

Thriving Through Turmoil: Managing Sales and Marketing Regulation of the Medical Device Industry

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Medical devices range from simple products, such as tongue depressors and surgical gloves to complex technological equipment, such as pacemakers and incubators. Just as medical devices vary widely, so too do the laws and regulations that govern their sales and marketing. As a result, in order to succeed in this challenging market, medical device manufacturers must master a complex assortment of conflicting laws, state and federal, that control their ability to effectively promote their products.

What are Medical Devices?

The Food and Drug Administration (FDA) regards any “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” that exhibits the following characteristics to be a “device”:

- Recognized in the official National Formulary, or the United States

Pharmacopoeia, or any supplement to them,

- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.¹

By its very definition, there is a patent distinction between medical devices and other FDA-regulated products such as drugs and biologics. The definition of device specifically excludes those articles

that achieve their “primary intended purposes through chemical action” in or on the body or depend on being metabolized.² As such, products that interact with the body via metabolic, pharmacological or immunological means are regulated as drugs or biologics, rather than as devices.³ In contrast, products that qualify as medical devices generally achieve their primary effects through physical action.⁴

The FDA’s Center for Devices and Radiological Health (CDRH) is responsible for the regulatory oversight of medical devices and those firms that manufacture, repackage, label or import medical devices into the United States. As with pharmaceuticals and biologics, medical devices are regulated according to their general complexity and risk to the public. The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments Act of 1976, provides for an explicit risk stratification for medical devices—Class I, Class II and Class III—with the level of regulatory oversight increasing from Class I to Class III devices.⁵

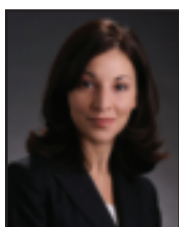
Why the Medical Device Industry is Unique

Inherent Differences

One of the key differences between the pharmaceutical and medical device



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industries is that there is an inherent intimacy between devices and healthcare professionals that is generally not seen in the pharmaceutical world. While pharmaceuticals are typically “discovered,” medical devices are designed and further refined in close collaboration with healthcare professionals. This practical distinction is significant when considering conflict of interest issues between the medical device industry and healthcare professionals.

By their very nature, most medical devices are primarily intended for professional use and therefore frequently serve as “an extension of a physician’s hands.”⁶ In the universe of devices, healthcare professionals function as “operators,” commonly deploying or using devices in their procedures, rather than merely prescribing them.⁷ As a result, physicians are often involved in both the conceptualization and evolution of cutting-edge device technology.⁸ Many healthcare professionals are medical device inventors or have been key advisors to a medical device company developing or refining a particular device.⁹ Healthcare professionals also frequently “test-drive” medical device equipment in order to make an educated decision about which device they will use or recommend for use.

In addition, medical devices require more extensive healthcare professional training and education than do pharmaceuticals. In fact, “the [FDA] mandates training and education to facilitate the safe and effective use of certain [medical device products]” post market approval.¹⁰ Given the inherent technique-specific character of medical devices, it is critical that healthcare professionals be closely involved with the device industry on this training and education. Healthcare professionals are in a unique position to

properly train and educate both their colleagues and the industry representatives who will conduct future educational and training sessions.

As “physician-industry interactions are necessary at virtually every stage of device development,” the medical device industry is replete with potential conflicts of interest.¹¹ These conflicts are more inherent in nature, but similar in kind, to those faced by the pharmaceutical industry: financial incentives for consulting, research grants and speaker positions.

Industry Guidance

Recognizing the distinctive traits of the medical device industry and the urgent need to manage potential conflicts of interest, the device industry developed the Advanced Medical Association (AdvaMed) *Code of Ethics on Interactions with Health Care Professionals* (AdvaMed Code). The AdvaMed Code—like its pharmaceutical counterpart, the Pharmaceutical Research Manufacturers of America (PhRMA) *Code on Interactions with Healthcare Professionals* (PhRMA Code)—is a voluntary code of ethics “intended to address the unique interactions” that occur between medical device companies and healthcare professionals.¹²

The AdvaMed Code draws a clear distinction between those activities that advance device innovation and those that inappropriately influence the independence of medical-decision making. In this regard, the AdvaMed Code addresses appropriate consulting arrangements, grants, sales and marketing meetings, the provision of gifts and meals, and support of continuing medical education events.¹³

As a code of ethics developed by the device industry, for the device industry, the AdvaMed Code also emphasizes the distinction between drugs and biologics, and medical devices. The AdvaMed

Code declares that devices “are dependent upon ‘hands on’ healthcare professional interaction” and underscores the importance of training healthcare professionals on the safe and effective use of medical technology.¹⁴

To this end, the AdvaMed Code, in contrast to the PhRMA Code, contains a section addressing company-conducted product training and education. In accordance with the AdvaMed Code’s principles, member companies may conduct training sessions in venues “that are conducive to the effective transmission of information,” including clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities.¹⁵

The AdvaMed Code also permits member companies to provide attendees with modest meals and refreshments in connection with these programs and to pay for the “reasonable travel and modest lodging costs” of the attending healthcare professionals.¹⁶

State Regulation of Medical Device Sales and Marketing Activities: A Nascent Hodgepodge of Method and Objective

The Existing Landscape

Perhaps there is no better demonstration of the disparate treatment of medical devices than in the myriad state laws and regulations governing marketing and sales activities and related interactions with healthcare professionals. In recent years, there has been increased scrutiny surrounding the interactions between the life sciences industries and medical professionals.

To date, seven states (California, Maine, Massachusetts, Minnesota, Nevada, Vermont and West Virginia) and the District of Columbia directly regulate sales and marketing activities of

the pharmaceutical industry. Yet, out of these seven states, only four—California, Massachusetts, Nevada, and Vermont—address the medical device industry.

California and Nevada regulate the promotion and marketing of medical devices by mandating the adoption of a “code of conduct” governing a medical device company’s interaction with healthcare professionals.¹⁷ These states are unique in that this requirement applies to both pharmaceutical *and* medical device manufacturers.

Under the California law, “every pharmaceutical company” must adopt a Comprehensive Compliance Program (CCP) that is in accord with the Office of Inspector General’s *Compliance Program Guidance for Manufacturers* and the PhRMA Code.¹⁸ The CCP must establish a company-determined limit on gifts or other incentives provided to healthcare professionals.¹⁹ A company must annually certify in writing that it is operating in compliance with its CCP and the law.²⁰

While at first glance the California law appears to regulate only pharmaceutical companies, a close reading of the statute reveals that a “pharmaceutical company” is defined as “an entity engaged in the production...packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs.”²¹ “Dangerous drug,” in turn, includes “any drug or *device* that, pursuant to federal or state law, may be dispensed only by prescription...”²² While devices fall within the purview of the California law, the law fails to address the unique traits of the device industry and instead imposes on device manufacturers the same strictures that were developed specifically for the pharmaceutical industry.

Although some have argued that the California legislature did not intend to regulate the marketing practices of the device industry, most major medical

device companies doing business in California comply with the law and annually certify to their compliance. In response to the law’s “one size fits all” approach, however, many medical device companies highlight in their annual declaration of compliance the inherent distinction between the pharmaceutical and medical device industries, and tailor their CCPs to the unique needs of the device industry. For example, as noted in the Becton, Dickinson and Company (BD) California Compliance Declaration:

The AdvaMed Code of Ethics on Interactions with Healthcare Professionals recognizes that the medical device industry is significantly different than the pharmaceutical industry. Consistent with the HHS-OIG Guidance, we have tailored our Comprehensive Compliance Program to the nature of our business as a medical device manufacturer.

*While the California law makes reference to compliance with the PhRMA Code on Interactions with Healthcare Professionals, we manufacture medical devices rather than pharmaceutical products, and have therefore adopted the AdvaMed Code policies and procedures for compliance, which are substantially similar to the PhRMA Code. Thus, while we have formally adopted the AdvaMed Code, we believe that adherence to the AdvaMed Code also constitutes compliance with the PhRMA Code for purposes of satisfying the requirements of the California law.*²³

Similarly, Medtronic Inc., one of the world’s largest medical device manufacturers, and DePuy Spine Inc., a Johnson & Johnson Company, also reference the adoption of the AdvaMed Code, rather than the PhRMA Code, as the basis of their CCPs, given that the AdvaMed Code “reflects the unique interactions between medical technology companies and health care professionals.”²⁴

In contrast with California’s pharmaceutical industry-driven CCP, Nevada’s marketing code of conduct law is explicitly directed towards both pharmaceutical and medical device manufacturers.²⁵ Specifically, the Nevada law requires that any “wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, *device*, or appliance” in the state “adopt a written marketing code of conduct which establishes the practices and standards that govern the marketing and sale of its products.”²⁶

Unlike California, Nevada also tailors the requisite topics to be addressed by the code to the specific needs of the particular industry. For example, Nevada permits medical device manufacturers to adopt, without modification, the AdvaMed Code.²⁷ Alternatively, medical device manufacturers may also develop their own marketing code of conduct, which must address the provision of product education and training, support for third-party educational conferences, sales and promotional meetings, arrangements with consultants, gifts, provision of reimbursements and grants and other charitable donations.²⁸

In contrast, a pharmaceutical manufacturer who chooses to develop its own code must ensure that the code includes principles governing the basis of healthcare professional interactions, detailing sessions, as well as the provision of educational and practice-related items.²⁹ The Nevada law also mandates that pharmaceutical and medical device companies adopt a training program on the code, as well as conduct annual audits and develop policies and procedures to detect infractions and ensure that employees are in compliance with the adopted code’s principles.³⁰

California and Nevada are not the only states to impose a mandatory code of

conduct. Nor are they the only states to regulate the promotional and marketing activities of medical device companies. As of July 1, 2009, pharmaceutical and medical device manufacturers alike must comply with the Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Act—an expansive law that imposes both a mandatory code of conduct, as well as marketing disclosure and limitation requirements.³¹

In accordance with the law, pharmaceutical and medical device manufacturers that employ or contract with individuals engaged in any promotional or marketing activities in the Commonwealth must adopt a *state-authored* marketing code of conduct, which incorporates components of both the PhRMA and AdvaMed Codes.³² The Massachusetts marketing code also imposes additional restrictions, including a broad prohibition against the provision of meals outside a healthcare professional's office or hospital setting and a restriction on paying travel expenses for continuing medical education sessions or other training events.³³ Pursuant to the law, pharmaceutical and medical device manufacturers also must adopt a training program on the code and submit a description of the program to the Massachusetts Department of Public Health (Department).³⁴ As in California, companies must also certify to the Department that they are in compliance with the law.³⁵

Although restrictive, Massachusetts has been relatively sensitive to the peculiar needs of the device industry. In the recently adopted regulations, “hospital setting” includes “a pharmaceutical or medical device specialized training facility, where the facility, as certified to the Department by the pharmaceutical or medical device manufacturing company,

is specifically designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory or to provide medical training on large and/or technical medical devices, such as surgical equipment, implants, and imaging and clinical laboratory equipment.”³⁶

As a result, medical device manufacturers are not strictly limited to providing meals in a healthcare professional's office. The Massachusetts law also allows for the “payment or reimbursement for the reasonable expenses, including travel and lodging related expenses necessary for technical training of health care practitioners on the use of medical device” provided that the manufacturer's “commitment to provide such expenses, and the amounts or categories of reasonable expenses to be paid, are described in the written agreement between the health care practitioner and the device vendor for the purchase of the device.”³⁷ Additionally, medical device manufacturers may also provide “reasonable quantities of medical device demonstration and evaluation units” for the purposes of assessing the appropriate use and functionality of the product.³⁸

The Massachusetts law also requires that both pharmaceutical and medical device companies disclose any gifts or payments that exceed a statutorily defined amount, provided either directly or indirectly to state-licensed healthcare professionals.³⁹ Specifically, a pharmaceutical and medical device manufacturing company “that employs or contracts with a pharmaceutical or medical device manufacturer agent” must publicly disclose the “value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50” that the company provides directly or indirectly to a healthcare professional.⁴⁰ Expenditures

subject to this annual disclosure requirement include compensation for *bona fide* consulting services and reimbursement of expenses made in conjunction with product training; evaluation and demonstration units, however, are exempt from disclosure.⁴¹

Until recently, the Massachusetts law was regarded as the most restrictive sales and marketing law in the nation.⁴² With the passage of Vermont Senate Bill 48 on June 8, 2009, Vermont's newly amended Vermont Prescription Drug Cost Containment law has arguably earned this distinction. While the earlier version of the Vermont law impacted only pharmaceutical companies, the amended version is broadly directed at “manufacturers of prescribed products,” which includes not only pharmaceutical manufacturers, but device manufacturers as well.⁴³ As amended, the Vermont law imposes, with few exceptions, a ban on the provision of “gifts” by “manufacturers of prescribed products.”⁴⁴ A “gift” includes anything of value provided to a healthcare professional for free, including any payment, food, entertainment, travel, advance or service, unless the healthcare professional reimburses the manufacturer at fair market value, or it is an “allowable expenditure.”⁴⁵

Vermont is thus the first state in the nation in which medical device manufacturers are prohibited from providing meals to a healthcare professional, even within an office or hospital setting. Nevertheless, as with the Massachusetts law, the amended Vermont Prescribed Products law attempts to address the medical device industry's concerns.

The law permits, as an “allowable expense,” the provision of reasonable travel and lodging-related expenses accrued in connection with the technical training of a healthcare professional on the use of a

medical device, provided the commitment to provide such expenses is captured in a written agreement between the healthcare professional and the manufacturer.⁴⁶

In addition, the law allows for the short-term loan of a medical device (not to exceed 90 days) for evaluation by a healthcare professional or patient, as well as the provision of “reasonable quantities of medical device demonstration or evaluation units to a [healthcare professional] to assess the appropriate use and function of the product . . .”⁴⁷

As amended, the Vermont law also includes the medical device industry within the purview of the state’s expenditure disclosure requirements. In accordance with the Vermont law, “every manufacturer of prescribed products shall disclose . . . the value, nature, purpose, and recipient information” for any allowable expenditure.⁴⁸ Although prescription drug samples are specifically exempt from disclosure, device manufacturers must disclose all transfers of value, including medical device samples, short-term device loans and demonstration units.⁴⁹ As in Massachusetts, these disclosures are part of the public record.⁵⁰ Additionally, the Vermont law shares one other similarity with the Massachusetts law: its effective date. Both the gift prohibition and disclosure requirements became effective on July 1, 2009.⁵¹

Legislative Trends

In 2008, approximately 52 bills regarding sales and marketing disclosures or limitations were introduced in 21 state legislatures. Of these 52 bills, only four were applicable to the sales and marketing activities of medical device companies. In 2009, approximately 35 marketing disclosure or limitation bills were introduced in 18 states, with 17 of these bills impacting the medical device industry. This year, in the month of Janu-

ary alone, seven bills have been introduced in five states, with more than half of the bills affecting the medical device industry-- continued evidence of the increase in the states’ efforts to regulate the activities of this industry.⁵²

One of the bills recently introduced, Massachusetts’ “An Act Making Technical Corrections to Health Care Practitioner and Pharmaceutical and Medical Device Manufacturer Conduct” (Massachusetts Bill), would set yet another benchmark in the state arena of sales and marketing legislation if passed: the imposition of a licensing requirement for all “pharmaceutical *and* medical device manufacturer agents.”⁵³

While a pharmaceutical detailer license is currently required in the District of Columbia,⁵⁴ the Massachusetts Bill, if adopted, will make Massachusetts the first state to impose this burdensome requirement on the medical device industry. Under the Massachusetts Bill and existing Massachusetts law, “pharmaceutical and medical device manufacturer agents” include any individual engaged in detailing or other promotional and marketing activities for the purposes of “promot[ing], oppos[ing], or influenc[ing] the prescribing of a particular . . . medical device or category of . . . medical devices . . .”⁵⁵

As medical device representatives’ interactions with healthcare professionals are typically centered on the training and education of healthcare professionals on the use of a device, it remains to be seen how the Department would apply the law to the device industry, given the industry’s training obligations.

Looking Forward

In the Wake of Transparency

There is a growing trend, on both the state and the federal level, towards

transparency in the sales and marketing of medical devices. As demonstrated by the number of medical device marketing disclosure bills introduced in recent years, more and more states are attempting to include medical devices within their regulatory rubric. In addition, in January 2009, United States Senators Grassley and Kohl introduced the Physician Payments Sunshine Act of 2009 (Sunshine Act), a reincarnation of a bill previously introduced in the past two congressional terms.⁵⁶

Portions of the Sunshine Act were incorporated into some of the recent healthcare reform bills, including the Affordable Health Care for America Act and the Patient Protection and Affordable Care Act.⁵⁷ Under the proposed federal legislation, pharmaceutical, biologics, and medical device manufacturers would be required to disclose all payments or other transfers of value over a statutorily defined amount that are provided to certain healthcare professionals.⁵⁸ The short-term loan of a covered medical device, and items or services that are performed under a contractual warranty for a device would be exempt from disclosure.⁵⁹

The federal legislation would also preempt any state disclosure laws that require a manufacturer “to disclose or report, in any format, the type of information . . . regarding a payment or other transfer of value” that must be reported under federal law.⁶⁰ Although the future of the proposed healthcare reform legislation is still unknown, in the event the Sunshine Act provisions become law, both the pharmaceutical and medical device industries would still be required to comply with any state-imposed requirements or limitations not otherwise preempted by federal law.

How the Medical Industry Can Manage the Divergent Regulatory Climate

It is virtually certain that state governments and investigative agencies will continue to “close the gap” and begin to regulate the sales and marketing activities of medical device companies to the same degree they do their pharmaceutical counterparts. While aimed at creating more transparency, these developments pose an undue burden on the device industry at large.

First, the disparate regulatory landscape complicates the implementation of compliance and training programs for medical device companies. Medical device companies must implement compliance programs that not only satisfy the different requirements of every state in which they do business, but must also create programs that are flexible enough to adapt to future legislation.

Second, the inconsistent treatment of pharmaceutical and medical device products in state laws is onerous for manufacturers that market both medical devices and pharmaceuticals. Recently, there has been a surge in dermal fillers and other aesthetics products that are regulated by the FDA as devices, but are marketed by traditional pharmaceutical companies. These companies must now carefully monitor the sales and marketing regulations of every state to ensure they are compliant with all relevant regulations, be they directed towards devices or pharmaceuticals.

Finally, the medical device industry risks a “one-size-fits-all” approach in those states that include both pharmaceutical and medical devices within their sales and marketing precepts. While some states make at least an overture of acknowledging the issues particular to the device industry, others attempt

to “force-fit” device companies into the existing pharmaceutical framework.

In an effort to self-regulate in advance of the impending sweep of state law, the medical device industry’s trade association, AdvaMed, revised and restated its AdvaMed Code effective July 1, 2009. Although the revised AdvaMed Code incorporates some of the tenets of the ubiquitous and recently updated PhRMA Code, including an explicit prohibition against the provision of entertainment or recreational events and non-educational branded promotional items, it continues to reinforce the distinction between the medical device and pharmaceutical industries given the “complexity and ‘hands on’ nature of [medical device technology] and the importance of having Health Care Professionals understand how to use the technologies safely and effectively.”⁶¹

While the revised AdvaMed Code represents a step in the right direction, the medical device industry must do more. Medical device companies must continue to educate state regulators on the unique traits of the device industry. These educational efforts are critical in ensuring that future legislation addresses the specific concerns of medical device manufacturers and existing laws are not amended to merely include medical devices absent a sensitivity to the fact that devices are developed, marketed, and used by healthcare professionals and patients very differently than are pharmaceuticals.

Although the incorporation of Sunshine Act in proposed federal healthcare legislation could create uniform disclosure requirements for the medical device industry, other elements of state regulation, such as marketing limitations, prohibitions, licensing and training requirements, would remain in effect. Thus, it is

imperative that device companies both monitor state legislative activity and begin tracking all marketing expenditures, including those to prescribers, pharmacists, group purchasing organizations, pharmacy benefit managers, hospitals, and medical schools. Further, in the event that proposed federal healthcare legislation becomes law, medical device manufacturers would still face applicable state gift limitations and any other disclosure requirements not otherwise preempted under federal law. Ultimately, medical device companies should consider voluntarily disclosing all payments to healthcare professionals.⁶² ▲

1 Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h) (2010).

2 *Id.*

3 See FDA/CDRH, *Device Advice: Is The Product a Medical Device?*, available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>.

4 *Id.*

5 See 21 U.S.C. § 360c(a); see also 21 C.F.R. § 860.3(c) (2010). Class I devices present minimal risk of harm to the patient, are typically simple in design and manufacture, and have a history of effective and safe use as compared to the higher-class devices. See FDA/CDRH, *Device Advice: General and Special Controls*, available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm> (hereinafter, “*General and Special Controls*”). Examples of Class I devices include stethoscopes, elastic bandages, and surgical gloves. Class I devices are subject to the least regulatory oversight and consequently must adhere only to certain “general controls,” which include listing with the FDA all devices which are to be marketed and the submission of a pre-market notification (510(k)) to the FDA before marketing a device. See *id.*; see also 21 C.F.R. § 860.3(c)(1). Class II devices, in contrast, are those for which “general controls alone are insufficient to provide reasonable assurance of [their] safety and effectiveness” and requires “special controls” to provide such assurances. *Id.* § 860.3(c)(2). These special controls may include compulsory performance standards, unique labeling requirements, and post-market surveillance. See *General and Special Controls*, *supra* note 5. Medical devices classified in this category include electric-powered wheelchairs, infusion pumps and x-ray machines. Class III is the most stringent regulatory classification for devices. See *id.* Medical devices in this category generally support or sustain human life, are of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury to the patient. See 21 C.F.R. § 860.3(c)(3). Like its pharmaceutical counterparts, Pre-Market Approval (“PMA”) submission and approval is gener-

- ally required prior to marketing a Class III device. See *id.*; see also *General and Special Controls*, *supra* note 5. Examples of Class III devices that require PMA include replacement heart valves, injectable dermal fillers and silicone gel-filled breast implants.
- 6 Advanced Medical Technology Association (“AdvaMed”), *Code of Ethics on Interactions with Health Care Professionals* 1 (Eff. July 1, 2009), available at <http://www.advamed.org/MemberPortal/About/code/> [hereinafter, *AdvaMed Code*].
- 7 See Paul A. LaViolette, *Medical Devices and Conflict of Interest: Unique Issues and an Industry Code to Address Them*, 74 CLEV. CLINIC J. OF MED. S26, S26 (Supp. 2007).
- 8 See *id.* at S27.
- 9 See *id.*
- 10 *AdvaMed Code*, *supra* note 6, at 3.
- 11 LaViolette, *supra* note 7, at S27.
- 12 *AdvaMed Code*, *supra* note 6, at 13.
- 13 See generally *AdvaMed Code*, *supra* note 6.
- 14 *Id.* at 1, 13.
- 15 *Id.* at 4.
- 16 *Id.*
- 17 See CAL. HEALTH & SAFETY CODE § 119402 (2009); NEV. REV. STAT. § 639.570 (2009).
- 18 CAL. HEALTH & SAFETY CODE § 119402(a)-(b).
- 19 *Id.* § 119402(c)-(d).
- 20 *Id.* § 119402(e).
- 21 *Id.* § 119400(c).
- 22 *Id.* § 119400(a)(2) (emphasis added).
- 23 BD, *California Compliance Declaration* (July 1, 2008), available at http://www.bd.com/investors/pdfs/corporate_governance/california_compliance_declaration.pdf.
- 24 Medtronic, Inc., *Medtronic Comprehensive Compliance Program* (July 1, 2008), available at http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@corp/documents/documents/ccp-statement.pdf; see also DePuy Spine, Inc., *Declaration for California compliance Law* (July 1, 2009), available at http://www.depuyaspine.com/misc/calif_hcc.asp.
- 25 See NEV. REV. STAT. § 639.570(1).
- 26 *Id.* § 639.570(1)(a) (emphasis added).
- 27 See NEV. ADMIN. CODE § 639.617(2) (2009).
- 28 See *id.* § 639.617(3)-(4).
- 29 See *id.* § 639.616(4).
- 30 See NEV. REV. STAT. § 639.570(1)(b)-(d).
- 31 See MASS. GEN. LAWS ch. 111N, § 2 (2009); see also 105 MASS. CODE REGS. 970.000 (2009). Note, according to guidance from the Massachusetts Department of Public Health, “the regulation applies to manufacturers of prescription medical devices as well as to manufacturers of Class II and Class III devices . . . manufacturers of Class I medical devices that are exempt from Premarket Notification under the federal Food, Drug and Cosmetic Act (510(k) exempt device manufacturers) are not subject to [the law]”. See Mass. Dep’t of Pub. Health, *Frequently Asked Questions: Pharmaceutical and Medical Device Manufacturer Conduct* (Apr. 2009), available at http://www.mass.gov/EOHHS2/docs/dph/quality/healthcare/pharmaceutical_medical_device_conduct_faq.pdf.
- 32 See MASS. GEN. LAWS ch. 111N, § 2; see also 105 MASS. CODE REGS. 970.005.
- 33 See 105 MASS. CODE REGS. 970.006-.008.
- 34 See *id.* at 970.005(1)(b).
- 35 See *id.* at 970.005(1)(c).
- 36 *Id.* at 970.004.
- 37 *Id.* at 970.008(2)(b).
- 38 *Id.* at 970.008(2)(f).
- 39 See MASS. GEN. LAWS ch. 111N, § 6(1); see also 105 MASS. CODE REGS. 970.009. Note, the first annual disclosure report is due July 1, 2010. 105 MASS. CODE REGS. 970.009(1).
- 40 105 MASS. CODE REGS. 970.009(1).
- 41 See 105 MASS. CODE REGS. 970.008(2)-.009(1); see also Mass. Dep’t of Pub. Health, *Guide to 105 CMR 970.00: Pharmaceutical and Medical Device Manufacturer Conduct* (2009), available at http://www.mass.gov/EOHHS2/docs/dph/legal/pharmacy_med_device_faqs.doc.
- 42 See generally Mass. Dep’t of Pub. Health, *Pharmaceutical and Medical Device Manufacturer Conduct Law Presentation* (Mar. 11, 2009), available at http://www.mass.gov/EOHHS2/docs/dph/legal/pharmacy_med_device_presentation.ppt.
- 43 See VT. STAT. ANN. tit. 18, § 4631a (2009).
- 44 See *id.* § 4631a(b)(1).
- 45 *Id.* § 4361a(a)(4). Examples of “allowable expenditures” include: (1) payments to the sponsor of an educational conference, provided the payment is not made directly to a healthcare professional, there is no industry influence, and the funding is used solely for educational purposes; (2) honoraria and payments to healthcare professionals who serve on the faculty of a conference; (3) payments for clinical trials; (4) payments for research projects that constitute a systematic investigation; and (5) other “reasonable” fees or payments provided at fair market value. *Id.* § 4631a(a)(1).
- 46 *Id.* § 4631a(a)(1)(E).
- 47 *Id.* § 4631a(b)(2)(B)-(C). Loans of medical devices for longer than 90 days are banned under the Vermont law. See Vt. Office of Atty. Gen., *Guide to Vermont’s Prescribed Products Law for FY10 Disclosures* (2009) [hereinafter, *Vermont Guide*].
- 48 *Id.* § 4632(a)(1).
- 49 See *Vermont Guide*, *supra* note 47. Note, according to the *Vermont Guide*, manufacturers need to report only the fact that a loan of a medical device, evaluation unit, or free samples of medical devices were provided, not the monetary value of the device. The monetary value for these items therefore should be reported as \$0. See *id.*
- 50 VT. STAT. ANN. tit. § 4632(a)(1); see MASS. GEN. LAWS ch. 111N, § 6(2).
- 51 Medical device manufacturers must disclose all reportable expenditures no later than October 1, 2010, for the 6-month period ending June 30, 2010. See *Vermont Guide*, *supra* note 47.
- 52 In January 2009, Colorado, Hawaii, and New York introduced marketing and disclosure legislation that, if passed, would impact the activities of medical device companies.
- 53 See S. 547, 186th Gen. Assembly § 5 (Mass. 2009) (emphasis added). As of the date of this article, the Massachusetts Bill is still pending.
- 54 See D.C. CODE § 3-1207.41-45 (2009).
- 55 MASS. GEN. LAWS ch. 111N, § 2; S. 547, 186th Gen. Assembly § 2.
- 56 See Physician Payments Sunshine Act of 2009, S. 301, 111th Cong. § 2 (2009).
- 57 See Affordable Health Care for America Act, H.R. 3962, 111th Cong. (2009); Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2009).
- 58 See Affordable Health Care for America Act, H.R. 3962; Patient Protection and Affordable Care Act, H.R. 3590.
- 59 See Affordable Health Care for America Act, H.R. 3962; Patient Protection and Affordable Care Act, H.R. 3590. Note, short-term loans, under the federal law, should not exceed 90 days. See Affordable Health Care for America Act, H.R. 3962; Patient Protection and Affordable Care Act, H.R. 3590.
- 60 See Affordable Health Care for America Act, H.R. 3962; Patient Protection and Affordable Care Act, H.R. 3590.
- 61 *AdvaMed Code*, *supra* note 6, at 13.
- 62 For example, in 2009, Medtronic announced that it will begin capturing payment data for all of its subsidiaries beginning January 1, 2010, and will then publicly report this information annually. See Medtronic, Inc., News Release: *Medtronic to Voluntarily Disclose Payments to U.S. Physicians* (Feb. 24, 2009), available at http://www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1235482300024&lang=en_US.