The

Business Practice Standards

Revised February 2007

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Dear Employee,

At Cyberonics, our mission is to improve the lives of people touched by epilepsy, depression and other chronic disorders that may prove treatable with our patented Vagus Nerve Stimulation Therapy. Everything we do is intended to support that mission. Inherent in our mission is the obligation we have to those same people, as well as their families, friends, and caregivers, to operate in an honest and ethical manner.

At Cyberonics, we understand that the real value in conducting our business in an honest and ethical manner is the trust it allows us to build with patients, customers and the public. As employees of Cyberonics, we shall comply with all applicable laws and regulations in the United States, as well as the laws and regulations in any other country in which our Company does business. We shall also adhere to the highest standards of business ethics and comply with the written letter of the law, as well as the spirit of the law. These Business Practice Standards serve as the principals that guide our conduct.

Cyberonics seeks to (i) prevent the occurrence of illegal or unethical behavior, (ii) detect and halt any illegal or unethical behavior that may occur as soon as reasonably possible after its discovery, (iii) discipline those who violate these Business Practice Standards, including those responsible for the failure to exercise proper supervision and oversight to detect and report a violation by their subordinate employees, and (iv) promote honest, ethical conduct in our day-to-day business operations.

We consider compliance with these Business Practice Standards to be vital to our long-term success. Ultimately, we will be judged by the people touched by epilepsy, depression and other chronic disorders whose lives we've improved through treatment with our patented Vagus Nerve Stimulation Therapy. Nothing we do can jeopardize the trust those people have placed in Cyberonics.

Sincerely,
David S. Wise
Vice President & General Counsel

Chapter 1

Overview

1) Introduction

a) *Compliance is both doing the right thing, and the right thing to do.* Integrity and ethical behavior are the bedrock values of the U.S. health care system and they are critical to Cyberonics' long-term success. To gain the trust of the customers we serve, Cyberonics employees must meet the highest ethical standards in the way we do business.

At Cyberonics, we recognize that the real value in compliance is the trust it allows us to build with patients, customers and the public.

b) Compliance with the U.S. health care laws, regulations, and rules that govern our interactions with customers, as well as the way we communicate about VNS Therapy™, demonstrate our commitment to ethical behavior.

2) What Are The Cyberonics Business Practice Standards?

a) The Business Practice Standards establish a framework for interactions between Cyberonics personnel and customers, as well as the way we communicate about VNS Therapy™. Any Cyberonics personnel unsure about the appropriateness or legality of a customer interaction, event or any other issue should consult with the Compliance Officer or the Legal Department prior.

Remember – just because it's legal, doesn't make it ethical or appropriate. At Cyberonics, we strive to do the right thing.

b) The Cyberonics Business Practice Standards offer an overview of the laws, rules and Cyberonics policies related to health care law compliance. The Business Practice Standards also provide a common reference for understanding:

i) How our Company is regulated
ii) How health care laws apply to our everyday activities
iii) Which activities and behaviors raise potential concerns
iv) What we must do to comply with health care laws and Company policies

First and foremost, compliance protects Cyberonics and its employees in a complex regulatory environment. Compliance also protects our customers, who are subject to many of the same health care laws and rules.

c) If you have a question about how a compliance policy relates to you, refer to the relevant section of the Business Practice Standards, consult with your manager, or ask the Cyberonics Compliance Officer.

d) The Business Practice Standards provide an overview of various health care laws, rules and Cyberonics policies that are designed to:

i) Best serve patients and improve the lives of those touched by epilepsy, depression and other chronic disorders that may prove treatable with VNS Therapy™
ii) Protect medical decision-making from inappropriate influence
iii) Help protect payors from the misuse of health care funds

e) All Cyberonics employees are expected to have a basic understanding of health care laws that apply to our industry. Those employees who interact with patients, providers, payors, advocacy groups, and other customers are expected to understand how health care laws, as well as the AdvaMed Code, affect our business. These include:

i) The Federal False Claims Act
ii) The Federal Illegal Remuneration Statute (the Anti-Kickback law)
iii) FDA Laws and Regulations
iv) HIPAA and Federal Privacy Laws
v) The AdvaMed Code of Ethics On Interactions With Health Care Professionals
vi) Various State Illegal Remuneration, Privacy, and Consumer Protection Laws

3) Overview of Key Laws

a) Certain activities that are common practice in many businesses can violate several laws in the health care industry. Violations can lead to criminal and civil penalties for both the offending company and the offending individual(s). Health care companies have paid hundreds of millions of dollars in fines, had employees criminally prosecuted, and been subjected to intense government oversight of their marketing and other programs as a result of violations.

It is a virtual certainty that government scrutiny of medical device industry practices will only increase in the years ahead.

b) *Illegal Remuneration Statute (Anti-Kickback Law)*

i) The Anti-Kickback law, 42 U.S.C. §1320a-7b(b), prohibits the offer, payment, solicitation, or receipt of *any* remuneration, directly or indirectly, for (1) the referral of patients, or the purchase, lease, or order, or arranging for the purchase, lease, or order, of any good, facility, service or item for which payment may be made by the government. Essentially, this provision prohibits an exchange of value for patient service opportunities. Both civil and criminal sanctions can apply to both parties to a transaction (*i.e.*, the party who offers or pays and the party who solicits or receives illegal remuneration).

ii) Because of the use of broad terms such as "any remuneration" and "directly or indirectly," the Anti-Kickback law establishes the general principal that the referral of a government health care program patient cannot be the *quid pro quo* (*i.e.* expected result) for any payment of money or other item of value. Consequently, arrangements that involve an exchange of value between Cyberonics and persons in a position to refer or arrange for the referral of patient service opportunities to Cyberonics should be carefully structured to avoid violation of the Anti-Kickback law.

iii) Persons in a position to refer or arrange for the referral of patient service opportunities to Cyberonics can include:

(1) Patients themselves;
(2) Physicians and other health care professionals;
(3) Institutions and their employees; and
(4) Virtually anyone else involved in the patient care process.

iv) For example, the Anti-Kickback law prohibits the following:

(1) Providing a gift to a neurologist to influence the selection of VNS Therapy™ for one of her patients
(2) Providing a grant to an institution as a reward for purchasing VNS Therapy™
(3) Retaining a key thought leader as a speaker at a fee above reasonable, fair market value for her services
(4) Paying for a psychiatrist's office holiday party as a gesture of goodwill for being such a big VNS Therapy™ advocate

A health care provider's decisions about patient treatment must not be influenced by inappropriate inducements. The Anti-Kickback law and other laws seek to protect patients and government payors from improper influence on health care decisions.

c) *Anti-Kickback Safe Harbors*

i) Since the Anti-Kickback law is so broad, read literally it could apply to many marketing activities and even many non-promotional activities. For this reason, the government created exceptions to the statute for certain arrangements that would not be subject to sanction. Commonly referred to as the "safe harbor regulations," these require that an arrangement meet all of the criteria for that safe harbor in order to be protected.

ii) These safe harbors permit legitimate marketing and promotional activities, as well as *bona fide* arrangements with customers.

iii) A number of safe harbors are relevant to Cyberonics' business; however, two are particularly important. The first is the ***discount safe harbor*** and the second is the ***personal services safe harbor***.

(1) The discount safe harbor permits price discounts (or rebates) as long as the discount is properly reported to the government and other conditions are met.

(2) The personal services safe harbor allows Cyberonics to pay customers fair market value compensation pursuant to legitimate service arrangements (*e.g.* consulting arrangements, research engagements, speaker engagements, *etc*.) if certain conditions are met.

d) *The AdvaMed Code*

i) The AdvaMed Code was developed and adopted (effective January 1, 2004 and updated in April, 2005) by the country's leading medical technology companies to continue to assure a high standard of ethical conduct by our industry. Key points of the Code include:

(1) *General Interaction.* Interaction should focus on ethical business practices and socially responsible industry conduct.

(2) *Gifts*. Educational and patient-benefiting gifts may be provided occasionally to health care professionals. Such items should be of modest value ($100 or less). Items for the personal benefit of the health care professional must not be offered or distributed.

(3) *Meals & Hospitality.* Informational interactions may not include entertainment (*e.g.*, golf, theater, sporting events, *etc.*). On occasion, however, it may be appropriate to conduct an informational sales session over

a modest meal. Meals and hospitality should be modest in value and subordinate in time and focus to the scientific or educational information.

(a) "Modest," as used in connection with these Business Practice Standards, means moderate or low cost among several suitable alternatives and in the context of all relevant considerations, including, for example, the time of year, the geographic location, the number of persons involved, the availability of other suitable alternatives, and the particular needs, requirements, or exigencies of the circumstances under which Cyberonics must make a determination.
(b) "On occasion" as used in connection with these Business Practice Standards, means infrequent.

(4) *Continuing Education & CME*. Companies may provide support to a medical conference sponsor, but should not underwrite individual attendees' expenses.
(5) *Consultants.* Legitimate consulting or advisory arrangements are appropriate, but token consulting arrangements should not be used to justify payments to health care professionals. Characteristics of legitimate consulting arrangements include a documented need for services, retaining professionals to provide those services based on their expertise (not as a reward or improper inducement for prescribing), retaining no more consultants than needed for the specific business purpose, and obtaining a deliverable from the consulting work that is used by the business.

Both the AdvaMed Code and the Anti-Kickback law are intended to protect patients from the undue influence of money on quality health care decisions.

(6) The AdvaMed Code can be viewed in its entirety at http://www.advamed.org/publicdocs/coe_with_faqs_4-15-05.pdf.
(7) Cyberonics endorses the AdvaMed Code and it is part of our Business Practice Standards. All employees should be familiar with its contents, but especially Cyberonics' personnel with sales and marketing responsibilities.

e) *False Claims Act*

i) A number of federal and state criminal and civil laws prohibit individuals and organizations from submitting false information or false claims for payment to the government or other third party payers (*e.g.*, insurance companies).
ii) The False Claims Act also applies to a third party who causes someone else to make a false claim to the government. This means that a device company that encourages or causes a customer to make a false claim for reimbursement can also be liable for the customer's false claim.

iii) A number of behaviors can lead to a false claim allegation including off-label promotion, anti-kickback law violations, and unreported discounts, to name a few.

f) *FDA Laws & Regulations*

i) FDA's mission is to protect the health and safety of the American people by approving new medical products and regulating how they are manufactured, marketed and sold. Accordingly, FDA regulates most of our business, from research and development to manufacturing and distribution to sales and marketing; in short, almost everything about VNS Therapy™ and what we say about it.

ii) FDA regulation of product advertising and promotion directly affects our customer relationships. Therefore, each employee must understand the basic rules we follow to help ensure compliance with FDA law and regulations.

iii) FDA regulates the ***labeling*** of VNS Therapy™ in the United States. "Labeling" includes:

(1) All information on the VNS Therapy™ package/label
(2) The prescribing information (physicians manual or "PM")
(3) Other written, printed, or graphic materials provided by Cyberonics about VNS Therapy™

iv) Any materials we use to promote VNS Therapy™ – including all media advertising, brochures, sales aids, promotional programs and third party materials – must be consistent with labeling. In addition, the FDA requires that all promotional materials be:

(1) Truthful and not misleading
(2) Presented with a fair balance of benefits and risks
(3) Inclusive of full prescribing information or a brief summary of labeling, depending on the type of promotional material

v) In order to help ensure that Cyberonics meets the FDA marketing and promotion requirements, we take a multidisciplinary approach to reviewing materials related to all promotional activities. Cyberonics has a Compliance Review Board ("CRB"). CRB is comprised of representatives from Clinical & Medical Affairs, Regulatory, Engineering and Legal. CRB evaluates and approves all promotional materials prior to use. Cyberonics representatives may only use promotional materials approved by CRB. Any alteration of approved material – even something as seemingly innocuous as a handwritten note – transforms an approved piece into a "homemade" piece that does not comply with FDA regulations or Cyberonics policy.

vi) *Off-Label Use*. It is important to understand that FDA approves VNS Therapy™ for use only as described in the approved labeling (*e.g.*, to treat specific diseases in specific patient populations). Any other use is considered "off-label".

As a general rule, health care providers can prescribe products for off-label uses in the exercise of their professional judgment. However, Cyberonics may not encourage or promote unapproved uses of a product.

(1) While manufacturers are not permitted to promote unapproved uses of their devices, companies are permitted to provide truthful and non-misleading scientific information about unapproved products or unapproved uses in certain limited circumstances (*e.g.*, in response to unsolicited requests for such information from a health care provider).

(2) All off-label inquiries must be addressed in compliance with the Cyberonics *Policy and Procedures for Handling Requests for Information Relating to Unapproved Uses of VNS Therapy*™ set forth on Cyberonics intranet (see Clinical and Medical Affairs Department page under "Off-Label Inquiries"). In short:

(a) First – remind the person that the question relates to an off-label use and remind the person of the approved labeling; and

(b) Second – tell the person that they can (and should) submit the question to the Cyberonics Clinical & Medical Affairs Department at 1-888-748-1652 or 1-800-332-1375 (enter extension 7690 when prompted for an extension).

(3) Cyberonics employees and anyone retained to speak on behalf of Cyberonics cannot proactively offer off-label information in a promotional manner, nor can they solicit questions about off-label uses.

g) *HIPAA and Privacy Laws*

i) Both Cyberonics and firms working for us (*e.g.*, advertising and promotion agencies and other vendors) collect, process and transmit various types of personal data. We are responsible for ensuring that the data are handled carefully and in compliance with applicable privacy laws and regulations. Mishandling personal data can expose Cyberonics to significant legal liability. If the confidentiality of an individual's personal data is breached, the individual could be exposed to embarrassment, stigmatization, harassment or discrimination in insurance coverage or employment.

The greater the likelihood that individuals or personal facts about them can be identified from their data, the greater the need for safeguards and special handling.

ii) Many federal and state laws and regulations protect personal data. Comprehensive privacy regulations under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), focus on two equally important concerns: (i) inappropriate disclosure, and (ii) unauthorized use of personal information. The data user must maintain the confidentiality of sensitive or nonpublic information, and use personal information only as authorized by the individual. For example, under HIPAA, health insurers, hospitals and other health care providers may not use their patients' health information to make certain marketing communications on their own behalf or on behalf of third parties, unless they have obtained individualized authorizations that comply with federal standards.

iii) Cyberonics' policies on data privacy address the central elements of compliance and can be found on the intranet at http://cybernet/compliance/. All employees who gather or handle personal data on Cyberonics' behalf, including IVEA and PIQ forms must be familiar with Cyberonics HIPAA Security Manual.

h) *Various State Laws*

i) Many states have laws that apply to marketing and sales practices and to privacy. It is important to be aware of and act in accordance with applicable state laws. For example, virtually all states have broad laws prohibiting "unfair" or "deceptive" trade practices. Some state Attorneys General contend that those laws encompass off-label promotion. Any questions regarding state laws should be directed to the Compliance Officer or the Legal Department.

4) Enforcement Environment

a) Both the Office of Inspector General and the Department of Justice aggressively enforce the anti-kickback law and False Claims Act. Each violation of each law can be criminally prosecuted as a felony and punished by a fine and/or imprisonment, as well as by imposition of civil monetary penalties. Conviction of a device company under these laws can result in exclusion of that company from participation in federal health care programs for five years, as well as imprisonment of officers and/or employees responsible for each violation.

b) FDA laws and regulations are also enforced through both the civil and the criminal justice systems. Failure to adhere to FDA advertising and promotion standards can result in a requirement to run corrective advertising or "pre-clear" future promotional materials. These enforcement tools can result in major business disruptions. Violations may also result in criminal sanctions, including imprisonment.

c) The consequences of violating individuals' privacy rights can include civil liability for damages, legal action by the Federal Trade Commission (or similar state agencies) for unfair trade practices, and/or federal prosecution for HIPAA violations.

d) Privacy is not the only area where an activity may raise issues under multiple laws. For example, the government could characterize an educational grant from Cyberonics that is contingent on a separate purchase as:

i) Improperly inducing customers to purchase products (a kickback)
ii) An undisclosed discount through failure to report the grant as a discount
iii) Causing the submission of false pricing information to the government
iv) Leading customers to submit false claims for reimbursement

e) Penalties are based on each incident. The government could consider the same kickback disguised as a grant to 100 physicians as 100 violations of the anti-kickback law. Thus, fines can quickly run into millions of dollars. Penalties for infractions of health care laws, civil or criminal, may be imposed on both Cyberonics and individual employees.

5) Particular Risk Areas for Cyberonics

a) Certain activities are especially likely to receive heightened government scrutiny.

Most higher-risk activities are those in which we provide funds to a physician or other customer, either for doing work for us (e.g., as a speaker, consultant, investigator, mentor, or preceptor) or through a grant, fellowship, charitable contribution or other payment.

b) Other activities the government is targeting will depend on the surrounding facts and circumstances. Generally, however, providing remuneration to customers is illegal under the anti-kickback laws if ***one purpose*** of the payment is to increase or reward the prescribing of our VNS Therapy™.

c) For this reason, particular care needs to be taken with regard to activities within the following risk areas:

i) *Off-label Information:* Physicians and scientists may engage in scientific exchange of information not contained in approved product labeling, however any plan or strategy to promote off-label use of products is generally considered to be illegal. For this reason, all employees need to be careful to avoid statements that would be construed as promoting the off-label use of VNS Therapy™ or encouraging others to do so. Unsolicited requests for off-label information should be referred to Cyberonics' Clinical & Medical Affairs Department (1-888-748-1652 or 1-800-332-1375 and then entering extension 7690 when prompted for an extension).

ii) *Educational Grants & Fellowships:* Educational grants and fellowships must be used solely to support bona-fide educational programs. Use of educational grants or fellowships for any other reason is improper. When evaluating the award of an educational grant or fellowship to a customer, the government will consider a number of factors, including the extent of sales or marketing's involvement in the decision to provide the grant, whether the grant was being used primarily or in large part to build sales or marketing relationships, and whether the grant was made for bona-fide educational purposes.

iii) *Research Grants:* Independent research grants must be awarded solely to support scientifically compelling research. Use of independent research grants to establish or build relationships with a health care professional or institution to achieve marketing or sales objectives, rather than to support bona-fide research, is likely to be considered illegal. When evaluating an independent research grant the government will consider whether and to what extent sales or marketing were involved in the decision to provide the grant to the customer.

iv) *Charitable Contributions & Customer Programs:* Charitable funds must be used solely to support truly charitable or public interest activities. If a charitable contribution is made for the purpose of increasing the recipient's prescribing or use of VNS Therapy™, such a contribution is likely to be deemed to be illegal. When valuating a charitable contribution, the government is likely to consider whether and to what extent sales or marketing were involved in the decision to make the contribution and whether the contribution was made to enhance a relationship with a customer rather than to further the charitable or public-interest activities of the recipient.

v) *Consultants:* Cyberonics may retain and pay qualified physicians and other experts to provide services, such as speaking at promotional programs and training company employees through mentorships and preceptorships. However, care must be taken to ensure that only those services that are actually needed are purchased. Using a consulting arrangement or service arrangement to pay a customer and thereby establish or build a sales or marketing relationship is inappropriate and suspect.

If a speaker is solicited or chosen to increase or influence her use of VNS Therapy™, such an engagement is likely to be illegal.

vi) When evaluating a service arrangement with a consultant or speaker, the government will consider whether and to what extent any sales or marketing goals involving the proposed service provider, or his or her prescribing, were considered in selecting that provider. The government also will consider whether there was a legitimate business need for the consultant's services, whether the consultant was qualified to provide the contracted services, and whether the services resulted in a deliverable that was used by the business.

(1) Extensive use of a "key opinion leader" as a consultant or speaker, especially where the individual is involved in policy decisions about an institution's use of VNS Therapy™, or where the remuneration exceeds a reasonable market rate, may cause the government to question the propriety of the arrangement.
(2) All compensation of external physicians and health care professionals must be based on the reasonable, fair market value of the services and the services must be legitimate and necessary.

vii) *Clinical Trials:* Reasonable compensation of clinical investigators for research services is appropriate as long as the trial is designed and implemented in accordance with professional standards and undertaken to obtain bona-fide scientific data. Funding a clinical trial to encourage a group of investigators to prescribe VNS Therapy™ or to collect data that are not scientifically significant is likely to be viewed as illegal. Studies must be clinically and statistically meaningful.

viii) *Evaluating Financial ROIs of Non-Promotional Activities:* Assessing changes in a physician's or health care professional's use of VNS Therapy™ after that physician or professional has received a grant or service agreement is improper. Such ROI (return on investment) assessments may be construed as a sign that a program, grant, or service agreement was offered to influence professional judgment. When undertaking to evaluate a company's efforts to measure the usefulness of a program, grant, or service agreement, a pivotal factor is whether and to what extent the analysis focused on particular recipients' use of VNS Therapy™. A retrospective measurement of the effect of a non-promotional activity on the prescribing practices of recipients of a customer program, grant, or service agreement is improper and can be illegal.

6) Reporting Compliance Concerns

a) Cyberonics seeks to create an environment in which all employees are comfortable consulting with directors and the Compliance Officer about ongoing and proposed programs and in reporting, without fear of retaliation, conduct that they reasonably believe violates applicable laws, regulations, or Cyberonics policies. If you have a question about the legality or propriety of a proposed or ongoing program, you should always feel free to consult the Compliance Officer. If you become aware of or reasonably believe that there has been a potential or actual violation of a law, regulation, policy or procedure, ***you have an obligation*** to report it to your director, the Legal Department, or to the Compliance Officer.

b) While you are encouraged to first speak with your supervising director or the Compliance Officer, Cyberonics maintains three different mechanisms for reporting violations and concerns related to these Business Practice Standards. These include the Cyberonics Compliance Website, the Compliance Hotline, and the Compliance E-mail Box.

i) The Compliance Website may be accessed through a "Compliance" link on the intranet (http://cybernet.cyberonics.com/index_all.asp). The Compliance Website includes a mechanism for sending an anonymous message to the Compliance Officer.

The Company does not have the ability to trace the origin of any message sent from this link.

ii) The Compliance Hotline is a toll-free telephone line (1-877-671-5139). The Compliance Hotline is answered by voice-mail, and anyone may leave a voice-mail message for the Compliance Officer.

iii) The Compliance E-mail Box (compliance-CYBX@cyberonics.com) is an electronic mailbox directed to the Compliance Officer.

c) The Compliance Officer may always be contacted through the Corporate Legal Group (see below). All investigations of compliance matters are conducted by, or under the supervision of, the Compliance Officer. Reports of a violation, possible violation, or general compliance concern may be made by telephone, in person, or in writing to:

Cyberonics, Inc
Compliance Officer
Corporate Legal Group
100 Cyberonics Blvd.
Houston, Texas 77058
Telephone: 281/228-7248
ComplianceOfficer@cyberonics.com

d) All persons making reports to the Compliance Officer or Compliance Hotline are assured that such reports will be treated as confidential, consistent with the need to investigate the matter. Any issue will be discussed only with those individuals who have a "need to know." Additionally, Cyberonics' policy strictly prohibits any adverse action against persons making reports of actual or potential compliance issues in good faith, whether or not the reports ultimately prove to be well founded.

In circumstances where conduct prohibited by these Business Practice Standards does not implicate underlying legal or ethical concerns, it may be appropriate to grant infrequent, fact-specific exceptions. Exceptions must comply with all legal and regulatory requirements and require the specific written approval of a Company Vice President (or the Company's Chief Executive Officer) and either the Vice President and General Counsel or the Company Compliance Officer.

e) Amendments to the Business Practice Standards require the written approval of Cyberonics' Chief Executive Officer and the Vice President and General Counsel.

7) Sanctions

a) Sanctions for noncompliance with health care law requirements may include oral or written warning, disciplinary probation, suspension, reduced compensation, demotion, or dismissal from employment. Any Cyberonics employee who materially or repeatedly violates health care law requirements will be required, at a minimum, to participate in a remediation program developed at the direction of the Compliance Officer in coordination with the employee's supervising director. Additional sanctions for behavior that violates Cyberonics policies and procedures are assessed on a case-by-case basis. These disciplinary actions also may be applied to a supervisor who directs or approves improper actions, is aware of those actions but does not act appropriately to correct them, or otherwise fails to exercise appropriate supervision.

Chapter 2

Sales & Advertising

1) Key Points

a) The promotion of medical device products helps physicians recognize and treat disease. It also can help patients by informing them about medical conditions and encouraging them to seek appropriate treatment.

b) Cyberonics is committed to complying with legal and regulatory requirements and professional standards for advertising and promotion. This includes ensuring that our statements are truthful, not misleading, and consistent with VNS Therapy's™ approved labeling.

c) As a matter of integrity and compliance, all Cyberonics product advertising and sales aids must be accurate and must disclose material information about our product's benefits and risks (this is often referred to as having "fair balance"). Care needs to be taken to ensure that Cyberonics representatives use only Compliance Review Board (CRB)-approved sales materials.

2) Critical Compliance Issues

a) By law, materials that promote VNS Therapy™ (including all television commercials, print ads, brochures, sales aids and the like) must present information that is consistent with approved product labeling. In addition, the FDA requires that all promotional materials:

i) Must be truthful and not misleading
ii) Must reflect a fair balance of benefits and risks
iii) Must include the full labeling information, a brief summary of labeling, or a full physicians manual (PM) depending on the type of promotional material

b) FDA regulations and guidance also address questions such as:

i) When can a medical device company make a superiority claim, or compare products?
ii) How do we advertise directly to consumers?

c) It's illegal for a medical device company to promote an unapproved device or to solicit off-label use of an FDA-approved device. Soliciting off-label use of approved products can result in prosecutions, substantial fines and loss of eligibility to participate in federal health care programs such as Medicare.

d) The FDA can choose to respond to noncompliance with regulations on advertising and promotion with a notice of violation or, in more serious situations, a warning letter to our CEO, product seizure or recall, a fine or civil and/or criminal litigation.

e) Competitors can challenge false and/or misleading claims under a law called the Lanham Act. Thus, misleading claims, even if literally true, may result in court orders as to future advertising and sales materials and/or financial damages awards.

f) All marketing and sales messages about VNS Therapy™ are carefully reviewed to help ensure that they will stand up to government and competitor scrutiny.

3) Compliance Measures

a) In order to help ensure compliance with FDA advertising and promotion requirements, Cyberonics requires a multi-disciplinary review of promotional materials. Cyberonics has a Compliance Review Board (CRB) that includes representatives from Medical & Clinical, Regulatory, Engineering and Legal.

b) CRB reviews all materials proposed for use in promotion and by our sales representatives.

The marketing Senior Directors for each product indication are responsible for developing materials and securing their timely review by CRB. Only CRB-approved materials may be used to promote VNS Therapy™.

c) Altering approved promotional materials (*e.g.* by adding or attaching a handwritten note, or using underlining or highlighting) transforms a CRB-approved document into a new and unapproved document. Documents that are annotated, edited, otherwise modified or created without CRB review and approval are called "homemades." Homemades violate Company policy and may violate FDA regulations. Their use can result in discipline up to and including termination of employment.

d) *General Requirements for Advertising and Sales Materials (including sales presentations)*

i) Only CRB-approved materials may be used to promote a product.

ii) Materials may not be false or misleading (*e.g.*, ads with graphics that portray a toddler — and thereby imply that toddlers can use VNS Therapy™ — could be deemed to be misleading).
iii) Text must present a "fair balance" of VNS Therapy's™ risks and benefits. This means that relevant safety information, warnings or precautions, side effects and other material information about VNS Therapy™ must be conspicuously disclosed or discussed.
iv) Text must reveal the material facts. These are the key facts and information that help put the claims made in the ad about VNS Therapy™ and its efficacy or safety into the proper context.
v) Branded ads must include the full labeling information or a brief summary (or make adequate provision for obtaining them).
vi) Direct-to-Consumer (DTC) advertising and other DTC sales materials should communicate in consumer-friendly language.

e) *Claims* -- General rules for making *claims* in advertising and sales materials (include sales presentations) include:

i) Claims must be accurate and cannot be false or misleading.
ii) Claims must be based on substantial scientific evidence and consistent with the approved VNS Therapy™ labeling.
iii) References to or excerpts from data sets, studies and/or publications must not be used if they have been superseded, rendered obsolete or substantially challenged by the consensus of scientific authority.
iv) The more specific the claim, the more specific the evidence must be to support it. Care must be taken to ensure that claims are only as strong as the supporting evidence.
v) Any non-clinical studies forming the basis of a claim must be identified clearly and may not be used to suggest or imply clinical relevance where none has been established.
vi) Quotations and studies must be referenced.
vii) Graphs or other presentations of study data must be accompanied by information about the study design, number of patients enrolled, statistical significance of study endpoints and other material information that a health care professional would need to know in order to understand the graph or data presented.

f) *Fair Balance* – Balanced presentation of both benefits and risks.

The FDA requirement of fair balance means that promotional materials must be truthful, must represent a product accurately and must present side effects and contraindications with a "prominence and readability reasonably comparable" to the presentation of efficacy information.

g) Additionally, product warnings, precautions and possible product hazards may not be "diluted" by disclaimers or any other statements. Fair balance also means that Cyberonics must avoid:

(1) Using out-of-context quotations that can tend to distort the actual meaning of the quoted source
(2) Omitting facts, if such omissions may cause the statements in the promotional materials to be seen as misleading
(3) Failing to make safety information prominent and legible

Each promotional or advertising piece must be fairly balanced in content and format; efficacy claims must be balanced with safety information; and our claims must be consistent with approved labeling and supported by substantial medical evidence.

h) As a general rule, promotional materials are judged in their entirety to determine if they're fair overall in portraying a balanced view of VNS Therapy™.

i) *Sales Aids*

i) Sales interactions with physicians and other health care professionals educate them about VNS Therapy™ and provide them with reliable scientific information. Only CRB-approved sales aids may be used in promotion. Claims have been deemed to be substantiated by appropriate scientific or other evidence, and are balanced by prominent and readable safety information.
ii) The FDA and Cyberonics both prohibit "homemades." Examples of prohibited materials include, but are not limited to:

(1) Therapeutic Consultant-created materials that have not been approved by CRB
(2) Approved reprints with a handwritten note describing study results
(3) Altered sales aid pages (*e.g.*, highlighting)
(4) Thank-you notes with a product message
(5) Unapproved journal reprints

iii) Presenting an internal document that has not been CRB-approved for use in promotion is similar to presenting a "homemade" document to a customer. Both can result in disciplinary action, up to and including termination of employment.
iv) To help ensure compliance, Cyberonics sales representatives may only use CRB-approved materials.

j) If a health care professional asks an ***off-label question*** during a product sales call, the inquiry should be referred to Cyberonics' Clinical & Medical Affairs Department (1-888-748-1652 or 1-800-332-1375 and then enter extension 7690 when prompted for an extension).

k) Cyberonics abides by legal decisions in the so-called Washington Legal Foundation (WLF) string of cases. These cases address the limited distribution of independent, peer-reviewed scientific articles. Very specific guidelines regulate the distribution of such reprints, however, and all reprints proposed for WLF distribution must be approved by the CRB.

Remember that the FDA treats all promotion as labeling, therefore, promotional activities must be consistent with the FDA-approved label.

Chapter 3

Consultants

1) Key Points

a) Cyberonics retains health care professionals to help design clinical programs, meet post-launch regulatory requirements and develop marketing programs. In addition, practitioners' and opinion leaders' hands-on experience with Cyberonics products makes them especially knowledgeable, credible and effective speakers and mentors.

b) It is legal for Cyberonics to retain and pay potential customers for actual *bona fide* services. However, it is illegal to pay physicians or other customers to gain favor, to gain access to an institution, or to influence VNS Therapy™ prescribing.

c) Ongoing government investigations of the device and drug industry typically focus on improper payments to physicians and the intent behind such payments.

Your intent as well as the facts and circumstances surrounding your intent when entering consulting arrangements must be above reproach.

d) Cyberonics has guidelines to prevent impropriety, or the perception thereof, when entering into consulting arrangements with health care professionals and other customers or potential customers.

2) Critical Compliance Issues

a) Cyberonics retains health care professionals as consultants for a myriad of reasons (*e.g.* to educate other health care professionals about VNS Therapy™). Retaining and meeting with consultants are activities governed by FDA rules on promotion, AMA guidelines, the AdvaMed Code, federal and state anti-kickback laws (including the personal services "safe harbor") and other statutes.

b) Consultant meetings, for example, present a number of challenges because they can involve large numbers of physicians, payments to participants and discussion leaders, entertainment and discussion of off-label information about VNS Therapy™.

c) Finally, retaining mentors or preceptors (two special types of consultants) requires sensitivity to patient privacy issues in addition to other compliance issues. Mentorships and preceptorships permit Cyberonics employees to observe treatment and/or consultation sessions. We want patients to give their informed consent to our presence during their evaluation and treatment; accordingly, we need to structure our contractual relationships with mentors and preceptors in ways that help assure that result.

3) Compliance Measures

a) Our guidelines for engaging consultants are based on the AdvaMed Code and the Anti-Kickback law personal services safe harbor, which recognize that consultants can provide *bona fide* services to Cyberonics and receive fair market value compensation in return.

b) When contracting with consultants, the Department of Health and Human Services Office of Inspector General (OIG) Compliance Guidance should be considered. With regard to persons or entities in a position to generate federal and health care business for Cyberonics:

> ***"If one purpose of the remuneration may be to induce or reward the recommendation of business payable in whole or in part by a federal healthcare program … a lawful purpose will not legitimize a payment that also has an unlawful purpose."***

c) Thus, consulting positions may not be offered to:

i) influence VNS Therapy™ prescribers or potential prescribers
ii) develop relationships or gain access
iii) promote off-label use of VNS Therapy™

d) Before Cyberonics engages a consultant who is a health care professional (thus a potential source of VNS Therapy™ referrals), we must have ***persuasive*** answers to these questions:

i) What is the business need to retain this consultant?
ii) Is that need adequately documented?
iii) What services will the consultant provide? Are they necessary and substantive? In other words, will he/she do real work for us?
iv) Do his/her professional qualifications meet the identified, documented business need?

v) Is there a written agreement that specifies:

(1) the services that he/she will provide
(2) the basis for all payments that may be received
(3) the invoice detail needed to prove the rendering of services for value

vi) Have we documented the proposed payment for the proposed services is fair market value? How?
vii) How will we capture the value of the services?
viii) How will we show that we have actually used the consultant's services?

e) Similarly, when organizing a non-promotional discussion with experts for *bona fide* business purposes, including roundtables, advisory boards and regional consultant meetings, investigator meetings or speaker-training meetings, the Cyberonics department organizing the event must complete and retain a written "Needs Assessment" including the following elements:

i) Element #1 - Business Need:

(1) Purpose: What is the purpose of the meeting and what are its anticipated benefits?
(2) Output: What needed services will consultants provide in the context of the meeting?
(3) Frequency: If multiple (regional) meetings are proposed, can the number be supported objectively?
(4) Repetition: Have meetings addressing the same subject or issue been held before? If so, is there a legitimate need for another meeting on the same subject at this time? How does this meeting (series) build on the prior meeting(s)?

ii) Element #2 - Consultant Selection:

(1) Number: How many consultants are proposed to attend? Can the number be supported objectively?
(2) Qualifications: Do the qualifications of the consultants meet the identified, documented business need? How were they nominated?

iii) Element #3 - Using Consultant Services:

(1) Collection of Advice: How will the consultants' advice be collected?
(2) Report: Will anyone prepare a report of the meeting and identify recommendations?
(3) Use in the Business: What Cyberonics employees will evaluate the recommendations, and within what time frame? How will the consultants' recommendations be used, and how will that use be documented?

iv) Element #4 - Meeting Logistics:

(1) Invitations: Is it clear that the event is a consultant meeting, not a scientific symposium or promotional program? Does the invitation emphasize the venue or hospitality to be offered at the meeting? Does the invitation make it clear that pursuant to the AdvaMed Code, spouses or other guests may not attend the meeting?
(2) Consultant Agreements: To the extent that the consultants are not already retained and providing services, has a suitable consultant agreement been developed? Will Cyberonics make sure that all consultants sign their agreements before the meeting? How will that be accomplished?

f) The Cyberonics Compliance Officer will review the Needs Assessment and associated documents to assure that the proposed meeting conforms to Cyberonics guidelines.

g) Additional points addressed by the Needs Assessment include:

i) The purpose of a consultants' meeting:

(1) Cannot be to influence the invited consultants or to change their prescribing preferences
(2) Cannot be to have physicians listen passively to promotional message about VNS Therapy™
(3) Cannot be to have physicians merely listen to new (and, therefore, potentially off-label) information about Cyberonics products

Physicians and other healthcare professionals who attend meetings in a passive capacity are not consultants performing services and cannot be paid. However, this does not mean that Cyberonics cannot engage physician consultants to provide active input into our promotional materials. Cyberonics can conduct focus groups to help develop and test promotional messages.

ii) Consultant Selection Criteria

(1) Attendees must be chosen for their expertise and/or medical experience-- not to influence their prescribing habits.

iii) Venue and Hospitality. The venue for a consultant meeting must be:

(1) Conducive to the business purpose of the meeting
(2) Convenient for the consultants who will travel to the meeting

(3) Comfortable to the extent that it permits the extension of modest hospitality to our consultants
(4) Commercially reasonable given the totality of the circumstances, and not susceptible to characterization by third parties as "resort-like" or "lavish"

iv) Attendees may be reimbursed for reasonable business travel (*e.g.*, coach airfare for flights lasting a few hours) and lodging expenses. Cyberonics cannot pay for extended stays at a hotel prior to or after the meeting, nor can it pay for travel or additional lodging costs for spouses or other guests.

v) Consultant meetings may never involve extravagant entertainment. Hospitality must be modest and must facilitate the purpose of the meeting. Cyberonics employees are expected to exercise good judgment in selecting venues and organizing hospitality.

vi) Gifts are always subject to the $100 (retail value) AdvaMed Code limit, and may be subject to further state-imposed restrictions on the type and dollar value of gifts, as well as disclosure rules.

vii) Written Consultant Agreement. A consultant's contract for participation in a consultant meeting must state:

(1) Purpose of the meeting, and whether that purpose is the sole purpose
(2) Services, work products or ***deliverables*** expected from the consultant
(3) Why the consultant was selected (*i.e.*, why his/her expertise is needed)
(4) Date and location of the meeting (if the intention is for participation in a meeting)
(5) Payment specifications, including:

(a) Reimbursable expenses must be identified
(b) Consulting fees must be reasonable and may not exceed the fair market value of the services to be provided
(c) Payment is contingent on active participation and on completion of any written work product or other deliverable, which must be described in the agreement

viii) Reporting

(1) A bona fide consulting meeting involves information collection for business use. The Cyberonics department originating the meeting must arrange for systematic data collection and reporting.

(2) The consultants' advice and recommendations must be compiled in a brief, written report. The Department Director who signs off on the meeting must compile the report and document how the department uses it.

(3) Each Department must keep a file on all meetings originating with a request from that Department (*e.g.* Sales, Marketing). The file should contain the

Needs Assessment and the summary report. In addition, the Meeting Services department must separately keep a copy of the meeting report and a record of how it was used, along with the Needs Assessment and financial records. "Financial records" include all invoices or payment requests, such as invoices from the vendor to Cyberonics or those submitted to Finance by Meeting Services. Departments should expect this paperwork to be audited and files should be kept accordingly.

ix) Investigator Meetings: From time to time, Cyberonics meets with clinical investigators to initiate studies, discuss issues during ongoing studies, or to review results of a completed study. General guidelines for investigator meetings include:

(1) Their substance and tone must be scientific or clinical.
(2) Investigators may be paid a reasonable, fair market value fee to attend (in addition to their compensation for conducting the study, unless the study fee accounted for such a meeting).
(3) Payment should come from Clinical & Medical Affairs as part of the study budget and pursuant to a signed contract.
(4) As a general rule, "takeaway" slide kits should be treated as "promotional" information subject to FDA requirements and Cyberonics Compliance Review Board review and approval. If the information is only to be provided to sub-investigators for use solely in the context of the study, it does not require Cyberonics Compliance Review Board review.
(5) New data, outside the approved labeling, may be shared with the investigators and distributed in hardcopy ***if relevant to the study***.

x) Focus Groups: These are non-promotional meetings with randomly selected physicians/health care professionals (or those selected on the basis of objective criteria) to obtain representative information about a product or treatment. General guidelines for focus groups include:

(1) A documented, defined business need
(2) Attendees *randomly selected* or selected based on relevant, objective criteria, to gain representative perceptions of the specialty or group
(3) A reasonable number of participants
(4) A reasonable fee for active participation
(5) No dissemination of promotional information, except when testing a particular promotional item
(6) Receipt of a deliverable from the focus group for an identified business use

xi) Speaker Training Meetings. Health care professionals who participate in Cyberonics speaker programs must be trained on FDA rules and familiar with VNS Therapy™. Cyberonics allows reasonable compensation for health care professionals who spend time in speaker training, if

(1) Training enables the participants to provide a valuable service to Cyberonics, and
(2) Cyberonics intends to use the speakers.

xii) General guidelines for all speaker training meetings include:

(1) Speakers must be selected for their qualifications (*e.g.*, medical expertise, experience, communication skills)
(2) The number of speakers trained must be reasonably related to the number of expected speaking engagements and geography
(3) Cyberonics can pay for reasonable transportation and lodging associated with speaker training
(4) The speaker's fee for a promotional presentation must be reasonable and may not exceed the fair market value of the speaker's time
(5) Both the invitation to the speaker training meeting and the training itself must explain that

(a) Speakers will be speaking promotionally on behalf of Cyberonics
(b) Speakers may answer unsolicited questions that require a limited discussion of information outside the approved labeling
(c) Presentations must reflect fair balance

xiii) Mentorships and Preceptorships

(1) A mentorship allows a *Cyberonics employee* to observe a health care professional engaged in her daily office or institutional practice.
(2) A preceptorship is a training presentation by a physician to another physician about the clinical use of VNS Therapy™ in professional practice.
(3) Both are forms of consultants and their use must adhere to these Business Practice Standards.
(4) Mentorships and preceptorships are valuable educational tools and their appropriate use as part of a well-rounded training program is encouraged. Mentorships may only be arranged by the Sales Training Department.
(5) Universities and teaching hospitals can be retained to provide mentorships and preceptorships to train company employees. From time to time, we may also engage individual physicians or other health care professionals as mentors or preceptors. When we do so, careful attention must be paid to the selection and compensation of the physician preceptor or mentor. Mentors and preceptors must be selected based on their expertise and qualifications.
(6) These programs may not be used as selling opportunities, or offered to influence the prescribing practices of a particular physician. Doing so will put Cyberonics at risk for health care law violations and will result in sanctions against employees who engage in such conduct. Physicians who serve as mentors or preceptors may be paid reasonable compensation. All payment

terms must be documented in a written agreement with the proposed mentor or preceptor.

(7) Privacy laws require that a health care professional obtain patient authorization from any patient whose health care information may be disclosed for other than treatment purposes. Doctors can obtain oral authorization from their patients when Cyberonics employees "shadow" them during a mentorship. However, Cyberonics strongly prefers written patient consent. A Patient Authorization Form should be offered to physicians for their use in connection with a mentorship or preceptorship. For more information about Cyberonics privacy policy, see the Cyberonics intranet at http://cybernet/compliance/.

xiv) Government Employees.

(1) We interact with doctors, pharmacists and other health care professionals employed by a governmental authority (*e.g.* Department of Veterans' Affairs). Special rules regulate government employees' attendance at meetings or their engagement as speakers or advisors.

(2) Government rules prohibit accepting gifts from contractors that do business with the government, and government employees are subject to rigorous conflict-of-interest rules.

(3) Be wary of these restrictions and consult the Legal Department when inviting government employees to a meeting, or engaging a government employee as a speaker or other consultant.

Chapter 4

Marketing Programs

1) Key Points

a) Marketing programs that provide exposure for VNS Therapy™, and materials that educate health care professionals and the public about them, are essential to Cyberonics' success.

b) Funds used to support marketing programs are considered promotional expenses and are addressed by a number of laws and guidelines, including the AdvaMed Code.

c) As a general rule, when engaged in marketing activities, Cyberonics (and its third-party agents) must adhere to FDA and other rules governing promotion. When planning marketing campaigns and related activities, assume that Cyberonics will be deemed to be ***solely responsible*** for all activities and statements undertaken on its behalf.

d) It's important that we conduct all marketing activities according to Cyberonics policy and procedure. For this reason, most of our marketing activities are subject to CRB assessment and approval.

2) Critical Compliance Issues

a) All Cyberonics promotional activities are regulated by the FDA. A medical device company cannot promote a product for off-label use or promote a product for an indication before it has been approved by the FDA.

FDA regulations require our marketing programs and materials to be balanced. That is, information and claims about efficacy must be accompanied by relevant safety information, warnings or precautions, side effects and other material information, and these disclosures must be conspicuous.

b) All marketing programs must present information consistent with VNS Therapy™ approved product labeling.

c) Marketing programs also need to comply with the federal Anti-Kickback law. This statute prohibits inducements (*e.g.*, financial remuneration) to customers to recommend or purchase VNS Therapy™.

3) Compliance Measures

a) Cyberonics' multi-disciplinary CRB structure is designed to ensure that marketing programs and promotional activities conform to applicable law and regulations. All the activities described in this chapter must receive CRB approval.

i) Endorsements and Testimonials

(1) Endorsements and testimonials provide first-person support for VNS Therapy™ and real-life examples of their efficacy and/or tolerability. Endorsements and testimonials generally involve an individual with personal experience with VNS Therapy™, or a person implanted with VNS Therapy™. Some endorsements and/or testimonials may involve celebrities.

ii) Internet and Web-Based Promotional Materials

(1) The rules and regulations that apply to print-based product claims and advertising also apply to the content of websites and other web-based promotional materials. This means that marketing and promotion rules that apply to the content in printed form apply to the online form, too.
(2) The rules, regulations and policies apply to all Cyberonics Websites and other online activities (such as banner ads, e-mail marketing campaigns, e-mail loyalty programs, search engine optimization techniques, *etc.*). They also apply to web-based activities originating outside the U.S. where the intended or likely audience is U.S. users. Additional laws, rules and regulations may also apply.
(3) It's the responsibility of each person creating internet or web-based materials to ensure that online activities comply with any applicable laws, rules and regulations.

iii) Commercial e-Mail

(1) The CAN-SPAM Act of 2003 establishes an opt-out framework for commercial e-mail and pre-empts state commercial e-mail statutes. The Act is enforced by the Federal Trade Commission, state Attorneys General, and Internet Service Providers (ISPs).

(2) The Act provides serious penalties for violations -- up to $6 million in fines and/or jail time and/or forfeiture of computers and software used in transmitting commercial e-mail.
(3) All Cyberonics commercial e-mail must abide by the provisions of the Act. Any such emails should be cleared through the Compliance Officer and the CRB.

iv) Viral Marketing

(1) Online discussion about VNS Therapy™ can be considered a form of promotion whether conducted directly by Cyberonics, or by some other 3rd party at Cyberonics' direction. Online discussion initiatives supported by Cyberonics must be reviewed by the Compliance Officer to ensure they do not require CRB approval.
(2) Such initiatives should not make claims about VNS Therapy™, engage in off-label discussions, or otherwise promote VNS Therapy™ in a way that is inappropriate if conducted through traditional promotional programs.

v) e-Sales Calls

(1) An e-Sales Call is a sales call in a different form -- over the Internet -- and is subject to the same FDA rules as conventional sales calls. All e-Sales Call materials must be approved by the CRB and consistent with product labeling.

vi) Public Relations Activities

(1) As a general rule, third parties that undertake PR activities on Cyberonics' behalf are subject to the same obligations to adhere to FDA and other rules governing promotion.
(2) Thus, in general, public relations activities require the same degree of review as any other promotional activity. This includes, but is not limited to, evaluation in light of the AdvaMed Code and other rules that apply to our internally generated communication about VNS Therapy™.

Chapter 5

Business Courtesies

1) Key Points

a) In connection with a business meeting, Cyberonics policy and the AdvaMed Code permit occasional hospitality for customers, but only in the form of modest meals and receptions for attendees and only if such hospitality is conducive to the exchange of business-related information at the meeting. A Company employee must be present during any meal or reception.

b) Nominal gifts to customers, and meals with customers, must be subject to applicable law and company guidelines -- particularly the principle of "*no quid pro quo*" and the AdvaMed Code. This means that gifts and meals (1) may not be used as inducements to solicit business and (2) cannot be used in a manner that might suggest that the recipient was being bribed or improperly influenced.

c) Cyberonics employees must not pay for (and Cyberonics will not reimburse) meals, hospitality, travel, or lodging of guests (including, but not limited to, spouses, children, and any significant others) of any other person who does not have a *bona fide* professional interest in the information being shared at a business meeting. In connection with a business meeting, business courtesies in the form of entertainment (*i.e.*, tickets to a sporting or theatrical event) are prohibited.

d) Any business courtesy offered to a health care professional (or others who prescribe or influence prescribing) should be made without any expectation of garnering business or any other "*quid pro quo*" from the recipient, in compliance with the anti-kickback statute.

e) Stringent conflict of interest rules in some states and the Federal government can make it illegal for manufacturers to offer gifts and meals. For example, in Minnesota, it's illegal for a manufacturer to offer or give any gift(s) that have aggregate value greater than $50. Similarly, federal and state government employees generally cannot accept gifts or meals from contractors.

2) Compliance Measures

a) We cannot offer a gift or meal as part of a quid pro quo arrangement, but we may provide occasional gifts and modest meals in strict compliance with the law and Company guidelines.

b) Cyberonics guidelines for gifts and meals, include the following:

i) Cash or cash-equivalent certificates are never appropriate gifts
ii) Items intended for the personal benefit of health care professionals (*e.g.*, tickets to sports events or the theatre, candy, flowers, *etc*.) should never be offered
iii) Items that primarily benefit patients may be offered occasionally to physicians or other health care professionals if they're not of substantial value ($100 retail or less)
iv) Items of minimal value may be offered if they're primarily associated with a health care professional's practice (*e.g.*, reminder items like pens or notepads)

c) Cyberonics policy additionally requires that:

i) Modest meals are allowed in conjunction with a product discussion and in a venue that is conducive to scientific or educational communication. So, having a lunchtime or dinnertime promotional meeting in a quiet, mid-priced restaurant can be appropriate.
ii) Meals must be documented in the employee expense report, including a description of the purpose of the associated meeting, the nature and amount of each courtesy, the full names of each person in attendance, and the employment, agency, or staff affiliation of each attendee. Each such expense report must be approved by a Company Manager, and all such expenses shall be coded as directed by the Finance Department.
iii) Company personnel may not provide meals or other modest hospitality to a customer's staff unless they are appropriate participants in a business meeting with the customer.

d) It's also important to keep in mind that some state laws regulate the type and value of gifts and/or meals that we can offer, or require you to report the fact that we have given a gift or provided a meal to a customer. For example, Minnesota essentially bans the offering of gifts to physicians. Gifts from a manufacturer may not exceed an aggregate annual retail value of $50. This ban does not apply to educational materials, which may still be offered, as can educational grants to institutions (but not to individuals).

e) In addition, there are separate and rigorous rules that regulate our interactions with federal government employees (*e.g.*, Department of Veterans' Affairs, Department of Defense, FDA, CMS and other personnel). Be sure to consult the Compliance Officer before offering a gift or meal to a federal government employee.

f) State conflict-of-interest laws may vary -- consult the Legal Department for specific guidance.

In sum, gifts or meals must never be given in exchange for the purchase or recommendation of VNS Therapy™, or to gain access to a customer's management or decision-makers. That's considered an improper inducement, and it's illegal.

Chapter 6

Patient Events

1) Key Points

a) Cyberonics provides an array of programs to organizations, clinicians, customers and patients. These customer programs include programs such as Territory Patient Education events (TPEs) and Patient Awareness and Qualification events (PAQs). Broadly, these programs present health-related information about therapeutic areas, disease states, patient care issues and diagnostic tools. They may or may not relate to VNS Therapy™.

b) Customer programs such as TPEs do not involve an exchange of funds between Cyberonics and its customers. Customer programs involve the provision of information to enhance patient care.

c) Our customer programs, generally, are promotional activities and are regulated by a number of laws and guidelines, including the AdvaMed Code and Company policies.

2) Critical Compliance Issues

a) All of our promotional activities are subject to FDA (Food and Drug Administration) regulations. If a customer program includes information about VNS Therapy™, the information we present must be consistent with our labeling and appropriately balanced. "Balanced" means that in addition to VNS Therapy's™ benefits, relevant safety information, warnings or precautions, side effects and other material information must be conspicuously disclosed or discussed.

b) Sales and marketing teams also need to be mindful of federal and state anti-kickback statutes when designing customer programs. The anti-kickback laws prohibit inducements (*e.g.*, financial remuneration) to prescribers or other customers to recommend or purchase products that are reimbursed by federal health care programs.

A customer program cannot be solely linked to use or recommendation of VNS Therapy™.

c) Offering a customer program with improper intent (*e.g.*, to selectively foster relationships, to cement an arrangement regarding the recipient's prescribing practices

or secure a position for VNS Therapy™), can raise criminal and civil liability issues under the anti-kickback statutes.

d) Offering a PAQ or TPE to supplant a physician's existing business obligation (*i.e.* educating her patients about therapeutic alternatives) is inappropriate. Physicians have an existing obligation to educate their patients. Accordingly, PAQs and TPEs must be broad-based and open to the general public (or a specific segment of the general public, but not tied or limited to a particular physician's or institution's patients).

3) Compliance Measures

a) Whether they're provided via print, software, seminars or workshops, customer programs must meet the standards described in this chapter. Every customer program must receive approval from the CRB before it is made available to the public.

b) Designing Customer Programs. Customer programs can be used to support the following objectives:

i) Enhance Cyberonics' corporate image, visibility, name recognition and general goodwill
ii) Enhance the quality of patient care or clinical research
iii) Offer free information of broad and general application to the target audience
iv) Provide scientifically sound information

c) Teams may not design or use customer programs for inappropriate purposes:

i) Never include prohibited gift items or tangible items of significant monetary value
ii) Never provide business support or personal benefit to a prescriber or customer
iii) Never design or commission a customer program for a particular customer
iv) Never allow a customer program to be connected by either the Therapeutic Consultant or by the customer to the customer's purchase of VNS Therapy™ or overall VNS Therapy™ volume

d) Distributing Customer Programs. Sales, marketing and others who distribute customer programs must follow these guidelines when offering customer programs to customer organizations and prescribers:

i) Do not distribute a customer program unless it has been approved by the CRB
ii) Do not connect your offer of a customer program to a customer and that customer's VNS Therapy™ purchases or prescribing
iii) Do not offer a customer program in response to a request for special pricing or a discount, or to meet a customer's business need

iv) Do not permit a customer to infer that the receipt of the customer program is conditioned on the purchase of VNS Therapy™

v) Customer events, whether hosted by Cyberonics alone or in cooperation with a charitable organization such as a local Epilepsy Foundation, are community-based events. Cyberonics shall use its best efforts to broadly publicize the event to affected patients throughout the local community

vi) The Marketing Department shall maintain a file for each PAQ or TPE event documenting the date, the location, the identity of each speaker, the number of attendees, and a summary of all expenses related to the event. The Marketing Department shall prepare and submit to Executive Management within two weeks following the end of each fiscal quarter a report listing each customer event held during the preceding quarter, including the venue, the date of the event, the number of patient-attendees, the identity of any speaker(s), the amount of any grant given to an institution, and the total cost of the event

Chapter 7
Speakers & Other
Promotional Activities

1) Key Points

a) Promotional activities that educate health care professionals and others about VNS Therapy™ include speaker programs, health care symposia, and convention or health fair displays, among others.

b) Any funds used to support these activities, such as payments to speakers, are considered promotional expenses and are addressed by a number of laws and guidelines, including the Anti-Kickback law, AdvaMed Code and Company policies. It is vital that all speaker programs and convention activities be conducted according to Cyberonics policy and procedure.

c) Cyberonics may hold meetings or conduct events to train and educate physicians and nurses and other customers (i) about the use or implantation of VNS Therapy™, including programming of the System for maximum efficacy and minimal adverse events, (ii) about the indications appropriate for use of VNS Therapy™, including education regarding the product-related disease states and the appropriate use of VNS Therapy™ in the continuum of care, and (iii) about the quality, properties, and design characteristics of VNS Therapy™ to the extent that such information is instructive on how to use the product safely and effectively.

2) Critical Compliance Issues

a) Speaker programs, like any other marketing activities that promote VNS Therapy™, must present information consistent with our FDA-approved product labeling. As with other promotional programs, these activities must also be balanced, which means that relevant safety information, warnings/precautions, side effects and other material information about VNS Therapy™ must be conspicuously disclosed or discussed.

Speaker programs can be undertaken only in support of product usage that is consistent with approved product labeling.

b) FDA regulations do permit manufacturers to disseminate certain scientific information about their products that is outside of the approved labeling. Information that is discussed as part of a bona fide scientific exchange (*e.g.*, "medical to medical" communication) is not considered product promotion; the parameters of this type of exchange are, however, limited.

c) Employees must understand the implications of the federal Anti-Kickback law when planning speaker programs and/or conventions. This statute prohibits inducements (*e.g.*, financial remuneration or gifts) to prescribers or other customers to recommend or purchase VNS Therapy™.

d) Cyberonics employees who engage in improper marketing or promotional activities, such as encouraging (overtly or tacitly) promotional speakers to tout VNS Therapy™ for off-label use or distributing off-label information in a promotional context may be violating FDA requirements. They may also be violating federal and state Anti-Kickback laws and/or other applicable health care laws. If so, they can subject Cyberonics to government investigation and prosecution.

3) Compliance Measures

a) Cyberonics' multi-disciplinary CRB structure is designed to ensure that promotional materials and activities conform to applicable law and regulations. All activities described in this Standard must receive CRB approval.

b) Promotional Speaker Programs

i) Speaker programs must conform to Cyberonics policy, the AdvaMed Code, and all FDA rules regarding promotion, including the need for fair balance and access to full prescribing information.

Cyberonics is responsible for the overall conduct, content and message of promotional speaker programs, even if the speakers discuss their own professional experiences and their own views about VNS Therapy™.

ii) To initiate a promotional speaker program, a Cyberonics TC, AE, or other employee chooses the presentation topic and venue (after consultation with Meeting Services). The topics and any materials proposed for use must meet all FDA promotion standards and have the approval of the CRB. There must always be full, clear and conspicuous disclosure that Cyberonics is the sponsor of the program, and promotional speakers must receive training about the topic and

materials, as well as about their responsibility for compliance with applicable FDA rules.

iii) Meeting Services or the Marketing Department needs to give the speaker a copy of the Cyberonics Speakers Policy on FDA-related speaking obligations. The originating representative must discuss the presentation with the speaker prior to the event to ensure that he or she understands that the presentation needs to be consistent with our approved prescribing information. In addition, the speaker must sign the standard Cyberonics Speaker Letter Agreement, confirming that he/she has received the instructional brochure and will abide by FDA requirements for promotional speakers, as well as the Cyberonics Speakers Bureau Form.

iv) Selecting or retaining speakers without ensuring they're properly trained about their speaking obligations (*e.g.*, FDA prohibitions against off-label promotion) may also result in Company disciplinary action.

v) Teams sometimes engage third parties (*e.g.*, advertising agencies or others) to facilitate major promotional events or programs.

It should always be remembered that Cyberonics remains responsible for the content of any promotional program, regardless of whether it is organized by the Marketing Department, a third party engaged by Cyberonics, or by the sales force.

vi) From time to time, a speaker wishes to use some of his or her own slides in a promotional presentation. It is permissible for a speaker to use his or her own slides. However, it's Cyberonics' obligation to make sure speakers know that everything they present—including slides—must be consistent with approved product labeling and include balanced information about any products mentioned.

c) Designing Speaker Programs

i) When designing a promotional speaker program, remember that in addition to FDA regulations, the AdvaMed Code and Cyberonics policies also govern the promotion of VNS Therapy™ to health care professionals.

(1) The purpose of a promotional speaker program is to educate physicians about VNS Therapy™, so the program must focus on educational content and the setting for the program must be conducive to the educational activity.
(2) An occasional modest meal is allowed in connection with a speaker program; however, entertainment may not be offered.
(3) A restaurant venue for a promotional speaker program must be modest as judged against the standards of the local area.

(4) Only speakers are paid, and they must be paid at a reasonable or fair market rate; attendees cannot be paid.
(5) Speakers must be evaluated and, if qualified, approved for inclusion in the Cyberonics Speaker Bureau. Qualifications considered shall include, but not be limited to:

(a) Reputation as an expert in the field (nationally, regionally, or locally);
(b) Speaking ability, effectiveness, and stage presence;
(c) VNS Therapy™ experience (where relevant);
(d) Clinical experience;
(e) Geographic convenience;
(f) Speaker's past effectiveness (if applicable);
(g) Ability to generate interest and discussion; and
(h) General availability.

(6) Only speakers are reimbursed for expenses associated with attendance at the program, including out-of pocket lodging, transportation or parking costs.
(7) Cyberonics does not pay for or reimburse any attendee expenses. Exceptions to this rule may be made for programs that are educational in nature and conducted in order to comply with the FDA mandate that Cyberonics adequately train physicians and health care professionals on the proper use of VNS Therapy™.

(a) Any program in which Cyberonics proposes to pay for or reimburse attendee expenses must be approved by the Compliance Officer before any invitations are extended.

(8) Invitations should specify that the health care professional's spouse or other guests may not be included.
(9) It is appropriate to have written invitations or advertisements for sponsored programs. These must utilize CRB-approved templates, follow Cyberonics standards, clearly display Cyberonics' sponsorship and reflect the program's compliance with FDA regulations, the AdvaMed Code and Cyberonics policy.

(a) The design and layout of an invitation must emphasize the educational presentation (as opposed to the venue)
(b) Invitations must relay the following message: "In accordance with the AdvaMed Code, attendance at this educational program is limited to health care professionals. Attendance of spouses or guests is not appropriate."
(c) Invitations must state: "This educational program is sponsored by Cyberonics Inc.," or prominently display the Cyberonics logo.

d) It is never appropriate to use a gift—even a token gift—to induce attendance at a promotional program. However, attendees may receive promotional items of nominal

value that comply with Cyberonics guidelines and the AdvaMed code, and that have been approved by CRB.

e) Engaging Speakers

i) Speakers are a type of consultant. We can pay them the fair market value of their services to Cyberonics (*e.g.*, discussion of VNS Therapy™ in accordance with FDA guidelines). Moreover, because "fair market value" can be subjective and very difficult to assess, such consultant fees should always be reasonable based on the speaker's expertise and the value of his or her time.

ii) Every speaker we use needs to be retained through a standard Consultant Agreement with Cyberonics. These contracts remind speakers of FDA law and regulations governing their presentations, and of Cyberonics' adherence to the AdvaMed Code. They also outline other Cyberonics requirements, such as submitting documentation of appropriate expenses for reimbursement.

Speakers cannot present, nor can they be paid, unless they have signed a consulting agreement in advance of the speaking engagement.

f) Displays & Conventions

i) Medical Device manufacturers are routinely offered the opportunity to purchase display space (booths) at medical meetings, or asked to sponsor health-related customer meetings that allow booths or displays. Such events may also include health fairs where consumers can be educated about Cyberonics and its products.

ii) Before agreeing to participate, we must determine whether other companies (device, pharmaceutical or otherwise) are being asked to sponsor or display, and whether there is a set fee for each participant or for each level of participation.

A fee schedule establishes a benchmark for testing the fair market value of sponsorship or display-related payments.

iii) On a commercial convention floor, all materials and communications must be consistent with product labeling, and any materials distributed to customers or consumers must be approved by the CRB. In contrast, materials and communications on the "scientific" floor of a medical society convention may be regulated by FDA rules governing "scientific exchange."

iv) Within designated scientific areas, it may be permissible to offer scientific information outside of approved labeling. The nature and extent of the scientific information that will be presented and the format of the presentation must be reviewed and approved by the Medical Science Liaison director with appropriate

input from the Compliance Officer to support compliance with the FDA rules that govern scientific exchange.

v) The only Cyberonics personnel who may occupy scientific (noncommercial) booths are MSL personnel. Sales and marketing personnel should not be present in scientific exhibit areas.

Chapter 8

Clinical & Medical Affairs

1) Key Points

a) The Food and Drug Administration (FDA) regulates almost everything a device manufacturer says about the products it makes and sells. However, the FDA does recognize that certain information about and access to current research and scientific data can be non-promotional. Accordingly, the FDA allows manufacturers to distribute some information, and make some communications, without being subject to the FDA rules governing product promotion. These activities are broadly described as "scientific exchange."

b) Non-promotional scientific exchange of information is subject to all of the other rules and regulations that govern our communications about VNS Therapy™. Scientific exchange does not allow us to disseminate off-label information that is potentially misleading or poorly substantiated, or allow us to encourage investigators or physicians to communicate off-label information. Those activities are subject to prosecution under the health care laws. This Standard addresses several types of activities that constitute bona fide scientific exchange, including distribution of medical reprints and "medical to medical" communications, and the Cyberonics policies that regulate their use.

2) Critical Compliance Issues

a) From our research and development and product support activities, we have extensive medical and scientific information about VNS Therapy™ and are a logical source of information for government purchasers, customers, health care professionals, patients, disease state advocacy groups and the myriad other interested parties. Our VNS Registry, for example, contains some of the most relevant data available about VNS Therapy™. Some of this information may not always be reflected in the approved labeling for VNS Therapy™. In certain circumstances, Cyberonics may provide certain types of interested individuals with scientific information that is outside the scope of approved product labeling. From a health care law compliance perspective, the three main challenges of scientific exchange are:

i) understanding what activities constitute scientific exchange

ii) understanding who at Cyberonics may engage in scientific exchange in different contexts
iii) understanding the consequences of improper scientific exchange

b) Scientific exchange that misrepresents VNS Therapy™ safety or efficacy can be challenged by state attorneys general, patients, and patient advocacy groups, who seek to demonstrate that they relied on such statements and were harmed.

All of the laws that prohibit disseminating untruthful or misleading information also apply to scientific exchange. In other words, disseminating untruthful or misleading information, even if the information is claimed to be part of a scientific exchange, violates FDA regulations.

c) Finally, scientific exchange that is viewed by the government as concerted activity to promote off-label use of a company's product, and/or concerted activity intended to result in improper claims for government reimbursement may lead to civil or criminal prosecution under the federal False Claims Act.

3) Compliance Measures

a) When engaging in "scientific exchange," Cyberonics cannot promote an unapproved use of VNS Therapy™. Activities and communications that present off-label information about VNS Therapy™ must always be scientific in tone and substance.

b) Marketing Reprint Distribution

i) From time to time, the Marketing Department may wish to disseminate a peer-reviewed article previously published in a reputable, peer-reviewed journal that is consistent with uses for VNS Therapy™ (*e.g.* refractory epilepsy and treatment resistant depression), but that describes a technically off-label use (such as use in a specific subpopulation) or other aspect of VNS Therapy™ that is not consistent with its approved labeling. Such off-label content should be minor and incidental when distributed in a marketing context.
ii) Cyberonics' policies are consistent with a line of legal decisions (the so-called Washington Legal Foundation, or "WLF" string of cases) that address limited distribution of peer-reviewed third-party, scientific information that contains off-label information. Our policies permit limited distribution in defined circumstances, and only after CRB review and approval.
iii) The following guidelines apply to CRB evaluation of a reprint for proposed distribution as a "WLF reprint":

(1) The reprint must be a peer-reviewed article from a recognized journal. Unless they have been peer-reviewed, editorials and letters to the editor generally will not qualify for WLF distribution.
(2) The reprint cannot contain false or misleading information about VNS Therapy™. It also cannot be an "outlier" when evaluated in the context of the broad array of scientific evidence. For example, continued distribution of an article that shows a positive outcome in the face of 20 subsequent articles that do not support that outcome would be misleading. This type of selective dissemination ("cherry-picking") is strictly prohibited.
(3) The proposed distribution format of the reprint must draw the reader's attention to any significant differences from the approved labeling (including, but not limited to, effectiveness rates, data, analysis, uses and regimens).

iv) Sales and marketing personnel may not discuss reprints. As with all queries about off-label product information, questions about the content of these reprints should be referred to Cyberonics' Clinical & Medical Affairs Department (1-888-748-1652 or 1-800-332-1375 and then entering extension 7690 when prompted for an extension).
v) It should be emphasized that Cyberonics' WLF policy limits distribution of off-label medical or scientific information by the Marketing Department to peer-reviewed journal articles published in reputable journals. Abstracts, transcripts or summaries of company-sponsored CME symposia are not published, peer-reviewed scientific materials and cannot be distributed to customers if they contain off-label data.

c) Textbook Distribution under WLF

i) Under Cyberonics guidelines, CRB may approve for distribution by sales representatives, unabridged medical textbooks from *bona fide* independent publishers (as opposed to works commissioned by Cyberonics) if the overall presentation of VNS Therapy™ is balanced and the quantity is limited. Note that the gift of a textbook to an individual health care practitioner is subject to the Cyberonics Standard and the AdvaMed Code's guidelines for gifts to physicians and other health care professionals.
ii) The gift of a textbook to an institution is not subject to the AdvaMed Code's financial rules for gifts, but needs to be reviewed as a grant.

d) Scientific Presentations and Exhibits at Conventions and Meetings

i) Scientific presentations and exhibits are developed, often with limited Cyberonics assistance, from the work of independent investigators who may have received Cyberonics support for their research and/or display efforts. Such presentations and exhibits are meant to address issues of scientific or medical interest to attendees at a medical event or congress. Generally, they are offered in noncommercial areas or beyond the perimeter of promotional booths. These

presentations may include content that is outside the scope of VNS Therapy's™ approved labeling.

ii) A key question that arises is whether a presentation at a medical meeting by an investigator who is speaking about her work constitutes non-promotional "scientific exchange" or whether it is promotional and, as such, must conform to all promotional requirements.

iii) Scientific posters and presentations can be supported by Cyberonics if they qualify as "scientific exchange." Such a determination must be made by the Cyberonics Publications Committee. If the Publications Committee determines that a poster or platform presentation at a meeting, congress, or convention constitutes "scientific exchange," Cyberonics can support the presenter in the form of limited assistance with travel and presentation costs. Such scientific presentations generally can qualify as "scientific exchange" if certain criteria are demonstrated to the Cyberonics Publications Committee:

(1) The speaker is a scientist or clinician
(2) The information is of important, current scientific interest and not widely known in the medical community (*e.g.*, the first, preliminary, or early report of the results of a new study)
(3) The proposed presentation is accurate and scientifically balanced as to its claims
(4) Any significant safety issues associated with the study or presentation are fairly represented and not minimized
(5) The full prescribing information is readily available
(6) The content is developed by, or in collaboration with, an investigator who is independent of Cyberonics
(7) Cyberonics' role in the research and presentation of the data is clearly disclosed
(8) The presentation has been peer-reviewed or accepted for display via some similar process (In many congresses and similar scientific meetings, non-promotional exhibits are peer-reviewed and formally accepted for display.)
(9) The presentation is segregated from promotional activities and venues. In some but not all instances, scientific exhibits are allocated to a designated sector (*e.g.*, a separate floor) at a congress or scientific meeting and are not displayed or featured at or near commercial (promotional) booths. In many cases, event organizers offer a location adjacent to a promotional display. In such situations, special care must be taken to ensure that there's a clear, "bright line" distinction between promotional displays and communications on the one hand, and scientific exchange on the other. The facts and circumstances surrounding the display set up will dictate compliance with this "bright line" requirement.

iv) Teams should expect FDA scrutiny of scientific presentations and displays at meetings. FDA representatives often attend scientific congresses and meetings incognito to ensure that the boundaries of scientific exchange are respected.

Always remember that, under the law and regulations of the FDA, it's illegal to disseminate information that is inaccurate, misleading and/or untruthful.

e) Press Releases

i) Suppose that a new use is found for VNS Therapy™ at the end of a long-term study, or the pivotal study of an unapproved use has positive results. Cyberonics may want to issue a press release. Before doing so, the rules governing required public disclosure for Securities and Exchange Commission (SEC) purposes must be considered (in addition to the principles of "scientific exchange").

ii) The major principles governing press releases containing new information—not reflected in approved product labeling —are as follows:

(1) A press release is a one-time event involving "new" product news
(2) A press release must meet SEC standards of substantiality and materiality
(3) A press release must be written factually and, for scientific announcements, should be non-promotional in tone

iii) FDA considers product-specific "press kits" to be subject to the regulatory requirements for printed promotional materials, including fair balance. Accordingly, press kits must be CRB-approved. To fulfill the fair balance requirement, press kits should be evaluated in their entirety, rather than on the basis of individual pieces, so long as their components are intended to be used together and not disseminated individually. Press kits must also include a copy of the full prescribing information for VNS Therapy™.

iv) Press releases and investor information may also be subject to FDA or SEC action if they contain misleading or unsubstantiated claims. Accordingly, press releases that make claims about VNS Therapy™ require approval by the Vice President and General Counsel or his designee.

v) Other key points to consider for press releases include:

(1) The regulatory status of any unapproved VNS Therapy™ indication described in the materials must be made clear.
(2) No comments can be offered regarding potential approval timelines for regulatory review.
(3) The materials should not imply that an unapproved product is "safe" or "effective," or that an unapproved use of VNS Therapy™ is "effective." Similarly, materials should not imply that VNS Therapy™ is "safe" without appropriate qualification (*e.g.*, disclosure of warnings, dosing information, side effects, description of the study limitations or data in subpopulations, *etc*.). Thus, VNS Therapy™ might be described as "well-tolerated" or "having a documented safety profile" (but not as "safe") with reference to the most common adverse events and other safety information.
(4) Safety or efficacy observations by reputable third parties should not be inappropriately minimized.

f) "Medical to Medical" Communication

i) Medical to medical communication—physicians and scientists speaking with other physicians and scientists about the appropriate use of VNS Therapy™—provides important information to health care professionals and other providers and benefits patients.

ii) "Medical to medical" communication is also part of the definition of scientific exchange—one physician or scientist engaged in non-promotional communication about a subject outside of approved product labeling with another physician or scientists. In their capacity, certain representatives from Cyberonics' Clinical & Medical Affairs Department qualify as "scientists."

iii) As a general proposition, FDA laws and regulations apply to comments by Cyberonics MSLs about VNS Therapy™ in much the same way that they apply to comments about VNS Therapy™ by sales representatives.

Statements by Cyberonics MSLs in a promotional context (e.g., in person, in a promotional dinner meeting, at a TPE or community health screening program, etc.,) must conform to approved product labeling. Cyberonics MSLs cannot engage in "off-label promotion" any more than sales representatives can.

iv) However, unlike a sales representative, a Cyberonics MSL who receives an ***unsolicited*** request for information that goes beyond the scope of approved product labeling (*e.g.*, during a question-and-answer session following a promotional dinner meeting) may provide a brief response to the question. (If the questioner has additional off-label inquiries, he should be referred to Cyberonics' Clinical & Medical Affairs Department at 1-888-748-1652 or 1-800-332-1375 (then enter extension 7690 when prompted for an extension).

v) In a similar vein, it is important to remember that a non-employee consultant retained as a speaker cannot engage in "off-label" promotion of VNS Therapy™ to other physicians (*e.g.*, when presenting at a promotional dinner meeting).

A promotional speaker retained by Cyberonics is "speaking for Cyberonics" when she presents. Failure to adhere to FDA guidelines for promotional speaking exposes Cyberonics - and the speaker—to the risk of prosecution and penalties.

g) Clinical & Medical Affairs

i) The Cyberonics Clinical & Medical Affairs Department provides accurate, timely and balanced medical information to internal and external customers, including responses to unsolicited customer requests. It actively interfaces with other departments to ensure the quality, applicability and availability of medical-information resources.

ii) Generally, communication between Clinical & Medical Affairs and medical professional customers is treated as "medical-to-medical communication," enabling Cyberonics to respond appropriately to unsolicited inquiries that may require reference to both on-label and off-label data.

Chapter 9

Research

1) Key Points

a) As a research-based medical device company, Cyberonics retains and supports health care providers and academic organizations to perform sponsored studies, including outcomes research (*e.g.* VNS Patient Registries) and prospective randomized clinical trials. Cyberonics also provides financial support for independent third-party trials in the form of Independent Research Grants (IRGs).

b) Both sponsored and supported trials can provide valuable scientific and clinical information about VNS Therapy™, improve clinical care, lead to promising new uses for VNS Therapy™ and promote better delivery of health care to patients.

c) Cyberonics policies, including Clinical Review Committee (CRC) procedures, help us ensure that our clinical trials conform to government and ethical requirements. In addition, Cyberonics embraces the concepts in the AdvaMed "Statement on Clinical Research" (see http://www.advamed.org/publicdocs/2003_research_statement.pdf.)

2) Critical Compliance Issues

a) Payments to physicians or others may violate federal or state anti-kickback statutes if such payments are made to influence the recipients' prescribing practices and if the payments are not for *bona fide* research or other legitimate services.

b) Both the AdvaMed "Statement on Clinical Research" and the health care laws forbid "token" consulting arrangements, which might include payments in a clinical trial context to encourage investigators to use VNS Therapy™ or reward past use of VNS Therapy™, rather than to address a real scientific question or to obtain important clinical information.

3) Compliance Measures

a) Cyberonics sponsors bona fide research activities that:

i) Have genuine scientific and/or clinical value

ii) Involve researchers and/or investigators selected on the basis of criteria relevant to the research effort
iii) Involve compensation consistent with the value of the research services actually provided by the researchers and/or investigators

Support of a clinical trial must involve the performance of bona fide research in return for fair market value compensation, and conform to generally-recognized ethical requirements for clinical trials. Trials that are intended to familiarize clinicians with VNS Therapy™, rather than to collect scientifically important new information, on the other hand, are inappropriate.

b) Cyberonics' policies on clinical trials are designed to comply with both legal and ethical requirements. All clinical trials must be approved by the Vice President for Clinical & Medical Affairs, Chief Medical Officer.

4) General Considerations

a) The following general legal requirements and company policies apply to Cyberonics-sponsored and Cyberonics-supported trials.

i) Cyberonics conducts both "sponsored" and "supported" clinical trials in accordance with local laws and regulations as well as recognized ethical standards. "Sponsored" trials are designed and conducted, or supervised, by Cyberonics. Cyberonics provides financial support and/or clinical supplies for "supported trials," but does not significantly participate in these trials (in terms of designing, conducting, supervising or monitoring them).
ii) All Cyberonics-sponsored and Cyberonics-supported clinical trials must be scientifically valid and likely to generate data that will be relevant to a defined use for VNS Therapy™ or other clinical and/or business need. Before an extramural research project begins, CRC needs to establish the purpose of the trial and how the data to be generated is likely to be used.
iii) Trials intended to support a significant change in the labeling of VNS Therapy™ or a new indication, should generally be conducted as sponsored trials. However, in some cases, these may be conducted as supported studies under the auspices of the NIH (or similar, well-established research institutions).
iv) Financial support to independent third-party trials ("supported trials") may be provided through independent research grants (IRGs). The recipient(s) of IRGs must be chosen on the basis of the merits of their research proposals and the scientific qualifications of the investigators.
v) A qualified Institutional Review Board (IRB) or Ethics Committee must review all Cyberonics-sponsored and Cyberonics-supported human studies to be

conducted in the U.S. or to support FDA approval of a new indication unless the study is exempt under FDA regulations. For animal studies, the institution's animal care committee must review all Cyberonics-sponsored and supported studies.

vi) Trials should be conducted under an Investigational Device Exemption (IDE) or a Humanitarian Device Exemption (HDE), where appropriate, unless exempt under FDA regulations.

vii) All human study participants must provide voluntary informed consent (or in the case of children and certain special patient populations, legally acceptable consent on the patient's behalf).

b) Compensating Investigators in Sponsored Trials

i) Cyberonics compensates investigators for the fair market value of their expertise and effort in conducting clinical research, consistent with the following requirements:

(1) Compensation must be linked to specific *bona fide* services (*e.g.*, medical procedures). It must be reasonable when compared with compensation for similar clinical trials. Compensation may include payment for the investigator's service time, as well as reimbursement of reasonable travel, lodging and meal expenses associated with clinical investigator or staff attendance at investigator meetings.

(2) Compensation cannot be tied to the outcome of a clinical trial.

(3) The venue and any amenities associated with investigator meetings must be modest and conducive to the business purpose of the meetings.

(4) Cyberonics does not pay physicians for referring potential subjects to investigators. Only physicians who participate in the clinical trial may be paid for services.

(5) The fact that investigators are compensated must be disclosed in the informed consent documents provided by Cyberonics to IRBs (*e.g.*, "the investigator or his/her institution is receiving compensation from the clinical trial sponsor for the investigator's participation in this clinical trial"). The basis for such compensation must also be specified in the written contract with the investigator.

(6) FDA requires investigators to make financial disclosures to confirm that they do not have a significant investment in the sponsoring company. Investigators must provide Financial Disclosure information (21 CFR §54) to Cyberonics.

(7) Compensation for clinical research services must not include Company stock or stock options (ownership of Cyberonics stock is not prohibited).

c) Supported Trials/Independent Research Grants (IRGs)

i) Cyberonics often provides Independent Research Grants (IRGs) to support clinical trials that are sponsored and conducted by independent investigators.

IRGs are coordinated by the CRC. Since IRGs are payments to individuals or institutions that can influence the use, prescription or recommendation of VNS Therapy™, they are subject to scrutiny under health care laws.

In particular, IRGs may not be used to reward a physician for his or her support of Cyberonics activities, or to influence VNS Therapy™ use. An IRG's appropriate purpose is to support research that has compelling scientific or clinical merit.

ii) Proposals for IRGs, including requests for clinical supplies (*e.g.*, study devices), that have scientific merit are sent to the CRC along with supporting documentation that describes the study. The CRC must record its scientific rationale for providing funding or other support at the time the decision is made to recommend funding an IRG proposal.

iii) The funding evaluation should include an assessment of Cyberonics' requested involvement in the clinical trial, to ensure that Cyberonics could not be considered the sponsor of the study. For additional guidance regarding the review and processing of IRG proposals, consult the CRC or information about IRGs posted at: www.cyberonics.com under the "Grants" link.

iv) All protocols for IRG-supported trials must be written by the sponsor or principal investigator, not by Cyberonics. Comments, advice and/or assistance, if requested by the investigator, may be provided. However, company employees may not write a protocol for an independent investigator.

v) A request for clinical supplies to support bona fide scientific investigations can be referred to the CRC for consideration as an IRG.

Chapter 10

Charitable Donations

1) Key Points

a) A charitable contribution by Cyberonics is generally a donation of funds or goods to a charitable organization -- an IRC section 501(c)(3) entity -- for a charitable purpose. Charitable contributions can also be made to certain government entities, such as a public university.

b) Cyberonics also makes "business donations" to certain nonprofit organizations that are not section 501(c)(3) entities. Some "business donations" are contributions that Cyberonics cannot deduct as charitable contributions. Examples of entities that may be eligible for a business donation include medical societies and civic associations classified as 501(c)(6) organizations.

c) Charitable contributions and business donations cannot be made to an individual or to an organization on behalf of a specific individual, no matter how worthy the request.

A charitable contribution must never be tied in any way to the past, present or future purchase, prescription or recommendation of VNS Therapy™.

d) Any charitable contribution or business donation must conform to Cyberonics policy and procedures. All charitable contributions and business donations must be reviewed and approved by the Grants and Donations Review Committee (GDRC).

2) Critical Compliance Issues

a) Charitable contributions have tax and health care law implications. They also need to conform to the AdvaMed Code. The tax implications are simple: A *bona fide* charitable contribution is deductible from revenue, dollar for dollar, and reduces Cyberonics' tax liability. Any benefit that Cyberonics receives in return for a donation (other than acknowledgement) reduces the amount that can be considered a contribution, and Cyberonics needs to document the value of any such offset.

b) As a matter of health care law compliance, a charitable contribution can raise concerns under the federal Anti-Kickback statute when it's given to or on behalf of an organization that's in a position to influence the prescription or purchase of VNS Therapy™.

Cyberonics personnel should never imply in any way (nor permit customers to infer) that the purpose of a contribution is to motivate increased use of VNS Therapy™.

c) By following Cyberonics policy and procedures, you'll help reduce the risk that a contribution or donation will be seen as a disguised inducement or "kickback" to encourage the use of our products.

d) Making a donation to a worthy cause is not acceptable if you are doing so to gain access to a potential customer or to secure a recommendation for VNS Therapy™. Charitable contributions must be made for a *bona fide* charitable purpose and without any expectation of return.

e) Examples of common charitable contributions that may be acceptable under Cyberonics policy, assuming no expectation of return, include:

i) Sponsorship of a benefit fund-raiser
ii) Sponsorship of a participant in a charity fund-raiser (such as a walkathon), if the contribution is made payable to the organization and not to the participant
iii) Contributions to a hospital to support the care of indigent patients
iv) Cyberonics' TRD Indigent Access Program or B.J. Wilder Therapy Access Program
v) Modest donations ($25 or less) to a charity or hospice in memory of a deceased individual
vi) Support for a community service project
vii) Support for an enduring program (such as a textbook program) at an institution

3) Compliance Measures

a) The following guidelines apply to all charitable contributions:

i) The dominant purpose of an event or recipient organization must be to raise money for the identified charity
ii) Any benefit received by Cyberonics must be minimal and incidental to the main purpose of the donation
iii) The amount of the donation must exceed the value of any goods or services provided to Cyberonics as a donor (*e.g.*, a banner, or a table at a benefit dinner)
iv) Only the excess counts as a charitable contribution

b) Tickets or invitations offered in return for sponsoring a charity event may be used by Cyberonics employees or returned to the charitable organization so it may donate the tickets to recipients of its own choosing. Again, the value of the benefit we receive reduces the amount of the charitable contribution.

***Example**: Suppose that Cyberonics contributes $1,000 to an Epilepsy Foundation and is given a table for 10 at a celebration dinner. As a matter of health care law compliance, Cyberonics could not use these tickets to invite physicians or other customers to that event. Under the AdvaMed Code, the tickets would constitute an impermissible gift to those physicians. From a tax law perspective, if the tickets were worth $100 each, the value of Cyberonics' contribution would be reduced to $0 to reflect the value of the tickets.*

c) A request for a charitable contribution must be in writing and in accordance with the procedure set forth at www.Cyberonics.com. The organization's request letter must clearly explain its request for funds and/or the activity that the organization wants Cyberonics to support. In addition, the organization should provide its tax-exempt identification number and proof of its section 501(c)(3) (or other) designation.

d) A Cyberonics employee who receives a request for a charitable contribution should direct the organization/individual requestor to the Cyberonics website (www.Cyberonics.com) under the "Grants" link.

e) At no time should any Cyberonics employee make any representation regarding the likelihood of a donation or contribution. In particular, sales representatives' involvement potentially taints the contribution process given the relationship between sales and potential customers. As a matter of course, requests to the GDRC that have been "pushed through" by a sales or marketing employee will be viewed skeptically by the GDRC.

f) The contribution check and Cyberonics' Acknowledgement of Charitable Contribution form should be sent to the recipient at the same time. The recipient organization should complete and return the Acknowledgement form to Cyberonics (Compliance Specialist).

g) Company process audits help ensure compliance with these procedures. Failure to maintain appropriate documentation may result in disciplinary action.

Chapter 11

Fellowships

1) Key Points

a) To establish Cyberonics as an industry leader in public health innovation, education and research, the GDRC considers a variety of initiatives, including awards, visiting professorships, scholarships, and fellowships.

b) Educational activities for health care professionals with broad educational output are funded by educational grants that require approval by the GDRC.

c) Cyberonics' sponsorship of research and charitable contributions are covered in the Grants and Charitable Contributions Standards.

2) Critical Compliance Issues

a) We must understand the implications of the Anti-Kickback law, which prohibits improper inducements (*e.g.*, financial remuneration) to prescribers to recommend or purchase VNS Therapy™. We also should be sensitive to the potential effect that an improper payment to a customer can have if the payment is deemed to be an undisclosed "discount."

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a customer in exchange for using VNS Therapy™ or for a commitment to continue using VNS Therapy™. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

b) The facts and circumstances surrounding our awards, visiting professorships, scholarships, and fellowships should never permit an observer to infer that any funding whatsoever was given to influence prescribing.

3) Compliance Measures

a) Cyberonics' awards, visiting professorships, scholarships, and fellowships are designed to conform to health care law compliance standards and Cyberonics policy and procedures. Whenever possible, these activities should be co-sponsored with nonprofit medical societies, professional groups or similar organizations.

b) To the extent possible, any fellowship, scholarship or visiting professorship program needs to be competitive and open to relevant institutions or candidates in a given geographic region, therapeutic area, *etc*. An example of an "open" initiative would be a program launched and promoted (by a letter requesting applications, for example) to all U.S. teaching hospitals or neurology residency programs. In contrast, a Cyberonics-funded fellowship, scholarship, or professorship requested by, designed for, or otherwise targeted at a specific customer would not qualify as an open or a competitive program.

c) The selection of award recipients must always be independent of Cyberonics. Candidates should be required to submit applications that meet widely published eligibility criteria. Where practical, either the candidates' academic institutions or an independent advisory board should select the award, fellowship, scholarship or visiting professorship recipients.

d) ***Awards Programs***

i) From time to time, Cyberonics may wish to work with an independent professional group to establish an award to recognize demonstrated professional excellence or outstanding commitment to patient care. In order to comport with Cyberonics policy, an awards program must conform to the following standards:

(1) The program must be approved by the GDRC.
(2) The application and selection processes must be clearly articulated and widely published.
(3) The program must be open to all medical schools, academic centers, or fellowship or residency programs in a particular geographic area or therapeutic area.
(4) An independent selection committee must select the award recipient(s). Cyberonics employees may not select the award recipients or vote as part of the selection committee.
(5) Cyberonics may pay the reasonable out-of-pocket expenses incurred by members of the selection committee, but members should not be compensated for serving on the committee (unless extensive work is expected of them and, even then, any fee paid must be modest).
(6) An award may consist of a token, (*e.g*. a plaque, a book, or any other gift that is compliant with AdvaMed Code standards). If the award recipient is a health care professional in training (*e.g.*, a resident or fellow), an award also

may include the reasonable cost of travel to enable the winner(s) to attend a major medical meeting in their specialty or field of professional endeavor.

(7) Sales and other Cyberonics personnel may attend awards presentations but may not make promotional presentations during or in conjunction with the ceremonies.

(8) The existence of awards programs can be promoted by field representatives and medical society partners.

e) ***Visiting Professorships***

i) These grants can help offset the expense of bringing a prominent physician-scientist to an academic institution for three or more days of educational programming (lectures, Grand Rounds, *etc*.).

ii) The following guidelines apply to Visiting Professorships and how Cyberonics may support these programs at academic medical centers and similar institutions:

(1) The program must be approved by the GDRC.

(2) The proposed visiting professor should be chosen by the requesting institution without any Cyberonics input.

(3) Funds can be used only for the direct expenses of the program, and may not be used to subsidize the recipient's existing, routine or ordinary business expenses.

(4) If the institution consents, local sales representatives may attend a program presented by a visiting professor, but cannot promote any products during or in conjunction with the program.

(5) The existence of visiting professorship programs can be promoted by field representatives.

f) ***Fellowships/Scholarships***

i) Guidelines for funding a Fellowship/Scholarship at a teaching or research institution for basic biomedical clinical and/or outcomes research in an academic setting at the postdoctoral and/or junior faculty level, include the following:

(1) The program must be approved by the CEO and CFO upon a recommendation from the GDRC.

(2) The program must be open to all eligible candidates in a reasonably defined geographic region or therapeutic area.

(3) The application and selection processes must be clearly articulated and widely published.

(4) Programs should be nationally competitive, with applications distributed nationally through a variety of channels (internet, direct mailings, *etc*.).

(5) Recipients must be selected by an independent committee. Cyberonics employees and consultants may not belong to the selection committee, nor may they vote on the selection of fellows.

(6) Cyberonics may pay the reasonable out-of-pocket expenses incurred by members of the selection committee.
(7) Funds must be paid directly to the successful applicant's institution as an educational grant. The monies cannot be paid to the successful applicant.
(8) Funds can be used only for the direct expenses associated with the fellowship(s). Cyberonics funds may not be used to subsidize the recipients' current/routine/ordinary business expenses (*e.g.*, overhead, etc.).
(9) If the position includes both billable services and research or teaching, the award must be pro-rated based on the amount of time that the fellow will devote to non-billable teaching or research. The fellowship funds cannot be used to cover salary for a position that bills services, or for that portion of a position that bills service.
(10) The applicants' institutions are solely responsible for selecting their fellows.
(11) Cyberonics can only provide funds to support the research activities of applicants who already have positions at academic institutions.
(12) Fellowship awards may be for one year or for multiple years of funding.
(13) Sales representatives and other Company personnel may attend an awards program but cannot promote any products during or in conjunction with the program.
(14) The existence of fellowship programs can be promoted by Cyberonics personnel.

Chapter 12

Educational Grants

1) Key Points

a) This Standard describes how teams handle requests by outside organizations for educational grants and the criteria for awarding them, and summarizes the review and approval processes.

b) Cyberonics makes other types of contributions that are discussed elsewhere in the Business Practice Standards, including:

i) Charitable contributions to I.R.C. Sec. 501(c)(3) organizations to support their overall mission and/or to support worthy, public interest initiatives (see Charitable Contributions).
ii) Fellowships and funded educational or training programs for individuals employed by a bona fide non-profit organization (see Fellowships).
iii) Advocacy initiatives are discussed with Charitable Contributions. Contributions for advocacy initiatives also may qualify as promotional expenses where the funding confers a substantial benefit on Cyberonics.
iv) Independent research grants (IRGs) are often made in order to support ongoing investigation related to VNS Therapy™ or in areas where we want to support important research (see Research).

c) Other initiatives that involve nonprofit activities but lack broad educational output may be reviewed by GDRC on a case by case basis.

As Cyberonics uses the term, a grant is tangible value (e.g., funds) given for a specific purpose without expecting -- or receiving -- substantial tangible value in return. (The recipient's gratitude is not "tangible value.")

d) In the education context, Cyberonics provides "unrestricted" grants. As used here, "unrestricted" means that Cyberonics does not control or influence the content of the supported activity, such as the selection of the curriculum or faculty. If Cyberonics has control or influence over the activity, we cannot support it by or through a grant.

e) Grants monies are, however, "restricted" in the sense that funds are earmarked for the supported activity and cannot be used by the recipient for other purposes. The purpose for which the grant will be used is specified by the requesting organization and is agreed to by all parties through the grant process.

f) We cannot give grants to market a product or generate business from the recipient. Thus, a grant cannot be used to:

i) Give preference to high prescribers or purchasers of VNS Therapy™
ii) Fulfill a customer's business needs
iii) Respond to a customer's request for product discounts

The facts and circumstances surrounding the award of a grant should never permit an observer to infer that the grant was given to influence prescribing or gain formulary access. The inappropriate use of grants exposes our employees, our customers, and the Company to criminal and civil liability under the healthcare laws.

g) Grant vs. Service Arrangement

i) When Cyberonics makes a payment or contributes value and receives tangible value (*e.g.*, services) in return, then our payment or contribution is not a grant. Instead, it's a payment for services.
ii) All service arrangements -- especially those that involve customers -- require a written Consulting Agreement that describes the business relationship between Cyberonics and the other party, as discussed in these Business Practice Standards.
iii) The GDRC, a multidisciplinary group consisting of representatives from Clinical & Medical Affairs, Legal, and Marketing, reviews and approves applications for educational grants.

2) Critical Compliance Issues

a) The government may view a grant tied to referrals as an "off-invoice" or unreported discount. This could expose Cyberonics to liability under the False Claims Act.

b) Grants that do not comply with Food and Drug Administration (FDA) and American College for Continuing Medical Education (ACCME) criteria are also suspect and likely to be viewed as inappropriate.

c) It's essential, then, that all grants comport with Cyberonics policy and procedure. Our grant review processes are designed to rigorously test the substance and form of grant requests for compliance with applicable laws and policies.

3) Types of Grants

a) Educational Grants -- Cyberonics provides educational grants for four general categories of educational activity:

i) Continuing Medical Education programs presented by accredited providers
ii) Education programs for Health care Professionals
iii) Patient or Community Education programs
iv) Disease Screening programs

b) Continuing Medical Education (CME) Grants

i) Accredited CME activities are subject to rules issued by the Accreditation Council for Continuing Medical Education (ACCME). ACCME applies standards for commercial support of continuing medical education, which can be found at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.
ii) Cyberonics follows these rules when providing financial support to accredited CME programs. Violating these rules can subject a program to challenge by the Department of Health and Human Services Office of the Inspector General (OIG) and other governmental agencies, and may even result in criminal prosecution.

c) CME Program Invitations and Business Reply Cards. ACCME guidelines allow the sponsor of an accredited CME program to ask a supporter's sales force to distribute invitations or business reply cards (BRCs) for the CME event.

i) Invitations or BRCs cannot be distributed by Cyberonics without a written request from the program sponsor as part of the sponsor's original grant proposal. Any CME program invitation or BRC proposed for sales representative distribution must be reviewed and approved by CRB.
ii) The CME provider also may request Cyberonics' support in distributing enduring materials associated with the CME program. Enduring materials may include slide kits or summaries of the program that are prepared after the presentation to provide an enduring record of its content. Any enduring materials must be reviewed and approved by CRB before they may be distributed by Cyberonics personnel.

4) Compliance Measures & Approval Guidelines

Cyberonics has six primary guidelines for educational grants. These guidelines guide the actions of the GDRC in their review of educational grant requests.

a) *Educational Focus* -- The grant must serve a clearly defined, legitimate research, health, education or scientific purpose. It also must result in educational output, and/or directly benefit patient care.

i) The focus of any meeting or event must be scientific or educational presentations that enhance the practice of medicine. Guiding principals of the educational focus include:

(1) The majority of the meeting time must be dedicated to education/science
(2) Business topics (*e.g.*, "coding," office management) are not appropriate, because they help the provider do business better rather than help patients or enhance the practice of medicine
(3) The venue must be appropriate for, and conducive to, educational programming
(4) Topics and programs that support Cyberonics' mission will be given preference

b) *Independence* -- To be considered "independent," the recipient of the grant (not Cyberonics) must choose:

i) Faculty, speakers, content, educational methods, materials and venue

Cyberonics employees may provide the recipient with input about faculty, speakers, content, etc. if asked in writing.

ii) Funding for educational grants is limited to programs that have not already been presented to ensure the "independence" of the educational content of the program. If decisions about funding were made after the presentation, that could be seen as a form of influence over its content.
iii) Similarly, making decisions about encore funding after the initial presentation could be interpreted as an endorsement or approval of the content of the program. If the presentation went beyond our approved labeling or discussed off-label use(s) for one of our products, it could be construed as a form of off-label promotion.

c) *Balance*

i) Accredited CME and other educational programs funded by Cyberonics grants must be unbiased and objective in their design. In most cases, this means that the outline or agenda presented to Cyberonics for consideration must broadly address relevant therapeutic options (rather than focus only on VNS Therapy™).
ii) The proposal must also ensure that Cyberonics' sponsorship will be clearly disclosed orally at the program and, where possible, in any written communications (*e.g.*, invitations) related to the program.

d) *Reasonable Cost and Venue*

i) The grant request must include a realistic and comprehensive budget to be used entirely for the sponsored activity. Cyberonics' financial support may cover all or part of reasonable fees for speakers and their reasonable travel-related expenses. Cyberonics cannot fund or subsidize the following costs:

(1) Travel, lodging or personal expenses for attendees
(2) Compensation for attendees
(3) Extravagant (beyond market-value) speaker fees
(4) Lavish venues
(5) Other costs that are neither reasonable nor customary

e) *Broad Audience*

i) A broad audience extends beyond a single practice group. For example, staff physicians plus all physicians with visiting privileges at a hospital could constitute a broad audience. A medical group or hospital that advertises the availability of a program to other physicians in the community and welcomes outside attendees is generally a sufficiently broad forum or audience for a grant.

f) *Future Program*

i) For the same reasons that Cyberonics cannot decide to fund encore presentations after the initial presentation of a program, we cannot approve a grant request for a program that already has occurred. A grant request must be reviewed and approved prior to the date of the program.

g) GDRC Review Process. In accordance with the procedure set forth at www.Cyberonics.com, grant applicants must submit the following documents:

i) Request letter on the institution's letterhead, addressed to a Cyberonics employee, preferably the Compliance Specialist (generic letters are not acceptable). The letter should include:

(1) Name and mission/background of the requesting organization
(2) Educational need or public interest to be addressed
(3) Statement that the request is for an educational grant
(4) Total amount of the grant request
(5) Name and description of program or activity
(6) Proposed date(s) and location(s) for the program
(7) Target audience for the program and projected number of participants
(8) Identification of the CME provider, if applicable
(9) Identification of any third-party logistics or education providers who will be involved in the delivery of the program, if applicable
(10) Name and address of the organization to whom the check is to be paid
(11) Tax ID Number

ii) Proposed detailed agenda for the program or activity, including each speaker's name, affiliation, and title of presentation (topic alone is insufficient).
iii) Proposed budget for the program or activity, preferably broken down to reflect all costs, including:

(1) Pass-through expenses (*e.g.*, speaker and coordinator travel, meals, hotel, mailing, *etc.*) and the number of people who will receive reimbursement for those expenses
(2) Speaker fees -- costs per person or organization
(3) CME accreditation costs and fees (or statement that these are being waived or absorbed, if applicable)
(4) Program development costs
(5) Service provider fees (*e.g.*, a meeting planner) and specific activities

iv) The Cyberonics Compliance Specialist will ensure that:

(1) The grant is for a *bona fide* independent activity
(2) The proposed budget is reasonable
(3) The recommendation to submit or fund the grant is based on the merits of the proposal, not on any business relationship between Cyberonics and the recipient or patronage of VNS Therapy™ by the recipient (or lack thereof)

v) Submit all required paperwork to GDRC 21-28 days before the proposed activity in order to help assure adequate time for review.
vi) The Grants and Donations Review Committee Review Process can be found on the website at http://www.Cyberonics.com.
vii) After the recipient conducts the funded activity, the recipient is expected to send a letter to Cyberonics that acknowledges the receipt of the funds and confirms that the requested funds were spent on the (completed) activity.

Chapter 13

Discounts

1) Key Points

a) All price discounts and rebates granted by Cyberonics to purchasers of VNS Therapy™ shall comply fully with the standards of the discount Safe Harbor (42 U.S.C. § 1320a-7b(b)(3) and 42 C.F.R. § 1001.952(h)).

b) As a general rule, discounts are encouraged by the government so long as the government shares in the discount where appropriate. Any arrangement that results in a payor receiving less than their proportional share of cost-savings resulting from a discount or rebate is prohibited.

2) Critical Compliance Issues

a) Because discounts provide a direct financial incentive for a customer to purchase VNS Therapy™, they must comply with the discount Safe Harbor to the Anti-Kickback law to be appropriate.

b) Cyberonics strictly prohibits so-called "one off" discounts. These are disguised discounts that are granted to a customer to incentivize that customer to purchase VNS Therapy™. For instance, telling a customer that they will not receive a discount, but that Cyberonics will support an educational grant instead, is a "one off" discount and strictly prohibited.

3) Compliance Measures

a) All discounts shall take the form of a simple volume discount; that is, a specified reduction in price in consideration of an agreement to purchase not less than a particular number of VNS Devices at one time or over a specified period of time not to exceed one year. The arrangement may be structured to provide discounts of increasing magnitude with increasing volumes of VNS Therapy™ devices purchased.

All proposed discount programs must be approved by the Legal Department prior to implementation.

b) Limited to a Single Fiscal Year of Purchaser. If the discount extends to purchases over a specified period of time, the discount must be earned based on purchases within a single fiscal year of the purchaser (*i.e.*, the amount of the price discount earned by the purchaser in one fiscal year of the purchaser cannot be dependent on the volume of purchases in a later fiscal year of the purchaser).

c) The discount must be described fully and accurately in a written document signed on behalf of Cyberonics and provided to the purchaser.

   i) Cyberonics' written acknowledgment shall include in substance the following statements calculated to call to the purchaser's attention its potential reporting responsibilities:

      (1) "In accordance with federal regulations (42 C.F.R. § 1001.952(h)), all discounts made pursuant to this agreement must be treated by the purchaser as discounts on the VNS Therapy™ on which the discounts are earned and must be properly reported on purchaser's Medicare and Medicaid cost reports, as applicable. Please retain a copy of this document, Cyberonics' invoices, and any other communications from Cyberonics regarding this matter and permit agents of the U.S. Department of Health and Human Services, any state Medicaid agency, or other authorized officials access to such records upon request."

d) Cyberonics must refrain from doing anything that would impede the purchaser from meeting its reporting responsibilities to the government. The discount must be recorded fully and accurately on the invoice or statement submitted to the purchaser. The discount must apply to all VNS Devices purchased by the purchaser at any one time, unless all VNS Devices purchased by the purchaser are reimbursed by the same federal or state health care program using the same methodology.

e) Only the Vice President of Sales, or his designee, can approve discounts to any purchaser. Sales representatives are not authorized to offer discounts to any purchaser, under any circumstances.

f) Cyberonics shall not offer or agree to provide any cash, services, or other benefits as an incentive to purchase VNS Devices.

g) Cyberonics' Finance Department shall prepare and submit to each member of Cyberonics' Executive Management no later than one week following the end of each fiscal quarter a report listing for each discount sale during the preceding quarter, the purchaser, the date of purchase, the type and quantity of VNS devices purchased, the purchase price, and the discount granted.

Chapter 14

Screening

1) Key Points

a) Cyberonics shall routinely screen current and potential new employees and independent contractors to insure that Cyberonics does not hire or engage or maintain the employment of or engagement of any person or entity ineligible to participate in federal health care or procurement programs.

b) "Ineligible Person" is an individual or entity who (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal Health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

2) Compliance Measures

a) Prior to employment of any individual or engagement of any contractor, Cyberonics shall ensure that such individual or contractor is not an Ineligible Person by screening such individual or contractor by

i) requiring such individual or contractor to disclose whether they are Ineligible Persons; and
ii) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the Department of Health and Human Services / Office of the Inspector General List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists shall hereafter be referred to as the "Exclusion Lists").

b) Cyberonics' Human Resources Department shall be responsible for screening employees and potential employees. Cyberonics' Legal Department shall be responsible for screening independent contractors. The Human Resources and Legal Departments shall maintain records reflecting the screening of each employee, potential employee, and independent contractor.

c) Cyberonics shall require all employees and contractors to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

d) At least once each year, Cyberonics shall review a list of all current employees and contractors against the Exclusion Lists to identify any current employees or contractors who are Ineligible Persons.

e) If Cyberonics has actual notice that any individual or contractor has become an Ineligible Person, Cyberonics shall terminate such individual or Cyberonics' engagement with such contractor as soon as practicable.

f) If Cyberonics has actual notice that any individual or contractor is charged with a criminal offense related to any Federal Health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, Cyberonics shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any patient, or the accuracy of any claims submitted to any Federal Health care program.