilead Personnel interact with healthcare professionals (HCPs), healthcare entities, and the community when conducting sales, marketing, education, and other activities within the United States. It reflects the dynamic legal and regulatory environment in which we conduct business and demonstrates our commitment to ethical conduct as we continue to grow and move into new therapeutic areas. Please consider these rules against the backdrop of Gilead's core values:



Integrity:

Doing the right thing

Teamwork:

Collaborating in good faith

Accountability:

Taking personal responsibility

Excellence:

Being your best

It is the responsibility of every Gilead employee and agent who engage in the activities described in this Pocket Guide to be knowledgeable about and comply with Gilead's policies. The Company takes violations seriously, so it is important to know the policies and comply accordingly.

This Pocket Guide provides a brief summary of the Business Conduct Manual policies. This is a public document that may be shared freely with any person who is interested in understanding Gilead's commitment to compliance. Gilead Personnel should consult the full policy in the Manual if they are interested in specifics or encounter a situation governed by a particular policy. If you have any questions regarding the rules, practices, and activities described in this Guide, please feel free to contact one of the Company's attorneys in the Business Conduct Department. Working together to move our business forward in the spirit of these rules, we will continue to enhance the reputation of Gilead Sciences.

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Overview of Relevant Laws and Regulations

Gilead is committed to complying with all applicable laws, regulations, and ethical standards in conducting its marketing, promotional, research, educational, and other activities. Gilead Personnel should be familiar with the relevant U.S. federal and state laws and regulations that affect the Company's business. When interacting with healthcare providers located in other countries, U.S. employees must coordinate with the Gilead affiliate supporting that country to assure compliance with the laws of that jurisdiction. While not an exhaustive list, below are summaries of key laws, regulations, and industry standards that apply to Gilead's primary activities.

FEDERAL AND STATE ANTI-KICKBACK LAWS

Healthcare treatment decisions should not be motivated by personal gain or enrichment. Federal and state anti-kickback laws prohibit improper influences by making it illegal to pay anything of value to induce someone to purchase, prescribe, or recommend a product that is reimbursed under federal or state government healthcare programs (e.g., Medicare or Medicaid). Some state laws are broader and apply to all items and services, even those not reimbursed under a government program.

FDA LAWS AND REGULATIONS

The U.S. Food and Drug Administration (FDA) regulates Gilead product research, development, manufacture,

distribution, and promotion activities. These rules govern all written and verbal communications to prescribers, patients, and other external third parties by Gilead employees, affiliates, and agents, including speakers, consultants, and advisors. Generally, these communications must not be false or misleading, lack fair balance of safety and effectiveness information, make unsubstantiated claims, or promote uses not described in the FDA-approved product labeling (also known as the package insert).

The Prescription Drug Marketing Act of 1987 (PDMA) and associated FDA regulations specify requirements related to the storage, record keeping, and distribution of drug samples. Gilead permits sample distribution only in full compliance with these requirements.

FEDERAL AND STATE FALSE CLAIMS LAWS

Federal and state laws prohibit submitting — or causing submission of — false claims to government programs or private insurers. There are other specific laws included in this body of law (e.g., the anti-kickback laws discussed above). California and many other states have enacted similar laws modeled after the federal *False Claims Act*. Examples of sales and marketing activities that might violate these laws include submitting fraudulent claims for government payment, reporting false pricing information to government agencies, and off-label promotion. These laws also provide a means for whistleblower (*qui tam*) complaints and protect whistleblowers from retaliation.

FEDERAL AND STATE PRIVACY LAWS

Gilead may handle certain personal health information that may be protected by federal and state laws. Company personnel must treat such information carefully and in compliance with privacy laws. These laws include the *Health Insurance Portability and Accountability Act of 1996* (HIPAA), among others. California and other states have enacted privacy laws that are stricter than federal law.

STATE CONSUMER PROTECTION AND LICENSING LAWS

Many state laws protect consumers from inappropriate sales and marketing practices, which have been construed to include off-label promotion. Some states have also used these laws against companies and individuals who misuse private information. Professional licensing laws provide for disciplinary action against practitioners who engage in unprofessional conduct. Although not directed at companies, Gilead will not engage in activities that could cause practitioners to violate their professional and ethical obligations.

PHARMA CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

The Pharmaceutical Research and Manufacturers of America (PhRMA) adopted, and recently updated, the *PhRMA Code* to ensure that pharmaceutical companies' interactions with healthcare professionals benefit patients and enhance the practice of medicine. Certain state laws require companies to adopt policies that comply with the *PhRMA Code*.

OIG COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS

The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services has issued the *Compliance Program Guidance for Pharmaceutical Manufacturers* (OIG Guidelines) to define the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program. The OIG Guidelines addresses the public and private sectors' mutual goals of preventing and reducing fraud and abuse in federal healthcare programs.

FEDERAL SENTENCING GUIDELINES: EFFECTIVE COMPLIANCE AND ETHICS PROGRAM

The United States Sentencing Commission issued revised guidelines November 1991 stating that a corporation

convicted of a violation may have its penalty reduced if it has an effective compliance program in place at the time of the violation. The *Federal Sentencing Guidelines* assist companies in their efforts to establish a program of self-assessment and monitoring to minimize exposure to risk and criminal activity and encourage ethical conduct and compliance with applicable laws.

ACCME STANDARDS FOR COMMERCIAL SUPPORT

The Accreditation Council for Continuing Medical Education (ACCME) identifies, develops, and promotes standards for quality continuing medical education (CME) programs for physicians to maintain competence and incorporate new knowledge to improve the quality of healthcare for their patients and communities. Gilead does not provide support for any CME program unless the program is accredited by ACCME and follows ACCME guidelines.

LAWS RESTRICTING FINANCIAL INTERACTIONS WITH HCPS

Numerous U.S. states have passed statutes that prohibit various kinds of transactions with HCPs, put dollar limits on others, and/or mandate public disclosure of such interactions. All Gilead Personnel must understand and comply with the laws and policies in the states where they conduct business. To facilitate compliance with these obligations, all payments to HCPs are aggregated and tracked through an enterprise-wide system called Gilead CompleteSpend™.

Detailing and Promotion

Gilead Sciences plays a vital role in educating healthcare professionals (HCPs), patients, and others about the safe and effective use of the Company's products. Because these activities involve the promotion of Gilead products by Gilead Personnel or Company-sponsored consultants, they are subject to strict federal and state laws and the rules of the receiving institutions.

ON-LABEL PROMOTION

All information disseminated through Gilead's promotional activities must be: 1) Consistent with the product's FDA-approved package insert and other labeling, or "on-label;" 2) Fairly balanced with respect to efficacy and safety information; 3) Truthful and not misleading; and 4) Targeted at HCPs who are reasonably likely to prescribe — or to patients/caregivers who are interested in — Gilead products for their FDA-approved use.

No Gilead Personnel may provide patient-specific medical advice or treatment recommendations, whether directed to an HCP or a patient or family member.

PROMOTIONAL MATERIALS, REPRINTS, AND OTHER MATERIALS

Only information and materials that have been approved for promotional use may be used or distributed in connection with product presentations. It is impermissible to use altered, modified, out-of-date, or "home made" sales materials. Only approved reprints or sealed reprints

may be used; reprints designated for “Internal Use Only” or obtained from any source other than Gilead’s home office may not be distributed or discussed with HCPs.

STATEMENTS ABOUT COMPETITORS’ PRODUCTS

Express or implied comparisons of the safety or effectiveness of a Gilead product to that of a competitor product are only permissible when approved by Gilead’s home office because head-to-head data are available that constitutes substantial evidence. Other comparisons are permitted without prior approval if limited to information in product package inserts that is unrelated to safety or effectiveness. These comparisons may relate to characteristics such as availability of indications, dosing recommendations, and how each product is supplied.

REQUESTS FOR OFF-LABEL INFORMATION

Gilead Personnel may not promote off-label; however, HCPs frequently ask off-label questions. Gilead has established specific procedures to ensure that HCPs and others who request off-label information receive important information about Gilead products while ensuring that Gilead is in full compliance with applicable laws and regulations.

In general, Gilead Personnel may not initiate discussions with HCPs about off-label information concerning Gilead or competitor products and may not solicit or encourage HCPs to request off-label information. If an HCP raises an off-label question or otherwise makes an unsolicited request for off-label information, the inquiry should be referred to the Medical Information Department (MID) for follow-up. Such questions may also be referred to a Medical Scientist. If available, certain questions also can be addressed using the Inquiry Response Summary (IRS) system.

Medical Information Request Form (MIRF). The MIRF is an electronic form in the TANGO system that should be used by Gilead Personnel to relay to MID any unsolicited requests for off-label and other medical or scientific information concerning Gilead or competitor products.

Standard Response Documents (SRD). SRDs are written responses to frequently asked medical or scientific questions about Gilead products. MID maintains SRDs for dissemination to HCPs upon request. Each SRD is objective, balanced, and scientifically rigorous; is addressed to a specific individual; and includes the labeled indication for the relevant Gilead product and appropriate disclosures regarding off-label information.

Inquiry Response Summary (IRS). IRSs are created by MID to provide immediate responses to a small number of frequently asked important medical questions. Each IRS summarizes some of the key information contained in the corresponding SRD. If a Commercial employee receives an unsolicited question that is addressed in an IRS, he or she may immediately convey the information provided by MID as well as submitting an MIRF to request the full SRD. When using an IRS, the Commercial employee must advise the HCP that the information provided may be off-label and that it only summarizes portions of the forthcoming SRD. In addition, the Commercial employee may only read or show data or information that specifically addresses the HCP's question and must not go beyond the scope of that question.

ADVERSE EVENTS, DRUG DIVERSION, AND CUSTOMER INQUIRIES

Adverse events associated with Gilead products that are disclosed to any Gilead Personnel must be reported within 24 hours to Gilead Drug Safety and Public Health (DSPH). For more information, please see the DSPH page on GNet (<http://gnet/DrugSafety/>), or call 1-800-GILEAD-5 (1-800-445-3235), Option 3.

Reports or questions about drug diversion, manufacturing, damaged goods, returns, distribution, labeling, or dating may be referred to Gilead Customer Service at 1-800-GILEAD-5 (1-800-445-3235), Option 8.

INTERNAL POLICIES OF PHYSICIANS' OFFICES AND INSTITUTIONS

Some healthcare institutions, practice groups, and HCPs have instituted their own rules related to pharmaceutical company marketing and promotional practices, such as rules governing sales calls, gifts, and the use of individual physician's prescribing data. Gilead respects these rules. Gilead employees are responsible for becoming familiar with and abiding by any such rules within their respective territory.

USE OF HCP PRESCRIBING DATA

The American Medical Association (AMA) administers the Physician Data Restriction Program (PDRP), whereby physicians may elect to prohibit the release of data regarding their prescribing practices to pharmaceutical sales representatives. Companies found to be in violation could lose access to AMA data altogether. If, through PDRP, an HCP elects to opt out of having his or her prescriber data released, Gilead will not provide his or her prescribing information to individuals who have direct contact with physicians or their managers

INSURANCE, REIMBURSEMENT, AND PATIENT ASSISTANCE INFORMATION

Gilead Personnel may provide HCPs with information regarding coverage for on-label uses of Gilead products or the products of competitors, provided that the information is accurate and complete. This information may include the availability of coverage, formulary status, and prior authorization requirements. Gilead Personnel may not, however, otherwise assist HCPs (including suggesting the content for forms) in obtaining coverage for Gilead products. Requests for coverage information for off-label uses of Gilead Products must be referred to MID or the relevant insurer/payor. Gilead Personnel may not discuss or provide information about the "spread" regarding Gilead products (i.e., the difference between the price charged by Gilead or others and the reimbursement received by the health care provider).

Gifts, Meals, and Entertainment

Gilead Sciences strives to ensure that interactions with persons or organizations in a position to purchase, prescribe, or recommend Gilead products are both lawful and consistent with the highest standards of ethics and good business practices. This spirit guides the Company's policy on the provision of gifts, meals, and entertainment, which incorporates, among other guidance, the *PhRMA Code on Interactions with Healthcare Professionals*, *OIG Guidance* and the *California Comprehensive Compliance Program Law*. Additionally, as detailed in the *HCP Expense Tracking Policy*, several states have enacted laws that limit or prohibit gifts, meals, or entertainment to healthcare professionals (HCPs), entities, and/or state employees.

GENERAL REQUIREMENTS

Gilead Personnel may not offer or provide anything of value with the intent of directly or indirectly influencing or encouraging the recipient to purchase, prescribe, or recommend a Gilead product, or as a reward for previously doing so. Where permissible under this policy, things of value must be modest and provided only on an occasional basis. Gilead has publicly committed to a \$2000 annual aggregate spending limit per HCP for all meals and gifts that are permitted under this policy. This includes meals and gifts provided by home office as well as field personnel, in-office and out-of-office meals, and meals that are provided to the attendees of speaker programs.

MEALS AND BEVERAGES

All meals and beverages provided under this policy must be 1) Modest as judged by local standards; 2) Provided only on an occasional basis; and 3) Provided in connection with a Legitimate Business Purpose, which includes:

- Informing an HCP about the risks and benefits associated with Gilead products;
- Providing scientific and educational information to an HCP in the therapeutic areas of interest to Gilead; and
- Receiving bona-fide consulting, research, or marketing services from an HCP under a valid Company agreement.

Meals provided by Gilead employees must comply with the following expense limits:

- Breakfast/snack/lunch in office: \$25/HCP
- Dinner in office: \$50/HCP
- Breakfast/lunch outside office: \$50/HCP
- Dinner outside office: up to \$125/HCP, consistent with reasonable business judgment given geographical variations in expenses

These dollar limitations encompass all expenses associated with the meal, including tips, beverages, parking, and room charges (if the meal is not in the context of a Speaker Program). Out-of-office dinners with HCPs (other than speaker programs) are limited to no more than two per quarter per HCP, regardless of which Gilead employee(s) attends the meal. Meals must be attended by at least one Gilead employee with no more than five HCPs present for each Gilead employee.

SPECIFIC MEAL RULES BY GILEAD ROLE

In compliance with the *PhRMA Code on Interactions with Healthcare Professionals*, Gilead has established rules that govern the setting in which different types of Gilead employees may provide meals to recipients. A brief summary of these rules is provided below, but Gilead

employees should be familiar with the complete list of rules provided in the *Gifts, Meals, and Entertainment Policy*.

Field Sales personnel, including Therapeutic Specialist (TS), Institutional Specialist (IS), Community Liaison (CL), Key Account Sales (KAS) or Regional Director (RD) may not provide any out-of-office meals to HCPs. Such Sales personnel may provide a meal (breakfast, lunch, dinner, or snack) to an HCP in connection with a Legitimate Business Purpose, only in an in-office or in-hospital setting. Field Sales personnel may attend an out-of-office meal provided to an HCP by a Senior Regional Director (SRD) or a non-field-based employee who is a Director or above.

Senior Regional Directors may provide appropriate in-office or out-of-office meals to HCPs and may permit Field Sales personnel to attend these meals.

National Accounts Managers (MC, GA, RSP) may not provide out-of-office meals to any HCP who is either 1) Regularly involved in patient care, including any practicing physician, nurse, physician assistant, or similar caregiver or 2) A voting member of a P&T committee or similar formulary-determining body. On an occasional basis and in connection with a Legitimate Business Purpose, National Accounts personnel may provide modest out-of-office meals to other customers, including medical or pharmacy benefit directors, contracting managers, quality directors, and case management directors.

Medical Scientists: Medical Scientists (MSs) and MS Directors may provide appropriate in-office or out-of-office meals to HCPs. Field Sales personnel may attend a meal with an MS and an HCP only if permitted by the joint call rules in the *Medical Scientist Policy*.

Home Office Personnel: Non-field-based employees from any Commercial or non-Commercial function may provide appropriate in-office or out-of-office meals to HCPs. Only those at or above Director level may host meals with HCPs that field Sales personnel may attend.

GIFTS AND PROMOTIONAL ITEMS

Gilead Personnel may occasionally provide HCPs with items that are designed primarily for the education of patients or HCPs and have a retail value of less than \$100. Only Company-approved items may be provided; Gilead Personnel may not purchase items on their own even if such items would otherwise be permissible. Inherently non-educational items may not be offered to HCPs or members of their staff, even if they are accompanied by or imprinted with patient or physician educational materials or content. Gilead Personnel may occasionally provide gifts of nominal value to consumers, who may include patients, caregivers, and other persons interested in Gilead or Gilead products. Such gifts need not have an educational or disease-related purpose but must not be cash or cash-equivalents. Consumer gifts may be distributed by mail or in person but must not be distributed through any HCP (prescriber or non-prescriber) or medical or disease-related institution.

STATE EMPLOYEES

Many states have laws that limit or prohibit providing gifts, meals, or other things of value to state employees, including state-employed physicians and other HCPs. Some states also limit or prohibit the payment of honoraria or other compensation to state employees. Gilead Personnel who conduct business within states that have their own relevant laws must also understand and comply with those rules and should contact the Business Conduct Department for further guidance if necessary.

HCP Expense Tracking

Legislators and regulators at the federal, state, and municipal levels, as well as individual institutions, have enacted a variety of restrictions and disclosure requirements concerning meetings and financial interactions between pharmaceutical companies and healthcare professionals (HCPs) and entities (HCEs) that provide medical care or directly influence prescribing in the United States.

These restrictions and disclosure requirements reach across the Gilead enterprise, including all Commercial, Research & Development, and Corporate activities. To ensure compliance and accuracy in its reporting, Gilead has implemented Gilead CompleteSpend™, a system and associated processes for the collection of all payment and expense information, wherever such data reside. When states enact restrictions on physician payments, all Gilead Personnel who conduct business in those states or interact with HCPs licensed there must be aware of and comply with all applicable requirements.

RESTRICTION AND REPORTING REQUIREMENTS

There are three forms of restrictions or reporting requirements pertaining to financial interactions between companies and HCPs/HCEs:

- 1) Direct restrictions that prohibit or limit certain types of interactions;

- 2) Institutional, state, or federal disclosure requirements under which companies must report all economic benefits provided to HCPs/HCEs; and
- 3) State or institutional requirements that companies report the amount spent for pharmaceutical promotion.

It is the responsibility of all Gilead employees to be aware of and comply with the restrictions and requirements of each state, municipality, and institution in or with which they conduct business.

GILEAD COMPLETESPEND

Gilead CompleteSpend enables the Company to collect the information required to respond effectively to restrictions on interactions with HCPs/HCEs and to satisfy applicable disclosure requirements. Given that diverse groups within Gilead may have non-overlapping interactions with an HCP/HCE, the Gilead CompleteSpend system is critical to tracking aggregate benefits or expenses in real time, which is essential for adhering to internal and external limits on these interactions. Maintenance of the CompleteSpend Expense Submission Process is the responsibility of the Gilead Expense Reporting Coordinator (ERC), in the Commercial Legal Affairs Department. Questions concerning CompleteSpend should be directed to the ERC.

EXPENSE SUBMISSION PROCESS

Many Reportable Expenses will be reported automatically to Gilead CompleteSpend via systems such as Concur, TANGO, and the Gilead Grants System. Reportable Expenses that are not captured automatically are submitted to CompleteSpend directly using an Expense Submission Form. To assist with the ongoing implementation of CompleteSpend, Department Reporting Leads (DRLs) have been identified within each Gilead department that generates Reportable Expenses. DRLs are responsible for ensuring that all Reportable Expenses not captured automatically are submitted to CompleteSpend.

STATE-SPECIFIC RESTRICTIONS

Numerous states have passed statutes regulating the activities of pharmaceutical manufacturers and their employees. Some of these laws closely track either federal requirements or industry self-regulatory codes (such as the *PhRMA Code*) and therefore impose no specialized restrictions on Gilead employees different from those in the Business Conduct Policies. However, a small number of states have enacted laws that place significant additional limits on various activities occurring in those states and/or interactions with HCPs/HCEs licensed in those states. When interacting with HCPs at conferences or other locations to which they may travel, it is the responsibility of all Gilead employees to be aware of the state in which each HCP is licensed and to comply with applicable laws.

In several states, Gilead is required to submit itemized reports detailing Reportable Expenses paid by Gilead to HCPs/HCEs. In many cases, these reports will be posted on public web sites. Some HCPs/HCEs and other persons subject to these reporting rules may be unaware that these payments will become public. For this reason, before engaging in any transaction that may result in a Reportable Expense, Gilead employees should explain the implications to the Reportable Recipient HCP.

Currently, the District of Columbia, Louisiana, Massachusetts, Maine, Minnesota, Vermont, and West Virginia have state-specific restrictions and/or disclosure requirements regulating the activities of pharmaceutical manufacturers and their employees. Gilead Personnel conducting business with HCPs or HCEs licensed in those jurisdictions must review and comply with the detailed requirements specified in the full Business Conduct Manual. A continuously-updated list of states with specific laws and a summary of their requirements can be found on GNet.

Advisors and Consultants

Gilead Sciences periodically engages healthcare professionals (HCPs) and community leaders to advise the Company on various scientific and commercial topics and to provide other specific consulting services. Gilead engages advisors only when their input is needed to provide advice related to product development, scientific, marketing, and promotional strategies and materials. The sole focus of meetings with advisors (“Advisory Meetings”) is to obtain this valuable advice, which will be used to advance the Company’s operations. Gilead engages consultants for a variety of purposes, including training of employees and Speakers, review of scientific papers, and assisting with the development of unbranded promotional materials. Neither Advisory Meetings nor consulting arrangements may be used as educational opportunities, promotional tools, or to reward or induce the prescription, use, or recommendation of Gilead products.

GENERAL REQUIREMENTS

The number and type of advisors participating in an Advisory Meeting must be consistent with the legitimate business purpose, designed to facilitate active participation by every advisor who attends, and reflect the diversity of the advisors and of their feedback. At least half of any Advisory Meeting should be devoted to interactive sessions and discussion during which advisors provide feedback and insight. Gilead Personnel may not conduct return-on-investment (ROI) analyses of advisory programs; nor may they analyze the impact of advisory programs on

HCPs' prescribing practices in connection with any Gilead-supported programs.

PLANNING AND IMPLEMENTING ADVISORY MEETINGS

The Legal Department must review and approve the rationale, agenda, form Advisor Agreement or Consultant Agreement, list of attendees, and other relevant documentation before any Advisory Meeting may be conducted.

Gilead attendance at large and small Advisory Meetings is limited to personnel from the Marketing, Medical Affairs, and Clinical Departments, and Regional Directors or higher from the Sales and National Accounts Departments. Attendance by Marketing and Sales personnel should be kept to a minimum to avoid the misimpression that the meeting has a promotional purpose. A qualified professional, such as a Gilead Medical Scientist or outside moderator, should present scientific information.

SELECTION OF ADVISORS

Advisors and consultants must be selected based on their knowledge, experience, patient demographic, size or type of practice, and other skill-based qualifications and not based on their history of or potential for purchasing or prescribing Gilead products.

CONSULTANTS

Gilead frequently retains HCPs to provide non-advisory consulting services. Gilead Commercial or Medical Affairs employees may retain an HCP consultant only if: 1) There is a documented legitimate business need for the service to be provided; 2) The Consultant was selected based on specific skills and expertise in providing the necessary service; 3) Gilead's payment to the HCP reflects reasonable fair market value for the service provided; and 4) Prior to initiation of work, a Consulting Agreement is executed detailing the precise service to be provided, the payments to be made, and other key information. Field-based Sales and

Medical Affairs personnel may not retain consultants to provide training or perform any other service.

COMPENSATION, TRAVEL, REIMBURSEMENT, AND ENTERTAINMENT

Advisors and consultants may receive reasonable compensation for attending an Advisory Meeting based on the fair market value of the services provided. Fair market value should be determined in consultation with the Business Conduct Department. The total annual compensation that may be paid to an individual HCP in connection with these services for Gilead is \$100,000.

Gilead may reimburse advisors and consultants for the reasonable expenses incurred (e.g., travel, lodging, and meals) in connection with providing contracted services to Gilead. Advisory Meetings must be held in locations that are conducive to the business orientation of the meeting; entertainment and recreational activities may not be provided in connection with advisory meetings.

RETENTION OF NON-U.S. HCPS

The U.S. Commercial and Medical Affairs organizations occasionally retain as consultants and advisors HCPs who practice in other countries. In order to assure compliance with the laws of all relevant jurisdictions, prior to retaining such individuals, the responsible employee must obtain approval from the Regulatory department of the HCP's local Gilead affiliate and/or the applicable Legal group supporting that country.

Speaker Selection and Training

Through its speaker bureaus for professional (“Professional Speaker Bureau”) and community-based audiences (“Community Speaker Bureau”) (collectively, “Speaker Bureau”), Gilead retains qualified third-party healthcare professionals (HCPs), peer educators, case managers, and patients to speak on the Company’s behalf concerning its products and the diseases that they treat, consistent with the products’ on-label uses. The Speaker Bureau is designed to educate speakers about Gilead products and the Company’s compliance policies so that they can deliver effective and appropriate presentations at a speaker program directed to either HCPs (“Professional Programs”) or the community (“Community Programs”) (collectively “Speaker Programs”).

SPEAKER SELECTION

The Marketing Department is responsible for selection and retention of Professional and Community Speakers. On an annual basis and as part of the relevant therapeutic area’s business plan of action, Marketing will create a strategic plan with respect to Speaker Programs, and will draft criteria based on such needs but at a minimum, will be as follows:

- A **Professional Speaker** must be a licensed HCP who has clinical expertise in a particular therapeutic area and/or product category, acceptable public speaking skills, and previous public speaking experience. Prospective

Speakers must not be debarred or excluded by the FDA or HHS OIG.

- A **Community Speaker** must be an individual with professional and/or personal experience in a particular therapeutic area and/or product category, acceptable public speaking skills, and previous public speaking. If a prospective Community Speaker is a licensed HCP, he or she must not be debarred or excluded.

Sales employees and Medical Scientists (MSs) may nominate individuals who they believe fit the speaker selection criteria established by the Marketing Department. The nominating employee must provide supportive information about the potential speaker, such as medical specialty, years in practice, or other information necessary for verification of their capabilities. The Marketing Department, in consultation with the Medical Affairs Department, makes the final determination whether or not to invite any prospective speaker.

Speakers may not be nominated or selected based on an explicit or implicit understanding, hope, or desire that they will prescribe, purchase, or recommend Gilead products as a result of participation in the Speaker Bureau. Speakers (and advisors and consultants) who are members of a formulary or clinical practice guidelines committee must disclose to the committee the existence and nature of their relationships with Gilead. This disclosure requirement extends for at least two years beyond the termination of a speaker arrangement.

ONGOING SPEAKER BUREAU PARTICIPATION

To remain active in the Speaker Bureau, all speakers must attend a training session (live or field) at least once per year. Each speaker must provide at least two promotional lectures per year for Gilead to appropriate audiences starting from the date of the signed Speaker Agreement. The total annual compensation that may be paid to an individual HCP in connection with all services for Gilead (including Commercial or Medical Affairs advisory

engagements, speaker training, and Speaker Programs) is \$100,000. Compensation does not include reimbursement for expenses incurred while providing those services.

SPEAKER TRAINING PROGRAMS

Generally, Gilead Professional and Community Speakers should be trained through live, in-person speaker training programs. In limited cases, the Marketing Department may approve refresher training in the field using web resources and an MS for speakers who are current members of a Speaker Bureau and who are unable to attend the live speaker training program prior to a scheduled speaking engagement. If circumstances require, Gilead may periodically require speakers to attend tele-web sessions in between live training programs to educate speakers when new products are released, new data become available, or the package insert is updated. Gilead also maintains password-protected websites that support its speakers.

INFORMATION PRESENTED DURING TRAINING

Information and materials presented to speakers must be limited to that which speakers will reasonably need to make presentations on behalf of Gilead and to respond appropriately and effectively to unsolicited questions (HCP speakers only). All training programs must at a minimum cover the following topics: the on-label approved slide kit for use in promotional presentations; information on FDA regulatory requirements for speaking on behalf of Gilead, including Gilead's *Speaker Programs Policy* (which covers topics such as when/how the speaker may answer unsolicited questions regarding off-label information); and any updates to the relevant package insert(s) since the speaker's previous training session.

Speaker Programs

Gilead conducts promotional speaker programs for professional audiences and audiences composed primarily of individuals who are not health care professionals, e.g., patients and consumers (“Community Audiences”). Therapeutic Specialists (TSs), Institutional Specialists (ISs), Community Liaisons (CLs), Key Account Sales (KAS), and National Account Managers (NAMs) plan and implement Speaker Programs, with support and oversight from the Marketing, Medical Affairs, and Business Conduct Departments, and other departments.

SCHEDULING A SPEAKER PROGRAM

Field-based Sales and National Accounts personnel are tasked with efficient use of the programs by scheduling them at times and in locations convenient to prospective attendees, selecting qualified and engaging speakers, and inviting as many appropriate attendees as practical. Regional Directors allocate funds to their employees to hold Speaker Programs based on a budget determined by Gilead’s home office. The Marketing Department has retained an outside vendor, SCS Healthcare Marketing, to facilitate and arrange logistics for Speaker Programs, and all Speaker Program costs must be paid through the outside vendor.

Gilead Speaker Programs may be conducted in association with a larger event, such as a scientific symposium or an event sponsored by a patient advocacy organization that includes other programs funded by third parties. In such cases, the portion of the content provided by Gilead and

the portion provided by other entities must be entirely clear to all attendees. Gilead Personnel may not support Speaker Programs that combine content from different therapeutic areas within Gilead and may not coordinate support for Speaker Programs with other pharmaceutical manufacturers or share the cost of these programs with third parties.

CONDUCTING A SPEAKER PROGRAM

Gilead is responsible for all content presented during its Speaker Programs; therefore, speakers must use only Gilead-approved slides, both for their presentation and in response to unsolicited questions. Presentations must be consistent with the FDA product labeling, maintain “fair balance” between information on safety and efficacy, be truthful and non-misleading, and avoid unapproved comparative claims concerning competing products. The speaker at each program must present a complete Gilead-approved product or unbranded slide deck and may not edit, re-order, or hide slides or otherwise modify the content, emphasis, balance, or context of the presentation. The speaker need not verbalize all content on every slide, but should address points of interest or relevance for the particular audience or setting.

If an attendee asks an unsolicited off-label question, Professional Speakers and Community Speakers who are licensed HCPs may respond as long as the response is objective, balanced, scientifically rigorous, and within the scope of the question. CLs and other community speakers who are not licensed HCPs may not discuss off-label information, even in response to an unsolicited question. Professional speakers may answer questions verbally or using Gilead-approved back-up slides. Community Speakers may only answer questions verbally and must refrain from providing any medical advice to attendees.

All Gilead Personnel attending a Speaker Program are responsible for ensuring that the speaker complies with Gilead’s policies. The Responsible Gilead Employee must report any violations to the Opinion Leader

Program division of the Marketing Department (OLP) or the Business Conduct attorney assigned to his or her therapeutic area.

The venue at which any Speaker Program takes place must be conducive to a scientific or educational discussion. If the Speaker Program is scheduled in a restaurant or other public setting, it must be in a separate room or defined area. The venue also must include a mechanism for projecting or displaying the material in a prominent manner. It is not acceptable to display the speaker presentation on a laptop computer or to present from slide print-outs. A meal may be provided in connection with a Speaker Program in accordance with the *Gifts, Meals, and Entertainment Policy*. Entertainment and recreational activities are not permitted.

COMPENSATION AND EXPENSES

A speaker may receive a reasonable honorarium consistent with the fair market value of services to be provided. The specific amount of compensation provided is specified in each Speaker's Agreement, and shall be proposed by the Marketing Department and pre-approved by the Business Conduct Department. The total annual compensation that may be paid to an individual HCP in connection with these services for Gilead is \$100,000.

Gilead may reimburse speakers for the reasonable expenses incurred (e.g., travel, lodging, and meals) in connection with speaking at a Speaker Program. If an overnight stay is required for the speaker, the hotel accommodations should be four stars or less and selected based upon business considerations such as proximity to the presentation, and not be based upon the existence or quality of amenities such as golf courses and spas.

Medical Conventions and Exhibits

Through its sponsorship of and participation in domestic and international medical conventions, symposia, and other meetings of healthcare professionals (HCPs), Gilead provides scientific, educational, and product data to HCPs through exhibits, medical information booths, oral presentations, posters, sponsoring symposia, and hosting social engagements at which scientific and medical information are discussed. The Commercial Strategy, Marketing, and Medical Affairs Departments collaborate on setting priorities at meetings with national scope. Gilead Sales personnel have primary responsibility for the Company's activities at smaller meetings, such as hospital displays and health fairs. Generally, the rules set forth in the *Detailing and Promotion* and *Gifts, Meals, and Entertainment Policies*, applicable state laws, sponsoring organization rules, and host country rule (if outside the United States) also apply to Gilead's participation in these activities.

MEDICAL CONFERENCES

For meetings with national scope, all Gilead Personnel who plan to attend the convention must attend an internal Company meeting before the event begins that provides instructions on appropriate behavior and rules applicable to the convention. For other meetings, the most senior Gilead employee in attendance should ensure that Gilead Personnel are briefed on such behavior and rules prior to the meeting.

For conventions held outside of the United States, the rules of the host country must be followed. Gilead's interactions with HCPs from the United States who attend the international conference are governed by U.S. law. Accordingly, Gilead Personnel must adhere to the U.S. *Gifts, Meals, and Entertainment* and *Detailing and Promotion Policies* with respect to those HCPs.

Any Gilead-sponsored educational symposia must comply with Gilead's *Independent Medical Education Programs Policy* as well as the rules of the convention sponsor. Any promotional seminars must comply with the *Speaker Programs Policy*, FDA and sponsoring organization rules, and be pre-approved by the Gilead Legal Department.

PROMOTIONAL EXHIBIT BOOTHS

As described in more detail in the *Detailing and Promotion Policy*, all materials and communications used at promotional booths and exhibits must: 1) Be consistent with the FDA-approved product labeling ("on-label"); 2) Reflect a fair balance of efficacy and safety data; 3) Be truthful and not misleading; 4) Target HCPs who are reasonably likely to prescribe the product for an FDA-approved use; and 5) Be pre-approved by the Promotional Review Committee (PRC). Materials and safety and efficacy claims regarding unapproved uses of current products or unapproved products are prohibited.

Gilead may restrict access to a portion of the exhibit booth to convention participants from other countries. The material and information provided in this restricted area need not comply with the specific FDA requirements, although it must reflect a fair balance of efficacy and safety data and be truthful and not misleading. It must also comply with other general exhibit-materials guidelines outlined above.

REQUESTS FOR SCIENTIFIC OR MEDICAL INFORMATION

Requests for off-label information must be directed to the staff at the Medical Information booth (if one exists), to a Medical Scientist (MS), or to the Medical Information Department (MID) for follow-up. When an MS or Medical Information booth is present, Inquiry Response Summaries (IRSS) and reprints may not be used by Sales or Marketing personnel.

When appropriate, Gilead's MID may erect a booth that is physically separated from any Gilead promotional booth and staffed only by qualified Medical Affairs or Clinical personnel. This booth may only proactively distribute a list of Gilead poster sessions. Booth staff may responsively address unsolicited questions from convention participants with Standard Response Documents, reprints, current posters, or booklets from prior conventions. The booth may also display approved investigator and participant recruitment materials for clinical studies not fully enrolled and FDA-approved expanded access programs. Poster materials and slides from oral presentations may not be displayed or affirmatively provided in any promotional exhibits/areas or in the Medical Information booth. In response to unsolicited questions, staff at the Medical Information booth may distribute or discuss poster books or slides from the oral presentations if within the scope of the question asked.

MEALS AT MEDICAL CONVENTIONS

Gilead may host a meal or reception during a medical convention, as long as it complies with the sponsoring organization's guidelines. The meal or reception should be modest and conducive to discussion among attendees, and the amount of time at the meal or reception should be clearly subordinate to the amount of time spent at the educational activities of the meeting. The normal dollar limits apply to these events. Please see the meal rules regarding conferences that are role-specific for certain

Gilead employees set forth in the *Gifts, Meals, and Entertainment Policy*.

FIELD-PAID EXHIBITS/ADVERTISING FEES

An exhibit is an opportunity to purchase space and time for a commercial interaction with customers or patients and may include branded or unbranded displays and distribution of materials. Such opportunities often occur at local conferences and hospitals. All content of exhibits must be PRC-approved and branded and unbranded materials may not be used together unless specifically approved for such dual use.

An advertisement is an opportunity to purchase space in a third-party publication in which to promote Gilead as a company or a specific Gilead product. All field advertisements must be PRC-approved and may only be placed in independent publications that would exist without Gilead support (e.g., local newspapers, newsletters, conference catalogs).

Field-based Sales and National Accounts employees may purchase exhibit or advertisement opportunities. Each such opportunity must be pre-approved by the applicable Regional Director and may require additional approvals based on the size of the request. Exhibit fees requests are submitted through the Commercial Exhibit Fee Portal on GNet (<http://exhibits.gilead.com/>).

Field-based employees may not provide grants, sponsorships, or any other financial support to third-party programs, even if an exhibit opportunity is also included. Requests for direct financial support should be referred to the online Gilead Grants website (<http://grants.gilead.com>).

Medical Scientists

Gilead's Medical Scientist organization is an arm of the Medical Affairs Department. Medical Scientists (MSs) help ensure the appropriate use of Gilead products by addressing the informational needs of healthcare professionals (HCPs), community organizations, and government and managed care institutions (collectively, the "MS Audience"). In light of their advanced education, experience, and training, MSs are qualified to interact as peers with the MS Audience concerning the Company's products, its speaker, advisory, and research and development programs, and the complex medical and scientific questions with which Gilead is concerned.

GENERAL REQUIREMENTS

In all situations, MSs must present objective, fair balanced, scientifically rigorous, and truthful information consistent with their obligations as medical professionals. The MS role is non-promotional and, as a result, MSs may not be compensated or receive financial incentives, and their job performance may not be evaluated, based upon Gilead product sales or market share. Medical Scientists may impart off-label information in response to an unsolicited request if the response is narrowly-tailored to the specific request, and the MS first discloses to the requestor that the information is off-label. Gilead Personnel may not conduct return-on-investment (ROI) or similar financial analyses on non-promotional MS activities. Medical Scientists must document each substantive interaction with a member of the MS Audience in TangoMed.

INDIVIDUAL INTERACTIONS WITH HEALTHCARE PROFESSIONALS

Medical Scientists have multiple opportunities for individual interactions with HCPs, including: proactive interactions designed to educate and inform the MS Audience regarding Gilead products and the Company's relevant therapeutic areas; support of Speaker Bureaus and advisory programs; support of Commercial field-based personnel; joint breakfasts or lunches with a Commercial field employee and an HCP; and interactions with clinical investigators. Gilead employees should be familiar with the interaction-specific rules regarding MS activities, which are detailed in the *Medical Scientists Policy*.

Commercial personnel and MSs have separate and distinct objectives in the field and their interactions with HCPs are subject to different policies. For this reason, "joint calls," or situations in which an MS and Commercial personnel are visiting with an HCP together, are disfavored and should be infrequent. Commercial personnel may only make a joint call with an MS if: 1) Either the Commercial employee or the MS has never met the HCP and the purpose of the joint call is to make an initial introduction (permitted only once per HCP), or 2) If the MS and the HCP do not have an established relationship and the Commercial field employee:

- Has received an unsolicited question and submitted a Medical Information Request Form (MIRF); and
- Does not engage in any promotional activity during or immediately after the visit; and
- Does not record the interaction as a promotional sales call.

GROUP PRESENTATIONS

Medical Scientists frequently deliver group presentations to various audiences, such as physician practice groups, unaffiliated HCPs (those who are not members of the same group or institution), community organizations, managed care entities, and groups of government employees.

For **proactive presentations** prompted or initiated by the MS or other Gilead Personnel, the MS must limit the affirmative presentation to on-label information or disease state information that is relevant to on-label uses of the product. The MS may respond to any unsolicited questions received before or during the presentation either verbally or with slides, provided that the MS discloses the off-label character of the information and maintains a fair balance of safety and efficacy information.

For **reactive presentations** in which a member of the group audience specifically requests a topic that calls for off-label information, the MS may present on the topic and need not begin with the approved on-label slide deck. The MS must document the request in TangoMed. In addition, if the off-label request originated with the Gilead Commercial organization, an MIRF must be filed.

PATIENT-SPECIFIC DISCUSSIONS

Although many MSs are licensed HCPs, they must never provide treatment advice to or about individual patients, review individual medical charts, or solicit the identity of specific patients.

Independent Medical Education Programs

Gilead supports high quality independent, non-promotional educational programs for healthcare professionals (HCPs). These Independent Medical Education Programs (IMEPs) are developed by external organizations. The organizations that sponsor and/or organize these programs must be consistent with the FDA's *Guidance on Industry-Supported Scientific and Educational Activities*, as well as other relevant laws, rules, or guidelines. Accredited programs must comply with the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support* and other applicable ACCME rules. The Public Affairs and Independent Medical Education Departments (collectively "IMED"), in collaboration with the Business Conduct Department, are responsible for managing applications for IMEP funding consistent with this policy

GENERAL RULES FOR IMEPS

The decision whether or not to support an IMEP should be based primarily on the program topic and must be made without regard to program content or faculty. Gilead may not consider the program participants' (including the provider, education partner, faculty, and attendees) past or potential behavior to purchase, prescribe, or recommend a Gilead product when determining whether or not to provide funding. IMEPs are, by definition, not promotional in nature. Accordingly, Gilead Personnel may not conduct return-on-investment (ROI) or similar analyses of IMEPs,

or assess the impact of IMEPs on the prescribing practices of attendees or faculty.

APPLICATION SUBMISSION AND REVIEW PROCESS

The IMEP Committee makes funding decisions for applications that have been submitted to IMED by independent program providers. All applications for IMEP support must be submitted via email at IMED@gilead.com or through an IMED employee. IMED notifies the requestor in writing if its application is approved or denied.

INDEPENDENCE OF IMEPS

IMEPs must be non-promotional, independent, and free of commercial bias. They may not be controlled or influenced by Gilead, nor may Gilead Personnel participate in program planning or development. IMEP providers make the following decisions free from Gilead influence or control: 1) Identification of educational needs; 2) Determination of program objectives; 3) Selection and presentation of content; 4) Selection of all persons and organizations that will be in a position to control the content of the IMEP, including faculty and content authors; 5) Selection of educational methods; and 6) Program evaluation.

The IMEP provider is responsible for promoting its program, but may request assistance from Gilead in distributing a small portion of invitations or “save the date” cards. Any enduring educational materials must be independently produced and disseminated by the IMEP provider. Gilead Personnel may attend IMEPs at the discretion of the IMEP provider; however, they may not participate in audience discussion or direct questions to the speakers. Gilead employees also may not conduct any promotional activities — including providing meals or entertainment — during an IMEP.

Investigator-Sponsored Research

Gilead actively supports investigator-sponsored research trials (IST) initiated and conducted by third parties on Gilead products or within Gilead's therapeutic areas of interest. This research can provide valuable information regarding the safety, efficacy, pharmacology, and tolerability of Gilead products or opportunities for development of new products.

GENERAL REQUIREMENTS

The proposed research must contribute to the broader medical community and the principal investigator should plan to publish the research results in a peer-reviewed medical journal or present them at a medical conference. Gilead will not support IST that are unnecessarily duplicative or a pretense to promote Gilead products. Funding decisions are not based on the principal investigator's relationship to Gilead or prescribing habits; nor are payments prefaced on research outcomes. Payments are made to the principal investigator's institution and not the individual principal investigator. IST budgets must be reasonable and based on fair market value.

DEVELOPMENT, SUBMISSION, AND REVIEW OF RESEARCH PROPOSALS

The Principal Investigator should submit the completed application materials directly to Gilead using the IST application materials found under "Research" on

Gilead's website at <http://www.gilead.com>. Alternatively, application materials may also be submitted directly to a Gilead Medical Scientist (MS), Medical Director or other appropriate Gilead employee who will advance them within the Medical Affairs Department for further review.

The application must include: 1) A study proposal containing key study metrics; 2) The principal investigator's curriculum vitae (CV) and contact information; 3) A Gilead form "Concept Sheet" that captures key information, resources, and the nature and scope of the requested support; 4) A detailed budget; and 5) Any additional supporting documentation.

GILEAD PERSONNEL INTERACTIONS WITH INVESTIGATORS

Gilead Personnel must limit their role to advisory only, and may not draft study protocols or regulatory submissions, or serve as primary architects of the study concept, design, implementation, or data analysis/dissemination. The study sponsor is responsible for all regulatory obligations, trial-related medical decisions, monitoring the study, and ensuring adequate medical care for volunteers.

Medical Affairs personnel, notably Medical Directors and MSs have primary responsibility for communicating with potential applicants regarding study-related activities. In such circumstances, Gilead's current research priorities, application process, and approval criteria may be discussed. Upon request, Medical Affairs personnel may provide comments, advice, and substantive feedback on draft applications. The application must be written by the applicant, however, and not by Gilead Medical Affairs personnel. If a Gilead Medical Affairs employee provides substantive feedback to a prospective applicant, he or she must make clear that such assistance does not imply that Gilead will approve the application, and that potential funding is not necessarily contingent upon acceptance of such comments or advice.

If requested, Gilead Medical Affairs personnel may provide scientific critique of the proposed study design, advice regarding regulatory matters, a right of cross-reference, or assistance with abstract submissions and poster production.

Gilead Sales and Marketing personnel may not assist potential investigators in applying for Gilead support or patient recruitment or discuss ongoing research projects with any third party. Questions must be referred to the appropriate MS and/or Gilead's application materials.

Grants

Gilead considers grant requests from a broad range of non-profit, health-related organizations. Grant applications are received through Gilead's Grants website, located at <http://grants.gilead.com>. The Public Affairs Department manages the grant application process, with oversight from the Business Conduct Department.

Gilead provides grants to support healthcare education, charitable, and general philanthropic initiatives, including independent medical education programs, scientific conferences, development of health education materials, patient education programs, and healthcare-related and disease-awareness community activities. Grants may be awarded to hospitals, patient care organizations, universities, patient assistance groups, charitable or social welfare organizations, and others institutions.

Funding determinations for individual grant requests are made on the basis of scientific, educational, medical, and public health criteria, as well as Gilead's overall funding plan. Grants may not be provided, directly or indirectly, as an inducement or reward for purchasing, prescribing, recommending, or providing other support for Gilead products. A grant also imposes no obligation, express or implied, on the recipient to purchase, prescribe, provide favorable formulary status for, or otherwise support Gilead products.

Grant recipients must control the content of their programs and activities. Gilead Personnel may not participate in planning or executing any Gilead-funded events, including selecting speakers, suggesting specific topics or attendees,

or otherwise scripting content of the sponsored activity or material. Gilead Personnel may not conduct return-on-investment (ROI) or similar analyses of grants; nor may they analyze the impact of grants on healthcare professionals' (HCPs) prescribing practices in connection with any Gilead-supported programs.

Gilead employees may responsively direct HCPs, organizations, and other potential grant requestors to the Gilead Grants website, but may not solicit grant requests. Commercial personnel may not participate in any part of the grants process and may periodically receive information on exhibiting opportunities. Occasionally Commercial personnel may be contacted for information related to a particular request, such as an exhibit-only request.

After a decision has been made whether to approve or deny a particular request a formal written notice of such determination is sent to the requestor. Only Public Affairs personnel may communicate funding determinations or deliver grant proceeds to recipients.

Institutional Preceptorships

Preceptorships provide opportunities for Gilead Personnel to receive training directly from healthcare professionals (HCPs) concerning when and how they evaluate and treat patients. Preceptorships are managed centrally by Gilead's Commercial Learning and Development (CLD) and Medical Affairs Learning and Development (MALD) Departments and must be pre-approved by the Business Conduct Department. Sales personnel, Medical Scientists (MSs), and other Gilead employees may not organize their own office preceptorships or pay for preceptorships out of their own budget.

Preceptorship programs are typically limited to personnel who are new to Gilead or a particular therapeutic or geographic area, or who have a particular need to learn about a specialized topic that will be addressed at the program. CLD or MALD determines which Gilead Personnel may participate.

Preceptorship programs may not be used as promotional tools, or to reward or induce the institution or preceptors to prescribe or purchase Gilead products or to influence formulary status. Gilead Personnel may not analyze, inquire, or conduct any type of return-on-investment (ROI) analysis as to whether or not an HCP's prescribing habits changed as a result of participating in a preceptorship.

All preceptorships are held at major medical centers and institutions based upon the entity's expertise in a relevant therapeutic area and capacity and interest in hosting a program. Most preceptorships take place in a classroom setting, and HCPs serve as primary faculty; however,

patient volunteers may be brought in by the hosting institution to discuss their condition and treatment and to answer questions. Occasionally, Gilead Personnel may accompany an HCP on patient visits in connection with the program. In such situations, the hosting institution and Gilead must comply with any relevant patient privacy laws, regulations, and/or rules. This includes, but is not limited to, the hosting institution obtaining any necessary written patient authorizations.

Prior to any preceptorship, Gilead and the institution must sign a written agreement. Any payments for preceptorship training must be consistent with fair market value and paid directly to the institution, rather than to the participating HCPs.

Prescription Drug Samples

Gilead Sales personnel in certain therapeutic areas occasionally provide samples of pharmaceutical products free of charge to licensed healthcare professionals (HCPs). Samples are intended to promote the sale of the prescription drug but are not intended to be sold. Gilead permits sample distribution only in an ethical manner and only in full compliance with the requirements for storage, record keeping, and distribution set forth in the *Prescription Drug Marketing Act of 1987* (PDMA) and associated FDA regulations. In addition, Gilead will not attempt to dictate to an HCP the conditions under which samples should be disbursed to patients.

SAMPLE DISTRIBUTION

Gilead employees may only leave samples with an HCP whose licensure and qualification to prescribe drug products have been verified. To ensure that validation has occurred employees may sample only if they either 1) Receive preprinted labels with that HCPs identifying information or 2) Verify within TANGO that the HCP's status is shown as "Yes-Valid". Reviewing the prescriber's actual license, being told a prescriber's license is valid by the prescriber or office personnel, or reviewing non-Gilead documentation of licensure is not acceptable. Before any samples may be distributed, the Therapeutic Specialist (TS) or Institutional Specialist (IS) must personally witness a validated prescriber signing a Sample Distribution Form (SDF). The prescriber's signature must match the prescriber name printed on the label or hand

written on the form. Sales personnel must never sign the prescriber's name or permit any person other than the validated prescriber to sign it.

SAMPLE HANDLING

Sample quantity and shipment frequency is determined by the Marketing and Sales Departments and samples are typically shipped to the TS or IS quarterly. Only the Gilead employee to whom the package is addressed is authorized to sign for samples. Upon receipt, the TS/IS must open each carton, count the inventory, compare the quantity against the packing slip, and complete the automated Acknowledgement of Delivery (AOD) via email. Each Gilead employee who distributes samples must conduct monthly and quarterly inventories.

Any theft or significant loss of samples is required to be reported to FDA on an expedited basis. As a result, it is vital that employees immediately communicate such occurrences to Sample Management (SM). If a theft of any number of samples occurs, the employee must immediately notify SM and the appropriate Regional Director by telephone. In addition the employee must: 1) File a report with the local police department and obtain the report number. 2) Before sampling any additional prescribers, conduct a physical count of the remaining samples in their possession. 3) Within 24 hours of notification, complete the Sample Transfer Form (STF) (select "Loss/Theft Incident") and fax it to SM. Following a theft, a TS/IS must not resume sampling activity until all documentation and a full inventory have been completed.

SAMPLE COMPLIANCE OVERSIGHT

Federal and state laws require that pharmaceutical manufacturers that engage in sampling have a comprehensive sample compliance system in place to prevent misconduct related to samples. FDA regulations require that Gilead conduct various types of audits to ensure that employees are complying with sampling rules.

As a result, the Company conducts Random Inventory Audits, Signature Verification Audits, For-Cause Audits, Annual Audits and Close-Out Audits. Any random or for-cause audit findings or other data or statements suggestive of a serious violation of Gilead policy or state or federal law will be thoroughly investigated by the Sample Compliance Committee (SCC). Gilead is required to report to the FDA and initiate an investigation if the Company:

- 1) Has reason to believe that any person has falsified drug sample requests, receipts or records or is diverting drug samples; or
- 2) Becomes aware of any known theft or significant loss (including a sample inventory variance greater than the significant loss threshold); or
- 3) Becomes aware of the conviction of any employee for a sampling-related violation of law.

Complaint Procedure and Non-Retaliation Policy

SCOPE AND PURPOSE OF POLICY

The people of Gilead Sciences are united by the shared values of integrity, teamwork, accountability, and excellence. One embodiment of these corporate values is Gilead's *Complaint Procedure and Non-Retaliation Policy*, which enables employees and contractors (collectively "Employees") to disclose legitimate concerns over suspected wrongdoing in a responsible and effective manner without fear of reprisal.

Gilead has established a committee responsible for receiving and investigating Employee complaints under this *Complaint Procedure and Non-Retaliation Policy*. Under this Policy, Employees are required to report credible suspicions of the following to their management, the Legal Department, or the Committee (as defined below), whether those suspicions originate with the Employee or from another source inside or outside the Company:

- Violations of laws, regulations, or governmental rules;
- Violations of Gilead's *Code of Ethics*;
- Violations of policies regarding financial disclosures, accounting, accounting controls, or auditing matters; or
- Any other serious wrongdoing within the Company.

Employees are strongly encouraged to follow this Policy, rather than discussing their concerns outside the

Company. This Policy is intended to assist individuals who believe they have discovered verifiable matters of concern. Voluntary disclosure of a situation in which the Employee is involved will be considered when determining what disciplinary or corrective actions are necessary, but will not preclude termination. Failure to report wrongdoing of which an Employee has knowledge is a violation of this Policy and is a basis for disciplinary action. This Policy is not, however, intended to replace the existing reporting mechanisms and channels of communication within the Company. For instance, Employees should raise concerns of a general human resources nature to their local HR generalist. If you are unsure whether your concern falls within this Policy, we encourage you to follow this Policy. The Committee will route any concerns that fall outside of this Policy to the appropriate department. This Policy is also not designed to facilitate interference with financial or business decisions taken by the Company, nor should it be used to cause reconsideration of any matters that have already been addressed under legitimate disciplinary, complaint, harassment, or other procedures.

SAFEGUARDS

Protection

Gilead will not tolerate any form of intimidation or retaliation by any person acting on behalf of Gilead against any Employee because of any good faith act taken by the employee under this Policy. Moreover, it is a federal crime for anyone to retaliate intentionally against any person who provides truthful information to a law enforcement official concerning a possible violation of any federal law. Please note, however, that no protection from internal disciplinary procedures is available to those who abuse this Policy.

Confidentiality

When an Employee in good faith discloses suspected wrongdoing, based upon a reasonable belief, and is not engaged in associated improper conduct, Gilead will keep the identity of the complainant confidential for as long as possible. In order to thoroughly investigate a matter, however, Gilead may find it necessary to share information with others on a “need-to-know” basis. While efforts will be made to maintain the confidentiality of the complainant’s identity, the existence and particulars of the complaint itself may have to be disclosed to the individual(s) against whom the complaint is made. In each instance, the receiving Committee member will determine the appropriateness of bringing the disclosure to the attention of some or all of the other Committee members, to the individual(s) against whom the complaint is made, and to the Gilead Audit Committee of the Board of Directors. If an Employee reports improper conduct in which they have been engaged with others, confidentiality will be determined upon a case-by-case basis.

Anonymous Allegations

This Policy encourages individuals to identify themselves when bringing any matters of concern/disclosures to the attention of the Committee. Concerns expressed anonymously will be given due consideration, but may be considered less credible due to the difficulty of investigating and confirming the matter of concern/disclosure.

Untrue Allegations

In making a disclosure, an individual should exercise due care to ensure the accuracy and completeness of the information disclosed. If an individual makes an allegation in good faith that is not confirmed by subsequent investigation, no action will be taken against that individual. If, however, an individual makes

malicious or unfounded allegations, and particularly if the individual persists with making them after they have been found by the Committee to be without merit, disciplinary action may be taken against that individual.

PROCEDURES FOR MAKING A DISCLOSURE

Persons in the following positions are members of the Committee responsible for enforcement of the *Complaint Procedure and Non-Retaliation Policy*:

- Executive Vice President, Corporate and Medical Affairs
- Executive Vice President and Chief Financial Officer
- Senior Vice President, Human Resources
- Senior Vice President, International Commercial Operations
- Vice President, Regulatory Affairs

The names of the persons presently on the Committee are listed on the GNet internal website at <http://gnet/hr/forms/complaintform.asp>. When Employees wish to raise a matter under this Policy, they should contact any Committee member by the Employee's preferred means of communication. As previously noted, reporting can be done anonymously. To facilitate disclosures and also permit them to be anonymous, if the complainant so wishes, the Company has established an online and telephone reporting system. Employees can access the online system at the GNet location noted above or call the toll-free Ethics Hotline at 1-888-631-3121. Each system enables Employees to direct a disclosure to a particular Committee member

Upon receipt of a disclosure, the receiving Committee member will take responsibility for its consideration, investigation and remedial action, as appropriate. All disclosures will be investigated.

MANNER OF FOLLOW-UP TO DISCLOSURES

Committee members may utilize internal and external resources, as appropriate, to make their investigations

and follow-up effective, keeping in mind confidentiality concerns. The Committee's responsibilities will be carried out in accordance with all applicable laws, regulations, governmental rules, Gilead's *Code of Ethical Conduct*, and good business practices.

Due to the diverse nature of disclosures under this Policy, the investigations may involve internal resources and/or law enforcement or government officials and have varied completion times. In all cases, the Committee member will ensure that investigations are undertaken as quickly and discreetly as reasonably possible, without affecting the quality and depth of those investigations.

After receiving a disclosure, Committee members will send a written acknowledgement of receipt to the complainant. From time to time, as practicable, Committee members may provide progress reports to the complainant and when the investigation is likely conclude. When the investigation is complete, the complainant will receive written notification of the outcome and steps taken as a result of the investigation. Unless requested otherwise, Committee members will send written communications to the complainant's home address. Obviously, if the complainant wishes to be anonymous, the Committee will not be able to acknowledge receipt of the complaint or advise the complainant of the investigation's outcome.

Should a complainant be dissatisfied with the manner in which a Committee member or the Company is following up on a disclosure, the complainant may raise the matter with another Committee member, or with any Gilead officer (VP, SVP, EVP, or CEO), in confidence. If the complainant remains dissatisfied with the outcome of the Committee's investigation and follow-up after all internal procedures have been exhausted, the Company recognizes that Employees and ex-Employees have the right to pursue the matter outside the Company.

NOTE:

Nothing in this Policy shall be construed to prohibit employees from reporting any suspected instance of illegal activity of any nature, any workplace safety, public safety, or environmental concern to the United States Department of Labor or any other relevant federal or state governmental agency. This Policy shall not be construed to prohibit employees from participating in any way in any state or federal administrative, judicial, or legislative proceeding or investigation.

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