



2006
Pocket Guide to Gilead's Promotional
and Customer Support Guidelines



Since Gilead 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. Fundamental to that reputation is Gilead's commitment to adhere to the highest legal and ethical standards of business conduct. Patient safety is protected when these standards are upheld. Moreover, adherence to these standards protects the company, its employees and business customers.

This Pocket Guide summarizes the Gilead Promotional and Customer Support Guidelines regarding operations in the United States. In short, it highlights how to do the right thing, the right way. Please consider these rules against the backdrop of Gilead's core values of:



Integrity:

Doing the right thing

Teamwork:

Collaborating in good faith

Accountability:

Taking personal responsibility

Excellence:

Being your best

For the complete standards, including definitions of terms used throughout this Pocket Guide, please consult your reference materials or GNET. It is the responsibility of every employee within Gilead's Commercial organization to be knowledgeable about these standards. If you have any questions regarding the rules, practices and activities described herein, please feel free to contact one of the company's attorneys in the Legal Department. By working together to move our business forward in the spirit of these rules, we will continue to enhance the reputation and success of Gilead Sciences.

Kevin Young

Executive Vice President,
Commercial

Gregg Alton

Senior Vice President,
General Counsel &
Chief Compliance Officer



Reporting of Suspected Violations through the Gilead Ethics Hotline

It is essential that each Gilead employee understands what to do if he or she knows or suspects that a violation of the Promotional and Customer Support Guidelines has taken place, or if he or she is directed, or believes another employee or third party has been directed to take action that would result in a violation. In such a case, the employee must report the suspected violation in accordance with Gilead's Complaint Procedure and Non-Retaliation Policy. This policy, which employees may reference in its entirety on GNET, allows for direct or anonymous disclosures of information concerning suspected violations of law, regulation or Gilead policy to certain members of Gilead senior management.

Employees may make such disclosures either through the Gilead Ethics Hotline at 1-888-631-3121 or by making a report via GNET at <http://gnet/forms/complaintform.asp>. No employee who reports suspected wrongdoing in good faith will be subject to retaliation or discipline for having done so. Moreover, if an employee who makes such a report took part in the possible violation, that fact will be given strong consideration in the determination of any related disciplinary action. Similarly, failure to report wrongdoing of which an employee has knowledge may be, in and of itself, a basis for disciplinary action.

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POCKET GUIDE REFERENCES TO
“COMMERCIAL STAFF” AND “CLINICAL STAFF”

“**Commercial Staff**” refers generally to all employees of Gilead’s Commercial Departments who interact, in person or through written materials, with healthcare practitioners on Gilead’s behalf. The document is of greatest relevance, to Commercial Staff in the field, including Therapeutic Specialists, National Account Managers and Community Liaisons, as well as the managers of each of these functions.

“**Clinical Staff**” refers generally to all employees of Gilead’s Medical Affairs and Clinical Research Departments, who interact, in person or through written materials, with health care practitioners on Gilead’s behalf. The document is of greatest relevance to Clinical Staff in the field, including Medical Science Liaisons (MLSs) and their managers.



Gilead Product Presentations

All product presentations, in public or private, in a physician's office or on a convention floor, must comply with the following guidance.

PRODUCT PRESENTATIONS MUST BE CONSISTENT WITH PRODUCT LABELING

Presentations about Gilead products must be consistent with the product's FDA-approved labeling. In addition, only information and materials that have been approved for promotional use may be used in connection with these presentations. It is impermissible to utilize altered or modified sales materials.

AVOID MAKING FALSE OR MISLEADING CLAIMS

Product presentations must not include claims or statements that could be considered false or misleading due to questionable scientific or medical foundation. Similarly, care must be taken not to "cherry-pick" information, but rather present all information relevant to the subject matter under discussion. Avoid exaggerating efficacy claims, minimizing safety data or presenting non-efficacy data (i.e. resistance data) as a clinical benefit because such statements could also be considered false and misleading.

FAIR BALANCE REQUIRED

Take care that all product presentations reflect a fair balance of efficacy and safety information. Describe black box warnings in all presentations and finish by presenting the healthcare practitioner with a current Package Insert for the product. Always match efficacy data from a particular study, patient population or data set with the corresponding safety information. And, if you suspect that a discussion may be cut short, make a strong attempt to cover both safety and efficacy information.

REFERENCES TO COMPETITOR PRODUCTS

Be prudent when discussing and characterizing competitor products. Direct comparisons of safety, efficacy and/or tolerability between products and related superiority claims may be made only if such comparisons have been approved for use in promotion based upon adequate data. Take care to ensure that, when promotional claims compare Gilead products and competitor products, the comparisons are based on relevant and comparable product attributes. Never inappropriately discredit or ever denigrate a competitor's reputation, trademark or brand.

RESPONDING TO “OFF-LABEL” QUESTIONS

Should a healthcare practitioner interrupt or follow the product presentation with an “off-label” question – a genuine question, the answer to which requires reference to information that is not consistent with the approved product labeling – adhere to the following rules when providing a response:

- **The Question must be Specific and Unsolicited.**
The question must be genuine and must not have been prompted in any way. It must also be sufficiently specific to warrant a detailed response.
- **Use of Inquiry Response Documents (IRS).**
When answering an “off-label” question, narrowly tailor the response to address only the question asked, and advise the inquiring healthcare practitioner that

the information requested is beyond the scope of the product's approved labeling. Inquiry Response Documents have been created by the Medical Information Department for selected frequently asked questions. Do not respond to any "off-label" question not specifically addressed within an IRS. Instead, refer the inquiring healthcare practitioner directly to a Gilead Medical Science Liaison (MSL) or to the Medical Information Department, as set forth below. In all cases, make sure that the response presents a fair, full and accurate description of all necessary and relevant safety information. While it is preferable that "off-label" questions be answered with a verbal response, the IRS may be shown, but not provided to healthcare practitioners.

- **Documentation and Follow-Up.**
The health care practitioner should sign a Medical Information Response Form (MIRF) to receive additional product information, such as the relevant Standard Response Document (SRD) from the Medical Information Department. If he or she requests follow-up from a Gilead MSL, please appropriately document that request, specifying the scope of the healthcare practitioner's inquiry, and the specific "off-label" question(s).

MATERIALS FOR DISSEMINATION ONLY

On occasion, Commercial Staff will be provided with sealed envelopes containing article reprints to be provided to healthcare practitioners for their subsequent review. Commercial Staff may not discuss the articles or their content at the time they are provided. If, during a later Product Presentation, the healthcare practitioner asks a specific question about the content of these articles, the article may be referenced in response; however, such materials may not be referenced to prompt on "off-label" question.

PROVIDING INSURANCE, REIMBURSEMENT AND PATIENT ASSISTANCE INFORMATION

Gilead employees may provide recommendations or advice regarding third-party reimbursement for Gilead products or related medical services or procedures. Gilead employees may also provide recommendations or advice regarding Gilead's Advancing Access Program, which provides assistance for people who cannot afford to pay for all or part of the cost of Gilead products. Any such information must be reviewed for accuracy and must reflect conservative interpretations of relevant coding guidelines. Furthermore, always advise those requesting information to confirm the accuracy of coding and billing requirements under third party reimbursement programs.

Promotional
Programs / HCPs

Promotional
Programs / HCPs



Promotional Programs for Healthcare Practitioners

Gilead conducts promotional meetings to educate healthcare practitioners about Gilead products. These meetings are usually arranged by Commercial Staff and the speakers are either Gilead Clinical Staff or external professionals who have received appropriate training through Gilead's Professional Speakers Bureau training program.

CONTENT

Because Gilead-sponsored programs for healthcare practitioners are promotional in nature, they are subject to the same rules that apply to Gilead Product Presentations. The content of all Promotional Programs must be derived from the approved Gilead Speaker Bureau Slide Library. The slides in this Slide Library have received extensive review and approval and may not be modified. While general disease state information and discussion may take place at Promotional Programs, this educational component of the program should be set apart from the discussion of particular products, including Gilead products.

PROGRAM ARRANGEMENTS

Arrangements for Promotional Programs should be modest and consistent with the meeting's educational objective. The agenda and format should facilitate discussion among attendees and speakers. Spouses and guests are not permitted to attend and entertainment or

recreational events are not permitted in conjunction with the meeting. Program attendees may not receive any compensation or reimbursement of expenses associated with their attendance.

THE GILEAD PROFESSIONAL SPEAKER BUREAU

Gilead has established a Professional Speakers Bureau that allows healthcare practitioners who speak on Gilead's behalf to engage audiences of other healthcare practitioners in a more meaningful dialogue than may be possible through most other promotional methods available to the company. This, in turn, leads to an increased understanding of the appropriate use of Gilead products. Selection of healthcare practitioners who are invited to join Gilead's Professional Speakers Bureau and receive appropriate training should in all cases be made on the basis of candidate expertise and speaking abilities, without consideration of any history or potential for purchasing or prescribing Gilead products.

Prior to speaking on Gilead's behalf, members of the Gilead Professional Speakers Bureau should be fully trained concerning Gilead's Promotional Presentation rules and how to respond to unsolicited requests for "off-label" information. They must also execute Gilead's "Consulting Agreement for Speakers and other Public Presenters," and this document must be on file at Gilead headquarters. In order to qualify for successive years of participation in Gilead's Professional Speakers Bureau, healthcare practitioners must have spoken on Gilead's behalf at least twice during the prior year. With appropriate approval, exceptions may be made where a second speaking engagement was attempted, but could not be scheduled.

Members of Gilead's Professional Speakers Bureau may be paid reasonable honoraria in exchange for their participation in training and speaking events, as well as reimbursement for reasonable travel expenses.

Promotional
Presentations/
Community

Promotional
Presentations/
Community



Promotional Presentations for Patients and Community Organizations

Gilead has established a Community Liaison group to interact with patients living with HIV or HBV infections and the community organizations that serve their needs. Presentations to these groups are made by Gilead Community Liaisons and other Commercial Staff or Clinical Staff. Regardless of who is making such a presentation, when presenting to patients and community organizations, Gilead employees and agents must never recommend a Gilead product, or any other specific treatment option, as appropriate for a specific patient. Moreover, please always emphasize that Gilead does not provide medical advice.

CONTENT

The rules applicable to all Gilead Product Presentations apply to Promotional Presentations for Patients and Community Organizations as well. The audience at such presentations often contains patients and other non-healthcare professionals; therefore, promotional presentations and responses to “off-label” questions at these events should be modified accordingly. Importantly, if a member of the audience solicits individual treatment advice, the speaker should direct the questioner to seek appropriate guidance from his or her healthcare professional, emphasizing that Gilead does not provide medical advice to patients. If a program is intended only to provide general disease state information and discussion, the speaker should not affirmatively recommend

or mention particular products, including Gilead products. If particular products will be mentioned, that promotional component of the program should be set apart from the disease state discussion. Finally, only materials specifically approved for use with patients and community organizations may be utilized with these groups.

PRESENTATION ARRANGEMENTS AND THE GILEAD COMMUNITY SPEAKERS BUREAU

As with Promotional Programs, arrangements for presentations to patients and community organizations should be modest and consistent with the meeting's educational objective.

Gilead has established a Community Speakers Bureau to support our interactions with patients and community organizations. Selection of healthcare practitioners who are invited to join Gilead's Community Speakers Bureau and receive appropriate training should in all cases be made on the basis of candidate expertise and speaking abilities, without consideration of any history or potential for purchasing or prescribing Gilead products.

Prior to speaking on Gilead's behalf, members of the Gilead Community Speakers Bureau should be fully trained concerning Gilead's Promotional Presentation rules and how to respond to unsolicited requests for "off-label" information. They must also execute Gilead's "Consulting Agreement for Speakers and other Public Presenters," and this document must be on file at Gilead headquarters. In order to qualify for successive years of participation in Gilead's Community Speakers Bureau, participants must have spoken on Gilead's behalf at least twice during the prior year. With appropriate approval, exceptions may be made where a second speaking engagement was attempted, but could not be scheduled.

Members of Gilead's Community Speakers Bureau may be paid reasonable honoraria in exchange for their participation in training and speaking events, as well as reimbursement for reasonable travel expenses.

Continuing
Medical Education
(CME)

Continuing
Medical Education
(CME)



Continuing Medical Education (CME)

Gilead supports independent meetings, symposia, conferences, and other programs designed to communicate valuable healthcare information and promote education and scientific exchange related to disease states of interest to the company. These CME programs are developed by organizations external to Gilead. Their content is consistent with both the FDA's Guidance on Industry-Supported Scientific and Educational Activities and the Standards for Commercial Support of the Accreditation Council for Continuing Medical Education (ACCME).

CME MUST BE INDEPENDENT

CME programs must be non-promotional and independent. They may not be controlled or influenced by Gilead. Gilead's Medical Affairs Department shall make all decisions concerning funding of CME programs based on applications that have been submitted to it by independent providers of CME. The decision whether to support CME must be made on the basis of the program topic alone, without knowledge of program content. To ensure CME programs are independent, Gilead employees may not participate in program planning or development.

After Gilead has agreed in writing to fund an independent CME program, the Gilead Medical Affairs Department may respond to unsolicited requests from the CME provider for speaker suggestions or materials. However, the CME provider must in all cases make the final speaker selection and must retain full discretion over program content.

The CME provider is responsible for promotion of its own program, but may request assistance from Gilead with distribution of invitations or “save the date” cards, on the CME provider’s behalf.

Gilead employees may attend CME programs; however, they may not participate in audience discussion or direct questions to the speakers. Gilead employees also may not perform any promotional activities – including the provision of non-program related meals or entertainment – at, or in connection with, a CME program.

Gifts, Meals &
Entertainment

Gifts, Meals &
Entertainment



Gifts, Meals and Entertainment for Healthcare Practitioners

In all interactions with healthcare practitioners, Gilead complies with the PhRMA Code and AMA Guidelines, both of which are available in the Sales and Marketing section of GNET. Under no circumstances may Gilead offer or provide gifts, meals or entertainment with the intent of directly or indirectly influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale or recommend formulary placement of any Gilead product.

Consistent with California law, Gilead has imposed an annual maximum of \$2,000 on the aggregate value of promotional meals and gifts that any individual healthcare practitioner may receive in a given calendar year. Gilead applies the limit to all promotional activities on a nationwide basis. Commercial Staff are responsible for maintaining proper records and documentation of amounts accumulated in gifts and meals. Prior to a gift or meal being offered to a healthcare practitioner, it is the responsibility of the associated Therapeutic Specialist to determine whether the annual limit has been reached.

GIFTS

A gift consists of anything of value given by a Gilead employee or agent to a healthcare practitioner without payment or an even exchange of services from the recipient. Gifts do not include items provided to persons who are performing services for Gilead if the items are

related to the provision of such services (e.g. memory sticks containing slides to members of Gilead's Speakers Bureaus).

The Gilead Marketing Department may provide Commercial Staff with gifts of nominal value (e.g. company or product branded pens and notepads) or with textbooks or other patient- or practice-related items (under \$100 market value) to be offered to healthcare practitioners appropriately. All gifts are subject to the California annual spending limit, and their distribution should be infrequent.

Prohibited Gifts include:

- Cash or cash equivalents (e.g. gift certificates)
- Gifts purchased by a Gilead employee without Marketing Department approval, with his or her own funds, even if the employee does not intend to seek reimbursement from Gilead
- Gifts for the personal benefit of a healthcare practitioner or his or her family member (e.g. clothing, golf balls), even when they bear a Gilead or product logo
- Tickets to recreational or entertainment events
- Gifts to federal, state or other governmental employees, unless prior permission has been obtained from the Legal Department.

MEALS AND ENTERTAINMENT

Modest meals may be provided to healthcare practitioners in connection with a legitimate business purpose.

Legitimate business purposes include:

- Informing healthcare practitioners about the benefits and risks associated with Gilead products
- Providing scientific and educational information to healthcare practitioners as it relates to the clinical areas in which Gilead has ongoing business interests

- Obtaining legitimate and valuable feedback and information from a healthcare practitioner
- Performing research, marketing or policy services under a proper agreement with Gilead

“Modest” means no more than \$25 per healthcare practitioner for all in-office meals, \$50 per healthcare practitioner for out-of-office breakfast or lunches and \$100 per healthcare practitioner for out-of-office dinners (\$125, with prior Region Director approval). These dollar limitations include all expenses associated with the meal, including beverages and parking. The names of all healthcare practitioners who attended a meal, as well as the business purpose of the meal, should be recorded in the company’s designated reporting tools. Such meals must be occasional and, independent of meals provided at Gilead Promotional Programs, dinners should not exceed once per quarter for any healthcare practitioners with any single Gilead employee, including meals associated with medical conventions. Other than Gilead Promotional Programs, meals should not be conducted with more than four healthcare practitioners per Gilead to maximize appropriate interaction.

Prohibited Meals & Entertainment include:

- Recreational and entertainment events, even where Gilead personnel are present
- No meals may be provided in cash or cash equivalents
- No meals may be provided where a Gilead employee is not present
- A Gilead employee may not provide meals and entertainment in a manner inconsistent with these rules, with his or her own funds, even if the employee does not intend to seek reimbursement from Gilead
- Spouses and guests of a healthcare practitioner should not be invited to attend.



Healthcare
Grants



Healthcare Grants

Through its Grants Website, located at www.gilead.com under “Corporate Social Responsibility”, Gilead receives and considers healthcare grant requests from a broad variety of health-related organizations. Grants are available to support healthcare and general philanthropic initiatives, including medical education programs, scientific conferences, the development of health education materials, patient education programs and healthcare-related community activities. They may be awarded to hospitals, patient care organizations, universities, patient assistance groups and charitable or social welfare organizations.

Decisions concerning whether to fund an individual healthcare grant are made by an internal Grant Review Committee solely on the basis of scientific, medical and public health criteria. Grant approvals may not be connected to, or conditioned upon, the purchasing, prescribing, providing favorable recommendations for, or otherwise supporting Gilead products. Grant award imposes no obligation, express or implied, on the recipient to purchase, prescribe, provide favorable formulary status for, or otherwise support Gilead products.

Gilead employees may provide information concerning the availability of Gilead’s healthcare grant funding to organizations that wish to make a grant request, but should not solicit grant requests. Gilead’s grant administrator, located at headquarters, will expediently process grant requests according to proper procedures.

The Grant Review Committee will make all funding decisions based on complete grant applications received through the Grants Website. Formal notifications of grant awards and denials will be made in writing to the applicant organization. Commercial Staff may not take part in delivery of grant proceeds to recipients.



Consulting Arrangements with External Professionals

Gilead may enter into agreements with healthcare practitioners or other professionals for research, policy, marketing or other services. All such service agreements must meet a legitimate Gilead business need by providing Gilead with a valuable benefit. Compensation for such services must not exceed fair market value, and under no circumstances may the arrangements be intended to directly or indirectly, influence or encourage the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale or recommend formulary placement of any Gilead product. Consultants and service providers must be selected based on their expertise and experience.

ADVISORY BOARDS AND REGIONAL CONSULTANT WORKSHOPS

From time to time, the Marketing Department gathers small groups of experts in Advisory Boards or Regional Consultant Workshops to advise Gilead on research, commercial and/or product development strategy issues. Such meetings are conducted solely for the purpose of obtaining necessary medical, scientific or commercial advice. They must not be conducted for the purpose of promoting Gilead's products or for providing education or training to consultants, and may not be conducted by members of the Sales Department. Participants must be selected based on their knowledge, experience, demographic, patient demographic, or size of practice and other skill-based qualifications and not on the basis of their history of, or potential for, purchasing or

prescribing Gilead products. The number of participants must not be out of proportion with the company's reasonable requirements for advice of this type. Gilead may pay reasonable compensation to consultants for their participation at these meetings and may reimburse them for reasonable travel expenses. Participant's spouses or other guests may not attend during the provision of services. Each participant must sign Gilead's Consulting and Non-Disclosure Agreement. Gilead may provide entertainment at these events, as long as that entertainment is considered in the determination of fair market value compensation for the services being provided.

Prior to any individual meeting or series of related meetings, the rationale, agenda and list of attendees must be reviewed and approved by the Legal Department. Gilead product information to be presented at the event should receive prior Legal Department review to ensure the scope of such information is narrowly-tailored to the rationale supporting the consulting arrangements. The Marketing Department must maintain written records documenting compliance with these Guidelines and for the purpose of ensuring that the feedback received during the workshop is appropriately recorded and put to use.

INVESTIGATOR MEETINGS

From time to time, the Gilead Medical Affairs or Clinical Departments gather investigators in Gilead-sponsored clinical studies to discuss issues relating to ongoing or planned studies and the product being studied. The discussions and presentations at such meetings must be non-promotional and must serve a genuine research purpose. The scientific portion of the meeting should account for a substantial majority of the total meeting time, in accordance with the AMA Guidelines. Gilead may pay reasonable compensation to investigators for their participation at these meetings and may reimburse them for reasonable travel expenses. Investigator's spouses or other guests may not attend. If the Investigator has not already signed a Gilead Clinical Trial Research Agreement

applicable to the meeting's subject matter, he or she should be asked to sign a Consulting and Non-disclosure Agreement.

PRECEPTORSHIPS

Preceptorships are opportunities for Commercial and Clinical Staff to receive training directly from healthcare practitioners concerning when and how they evaluate and prescribe Gilead products to their patients. As such, preceptorships are arranged, managed and paid for by the Sales Training Department.

Some preceptorships are classroom-based. Patient volunteers are brought in by physicians to discuss their condition and treatment and to answer questions. Other preceptorships take place in physician offices or clinics. In these situations, the Gilead participant may observe a healthcare practitioner while he or she treats patients. This latter form of preceptorship is for Commercial Staff who are new to their territory, in which case the number of such preceptorships is limited to two within six months following beginning work in the territory.

Gilead recognizes the unique value of preceptorship training. It can provide unique, practical insight and appreciation for the realities and concerns of healthcare practitioners and their patients. It must be emphasized, however, that it is not appropriate for those participating to engage in product promotion during this training opportunity.

Prior to any preceptorship, a written agreement must be in place addressing the preceptorship's faculty, the learning objectives and agenda, the requirement for patient disclosure and consent and an assurance of patient privacy. The agreement must also clarify that the sole purpose of the preceptorship is training, rather than to induce the prescription of Gilead products. The compensation to be paid for any preceptorship must reflect fair market value for the preceptorship training.

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