

**The**  
**Cyberonics**<sup>®</sup>

**International**

**Business Practice Standards**

# Introduction

At Cyberonics, our mission is to improve the lives of people all over the world 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 all over the world.

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 and agents and agents of Cyberonics worldwide, we shall comply with all applicable laws and regulations in any 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 International Business Practice Standards, along with the U.S. 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 International Business Practice Standards, including those responsible for the failure to exercise proper supervision and oversight to detect and report a violation by others, and (iv) promote honest, ethical conduct in our day-to-day business operations.

We consider compliance with these International 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,

Darren W. Alch  
Assistant General Counsel &  
Compliance Officer

# Chapter 1

## Overview

### Introduction

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- b) *Compliance is both doing the right thing, and the right thing to do.* Integrity and ethical behavior are bedrock values of the worldwide health care system and they are critical to Cyberonics' long-term success. To gain the trust of the customers we serve in every corner of the world, Cyberonics employees and agents 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 applicable 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.

### What Are The Cyberonics International Business Practice Standards?

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- b) The International Business Practice Standards establish a framework for interactions between Cyberonics personnel and customers, as well as the way we communicate about VNS Therapy™ in every market we do business. Any Cyberonics personnel unsure about the appropriateness or legality of a customer interaction, event or any other issue should consult with their manager, 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 International Business Practice Standards offer an overview of the laws, rules and Cyberonics policies related to compliance. The International 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 and agents in a complex regulatory environment. Compliance also protects our customers, who are subject to many of the same health care laws and rules.*

- b) If you have a question about how a compliance policy relates to you, refer to the relevant section of the International Business Practice Standards, consult with your manager, or ask the Cyberonics Compliance Officer.
- b) The International Business Practice Standards provide an overview of various 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
- b) All Cyberonics employees and agents are expected to have a basic understanding of laws that apply to our industry. Those employees and agents who interact with patients, providers, payors, advocacy groups, and other customers are expected to understand how health care laws affect our business.

### **Employee & Agent Responsibility**

- b) Employees and agents are expected to know and follow the laws of each relevant market in which Cyberonics does business. Employees and agents are also expected to comply with the provisions of these International Business Practice Standards. Managers are expected to ensure such compliance. It is the responsibility of every employee to promptly bring violations and suspected violations of these International Business Practice Standards to the attention of the Company, through management, Cyberonics Legal Counsel, or the Compliance Officer, or by using the Cyberonics Compliance Line described below.
- b) Employees and agents at all levels are prohibited from retaliating against or threatening anyone for reporting or supplying information about a policy or conduct concern. Cyberonics has established and will maintain a written program to ensure compliance with the law and with these and other policies the Company may adopt. The program consists, among other things, of these International Business Practice

Standards, the Cyberonics Code of Conduct, CyberU training programs, live training, periodic audits, and a Compliance Line. The toll-free Compliance Line, as well as an anonymous email address, is available to all employees and agents to report conduct believed to be in violation of these International Business Practice Standards or any applicable policy or law.

- b) Information transmitted through the Compliance Line or the Compliance email (See Section 7 of this Chapter) will be investigated thoroughly and the identity of the source will be maintained in confidence, unless otherwise required by law.
- b) Adherence to all laws and regulations in the countries in which we operate, and to the policies in these International Business Practice Standards, is a condition of employment for every Cyberonics employee. Violations could expose the employee and Cyberonics to civil and criminal liability and could harm the Company's reputation and competitive position. Violations will be dealt with promptly and may result in disciplinary measures up to and including the termination of employment.
- b) Although these International Business Practice Standards provide a framework to guide business conduct, they do not cover every situation. Please contact Cyberonics Legal Counsel if you need assistance in understanding or interpreting them.

### **Overview of Key Areas**

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- a) Certain activities that are common practice in many businesses can violate several laws in the health care industry. Violations can lead to 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 and agents 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) Improper Payments
  - i) No bribes, kickbacks, or other payments for illegal purposes shall be made to or for the benefit of government employees and agents or officials, customers, or others. This policy extends not only to direct payments, but also to indirect payments made in any form through consultants or other third parties.
  - ii) For example, this Standard 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. Laws in most countries seek to protect patients and government employees and agents from improper influence on health care decisions.***

c) Appropriate Payments

- i) Cyberonics may compensate customers for consulting, research and other services rendered, and reasonable costs incurred where the services have value to Cyberonics and are rendered for fair market value. Such arrangements must be in writing in a form approved by the Cyberonics Legal Department and must comply with local business conduct standards.
- ii) Cyberonics has a responsibility to provide instruction, education, and training on the safe and effective use of its products to health care providers. If Cyberonics provides honoraria or reimbursement of travel, living, or meal expenses to participants, the amount must be reasonable and in compliance with local Business Conduct Standards.
- iii) Cyberonics may, under some circumstances, underwrite the cost of continuing medical education conferences or professional meetings (e.g., registration fees, travel, living, and meal expenses). The laws regarding this type of support are complicated and such payments are not allowed in every country. In some countries, payments can be made only to the sponsor of the event or the institution of the attendee. All such payments must comply with local business conduct standards and be approved by the legal department.

d) Customer Relationships

- i) No benefit will be given to a customer with an explicit or implicit requirement to use or purchase Cyberonics products. "Customer" is used throughout these standards to mean any person or entity that is in a position to purchase or influence a decision to purchase Cyberonics products.
- ii) Certain discounts, rebates, free products, demos, equipment loaners, and warranty services furnished in the ordinary course of business are permitted, provided such benefits comply with local business conduct standards and Company policies regarding such issues.
- iii) Business courtesies such as meals, transportation, and entertainment provided to a customer must be modest in amount and related to a legitimate business purpose

(e.g., explanation or demonstration of Cyberonics products, application of products, service capabilities, or training).

e) Fair Dealing

- i) All employees and agents should deal fairly with Cyberonic's customers, suppliers, competitors and employees and agents. No one should take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts, or any other unfair-dealing practice.

f) Recordkeeping

- i) Cyberonics entities will maintain accurate Company records and accounts in order to ensure legal and ethical business practices and to prevent fraudulent activities. Finance managers for Cyberonics businesses, including subsidiaries worldwide, have the responsibility to express their independent views to, and raise any significant issues with, the Chief Financial Officer or the Compliance Officer. Records and accounts must be complete and not misleading. All Company accounting records, and the reports produced from those records, must be kept and presented in accordance with all applicable laws and relevant accounting standards.
- ii) No undisclosed or unrecorded funds or assets of Cyberonics may be maintained for any purpose. No more than one set of books may be maintained and no false or artificial entries may be made in any accounts.

g) Antitrust/Competition

- i) Antitrust laws in the U.S. and competition laws outside the U.S. exist to ensure free and open competition in the marketplace, a principle that Cyberonics fully supports. Violation of these laws can result in civil liability and criminal penalties for Cyberonics and its employees and agents. These laws are complex and, consequently, employees and agents may not take any collaborative action with a competitor, or take any action that could have an improper anti-competitive effect, without prior advice from Cyberonics Legal Counsel.
- ii) Examples of prohibited conduct include:
  - (1) Agreements or understandings with competitors, either directly or through others, to fix prices, divide customers or territories, or restrict sales;
  - (2) Exchange of pricing or other proprietary information with competitors; and
  - (3) Illegal tying, illegal price discrimination or refusals to deal.
- iii) Cyberonics management maintains basic familiarity with the principles and purposes of the antitrust laws as they apply to Cyberonics business, and abstains from any activities that might violate or create any appearance of intention to

violate such laws. Cyberonics employees and agents are expected to understand the antitrust principles that apply to their activities. All employees and agents are to seek guidance from Cyberonics Legal Counsel in any circumstances where doubt exists.

h) Export Controls, Economic Sanctions, and International Boycotts

- i) Cyberonics must comply with export control and economic sanctions laws of the United States, as well as those of other countries in which it does business. These laws restrict transfers, exports, and sales of products or technical data from the United States to certain prescribed countries and persons as well as re-exports of certain such items from one non-U.S. location to another. They also prohibit or restrict other business and financial dealings with certain countries, governments, and parties.

- (1) Cyberonics and its employees and agents are required to comply with these laws without exception. These laws are complicated and employees and agents should contact Cyberonics' Compliance Officer and/or Cyberonics Legal Counsel whenever a question arises.

- ii) In addition, U.S. law prohibits cooperation with certain boycotts imposed by some countries against others and further requires that any request in furtherance or support of such boycotts be reported to the U.S. Government. The most notable of these is the Arab boycott of Israel. Cyberonics employees and agents may not cooperate with any prohibited boycotts and must report any request for cooperation immediately to management, the Cyberonics Compliance Officer, and/or Cyberonics Legal Counsel.

i) Conflict of Interest

- i) Cyberonics employees and agents owe a duty of undivided business loyalty to the Company. This duty is breached when an employee engages in activities that cause a conflict of interest. Conflicts of interest may arise when considerations of gain or benefit to an employee or an employee's immediate family members conflict with or appear to conflict with the employee's obligation to serve Cyberonics' best interest or the employee's ability to perform company work objectively and effectively. Anything that would be a conflict of interest for an employee may also be a conflict of interest if it involves an immediate family member. Conflicts of interest can take many forms, not all of which can be addressed by these International Business Practice Standards.

- ii) The following are examples of conflicts of interest:

- (1) Consulting with or employment by a competitor, supplier, or customer of Cyberonics;

- (2) Holding a substantial equity, debt, or other financial interest in any competitor, supplier, or customer;
  - (3) Having a financial interest in any transaction involving the purchase or sale by Cyberonics of any products, materials, equipment, services, or property, other than through Company-sponsored programs;
  - (4) Using employees and agents, materials, equipment, or other assets of Cyberonics for any unauthorized purpose; or
  - (5) Accepting any cash, gifts, entertainment, or benefits that are more than modest in value from any competitor, supplier, or customer. A manager must approve acceptance of any benefit of more than modest value from a competitor, supplier, or customer.
- iii) Each employee and agent is responsible for avoiding conflicts of interest as well as the appearance of such conflicts. Employees and agents who are unsure whether they are involved in a conflict of interest or whether an action might create a conflict of interest should discuss the issue with their manager or with Cyberonics Legal Counsel. A conflict of interest or potential conflict of interest may sometimes be resolved or avoided if it is appropriately disclosed and approved. However, in other instances, disclosure may not be sufficient and Cyberonics may require that the conduct be stopped or that actions taken be reversed where possible.
- j) Insider Trading
- i) All Cyberonics employees and agents and agents are prohibited from engaging in insider trading. Insider trading is trading in Cyberonics stock while aware of confidential information about the Company that could, if it became public, affect the stock price. Disclosure of any information to another person, such as a spouse or friend, which would enable them to gain a trading benefit not available to the general public, is prohibited as well.
  - ii) Similar restrictions apply to trading in the stock of other companies using confidential information that an employee has access to because of his or her employment.
  - iii) This conduct is illegal and could subject the employee and Cyberonics to civil liability and criminal penalties.
- k) Intellectual Property and Confidential Information
- i) Cyberonics invests substantial resources in developing proprietary intellectual property and confidential information. Confidential information is information that is not generally known or readily available to others. Cyberonics protects its intellectual property by seeking patent, trademark, or trade secret protection. It protects its confidential information by taking precautions to prevent inappropriate disclosure or loss of such information.

- ii) Cyberonics respects the intellectual property of others. Early in the product development cycle, Cyberonics conducts patent searches to avoid infringing patents of others and, when necessary, makes design changes or seeks licenses. Confidential information is critical to Cyberonics' competitive advantage. This includes technical know-how and data, trade secrets, business plans, marketing and sales programs, and sales figures, as well as information relating to mergers and acquisitions, stock activities, divestitures, licensing activities, and changes in senior management.
  - iii) Confidential information also includes personal information about Cyberonics employees and agents, such as salaries, benefits, and information contained in personnel files. Confidential information must not be shared with others outside Cyberonics except pursuant to approved business relationships; nor may Cyberonics employees and agents accept confidential information from third parties, including competitors, without the authorization of Cyberonics Legal Counsel.
- l) Corporate Opportunities
- i) Employees and agents may not take for personal use opportunities that are discovered through the use of corporate property, information or position, nor may they use corporate property, information or position for their own personal gain or to compete with Cyberonics. Employees and agents have a duty to advance Cyberonics' interests when the opportunity to do so arises.
- m) Protection and Proper Use of Company Assets
- i) All employees and agents should protect Cyberonics' assets and promote their efficient use. Theft, carelessness and waste have a direct impact on Cyberonics' profitability. All Cyberonics assets should be used for legitimate business purposes.
- n) Clinical & Regulatory Affairs
- i) Cyberonics products are heavily regulated by governmental agencies, health ministries, and other regulatory authorities worldwide. Every employee is responsible for compliance with worldwide product regulation requirements, including marketing approvals, conduct of clinical studies, good manufacturing practice requirements and standards, design controls, labeling and advertising controls, and any other product regulations and controls promulgated by government agencies.
  - ii) Each employee is responsible for reporting any significant issues to management. Cyberonics is committed to maintaining an open, constructive and professional relationship with regulators on matters of regulatory policy, submissions, compliance, and product performance.

o) Quality

- i) Cyberonics is committed to producing the highest quality medical devices in the interest of patient safety and to maintain its reputation for excellence through customer-focused quality. Cyberonics will comply with all laws and regulations regarding the safety and efficacy of its products and the standards for its manufacturing plants.
- ii) Each employee is responsible for reporting any concerns that relate to a compromise of quality to management.

p) Environmental Management

- i) Cyberonics is committed to doing business in an environmentally responsible manner and will strive to improve its performance to benefit its employees and agents, customers, communities, shareholders, and the environment. All employees and agents are responsible for making sure that Cyberonic's business is conducted in compliance with all applicable laws and in a way that is protective of the environment.

q) Safety & Health

- i) Cyberonics is committed to a safe, healthy work environment that is in compliance with all applicable laws and regulations. All employees and agents are expected to develop a pro-active, cooperative attitude toward issues of health and safety throughout the Company.

r) Working Environment

- i) Cyberonics is committed to a productive work environment. Key elements for developing such an environment include freedom from harassment in any form, a culture that recognizes and appreciates the advantages of a diverse work force, and a decision process which seeks to ensure that all employees and agents are treated with dignity and respect.
- ii) Discrimination on the basis of race, religion, gender, color, ethnic or national origin, age, disability, sexual preference, or marital status will not be allowed. This includes discrimination in hiring, training, advancement, compensation, discipline, and termination.
- iii) Harassment, such as racial or sexual harassment, will not be tolerated and should be reported to the appropriate manager or Human Resources representative.

s) Political Activity

- i) Cyberonics supports your right to participate actively in the political process. However, you must have written approval in advance from the Cyberonics Chief Executive Officer or General Counsel for solicitations made during work hours or

- on Cyberonics property on behalf of any political party, candidate committee or other election fund.
- ii) No corporate funds, or other corporate assets, may be contributed directly to any political party, political committee, or candidate for public office at the federal level, or at the state level unless permitted by law, with the exception of funds used to administer any corporate political action committee that may be formed.
- t) People Acting on Behalf of Cyberonics
- i) Cyberonics expects its independent dealers, distributors and agents to comply with the policies set out in these International Business Practice Standards. The Cyberonics manager responsible for any such relationship must ensure that the terms of the relationship are set out in a written agreement, provide a copy of these International Business Practice Standards, and require compliance with these International Business Practice Standards in all dealings on Cyberonics' behalf. Promoting or engaging in any practices that violate the principles of this Code may result in termination of the relationship.
- u) Government, Analyst and Media Inquiries
- i) Cyberonics must be made aware of any inquiries from the government, the financial/analyst community, or the media so that it can properly and thoroughly respond. If a Cyberonics employee is contacted by a representative of a governmental agency seeking an interview or making a non-routine request for documents, that employee should immediately contact Cyberonics Legal Counsel so that appropriate arrangements can be made to fully comply with the Company's legal obligations.
  - ii) All inquiries from the financial/ analyst community should be referred to Investor Relations. All media inquiries should also be referred to Investor relations in the U.S.

### **Particular Risk Areas for Cyberonics**

- a) 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 in all jurisdictions. For this reason, all employees and agents 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.

- 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.
- 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 in all countries.
- iv) *Consultants:* Cyberonics may retain and pay qualified physicians and other experts to provide services, such as speaking at promotional programs. 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 in all countries in which we operate.
  - (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.

### **Reporting Compliance Concerns**

- b) Cyberonics seeks to create an environment in which all employees and agents 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.
- c) 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 International 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](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 International Compliance Hotline is an international toll-free telephone line. The Compliance Hotline is answered by voice-mail, and anyone may leave a voice-mail message for the Compliance Officer.
- iii) The International Compliance E-mail Box ([intlcomphotline@cyberonics.com](mailto:intlcomphotline@cyberonics.com)) is an electronic mailbox directed to the Compliance Officer.
- d) 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](mailto:ComplianceOfficer@cyberonics.com)***

- e) 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 International 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.***

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

### **Sanctions**

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- g) Sanctions for noncompliance with these International Business Practice Standards may include oral or written warning, disciplinary probation, suspension, reduced compensation, demotion, dismissal from employment, or termination of any contractual relationship the company may have. Any Cyberonics employee or agent who materially or repeatedly violates these International Business Practice Standards 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

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- 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 in every country in which we operate. 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.

### Critical Compliance Issues

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- d) It is generally illegal for a medical device company to promote an unapproved device or to solicit off-label use of an approved device. Soliciting off-label use of approved products can result in prosecutions, substantial fines and loss of reimbursement from state-supported payors.
- e) All marketing and sales messages about VNS Therapy™ are carefully reviewed to help ensure that they will stand up to government and competitor scrutiny.

### Compliance Measures

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- 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 in all countries.

***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. Their use can result in discipline up to and including termination of employment or termination of a contractual relationship.
- 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.
  - iii) Text must present a “fair balance” of VNS Therapy’s™ risks and benefits.
  - 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.
- 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 in the country where the claim is made.
  - 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) Quotations and studies must be referenced.
  - v) 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) 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.***

- g) 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™.
- h) *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) To help ensure compliance, Cyberonics sales representatives may only use CRB-approved materials.
- i) All ***off-label questions*** should be referred to Cyberonics' Clinical & Medical Affairs Department.

# Chapter 3

## Consultants

### 1) Key Points

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- 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) 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.

### Critical Compliance Issues

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- 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 specific laws and regulations in all countries.
- 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™.

### Compliance Measures

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- a) Our guidelines for engaging consultants are based on worldwide laws and regulations that recognize that consultants can provide *bona fide* services to Cyberonics and receive fair market value compensation in return.
- b) When contracting with consultants, consulting positions may not be offered to:
  - i) influence VNS Therapy™ prescribers or potential prescribers

- ii) merely develop relationships or gain access
  - iii) promote off-label use of VNS Therapy™
- c) 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?
- d) Government Employees and agents.
- (1) Sometimes, we interact with doctors, pharmacists and other health care professionals employed by a governmental authority. Special rules often regulate government employees and agents' attendance at meetings or their engagement as speakers or advisors.
  - (2) Some governments' rules prohibit accepting gifts from contractors that do business with the government, and government employees and agents are subject to rigorous conflict-of-interest rules.
  - (3) Be wary of these restrictions and consult the Legal Department when inviting government employees and agents to a meeting, or engaging a government employee as a speaker or other consultant.

# Chapter 4

## Marketing Programs

### 1) Key Points

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- 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) As a general rule, when engaged in marketing activities, Cyberonics (and its third-party agents) must adhere to 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.
- c) 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.

### Critical Compliance Issues

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- a) 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 appropriate country authority.
- b) All marketing programs must present information consistent with VNS Therapy™ approved product labeling.

### Compliance Measures

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- 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) 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. 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.

# Chapter 5

## Business Courtesies

### 1) Key Points

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- a) Cyberonics policy permits 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) 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.
- c) Stringent conflict of interest rules in some states and governments can make it illegal for manufacturers to offer gifts and meals.

### Compliance Measures

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- 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 that primarily benefit patients may be offered occasionally to physicians or other health care professionals if they’re not of substantial
  - iii) 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.

- d) A country's 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.*

# Chapter 6

## Research

### 1) Key Points

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- 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 help us ensure that our clinical trials conform to government and ethical requirements.

### Critical Compliance Issues

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- a) Payments to physicians or others may violate laws 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) Cyberonics policy and most countries' 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.

### Compliance Measures

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- 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.

### **General Considerations**

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- 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.
  - iii) All human study participants must provide voluntary adequate 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. The basis for such compensation must also be specified in the written contract with the investigator.
- 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. 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 the applicable jurisdiction's 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 evaluated by Cyberonics along with supporting documentation that describes the study, so that a decision can be 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 information about IRGs posted at: [www.cyberonics.com](http://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 and agents may not write a protocol for an independent investigator.
- v) A request for clinical supplies to support bona fide scientific investigations can be referred for consideration as an IRG.