QOL Medical, LLC

Comprehensive Compliance Program—California

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I. INTRODUCTION--ESTABLISHING A COMPREHENSIVE COMPLIANCE PROGRAM

QOL Medical hereby presents its Comprehensive Compliance Program ("CCP" or "Policy") to comply with California law (Cal. Health & Safety Code §§ 119400 – 119402.), regarding its interactions with healthcare professionals. To our knowledge as of the date of this declaration, November 2016, QOL Medical is in substantial compliance with our CCP, as described here, and with California Health & Safety Code sections 119400-119402. QOL Medical has modeled its Compliance Program after the "*Compliance Program Guidance for Pharmaceutical Manufacturers*" issued by the Office of Inspector General ("OIG") of the Department of Health and Human Services (HHS) in April of 2003. Likewise, QOL Medical has followed the spirit of the Pharmaceutical Research and Manufacturers of America ("PhRMA") "*Code on Interactions with Healthcare Professionals*" in designing this CCP which is an element of a more comprehensive Compliance Program at QOL Medical. QOL Medical has adopted its own Compliance Program in response to the complex issues and the responsibilities involved in interacting with healthcare professionals. This CCP is internal to QOL Medical and is not intended to convey any legal rights upon any customer, shareholder, or other third party.

The OIG Guidance focuses on three potential risk areas for manufacturers in its 2003 guidance. They are as follows: 1) the integrity of data used by state and federal governments to establish payment; 2) kickbacks and other illegal remuneration; and 3) compliance with laws regulating drug samples.

The compliance measures QOL Medical has adopted are unique to the Company. The ultimate responsibility for compliance lies not with QOL Medical's designated Compliance Officer, but with QOL Medical's Executive Committee.

This CCP incorporates and commits to the following:

1) This written CCP articulates the Company's commitment to compliance in the pharmaceutical industry;

2) Other written internal standard operating procedures may be adopted from time to time addressing specific areas of concern with and susceptibility to potential violations of the law in the interaction with healthcare professionals and other customers;

3) The designation of a Compliance Officer whose job it is to develop, operate, monitor, and facilitate training of employees on the Compliance Program. Given the size of QOL Medical, the role of Compliance Officer is an additional and part-time responsibility for an existing employee. This person is a member of and reports directly to the Executive Committee;

4) A regular and effective education and training program for all affected employees and subcontractors. Training consists of initial training and annual training thereafter of management and sales personnel by external experts, and covers the Federal Anti-Kickback Statute, the False Claims Act, the Food, Drug & Cosmetic Act as it relates to advertising and promotion, the Physician Payment Sunshine Act and related state laws, among other bodies of law;

5) An annual review and audit of the compliance program by management to identify problem areas and to address gaps and opportunities for improvement; and

6) The development of policies and procedures addressing the non-employment or retention of individuals or entities excluded from participation in federal healthcare programs and addressing appropriate disciplinary action against employees and subcontractors who have violated Company policies and procedures and applicable federal healthcare program requirements.

II. LAWS APPLICABLE TO INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND QOL MEDICAL POLICY

There are three primary federal laws which govern the interaction between healthcare professionals and medical device companies. These include 1) FDA's advertising and promotion regulations and guidance promulgated under and pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), 2) the Anti-Kickback Statute, and 3) the False Claims Act. These statutes are intertwined and sometimes all apply to the myriad of advertising and promotional programs that companies conduct as well as in the many other ways that companies interface with healthcare professionals. Some examples of how companies interact with healthcare professionals are conducting market research or using advisory boards, providing reimbursement advice and drug samples, providing grants for medical education and symposia, consulting with physicians, and supporting physician-initiated clinical trials. The regulatory environment in this arena is complex and this Policy will not cover every conceivable program or circumstance, but it provides some operating principles and a framework for analyzing issues.

FDA Advertising and Promotion Regulations. FDA's advertising and promotion laws and regulations address the claims a company can lawfully make about its products. To implement the law, we must be truthful, not misleading, and fairly balanced in the claims we make about our products. This requires that claims must be substantiated. The claims we make about our products can be direct, indirect, express, or implied. The FDA looks to the claims we make about our products to determine the true "intended use(s)" we claim for our products. Often the claims we make about our products are subtle and not direct or expressed. A company in its advertising and promotion of products can indirectly or impliedly expand the claims made about those products beyond the approved labeling. This can make our advertising or promotion unlawful.

The promotional arena has been impacted by some court cases, the most notable of which is the Washington Legal Foundation ("WLF"), in which WLF challenged three FDA Guidance documents which WLF alleged limited First Amendment commercial free speech. The FDA, in large measure, lost that case. This case and others have limited the way FDA regulates such things as a) the dissemination of information about off-label uses of a company's products, b) a company's ability to sponsor continuing medical education courses on off-label uses, and c) a company's ability to provide financial support for physician-initiated clinical trials on off-label uses.

In complying with FDA's advertising and promotional law, QOL Medical shall promote based upon the approved claims for its products. QOL Medical shall be truthful, not misleading, and fairly balanced in the claims it makes about its products. If off-label information is shared with healthcare professionals, it will be done appropriately and lawfully given the current state of the law.

Anti-Kickback Statute. Federal and some state laws impose criminal and civil penalties for offering or receiving any form of improper "inducement" to purchase, order, or recommend a healthcare item or service. The major purpose of these laws (often referred to as "anti-kickback" laws) is to ensure that the purchase or prescription of a product reimbursed by the government is based upon patient benefit, price, quality, service, and similar considerations. A purchase or prescription should not be based upon providing personal benefit to a customer who could compromise the purchase or prescription from being

made in the best interest of the patient. These laws are also intended to discourage the ordering or purchasing of medically unnecessary items or services. In addition, the federal government has become concerned that the increasing costs associated with sales "inducements" have an inflationary, and therefore harmful, effect on the nation's healthcare budget.

The Anti-Kickback Statute is designed to address paying "remuneration" to induce the purchase, prescription, or referrals to do the same, of goods or services reimbursed by the federal or a state government under Medicare, Medicaid, or a similar state or federal program. In addition to preventing improper inducements, here are some of the other principal purposes behind the statute: a) to prevent the over-utilization of goods and services reimbursed by the government, b) to level the competitive playing field to prevent distortions in the marketplace by competitors who do not abide by the law, and c) to ensure the government pays the true acquisition cost for goods and services and is the beneficiary of all discounts, whether explicitly disclosed or hidden. See 42 USC 1320a-7b(b).

Safe Harbors Under the Anti-Kickback Statute--The Anti-Kickback Statute does have "safe harbors" that protect certain types of conduct that actually fall under the scope of the statute and, but for the safe harbor, would be considered a violation of the law. The safe harbors, if followed, ensure that the conduct in question will not be the subject of a prosecution, hence the term "safe harbor."

QOL Medical shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement, i.e. remuneration, to induce the purchase, prescription, or referrals to do the same, of goods or services reimbursed by the federal or a state government under Medicare, Medicaid, or a similar state or federal program.

False Claims Act. The False Claims Act is designed to ensure the integrity of information provided to the government for the reimbursement of products. The statute applies when healthcare professionals submit claims for reimbursement to the government for products they have prescribed. A manufacturer is deemed liable for a False Claims Act violation if it somehow participates in a false claim for reimbursement being made by a healthcare professional where, for example, the healthcare professional miscodes, or otherwise seeks government reimbursement where no payment or a lower payment for reimbursement is due. In addition to inappropriate reimbursement payments, the False Claims act is triggered if there is an anti-kickback violation. The theory is that a party seeking reimbursement impliedly certifies that they are in compliance with all laws, such as the Anti-Kickback Statute, and if they are not, they are not entitled to reimbursement.

QOL Medical shall ensure that its role in providing reimbursement advice to healthcare professionals is in compliance with the law and does not encourage inappropriate reimbursement for its products.

III. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

A. AN OVERVIEW

This portion of the CCP addresses the Company's interactions with U.S. healthcare professionals and other customers and is intended to provide guidance about appropriate interactions with customers to all employees of QOL Medical conducting business within the United States to enable the Company to remain in compliance with the laws discussed above. To assure compliance, QOL Medical has a regular and effective education and training program for all affected employees and subcontractors. Contractors conducting business on behalf of QOL Medical must also comply with this Policy. These

policies apply to any expenditure by QOL Medical employees or contractors, regardless of whether the expenditure is reimbursed by the Company. In other words, any "personal" money given to or spent for the benefit of a QOL Medical customer is considered money given or spent by the Company.

Definition of "Customer"—As used in this Policy, the term "customer" means any individual or organization that purchases, recommends, uses, or prescribes products manufactured or distributed by QOL Medical, or an individual who is in a position to determine whether a QOL Medical product is purchased, recommended, used, or prescribed, if any of those products are reimbursed under a federal or state healthcare program. This can include physicians, nurses, physician assistants, medical assistants, office administrators, pharmacists, purchasing agents, hospitals, clinical practices, MCOs, HMOs, PBMs, GPOs, etc.

The following general standards and principles should at all times guide our interactions with customers:

- QOL Medical will encourage ethical business practices and socially-responsible industry conduct, and will not use any unlawful inducement in order to sell, lease, recommend, or arrange the sale, lease, or prescription of its products.

- QOL Medical believes that enduring customer relationships are based on integrity and trust. We seek to gain advantage over competitors through superior products, research, manufacturing, marketing and service never through improper business practices.

- QOL Medical's relationships with customers are intended to benefit patient care and enhance the practice of medicine. Interactions should be focused on informing customers and prospective customers about products, providing scientific and educational information, and supporting medical research and education and should not, at any time, entice representatives of customers to place their own personal interests above those of the organizations they represent or the patients who will use or need the Company's products.

- QOL Medical will not, directly or indirectly, offer or solicit any kind of payments or contributions for the purpose of obtaining, giving, keeping, or rewarding business.

B. GIFTS, EDUCATIONAL, AND PRACTICE-RELATED ITEMS

Subject to California law, QOL Medical has determined that the annual aggregate limit on covered promotional expenditures is set at $3,000.00 per healthcare professional for annual periods commencing on January 1st of each year. This limit may be revised by QOL Medical from time to time. The foregoing limit does not represent a usual, customary, average, or typical amount for medical or healthcare professionals.

Items primarily for the benefit of patients may be offered to customers or prospective customers if they are not of substantial value. For example, an anatomical model for use in an examination room is primarily for the medical education of the patient, whereas an iPod® is not. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Special laws related to gifts, educational, and practice-related items apply in other states. QOL Medical is in compliance with these laws.

IV. EXCEPTIONS TO THE CCP

Compliance with these Policies is mandatory and exceptions should be infrequent. All exceptions must be pre-approved by the Compliance Officer, must be supported by justification for the deviation, and must comply with applicable law.

V. CONSEQUENCES FOR NON-COMPLIANCE

Any employee who violates this CCP and any manager who knowingly permits or directs a subordinate to do so, will be disciplined accordingly, up to and including termination of employment. Any employee who suspects a violation of this policy is encouraged to discuss the matter with his or her supervisor. Employees may also contact the Compliance Officer.