

**Impact of the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct on Medical Device Physician-Industry Collaboration**

by

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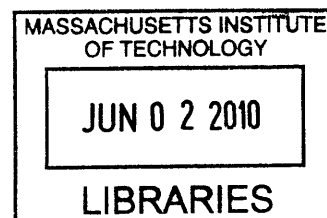
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# **Impact of the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct on Medical Device Physician-Industry Collaboration**

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at the Massachusetts Institute of Technology

## **Abstract**

The Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct (PCOC) or 105 CMR 970.000 was enacted by the Massachusetts state legislature and adopted by the Department of Public Health (DPH) in July 2009 under Chapter 305 of the Acts of 2008, An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care. The state law requires pharmaceutical and medical device manufacturers to comply with a marketing code of conduct, obey specific compliance activities, and disclose payments to Massachusetts-licensed healthcare providers with a value of \$50 or more in connection with sales and marketing activities. This thesis qualitatively assessed the impact of 105 CMR 970.000 on physician-industry collaboration related to technology development and physician education in the Massachusetts medical device industry, as depicted by academic physicians and representatives of medical device companies during the first quarter of calendar year 2010.

A pilot study comprising interviews and surveys of stakeholders in the Massachusetts medical device industry was conducted to summarize the initial impressions of the impact of 105 CMR 970.000 on medical device physician-industry collaboration, with the intention of creating a roadmap for future analysis. Informal interviews (36) included individuals at medical device manufacturers, distributors, academic medical centers, venture capital firms, law firms, consulting firms, MassMedic, and the DPH. Formal surveys (40) included academic physicians and medical device company representatives selling to Massachusetts-licensed physicians.

The hypothesis was confirmed that 105 CMR 970.000 has impaired medical device physician-industry collaboration related to technology development and physician education in Massachusetts. Our results may have state and federal regulatory implications for the medical device industry and can serve as a guide for future analysis.

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## **Dedication**

*To my wife, Divya, for her constant love, support, and inspiration.*

*To my sister, Anne, for her great friendship, encouragement, and advice.*

*To my parents, Tom and Erica, for providing me with endless opportunities and late night pathophysiology lessons.*

## **Acknowledgements**

During my career, I hope to play a significant role in the development and commercialization of biomedical technologies that improve the quality of human life. I chose a thesis topic that would best position me to achieve my career goals, by exploring the changing dynamics of physician-industry collaboration in the Massachusetts medical device industry.

I would like to express my sincere gratitude and appreciation for the guidance of my thesis advisors, Prof. Teo Dagi and Kevin Ohashi, in helping me define and articulate my research over the past several months. I would also like to thank Jay Robins for his advice and introductions. I would like to thank the physicians and company representatives who generously offered me their time for interviews and surveys.

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## **Chapter 1: Introduction and Background**

### ***Physician-Industry Collaboration and Innovation***

Modern physician-industry collaboration has been at the heart of medical device innovation since the birth of the industry in the 1950's, when Dr. Walton Lillehei at the University of Minnesota Medical School partnered with electrical engineer Earl Baaken to develop the first battery-operated, wearable pacemaker for pediatric heart block patients [36]. Since then, the interactions between physicians and medical device companies have driven the development and commercialization of countless diagnostic, therapeutic, and monitoring devices to extend and improve the quality of human life.

Over the past six decades, physician-industry relationships have paired the clinical expertise of physicians with the technical, strategic, and financial capabilities of industry. Numerous devices have allowed surgeons to intervene where systemically delivered pharmaceuticals and medical management have failed, through structural interventions (e.g. artificial joints, bare metal stents), electrical stimulation of tissue (e.g. pacemakers, implantable cardioverter-defibrillation, neuromodulation), and drug delivery (e.g. drug eluting stents, insulin pumps, implantable tissue grafts and scaffolds). Collaboration between physicians and companies has also accelerated the medical device innovation trend of decreasing invasiveness, improving clinical outcomes and reducing treatment and hospital costs. A commonly cited example is the substitution of open-heart, coronary artery bypass graft (CABG) procedures with transcatheter coronary stenting. The transcatheter disruption of more invasive cardiovascular procedures is now expanding to aortic valve replacement.

Now more than ever, there is a dire need for close collaboration between physicians, academia, and industry. There is an increasing number of unmet medical needs that cannot be solved by medical management and systemic delivery of pharmaceuticals or biologics. The convergence of delivery devices and scaffolds with biologics will require even closer collaboration between physicians and industry, as tissue engineering and cell therapies become more clinically relevant and technological and procedural complexities multiply. This collaboration will require strong and transparent alliances between academic institutions, innovative venture-backed companies, and large medical device manufacturers.

### ***Medical Device Industry Landscape***

The global medical instrument and supply manufacturing industry is forecast to generate revenue of \$89.3 billion in 2010, an annual increase of 2.5% [25]. Surgical and medical instruments account for approximately 36.3% of this total. The four largest players in the industry measured by annual revenue are Johnson & Johnson, General Electric, Medtronic, and Baxter International, which account for roughly 40% of the revenue. The four most acquisitive firms are Medtronic, Inverness, Boston Scientific, and J&J, with acquisitions of 30, 29, 26, and 26 companies, respectively, since 2000 [57]. The largest company focused solely on medical devices is Medtronic, with a market capitalization of approximately \$48 billion and annual sales of \$15 billion, with roughly 10% directed towards research and development. Other large manufacturers include Boston Scientific, St. Jude, Zimmer, Edwards Life Sciences, Intuitive Surgical, Stryker, Cook Medical, Synthes, and Covidien.

In Massachusetts, the medical device industry provides an abundant source of employment and investment. In 2004, the industry employed 20,555 people, roughly a third of whom worked for surgical and medical instrument manufacturers [18]. Relative to other states, Massachusetts ranked second for device employment per capita and third for absolute employment. There are 131 hospitals in the state [33] and approximately 23,500 physicians with a full and active license and a Massachusetts practice, 20 percent fewer than the total number of physicians registered with the Massachusetts Board of Registration in Medicine [34]. In terms of venture capital funding, Massachusetts received approximately 10% of national medical device and equipment venture capital funding in 2009 [46]. In 2009, small Massachusetts medical device companies raised a total of \$242 million in 32 deals, relative to \$2.5 billion in 309 deals in the United States.

The early development of medical devices is often accomplished by small, venture capital-backed entrepreneurial companies [18]. Exceptions include more costly to develop and commercialize devices like imaging equipment. Possible explanations for this phenomenon include the greater financial and cultural risk tolerance of small companies and their investors relative to that of large medical device manufacturers, the greater strategic flexibility of small enterprises to change course, limited bureaucracy and efficient decision making, the preference of physician inventors to partner with smaller firms to gain more dedication to their technology, the weak patentability of design methods providing for low barriers to entry, the historically looser regulatory standards relative to pharmaceuticals enabling a less costly regulatory approval process, the cash-constraints and urgency of small

firms to gain proof of concept and market adoption, and undervaluation and avoidance of lucrative market opportunities by large manufacturers [18].

Where small companies have increasingly taken on the industry role of early technology development, larger manufacturers have accordingly devoted their resources to product refinement, market expansion, and distribution. Large companies like Medtronic, Boston Scientific, St. Jude, and J&J have grown significantly through acquisitions of smaller companies with FDA approved products and initial proof of market adoption and sales traction potential. This phenomenon has become an important growth strategy for larger manufacturers. The ability to gain market traction with physicians and hospital buyers following FDA approval is a necessary ingredient for the clinical impact of a new device. A small company's value proposition to shareholders, physicians, and patients will not be realized without effectively educating and training physicians.

### ***Technology Development Differences Between Medical Devices and Drugs***

The global pharmaceutical industry is expected to generate revenue of roughly \$925.0 billion in 2010 [20], of which the biotechnology industry is expected to contribute \$86.8 billion [19]. The pharmaceutical industry includes companies that manufacture biological, medicinal, and pharmaceutical products, which are primarily distributed through wholesalers and sold through pharmacies or distributed via hospitals. Relative to the medical device industry, the pharmaceutical industry is less concentrated with the top ten companies controlling less than 50% of the total market and the top four firms controlling less than 25% [20]. However, concentration can be much higher within individual therapeutic categories.

The large company acquisition strategy in the medical device industry of tucking in companies with initial proof of market traction is very different from that of large acquirers in the pharmaceutical and biotechnology industries, in which small drug companies are effectively in-licensed at earlier stages in technology development, often with only initial signs of proof of efficacy and safety in human trials. Large drug companies play a greater role in earlier stage technology development, often acquiring companies in early clinical development and devoting resources to toxicology and dosage studies. One explanation for this is the relatively higher costs of product development for drugs, often approaching \$1 billion in R&D costs per product [1].

There are additional structural differences between the medical device and drug industries that create this divergence in acquisition strategies and thus define the innovative roles of small versus large firms. One primary difference is the disparity in value inflection points. A large proportion of a typical biotech company's risk is reduced after Phase 2 clinical trials, in which substantial efficacy and safety data are established in roughly 100-300 patients [25]. Most biotech companies that fail often do so before or during clinical development [39]. Conversely, efficacy and safety of a medical device is often cheaper and faster to establish and significant risk reduction occurs with proof of market adoption, not safety data. In medical device development, the procedural complexity, device usability, and physician interest play an important role in a device's clinical success. In other words, significant value creation in the biotech industry occurs with the production of superior *in vivo* efficacy data, while value creation in the device industry occurs with proof of the potential for market adoption.

Another notable difference between medical devices and drugs lies in the timing and process of product development. Drug products are usually fully developed during the clinical evaluation and federal regulatory approval processes. Proof of concept for the alteration of a molecular pathway is often established *in vitro*, verified in animal preclinical studies, and tested for safety, efficacy, and dosage in human clinical studies. With FDA approval, there is little allowance for change to a drug's formulation, dosage, or composition [18]. In drug development, industry relationships with physicians are crucial for advancing clinical studies and pursuing efficacy, safety, and dosage data. However, very few if any changes to the actual product occur through these interactions. By the time of Phase 1 clinical studies, much of the drug's design and composition have been established. New indications for a specific drug may be discovered during clinical trials, but product modifications and performance improvements for the studied application are difficult.

This is significantly different from device development, in that physician-industry collaboration is required throughout the development process, from bedside to bench to bedside. Physicians collaborate with companies in the identification of an unmet clinical problem. Companies interact with physicians to design procedure-based device solutions that leverage the physician's skill set. This close collaboration requires constant, frequent, and open communication, so that product defects, limitations, and performance improvements can be translated at minimum cost between manufacturers and customers. Product modifications are most frequent during the first six months of market approval [18], as product limitations are exposed in clinical practice and physicians communicate these

issues with manufacturers. This process of continuous product modifications and iterative, follow-on innovation shortens the life cycles of most medical devices [39] and reduces the value of their intellectual property over time.

### ***The Role of Sales and Marketing in Medical Device Innovation***

The sales and marketing functions in the medical device industry enable manufacturers to collaborate with physicians to design and develop clinically relevant products, expose physicians to new products, train physicians on new device procedures, and support general physician education. Manufacturer representatives work with physicians to solicit valuable feedback and constructive criticism of existing devices and discover new clinical applications. This interaction and communication enables more effective and efficient product development of new device iterations, and can similarly lead to breakthrough innovations of new device approaches to solve unmet clinical problems.

When a clinical need is identified and the market assessed, device manufacturers engage with physicians through consulting agreements on preclinical and clinical research for novel device concepts. Physicians may be reasonably compensated for their time, reputation, and expertise on research through consulting agreements and reimbursed for related expenses. These agreements may include royalty, financial interests, and cash compensation components to optimally incentivize and reward inventors. The form of compensation depends on the trial sponsor, physician, state regulations, and the physician's institutional policies. For example, in the Partners Healthcare system, a physician cannot be directly compensated by a company sponsor for research conducted at the institution or with institutional property and Harvard Medical School will similarly not allow their faculty to be compensated with equity or other financial interests by companies. At academic medical centers, payment for clinical research often flows to the institution, which may then compensate the physician. Some academic physicians also serve on scientific advisory boards at companies, allowing them to interact with other thought leading physicians and provide guidance on the company's product development projects.

Marketing representatives are often heavily involved in a company's relationship with a physician investigator, since the product's scope requires initial market validation and valuation, the device concept is an iteration of an existing device, the physician is an existing customer, or the physician has an existing professional relationship with a sales representative. Large companies establish a product team comprising representatives from

R&D, legal, financial, clinical, regulatory, and marketing to engage with a physician inventor or principal investigator. Marketing representatives are responsible for determining the scope and value of a new clinical innovation and thus the value and structure of a physician compensation agreement. Companies often seek out key opinion leaders (KOLs) at academic medical centers to assist with the clinical validation of a new technology. These KOLs are similarly compensated for their work and are often the first physicians to use the implantable device on patients in experimental cases to prove the technology's safety and efficacy. Through this collaboration with physicians, marketing representatives solicit valuable feedback to direct incremental improvements to devices.

As a product finishes clinical trials and approaches FDA approval, KOLs work with clinical specialists and sales representatives from the manufacturer to optimize the surgical procedure for a given clinical application. Physicians attend training events on-site at manufacturers to learn new procedures and are compensated for their time. At academic medical centers, these attending physicians are responsible for training the fellows on the new device procedure and the fellows are responsible for training the residents. In reality, clinical specialists and sales representatives from manufacturers visit hospital settings and often train attendings, fellows, and residents on new device procedures as well. At community hospitals, sales representatives play a larger role in training physicians on new procedures. Larger manufacturers with significant resources have also sponsored fellowships at major academic medical centers, as method of supporting physician education, encouraging device innovation, training physicians, and promoting their products.

Sales representatives play a notable role in a physician's preferences and decision to use one device over another. Montgomery et al. show that physicians often make this decision without cost in mind, relying on factors like clinical data, personal experience with a device, and their relationship or trust in the manufacturer [38]. However, although physicians ultimately decide which device to use for a specific procedure, it is hospitals that bear the cost. Depending on the surgical procedure, hospitals receive a fixed payment per case as determined by the Medicare DRG or APC code. This fixed payment bundled amount is intended to serve as reimbursement for all of the services of the procedure, including the use of the device. However, Medicare's per case payment to hospitals has been decreasingly annually, especially in markets like orthopaedic joint implants [54]. Implantable devices like joint implants, spinal cages, and coronary stents can contribute up to roughly 60% of a hospital's total supply costs [54], creating an incentive for hospital new technology review

committees to contain costs by limiting physician exposure to expensive technologies by weakening their relationships with manufacturers or limiting access of sales reps to physicians. Strict institutional policies that restrict these relationships beyond state or federal regulations are partially successful at doing this, leveraging the logic that sales representatives have undue influence over physicians' device purchase decisions.

Sales representatives play an important function in the adoption of new medical devices by physicians, serving in a technical support and inventory stocking capacity to surgeons during procedures. The actual role of the device manufacturer's sales representative varies depending on the procedural complexity, the experience of the physician, and the hospital setting. Manufacturers may also contract with independent product distributors to sell devices. Sales representatives often have an extremely specialized knowledge in their products' capabilities and technical function, and are often relied upon by their physician customers for their product expertise, procedural support, and inventory reliability. Having seen numerous procedures under a variety of circumstances and different physician techniques, the sales representative often serves in an advisory and inventory stocking capacity to the physician, ensuring the correct device's components are used and match the patient's specific needs. For many complex procedures, the surgeon will not know the necessary device measurements until the pathology is fully exposed. The exact technique of implantation may also require technical support from the sales representative. In simpler procedures and with more experienced surgeons, the representative may not even be in the hospital, and many physicians prefer to have very limited interaction with sales representatives for a variety of reasons, including a hesitancy to be conflicted or appear conflicted. This is more feasible at premier academic medical centers with a high volume of procedures, since the departments tend to be fully stocked, and the physicians functionally experienced. However, community hospitals often have less inventory and physicians often rely more heavily on sales representatives for inventory and procedural consultation.

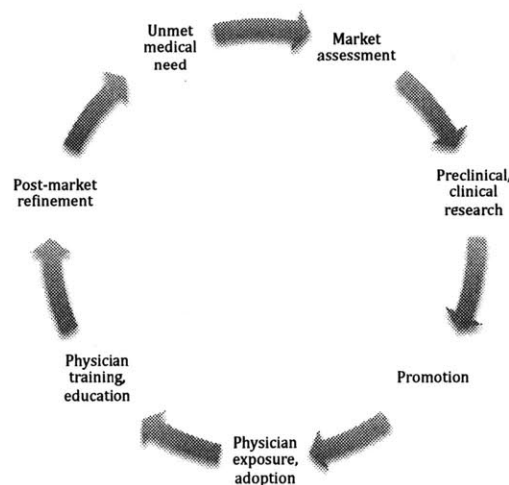
Physicians also rely on sales representatives for exposure to new device technologies and staying updated on new products. This exposure occurs in the hospital, at promotional events and tradeshows, educational conferences, continuing medical education (CME) events, and informal professional gatherings, e.g. "resident nights" for academic departments. A significant number of these educational events have been historically supported by industry. At tradeshows in states like Massachusetts with strict regulations on providing meals and gifts to physicians, some companies have avoided violations by erecting signs proclaiming "Not for Massachusetts-licensed physicians." CME grants are given by

companies to third parties conference sponsors to defray the cost of conferences, to training institutions to enable attendance by medical students, residents, fellows, and other physicians, and for reasonable provision of meals, travel, and lodging. Educational grants are also given to hospitals and academic departments, sometimes restricted to certain physicians or charities of their choosing, and other times non-restricted. Even with unrestricted grants, there is the potential for conflict if physicians are deemed to be overpaid for promotional speaking engagements, especially if connected to the off-label usage of devices.

### ***Potential Negative Consequences of the Massachusetts Law on Medical Device Innovation***

As it is currently written, the Massachusetts Manufacturer Code of conduct poses potential problems for medical device innovation in Massachusetts. For the purposes of this thesis, *innovation* is defined as the process of translating new technologies into commercially successful products with significant clinical impact. Medical device innovation thus encompasses the cycle of technology development through physician adoption: identification of an unmet medical need, market assessment, preclinical and clinical research, product promotion, physician exposure and adoption, physician training and education, and post-market approval product refinement. The close interaction and collaboration of physicians with industry drives this cycle of technology development and market adoption (Figure 1).

**Figure 1: Medical device innovation: cycle of product development**



There are physician and industry concerns that the Massachusetts regulations increase the barriers between physicians and medical device companies, impairing physician-industry collaboration on technology development, new device training, and medical education. Anecdotal evidence suggests that medical device companies are withdrawing from technology development and educational relationships with Massachusetts-licensed physicians. There are additional concerns from Massachusetts-licensed physicians that this industry withdrawal will impair their ability as physicians to innovate and deploy new device therapies, educate the next generation of physicians, and provide optimal patient care.

There is additional anecdotal evidence suggesting that companies prefer to collaborate with physicians not licensed in Massachusetts, because the law poses excessive transaction costs and legal liabilities on manufacturers to interact with Massachusetts-licensed physicians. There are concerns that companies are reducing the number of invitations to Massachusetts-licensed physicians for educational and professional gatherings. There is additional concern from physicians that companies are reducing or eliminating financial support for academic departments to hold informal educational events that companies once energetically supported.

The Manufacturer Code of Conduct also potentially poses unnecessary economic costs on manufacturers, which could negatively impact their ability to dedicate adequate resources to research and development. Compliance to the Massachusetts law adds to a disparate set of state and institutional regulations that medical device manufacturers must comply with on an individualized basis. It is arguable whether a state-by-state system complicated by an institution-by-institution system makes economic and legal sense from a systems cost perspective. A more optimal outcome might be a federal law that preempts all state laws and institutional conduct policies. Compliance can become extremely costly for companies and draw resources away from valuable projects within the company. Given the option, medical device companies may choose to work with physicians in less regulated states for cost reasons in order to avoid the legal liabilities of not keeping up with every state's unique compliance regulations. (One counter argument, however, confidently asserts that the DPH rules are not enough of a barrier to incent companies to work with non-Massachusetts physicians, since Massachusetts is home to some of the most preeminent academic institutions in the world.)

A separate concern is that the law hinders innovation in Massachusetts because it is regressively falls on smaller medical device companies. This argument suggest that large companies are already compliant with the Advanced Medical Technology Association (AdvaMed) Code of Ethics and thus have the infrastructure and employees in place to follow additional Massachusetts compliance requirements at relatively lower cost. These same conduct, compliance, and disclosure policies may be overwhelming for small companies. Some in the industry believe that there are economies of scale to compliance, allowing large companies a competitive advantage. However, others contend that many of the associated compliance costs are variable. These individuals point out that large medical device companies have historically grown through acquisition and are thus faced with a decentralized cost structure for compliance. Each business unit will need to comply under separate parameters.

Another potential consequence of the Massachusetts regulations is that large manufacturers will gain market share from smaller companies, especially in more fragmented markets like orthopaedics and spine in which product approvals have been historically less costly and a large population of small companies has flourished. This market power shift could occur for two reasons: 1) the law will alter the basis of competition between companies, by changing the factors influencing a physician's decision to use a medical device and increasing the relative importance of manufacturer brand over the relationship with a company's sales representative. Already established brands stand to benefit when limitations on promotion and marketing are enacted; 2) the law levels the compliance playing field for all companies, forcing small firms that had not been entirely AdvaMed compliant to obey costly conduct and disclosure regulations. The increase in barriers that small companies might face when trying to promote new technologies to physicians would inhibit their ability to exposure physicians to new device technologies. This shift in market dynamics would inevitably increase the buying power of large firms by improving their competitive advantage in marketing and distribution, enabling them to consolidate more fragmented markets. As marketing and promotion become relatively more costly for small firms, acquisition by a large manufacturer will become a more efficient path to expanded distribution and growth.

### ***Thesis Objective***

The objective of this thesis is to determine whether 105 CMR 970.000 has impaired medical device physician-industry collaboration related to technology development and physician education in Massachusetts. To assess our hypothesis that the law has impaired

collaboration and address the anecdotal concerns described, the following questions were proposed within four categories and a pilot study was developed:

**Stakeholder Understanding of the PCOC:**

- 1) How familiar are company representatives and physicians with the Massachusetts regulations, AdvaMed Code, academic institutional policies, and differences between them?
- 2) What ambiguities still exist in the law as it is currently written, as perceived by company representatives?
- 3) What are the most restrictive aspects of the law, as perceived by company representatives?

**Product Development:**

- 1) Has there been an impact on the decisions of company representatives and physicians to collaborate on preclinical or clinical research, regardless of the law's exception?
- 2) Has there been an impact on the decisions of company representatives and physicians to collaborate on post-market research?
- 3) Has there been an impact on the decisions of company representatives to interact with physicians on scientific advisory boards?

**Physician Education:**

- 1) Has physician exposure to new and existing devices decreased since the law's adoption, as measured by:
  - a. Number of sales representatives carrying these devices
  - b. Physician observations on their own and colleagues' exposure
- 2) Has physician training on new devices been impacted since the law's adoption, as measured by:
  - a. Company representative observations on change in number of training opportunities
  - b. Physician observations on number of training opportunities
  - c. Decisions of company representatives to reduce interactions with physicians on new device procedure demonstrations
- 3) Has general physician education been impacted by the law, as measured by:
  - a. Physician opinions

- b. Physician observations on change in invitations to industry-sponsored events
- c. Physician observations on change in industry funding for academic departments
- d. Physician observations on change in ability to stay updated on new technologies
- e. Company representative observations on change in invitations to Massachusetts-licensed physicians for sponsored events
- f. Decisions of company representatives to reduce interactions with physicians for educational and promotional events (CME and non-CME accredited)

**Market Dynamics:**

- 1) What is the total annual cost of compliance with the Massachusetts regulations?
- 2) Will the law impact the financial performance of medical device companies?
- 3) Has the basis of competition changed, since the law's adoption, i.e. has manufacturer brand become more important, as measured by:
  - a. Physician observations
  - b. Company representative observations
- 4) Has the law affected small and large companies equally, i.e. has it leveled the playing field?
- 5) Has there been an impact on the ability of physicians to introduce new devices to other physicians?

## **Chapter 2: Federal, State, and Institutional Regulations Governing the Promotion of Medical Devices**

In recent years, federal, state, and institutional regulations have become stricter in response to public concern regarding significant abuses of the reasonable physician compensation standards and criminal abuses with regard to off-label promotion. Device manufacturers have historically settled for multimillion-dollar penalties with the Department of Justice and the majority of these offenses have occurred in the orthopaedics market. Federal violations have involved companies providing payments to physicians for preferences in prescribing patterns, which violates the federal Anti-kickback statute. Although physicians are legally allowed to prescribe and use devices off-label, manufacturers face criminal charges for off-label promotion.

### ***US Federal Regulations: Anti-Kickback Statute and Stark Law***

As part of the Medicare and Medicaid Patient Protection Act of 1987, the Anti-kickback Statute seeks to protect physician independence by imposing criminal penalties up to \$25,000 or imprisonment up to five years, for specific illegal acts related to Medicare or Medicaid reimbursable services [14]. The Anti-kickback law specifically holds individuals criminally accountable for knowing and willful receipt or payment used to influence the referral of federal healthcare program business, primarily Medicare and Medicaid. The law prohibits the offer or receipt of compensation in return for referrals or recommendations for purchase of supplies or services. The Stark Law is similar to the Anti-kickback statute and comprises three provisions governing physician self-referrals for Medicare and Medicaid patients.

### ***Physician Payments Sunshine Provisions***

In early 2009, US Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) introduced the Physician Payments Sunshine Act, a bill “to amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP” [51]. The Physician Payments Sunshine Act provisions were incorporated into the Patient Protection and Affordable Care Act of 2009, signed into law on March 23, 2010. The federal law requires public disclosure of payments to physicians or

individuals at academic hospitals, beginning in March 2013. All US manufacturers of drugs, biologics, and medical supplies covered under Medicare, Medicaid, or SCHIP will be required to report payments to the US Department of Health and Human Services (HHS). This information will be posted on a public website. Reportable payments include cash and in-kind transfers, including: compensation, food, entertainment, gifts, travel, consulting fees, honoraria, research funding, equity, options, investment interests, royalties, licenses, and charitable contribution. Except for expert witness fees, most physician payments would be reportable to the public, including consulting fees, compensation, and reimbursement for research, education, and grants. The bill also requires reporting of physician ownership interests in companies.

The law exempts educational materials provided for the patient’s benefit, loans of devices, payments made to physicians who are employees of the reporting company, and other allowances including honoraria for market research if paid by a third party. Payments related to clinical trials are allowed a reporting exemption for four years or until FDA approval, whichever comes first. Exclusions related to medical devices include a device loan for less than 90 days (Figure 2).

**Figure 2: Overview of US Physician Payments Sunshine Act provisions**

Scope	Reportable payments	Notable exemptions
<ul style="list-style-type: none"> <li>▪ Physicians</li> <li>▪ Individuals at academic hospitals</li> </ul>	<ul style="list-style-type: none"> <li>▪ Compensation</li> <li>▪ Food</li> <li>▪ Entertainment</li> <li>▪ Gifts</li> <li>▪ Travel</li> <li>▪ Consulting fees</li> <li>▪ Honoraria</li> <li>▪ Research funding</li> <li>▪ Educational grants</li> <li>▪ Equity or stock options</li> <li>▪ Investment interests</li> <li>▪ Royalties</li> <li>▪ Licenses</li> <li>▪ Charitable contributions</li> <li>▪ Company ownership interests</li> </ul>	<ul style="list-style-type: none"> <li>▪ Educational materials for patient benefit</li> <li>▪ Device loans (90 days)</li> <li>▪ Payments to employees</li> <li>▪ Market research conducted by an independent third party</li> <li>▪ Four years/pre-FDA approval window during clinical trial</li> <li>▪ Expert witness fees</li> </ul>

The scope of the Sunshine provisions is limited to company interactions with physicians and providers at academic hospitals, whereas Massachusetts state regulations, for example, are

broadened to include all healthcare practitioners (HCPs) licensed in Massachusetts. Additionally, the Sunshine provisions are limited to specific disclosure rules and will not preempt state regulations on marketing codes of conduct. Beginning in 2013, the Sunshine provisions will only preempt state disclosure rules to the extent that states are prohibited from collecting the same exact information as collected by the HHS. Beginning in 2014, the law will require annual reporting and public disclosure of cumulative physician payments by industry over \$100 in a given year. For example, ten payments of \$10 per payment would require disclosure. States are allowed to continue to collect information not covered within the scope of the Sunshine provisions. States and institutions have the right to create additional reporting and conduct requirements that manufacturers would be required to obey, even with regard to physician payments. The Sunshine provisions will not obviate the need for manufacturers to report to a patchwork regime of state and institutional reporting, disclosure, compliance, and conduct regulations.

The US Attorney General's Office (AGO) will enforce the law for violations of off-labeling marketing or kick-backs. Tracking physician failures to disclose taxable income may be the easiest method of enforcement for the AGO. For each failure to disclose to the HHS, manufacturers face penalties of \$10,000 per incident not to exceed \$150,000 annually. For each knowing violation, fines up to \$100,000 not to exceed \$1,000,000 will be federally enforced.

### ***AdvaMed Code of Ethics***

The Advanced Medical Technology Association (AdvaMed) is the primary medical device industry trade association, with a member base producing roughly 90 percent of healthcare technology purchases in the United States and 50 percent worldwide [3]. All members are asked to pledge to abide by the AdvaMed Code of Ethics, a set of recommendations established by the association board governing appropriate interactions between member companies representatives and healthcare practitioners. Although not a legal requirement, the Code is seen as appropriate industry practice. However since it is recommendation only, it has no compliance or enforcement mechanisms. The revised AdvaMed Code of Ethics became effective July 1, 2009 and covers the provision of meals to HCPs, company-conducted product training and education, CME, third-party scientific and education conferences or professional meetings, sales or promotional events, entertainment or recreational items, gift giving, payments to HCPs, and consulting arrangements.

### ***Institutional Policies***

Many academic and community hospital institutions have implemented their own policies regarding HCP interactions with company representatives, many of which are more stringent than federal and state regulations. Many of the institutional conflict of interest policies like those of Partners are in response to public criticism and Senator Grassley's investigations into conflicted physicians across the United States, including a case at MGH. Partners Healthcare, for example, which owns Massachusetts General Hospital and Brigham and Women's Hospital, has recently modified its conflict of interest policies, to create some of the most stringent in the United States [12]. Under the new rules, Partners physicians are banned from paid speaking engagements at company-sponsored events, receiving financial interests in companies as compensation, or receiving compensation greater than \$5,000 a day for participating on the board of a medical device or pharmaceutical company. Faculty at Harvard Medical School are subject to a separate set of policies governing their interactions with industry.

### ***State Regulations***

In addition to Massachusetts, six states plus the District of Columbia have implemented various forms of regulations governing the marketing of medical devices to physicians. These states are California, Maine, Minnesota, Nevada, Vermont, W. Virginia and each has different forms of regulation (Figure 3). Other states are currently in the process of developing their own regulations. Massachusetts is currently the most stringent and broad in governance of activities, with a unique marketing code of conduct, a compliance program surpassing those of California and Nevada, and broader disclosure requirements than those of Vermont, Maine, Minnesota, Vermont, W. Virginia and D.C. [27]. For example, Vermont's regulations do not require a purchase agreement prior to physician reimbursement for training events on a new device. Only a training agreement is required, which is more in line with standard industry practice for establishing training engagements. Other states including Connecticut are in the process of developing their own regulations governing the promotion of pharmaceuticals and medical devices, adding to the patchwork of state regulations with which companies must comply.

**Figure 3: Overview of state regulations**

State	Code of Conduct	Compliance Requirement	Disclosure Requirements	Disclosure Public?	Medical Devices Covered
California		√			√ (no disclosure)
Maine			√		
Massachusetts	√	√	√	√	√ (disclosure)
Minnesota			√	√	
Nevada		√			√ (no disclosure)
Vermont			√		
W. Virginia			√		
D.C.			√		

Source: Massachusetts Department of Public Health

**Overview of Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct**

In August 2008, Governor Deval Patrick signed the Pharmaceutical and Medical Device Manufacturer Code of Conduct (105 CMR 970.000) into law (Appendix C), in an effort to curtail improper industry-physician relationships that might inhibit physician independence and as part of the larger goal of cost containment. Gov. Patrick and the Massachusetts state legislature charged the DPH with the responsibility of developing and enacting the state regulations by July 1, 2009. The regulations adopted (Appendix D) require pharmaceutical and medical device manufacturers to 1) comply with a marketing code of conduct developed by the DPH, 2) undertake specific compliance activities related to training, auditing, and corrective action, and 3) disclose payments with a value of \$50 or more to providers in connection with sales and marketing activities [54]. From the perspective of the DPH, the regulations are intended to balance the transparency interests of patients and consumers with the industry concerns of maintaining the confidentiality of proprietary information. It also serves to place pharmaceutical and medical device manufacturers on “equal footing, with respect to the specific requirements” of the law [27]. The DPH’s interpretation of the law also helps to clarify certain permissible activities that were not originally specified in the statute and incorporates sections of PhRMA’s (the pharmaceutical trade association) code and AdvaMed’s code, in an effort to ease implementation.

*Scope*

The regulations govern manufacturers of devices, drugs, and biologics that market to Massachusetts-licensed healthcare practitioners, regardless of where the physician

practices. With regard to medical devices, the code of conduct applies to interactions between medical devices companies and HCPs. HCPs are defined by the statute as persons who prescribe drugs and are licensed to provide healthcare in the Commonwealth, including a partnership or corporation comprised of a healthcare practitioner or an officer, employee, agent, or contractor of such a practitioner. The regulations apply to both medical device manufacturers and distributors, although the statutes did not initially directly identify distributors.

“Sales and marketing activities” are defined to include any activity “used to influence the use of drugs, biologics or medical devices or to evaluate sales representatives as well as product education and training and the provision of any benefit with value of at least \$50 to healthcare practitioner other than as payment for services in connection with a clinical trial or genuine research project” [54].

### *Marketing Code of Conduct*

*Meals and Entertainment Restricted.* The provision of meals to HCPs is allowed under specific circumstances. Meals are allowed if provided as part of an informational presentation given by a manufacturer representative in a hospital setting. Hospital settings include academic medical centers, specialized training facilities, physician offices, and hospitals “specifically designed to approximate the conditions of a surgical suite or lab and provide medical training that uses human tissue or cadavers, on large and/or technical medical devices, such as surgical equipment, implants, and imaging and clinical laboratory development” [49]. The Code strictly prohibits the provision of entertainment or recreational events to HCPs who are not salaried employees or board members of the company. The provision of coffee or other snacks or refreshments at a booth at a conference is not considered a prohibited meal by the DPH [27]. Meals may be provided in hotel restaurants if in conjunction with CME-accredited or other third-party scientific, educational or professional meetings or conferences.

*Education.* Manufacturers cannot provide direct payments to HCPs in connection with continuing medical education. Manufacturer sponsorship of CME-accredited events and third party events that are accredited by official organizations, including the Accreditation Council for Continuing Medical Education, are allowed under the law. However, unaccredited education is prohibited. The law prohibits manufacturers from providing financial assistance for medical students, residents, fellows, and other HCPs-in-training to attend educational conferences. Manufacturers are also prohibited from providing input on

CME content or faculty choices. The code prohibits companies from providing financial support to HCPs for travel, lodging, or other personal expenses of non-faculty HCPs attending an educational or professional event. Companies are also expressly prohibited from compensating any HCPs for time spent at a CME-accredited event or other educational event.

A company is allowed to give non-restricted educational grants to an academic medical center for the purposes of fellowships or training. Grants may be used to benefit HCPs-in-training as long as the academic medical center selects the HCPs-in-training to benefit from the grant. The grant to the academic medical center is a publicly reportable transaction.

*Permitted Payments and Activities.* The law permits payment of expenses and reimbursement in connection with *bona fide* services, as defined in the regulations. This expands the prohibition, as previously defined by anti-kickback statutes, on payments to HCPs of any kind, including cash, financial interests, and tangible items. Gift giving is banned, except for those education items allowed under PhRMA and AdvaMed Codes. Permitted payments and activities includes: peer-reviewed scientific information, advertising, samples, consulting services in connection with genuine research or clinical trial, and expenses associated with training on a new medical device if that device is part of the vendor's purchase agreement contract. This presents potential ambiguity for many device manufacturers, since these companies enter into purchase agreements with distributors rather than HCPs directly. The ability of manufacturers to train physicians on new device procedures and to train new physicians on existing device procedures may become impaired.

Other permitted activities include: (1) price concessions given in the normal course of business, (2) reimbursement information unless provided to induce HCPs to use products, per AdvaMed Code, (3) medical device demonstration and evaluation units solely for use by and education of the HCP's patients, and (4) drugs or other support provided through established patient assistance programs that comply with the federal Anti-kickback statute. The statute requires the DPH to revisit and update the Manufacturer Code of Conduct at least every two years.

#### *Compliance Activities*

The regulations required manufacturers to comply with the code of conduct as described and implement the associated procedural and reporting requirements by July 1, 2009.

Manufacturers must certify their compliance to the law by July 1, 2010. Companies must certify that they have trained all employees engaged in sales and marketing activities on the code of conduct and general science and products to ensure that manufacturer representatives can “provide accurate, up-to-date information, consistent with state law and FDA requirements” [54]. Manufacturers must also certify that they are taking “regular assessments” to ensure that employees are compliant.

Companies are required to conduct annual internal audits, adopt procedures for investigating noncompliance internally, identify a compliance officer responsible for implementation and monitoring, and must annually submit to the DPH a description of their training and compliance programs as officially endorsed by the compliance officer.

*Disclosure Requirements*

A publicly accessible database will be maintained by the DPH, to which companies are required to disclose the “value, nature, purpose, and particular recipient of any fee, payment, subsidy or other economic benefit paid to a healthcare practitioner with a value of at least \$50” on an individualized, non-aggregated basis [31]. Annual disclosure of transactions valued \$50 or more is required beginning July 1, 2010 via a standardized form for the period July 1, 2009 through December 31, 2009, with an annual \$2000 annual fee payable to the DPH beginning July 1, 2009 (Figure 4).

**Figure 4: Massachusetts DPH reporting deadlines for disclosure of HCP payments**

<b>Report Due</b>	<b>Covering activities during the period:</b>
July 1, 2010	July 1, 2009 to December 31, 2009
July 1, 2011	January 1, 2010 to December 31, 2010
July 1, 2012	January 1, 2011 to December 31, 2011

Payments excluded from public disclosure requirements include those given to HCPs for services provided in connection with clinical trials or genuine research project, the provision of prescription drugs to a HCP for use by patients, demonstration and evaluation units, the provisions of in-kind items used for the provision of charity care, and price concessions including rebates and discounts. The clinical research exemption includes preclinical trials that are intended as precursor to clinical trails, but does not include post-market approval clinical evaluation research. Certain forms of market research are exempt from public reporting. If a company hires a third party to conduct a double-blind market research study

of HCPs and the HCPs are compensated with an honorarium, the payments are non-reportable (Figure 5). This exemption also holds true under the federal Sunshine provisions.

There is some industry concern regarding the scope of the clinical research exemption. Since a significant amount of medical device development and refinement occurs after a device gains FDA approval and has been launched in the market, industry representatives point out the dangers in publicly identifying physician who are involved in the evaluation of new products. Public disclosure of these physicians' identities may create biased evaluations or could inhibit companies from working with Massachusetts-licensed physicians for competitive concerns of divulging confidential relationships. As described earlier, in a formal clinical trial arrangement, companies usually pay the medical institution directly and not the physician for the sponsored research, so it is assumed that the facility's identity would be disclosed rather than the physician's. However, there is still ambiguity surrounding this matter of post-approval product evaluation research.

The economic value of a medical device provided to HCPs for training, product consultation, demonstration, and evaluation are excluded from the disclosure requirement if a purchase or lease agreement is established, however expense reimbursement and other forms of compensation to HCPs associated with training activities are not excluded from public disclosure. Reimbursement is allowed for travel, lodging, and meals if a contract for *bona fide* services is established and the following conditions are satisfied: "1) a legitimate need for the services [*is*] clearly identified in advance; (2) a connection [*exists*] between the competence and expertise of the health care practitioner and the purpose of the arrangement; (3) the number of health care practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose; (4) the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the health care practitioner; (5) the venue and circumstances of any meeting with the health care practitioner is conducive to the services and activities related to the services are the primary focus of the meeting; and (6) the decision to retain a health care practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company's sales personnel" [27]. Before reimbursement is provided, a "contract to purchase a medical device" must be in place between the company and the HCP or facility. Contracts can include an agreement to purchase or lease the device "pending an evaluation of the device to assess the appropriate use and functionality of the product" [27]. Companies will have the opportunity

to review and correct data before it becomes publicly disclosed on the DPH website, however HCPs will not.

**Figure 5: Overview of Massachusetts regulations**

Scope	Marketing Code of Conduct	Compliance activities	Reportable payments	Notable exemptions
<ul style="list-style-type: none"> <li>▪ Companies selling to MA-licensed healthcare practitioners, regardless of practice location</li> </ul>	<ul style="list-style-type: none"> <li>▪ Meals in hospital setting or CME events</li> <li>▪ Education restrictions</li> <li>▪ Entertainment prohibited</li> <li>▪ Gifts prohibited, unless educational purpose</li> </ul>	<ul style="list-style-type: none"> <li>▪ Training</li> <li>▪ Auditing</li> <li>▪ Corrective action</li> </ul>	<ul style="list-style-type: none"> <li>▪ All sales &amp; marketing activities</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pre-market clinical research</li> <li>▪ Evaluation units</li> <li>▪ In-kind units for charity</li> <li>▪ Price concessions</li> <li>▪ Blinded third-party market research</li> </ul>

*Penalties*

Knowing and willful violations of the regulation are enforced by the Massachusetts Attorney General and subject to criminal and civil violations and fines up to \$5,000 for each transaction, occurrence, or event.

*Comparison to AdvaMed Code of Ethics*

Since most medical device manufacturers and distributors are familiar with the AdvaMed Code in their interactions with physicians outside of Massachusetts, it is helpful to compare the Massachusetts regulations to the AdvaMed Code in order to highlight the additional transaction costs that AdvaMed-compliant companies will face in complying with the regulations in Massachusetts. The law builds upon AdvaMed national recommendations, but puts significant legal restrictions on physician gift giving, meals, physician consulting agreements, CME support, training events, and disclosure rules and enforces these regulations with penalties to manufacturers for noncompliance.

Regarding meals, similar to the AdvaMed recommendations, the Massachusetts regulations prohibit meals from being a part of an entertainment or recreational event, representatives from the company must be present, and no meals are allowed for spouses or guests of HCPs. However unlike AdvaMed, under the Massachusetts regulations meals cannot be offered, consumed, or provided outside of the HCP's office or hospital setting.

Regarding gifts, similar to AdvaMed recommendations, the Massachusetts regulations prohibit gifts, including complimentary items like pens, coffee mugs, and gift cards, entertainment or recreational items of any value to non-employees. Unlike AdvaMed, DPH rules allow provision only of “peer reviewed academic, scientific, or clinical journals” [27]. Similar to AdvaMed, the rules allow the provision of device demonstration and evaluation units to HCPs. Unlike AdvaMed, these units must be “exclusively for use by and education of the health care practitioner’s patients.”

Regarding device training and education, unlike AdvaMed, the Massachusetts regulations provide no specific references to “training” settings or meals for training purposes. In other words, the general rules for meals “in-hospital setting only” apply to training as well. Payments to HCPs for travel and lodging reimbursements related to technical training on the use of a medical device are allowed only if these expenses are specifically addressed in the written device purchase or lease agreement between the purchasing HCP or facility and the company. This creates concerns from industry since this does not necessarily reflect how device companies provide training to HCPs as described earlier. Moreover, clinical education and training are not always linked to a sales event, are often accomplished through third-party distributors, and hospitals often request trials with expensive devices involved at no charge. Also, many training and education events are for physicians and medical students that are not formally affiliated with a hospital purchasing the device.

With respect to disclosure requirements, unlike AdvaMed, DPH rules require companies employing marketers to disclose annually the value, nature, purpose, recipient, of any fee, payment, subsidy, or other economic benefit with a value of at least \$50 which the company provides to a covered recipient or facility in connection with a sales and marketing activity. As described earlier, “sales and marketing activities” include product education and training, but exclude reasonable compensation for the substantial professional or consulting services of a healthcare practitioner in connection with a genuine research project or clinical trial. Training devices are also excluded from public disclosure, however the services and reimbursement associated with training events are not excluded. Initial industry concerns included the fear that public disclosure of rebates would inhibit free negotiation of pricing and loss of access to discounts would harm physicians and patients. However, this ambiguity was resolved when it was later interpreted by the DPH that rebates would be exempt from reporting requirements.

Regarding physician CME credits, there is no language in the code prohibiting companies

from using hotels, convention centers, or other special event venues, although conference venues need to be “appropriate and conducive” to education. The DPH rules allow companies to offer support as long as CME-accredited education providers adhere to the standards of the relevant accreditation body. Non-restricted CME grants to facilities are allowed under the regulations, if the grants are not directed to an individual physician. However, these grants are reportable. Different from the AdvaMed Code, companies are liable to criminal and civil penalties under the Massachusetts regulations.

## **Chapter 3: Methodology**

### ***Review of Existing Literature***

An extensive review of the existing literature was conducted in order to begin to address the empirical questions proposed. A review of existing literature was conducted to understand the Massachusetts regulations and existing federal, state, and institutional regulations governing the marketing and promotion of medical devices. Literature specific to the Massachusetts regulations was limited to official legislative statutes and summaries of the regulations. Between announcement of the statute and adoption by the DPH in July 2009, there were several industry trade journal press releases and practical summaries produced by law firms. Following official adoption in July 2009, there were no articles published until late February 2010. MassMedic hosted a session for industry representatives that was attended by the DPH general counsel and Massachusetts U.S. Attorney General to address questions and ambiguities in the law. A partner from Goodwin Procter presented findings on a qualitative survey of 12 companies [22] regarding the tactical challenges associated with implementing compliance requirements. The AdvaMed website provided information on the AdvaMed Code of Ethics [3]. Institutional policies were found on their respective websites. The DPH website was also a good resource for an overview of the state regulations and answers to frequently asked questions regarding ambiguities in the law. Textbooks provided an additional resource for understanding US federal regulations as they compare to those of other nations.

In order to adequately understand the role of the sales and marketing function in medical device companies and evaluate the perceived impact of the Massachusetts regulations on physician-industry collaboration and medical device innovation, a combination of academic journal articles, textbooks, Harvard Business Review articles, and Harvard Business School case studies were used. However, the majority of my understanding of the sales and marketing function was developed through informal interviews with industry stakeholders.

### ***Informal Interviews***

In order to better understand the Massachusetts regulations and the role of marketing in medical device companies, 36 informal interviews were conducted with industry stakeholders at medical device manufacturers, distributors, academic medical centers, venture capital firms, law firms, consulting firms, MassMedic, and the DPH. Interviewees

were asked specific questions about their understanding of the Massachusetts regulations and how they perceived the law to impact physician-industry collaboration related to medical device development and physician education. These conversations were used to provide context for the development of a more formal survey for physicians and company representatives on the impact of the Massachusetts regulations on physician-industry collaboration.

A variety of device implantation and diagnostic procedures were also observed at MGH for additional context. These procedures included a deep brain stimulator, subdural electrode placement, artificial knee replacement, artificial skin graft, catheterization lab diagnostic tests, and spinal screws. Observing these procedures improved my understanding of the interactions between the surgical staff, physicians, and sales representatives in the operating room. The interactions of surgical staff and company representatives were observed, in order to better assess the value of these relationships.

Interview contacts were provided by my thesis supervisors, professors, or were within my professional network. The identity of interviewees will remain confidential and their responses anonymous for purposes of this thesis.

### ***Survey Design***

Using knowledge from the existing literature and context gained from the informal interviews and observed procedures, two parallel surveys were developed.

A two-page survey tailored to physicians and a two-page survey tailored to medical device company representatives were created using Adobe InDesign CS4 software and distributed via email. Participants were asked to complete a 10-minute survey and were informed that their responses would be kept strictly confidential and anonymous and would be used solely in connection with my research as a graduate student at the Harvard-MIT Division of Health Sciences and Technology. Participants were provided with a limited, two-sentence overview of the Massachusetts regulations in order to provide only a frame of reference. All participants were asked to answer questions based on their own experiences, perceptions, and opinions.

Leading questions were avoided. The surveys emphasized open-ended questions that allowed respondents to openly communicate their perspectives as well as more discrete

questions demanding a forced ranking (scale of 1-5), multiple choice responses, or quantitative answers. Open-ended questions were intended to allow issues to be raised that had not been previously considered. Questions demanding discrete answers were intended to standardize responses, but more importantly to distinguish between anecdotal perspectives and actual evidence of changed behavior resulting from the law's enactment. For example, one open-ended question asked company representatives, "How has the MA law influenced your or your colleagues' ability to update physicians on new device technologies?" Later in the survey, two follow up questions demand discrete responses: "In the past 12 months, what proportion of physicians that your company invited to sponsored events were from MA?" and "In the year prior, what was this proportion?" The physician and industry surveys used for our analysis can be found in Appendices A and B, respectively.

### ***Selection of Survey Participants***

The survey participant sample was selected with the objective of conducting a pilot study, from which initial results could be drawn. The goal was not to reach statistically significant conclusions, but to synthesize the initial impressions of industry stakeholders several months after the law's implementation and to highlight any potential impacts of the Massachusetts regulations on medical device physician-industry collaboration. The selection of survey participants was intended to enable the pilot study to serve as an initial, unbiased evaluation of the law and framework for further study with more significant resources. It is acknowledged that a larger study with more significant resources may be necessary to justify public policy implications, but this pilot study should serve as a roadmap for future research regarding the law's impact on the medical device industry.

Three device-intensive clinical areas were targeted in order to focus the results, standardize responses, and simultaneously gain insight into a variety of device procedures. These three main focus areas were cardiovascular, orthopaedics, and neurosurgical. The three specialties were chosen for their medical device intensity, variety of technical and procedural complexities, and variety of company sizes. An additional fourth category included all other device-oriented clinical specialties, but was primarily comprised of general surgeons. 37 company representatives and 106 physicians were selected for survey based on their respective categorical designations. Company representatives were categorized based on designation of their target markets and physicians were categorized based on designation of their clinical specialty. Company representatives were selected as participants with the intention of having a variety of positions and perspectives, including

product managers, sales representatives, distributors, and executive managers from various sizes of companies. Academic physicians in the Partners Healthcare system, Tufts University, and University of Massachusetts were selected by way of primary contact or introductions. Physicians were distributed the email survey directly or through staff at these institutions.

A total of 67 physicians and company representatives were initially selected as survey participants. An additional 65 physicians on the surgical staff distribution list at University of Massachusetts were forwarded the survey, as were 11 orthopaedic surgeons at MGH, bringing the total potential survey participant list to 143 individuals. Of the 67 primary contacts, 37 were company representatives and 30 were physicians. Of the 37 company representatives: 11 were identified as cardiovascular, 3 as neurosurgical, 14 as orthopaedic, and 9 as other. Of the 30 physicians initially selected: 12 were cardiovascular, 6 were neurosurgical, 6 were orthopaedic, and 6 general or trauma. In designing the study, it was assumed that there would be a significant number of non-responders. I followed up with non-responders twice if no response was received.

## **Chapter 4: Interviews and Survey Results**

Of the 143 individuals who received the survey, 40 responded (28% response rate). This total comprised 16 company representatives and 24 physicians. An additional 36 informal interviews were conducted with industry stakeholders at medical device manufacturers, distributors, academic medical centers, venture capital firms, law firms, consulting firms, MassMedic, and the DPH. Representatives from one large company were advised by their legal department not to respond to the survey, however informal interviews were conducted with representatives from this company for additional perspective.

### ***Summary of Informal Interviews***

A total of 36 informal conversations were conducted with industry stakeholders to provide context for the development of physician and industry surveys and to improve my understanding of the role of sales and marketing representatives in the medical device industry. There were significant concerns that the Massachusetts regulations will increase the barriers between physicians and medical device companies, impairing physician-industry collaboration on technology development, new device training, and medical education. Representatives from manufacturers and distributors expected their companies to withdraw from technology development and education relationships with Massachusetts-licensed physicians. One individual from a large manufacturer involved with physician education said the company “would walk away from all Massachusetts-licensed physicians if it weren’t for specific pre-existing, individual relationships.”

Manufacturer and distributor representatives, in addition to individuals from professional service firms (e.g. legal, consulting, venture capital) suggested that significant ambiguities still remained in the law’s interpretation. Manufacturers and distributors described the high costs of interpretation and implementation of the regulations, and the need to hire legal counsel and buy new software tracking systems to obey disclosure requirements on a state-by-state basis. Through conversations with DPH officials, it also became evident that the legislation had originally been passed with pharmaceutical companies in mind, and the DPH was relied upon to incorporate the specific needs of medical device companies.

Several physicians interviewed were concerned that the perceived industry withdrawal would impair their ability to innovate, educate new physicians, stay updated on new therapy options, and provide optimal patient care. One senior attending physician warned that “the

medical device industry would be decimated.” Conversely, a surgical quality officer at an academic medical center believed the regulations were beneficial to hospitals, because they “provide a materials management check on costs, before exposing new technologies to physicians.”

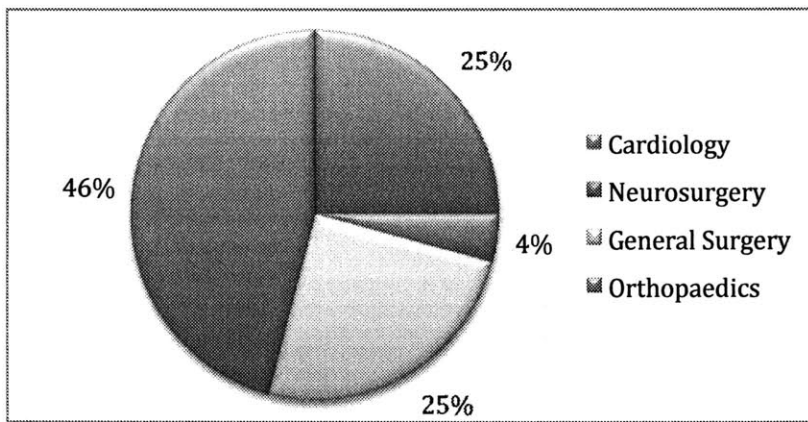
### ***Summary of Survey Results***

Physician-industry collaboration related to physician education and technology development was impaired by the Massachusetts regulations, with evidence of a larger negative impact on physician education. Within physician education, new device procedure training, non-CME-accredited education, and promotional events experienced the most significant impact. A significant majority of physicians claimed that physician education has been impaired as a direct result of the Massachusetts regulations and a majority of company representatives stated that their ability to keep physicians updated had been impaired as a result of the law. Over half of all physicians believed that the Massachusetts regulations would have a negative impact on patient care in the long term, through impaired physician education and ability to stay updated on new therapies.

### ***Physician Survey Participant Characteristics***

The physician respondents were diversified across four clinical specialties: orthopaedic surgery, interventional cardiology, neurosurgery, and general surgery (Figure 6). These physicians performed an average of approximately 310 procedures annually and have been in practice between 1 and 34 years. All participating physicians have an academic practice within the institutions of the University of Massachusetts, Partners Healthcare, or Tufts University. Two of these physicians also have a community practice. As academic physicians, all are involved in physician education and training; 15 of the physicians serve on at least one hospital committee; 19 are involved in academic research with between 5 and 250 peer-reviewed published articles; 7 are involved with their institution’s purchase of new medical devices; and 11 have contractually engaged with industry between 1 and 25 times. All 24 physician participants declared that there is value in working with industry; of these, 14 contended that there is the potential for conflict within this capacity.

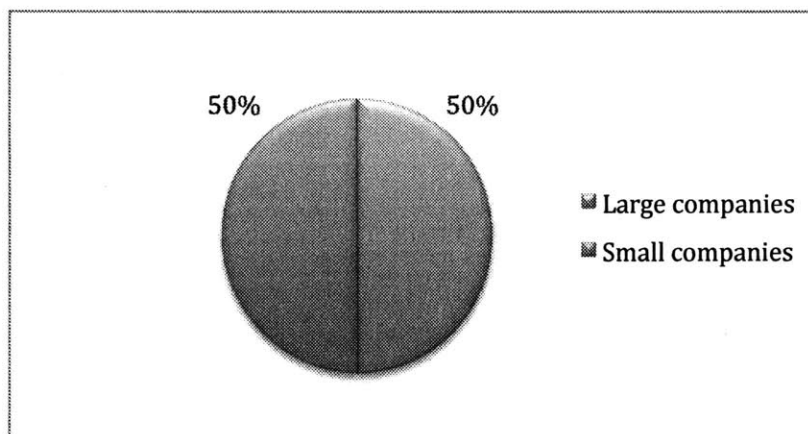
**Figure 6: Distribution of physician survey participants by clinical specialty**



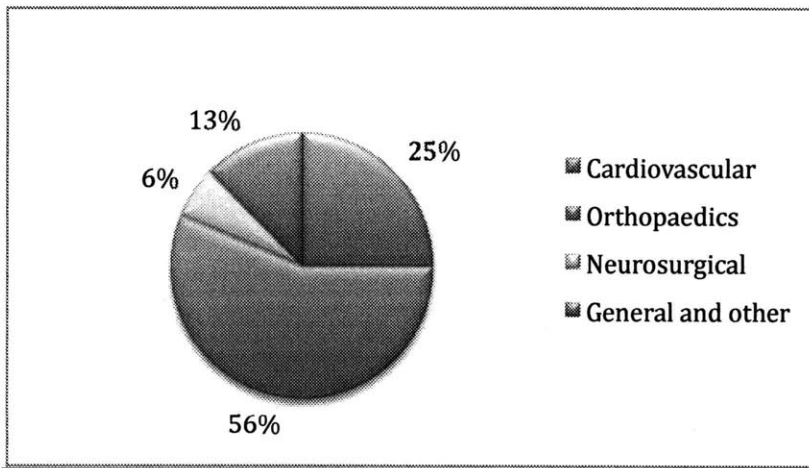
***Company Survey Participant Characteristics***

A total of 16 medical device company representatives participated in the survey. Of the companies represented, 50 percent were defined as large companies and 50 percent were small companies, based on annual revenue (Figure 7). The large companies each had annual revenue of greater than \$1 billion and the small companies each had annual revenue of less than \$150 million. Of the small company representatives, 62.5 percent claimed annual revenue of less than \$10 million. The 16 companies were diversified across four target market categories: cardiology, orthopaedics, neurosurgical, and general/other (Figure 8). The large companies that targeted multiple clinical markets were categorized based on the surveyed representative's role. Representative roles included medical education managers, business unit vice presidents, compliance officers, sales representatives, distributor regional managers, executive officers, commercial operations managers, and business development managers.

**Figure 7: Distribution of company survey participants by company size**



**Figure 8: Distribution of company survey participants by target market**

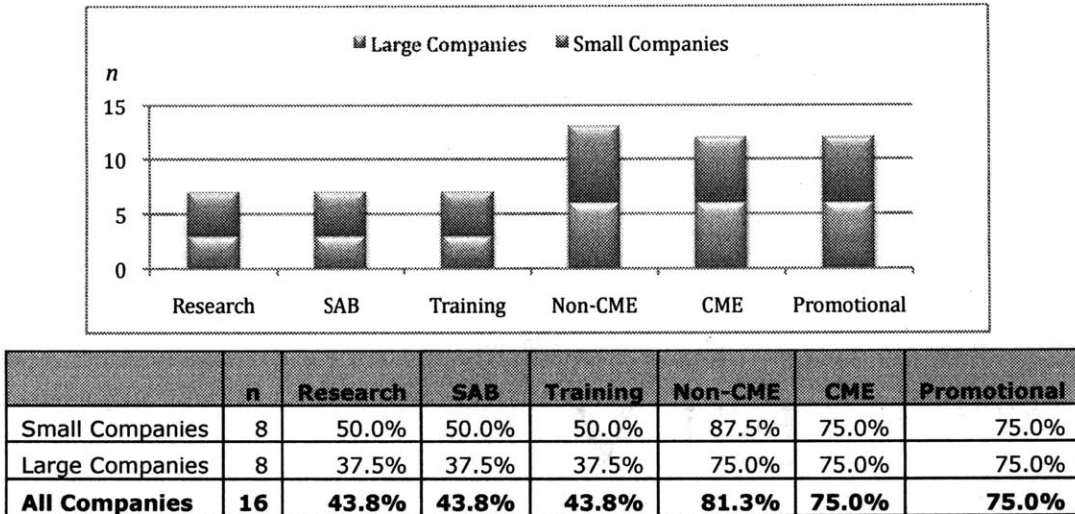


### ***Withdrawal from Collaboration Relationships***

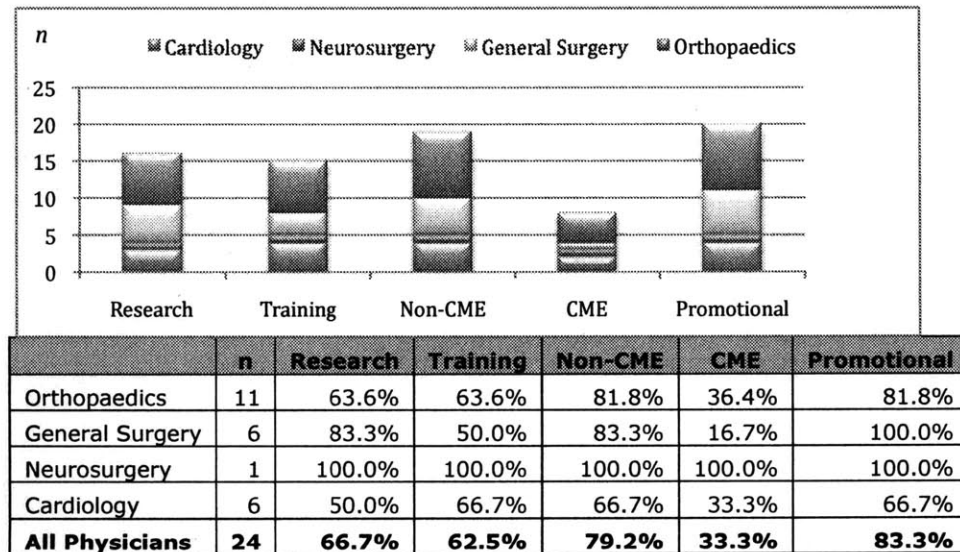
Company representatives claimed an impact on their decisions to collaborate with physicians with regard to research, scientific advisory boards, new device procedure training, non-CME accredited educational events, CME accredited educational events, and promotional events. Company financial support for non-CME educational events had the largest impact, followed by promotional events, and support for CME-accredited events (Figure 9). Large and small companies had a relatively even distribution across these categories.

Given the new regulations on disclosure of physician expense reimbursement and compensation, physicians were asked as to their willingness to participate in several categories of industry collaboration, without expense reimbursement or compensation. Promotional events had the largest physician withdrawal, followed by non-CME educational events, research, and training events for new device procedures. Notably, a majority (62.5 percent) of physicians claimed they would not attend a training event without expense reimbursement or some other form of compensation. Moreover, only a minority (37.5 percent) of physicians surveyed would agree to attend a new device procedure training event without reimbursement or compensation (Figure 10). A minority (33.3 percent) of the physicians would participate in industry-supported research without reimbursement or compensation. A majority (66.7 percent) of the physicians would still attend CME-accredited events without expense reimbursement or compensation for their time.

**Figure 9: Impact on company's ability to interact with Massachusetts-licensed physicians in specific categories**



**Figure 10: Impact on physician's ability to collaborate with companies. Which of the following would you not attend without expense reimbursement or compensation?**



**Stakeholder Understanding of the PCOC**

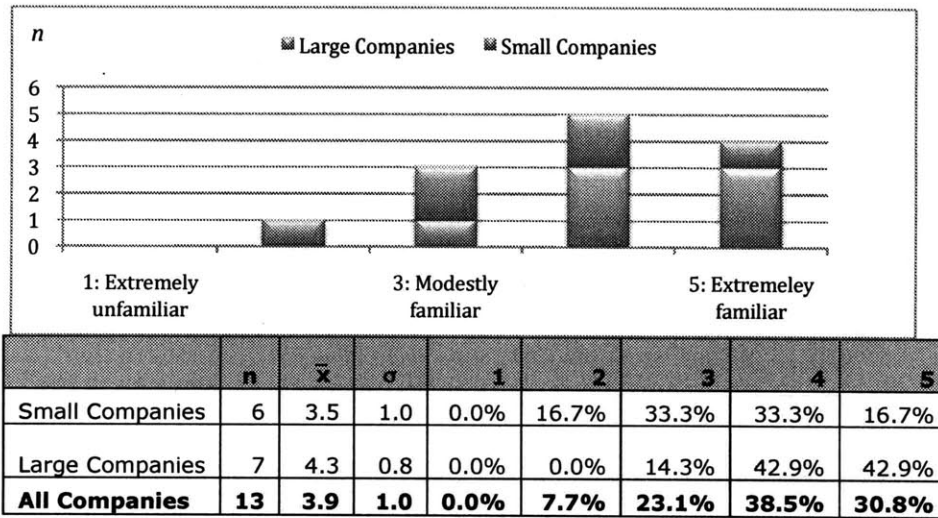
*How familiar are company representatives and physicians with the Massachusetts regulations, AdvaMed Code of Ethics, academic institutional policies, and differences between them?*

As a group, companies were most familiar with the AdvaMed Code, relative to their customers' institutional policies and the Massachusetts regulations (Figures 11, 13, 15). Large and small companies were equally familiar with the intricacies of the AdvaMed Code, however the Massachusetts regulations and customer institution policies disproportionately favored large companies. None of the company representatives surveyed claimed they were "extremely familiar" or "extremely unfamiliar" with the Massachusetts law and none of the

small company representatives were more than “modestly familiar,” implying that ambiguities in the law’s interpretation still existed.

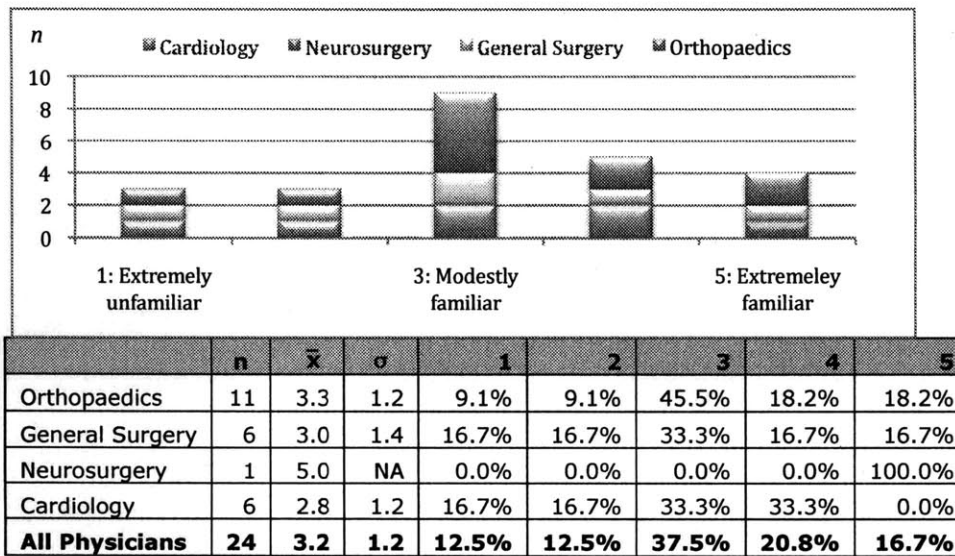
As a group, physicians were most familiar with their own institutional policies, relative to the AdvaMed Code and the Massachusetts regulations (Figures 12, 14, 16). Roughly half (54.2 percent) of physicians claimed they were “extremely familiar” with their own institution’s policy and 91.7 percent claimed they were at least modestly familiar. Clinical specialties were fairly distributed. Less than half (39.1 percent) of the physicians surveyed were extremely unfamiliar or unfamiliar with the Massachusetts law and only 8.7 percent claimed extreme familiarity.

**Figure 11: Company familiarity with AdvaMed Code of Ethics**



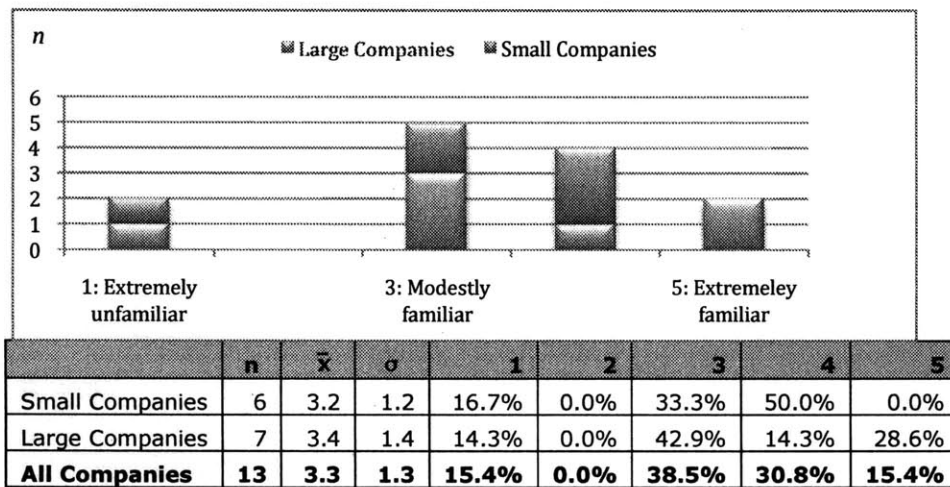
Scale 1-5: 1=extremely unfamiliar, 5=extremely familiar

**Figure 12: Physician familiarity with AdvaMed Code of Ethics**



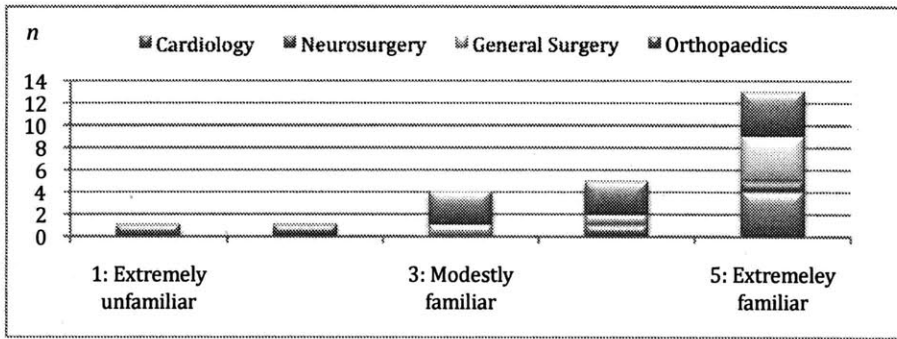
Scale 1-5: 1=extremely unfamiliar, 5=extremely familiar

**Figure 13: Company familiarity with customers' policies**



Scale 1-5: 1=extremely unfamiliar, 5=extremely familiar

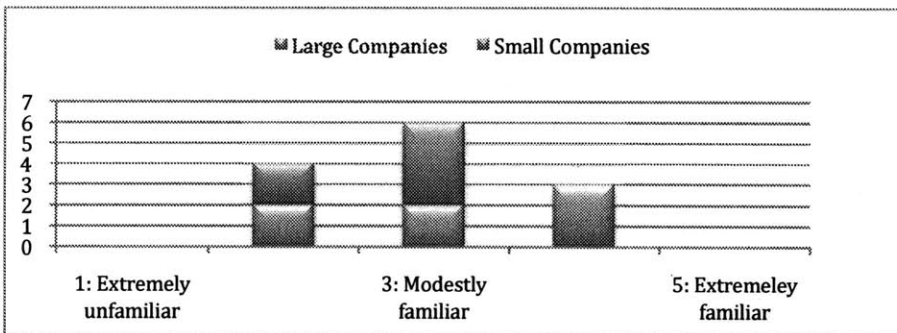
**Figure 14: Physician familiarity with institutional policy**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	11	3.9	1.0	0.0%	9.1%	27.3%	27.3%	36.4%
General Surgery	6	4.5	0.8	0.0%	0.0%	16.7%	16.7%	66.7%
Neurosurgery	1	5.0	NA	0.0%	0.0%	0.0%	0.0%	100.0%
Cardiology	6	4.2	1.6	16.7%	0.0%	0.0%	16.7%	66.7%
<b>All Physicians</b>	<b>24</b>	<b>4.2</b>	<b>1.1</b>	<b>4.2%</b>	<b>4.2%</b>	<b>16.7%</b>	<b>20.8%</b>	<b>54.2%</b>

Scale 1-5: 1=extremely unfamiliar, 5=extremely familiar

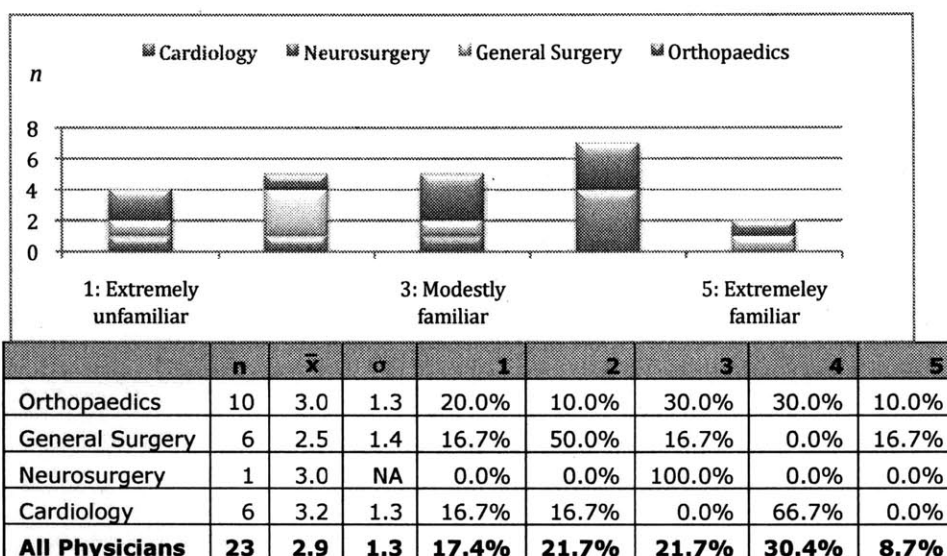
**Figure 15: Company familiarity with exact differences from Massachusetts regulations**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Small Companies	6	2.7	0.5	0.0%	33.3%	66.7%	0.0%	0.0%
Large Companies	7	3.1	0.9	0.0%	28.6%	28.6%	42.9%	0.0%
<b>All Companies</b>	<b>13</b>	<b>2.9</b>	<b>0.8</b>	<b>0.0%</b>	<b>30.8%</b>	<b>46.2%</b>	<b>23.1%</b>	<b>0.0%</b>

Scale 1-5: 1=extremely unfamiliar, 5=extremely familiar

**Figure 16: Physician familiarity with exact differences from Massachusetts regulations**



Scale 1-5: 1=extremely unfamiliar, 5=extremely familiar

*What ambiguities still exist in the law as it is currently written, as perceived by company representatives?*

Several company representatives commented that considerable ambiguities still exist in the Massachusetts regulations as they are currently implemented. The majority of these ambiguities regard disclosure and the marketing code of conduct, specifically which company representative behaviors are allowable and which interactions are exempt from disclosure. As supported by informal interviews, there are considerable ambiguities among physicians, institution representatives, and companies regarding the scope of the “clinical research” disclosure exemption.

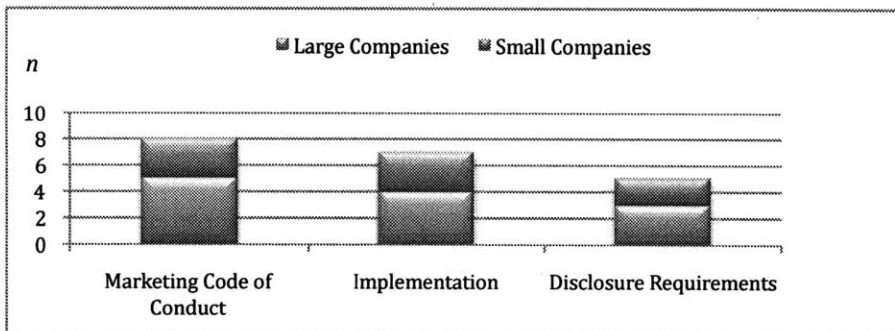
*What are the most restrictive aspects of the law?*

The most restrictive aspects of the law as perceived by company representatives reside in the marketing code of conduct, followed by implementation of the regulations and disclosure requirements (Figure 17). Responses of large and small companies were evenly distributed. Company representatives cited one of the most restrictive components of the marketing code as the prohibition of interactions with Massachusetts-licensed physicians in certain environments, for example holding modest receptions for physicians at trade shows. Also cited as a significant impairment was the ban on meals outside of a hospital-like facilities. This restriction impaired companies’ abilities to attract physicians and legitimately interact at these events. It also incited companies to significantly reduce event invitations to Massachusetts-licensed physicians and in some cases dismiss Massachusetts physicians from scientific advisory board positions.

Implementation challenges included the identification of allowable interactions, implementing training and compliance protocols, and the costs of complying on a state-by-state basis. Also cited were the challenges of managing interactions with the significant number of Massachusetts-licensed physicians who do not reside in the state.

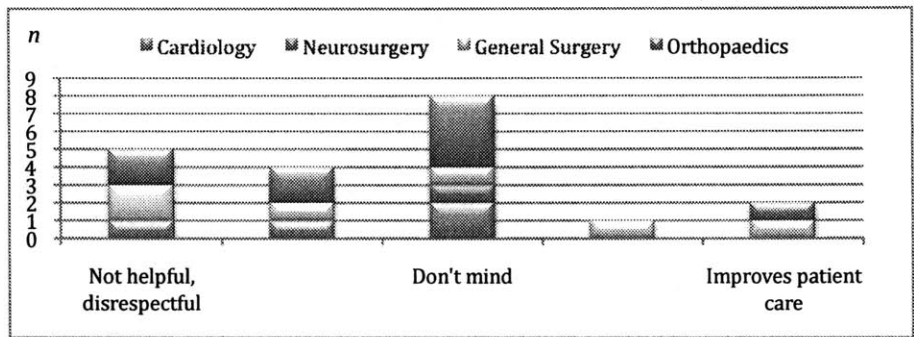
Disclosure requirement challenges cited include the maintenance of a robust reporting system. This was described as less of an issue for small companies, but a significant challenge for large companies that have grown through acquisition. When asked directly, all company representatives believed that disclosure requirements and the transparency they create are a good thing for the industry, since they limit physician kickbacks and help “level the playing field.” The majority of physicians similarly claimed that they don’t mind or see benefit in their names being publicly disclosed (Figure 18). A minority of physicians (25.0 percent) surveyed feel that disclosure requirements are not helpful or disrespectful to their profession; less than half (45.0 percent) minded to some extent. However, disclosure requirements on a state-by-state level were believed to be excessive and created unnecessary costs for companies, diverting limited resources that could be spent on research, development, and physician education.

**Figure 17: Most restrictive aspects of the Massachusetts regulations, as perceived by companies**



	n	Code of Conduct	Implementation	Disclosure
Small Companies	6	50.0%	50.0%	33.3%
Large Companies	6	83.3%	66.7%	50.0%
<b>All Companies</b>	<b>12</b>	<b>66.7%</b>	<b>58.3%</b>	<b>41.7%</b>

**Figure 18: Physician opinion on disclosure requirements**



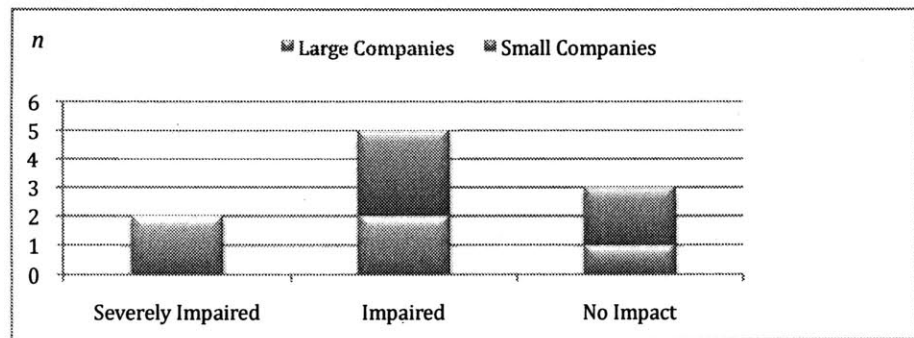
	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	9	2.6	1.2	22.2%	22.2%	44.4%	0.0%	11.1%
General Surgery	6	2.7	1.6	33.3%	16.7%	16.7%	16.7%	16.7%
Neurosurgery	1	3.0	NA	0.0%	0.0%	100.0%	0.0%	0.0%
Cardiology	4	2.3	1.0	25.0%	25.0%	50.0%	0.0%	0.0%
<b>All Physicians</b>	<b>20</b>	<b>2.6</b>	<b>1.2</b>	<b>25.0%</b>	<b>20.0%</b>	<b>40.0%</b>	<b>5.0%</b>	<b>10.0%</b>

Scale 1-5: 1=not helpful, disrespectful; 3=don't mind; 5=improves patient care

### Product Development

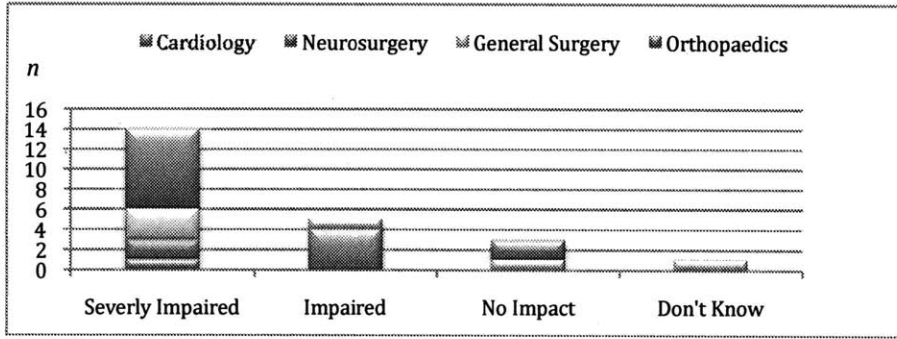
Company representatives and physicians were asked for their initial impressions on the law's impact on their medical device technology development relationships. The majority (70.0 percent) of company representatives claimed that their company's ability to collaborate with physicians had been impaired and of these 2 large companies claimed their ability to collaborate had been "severely impaired" (Figure 19). The strong majority of physicians (82.6 percent) claimed their ability to collaborate with industry had been impaired. Within this group, 73.7 percent claimed they were "severely impaired" (Figure 20).

**Figure 19: Impact on industry's ability to interact with Massachusetts-licensed physicians on technology development**



	n	Severely Impaired	Impaired	No impact
Small Companies	5	0.0%	60.0%	40.0%
Large Companies	5	40.0%	40.0%	20.0%
<b>All Companies</b>	<b>10</b>	<b>20.0%</b>	<b>50.0%</b>	<b>30.0%</b>

**Figure 20: Impact on Massachusetts-licensed physician's ability to collaborate with industry on technology development**

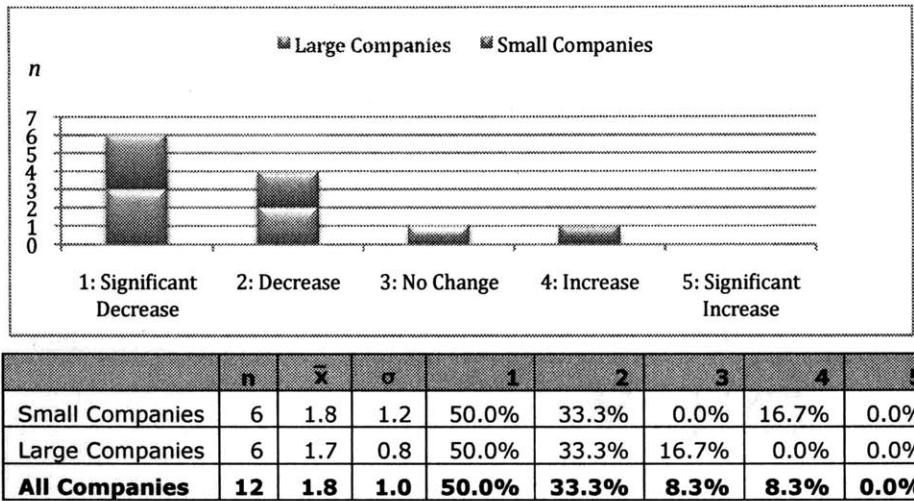


	n	Severely Impaired	Impaired	No Impact	Don't Know
Orthopaedics	10	80.0%	0.0%	20.0%	0.0%
General Surgery	6	50.0%	16.7%	16.7%	16.7%
Neurosurgery	2	100.0%	0.0%	0.0%	0.0%
Cardiology	5	20.0%	80.0%	0.0%	0.0%
<b>All Physicians</b>	<b>23</b>	<b>60.9%</b>	<b>21.7%</b>	<b>13.0%</b>	<b>4.3%</b>

*Has there been an impact on the decisions of company representatives and physicians to collaborate on preclinical or clinical research, regardless of the law's disclosure exemption?*

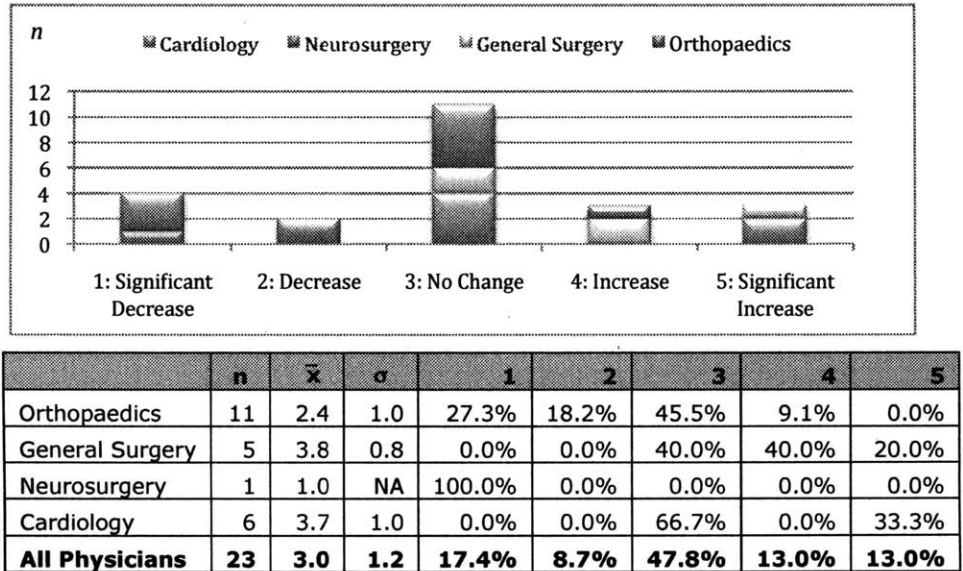
The majority (83.3 percent) of company representatives claimed a decrease in their company's interest in collaborating with Massachusetts-licensed physicians on preclinical or clinical research (Figure 21). Roughly half (47.8 percent) of physicians claimed no change or an increase in their interest to collaborate with industry on pre-market research (Figure 22). This is supportive of the finding that the majority of physicians don't mind or support increased disclosure and transparency of their industry relationships and the fact that the legal liabilities reside with companies, not physicians.

**Figure 21: Impact on industry interest in collaborating with Massachusetts-licensed physicians on pre-market R&D**



Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

**Figure 22: Impact on physician interest in collaborating with industry on pre-market R&D**



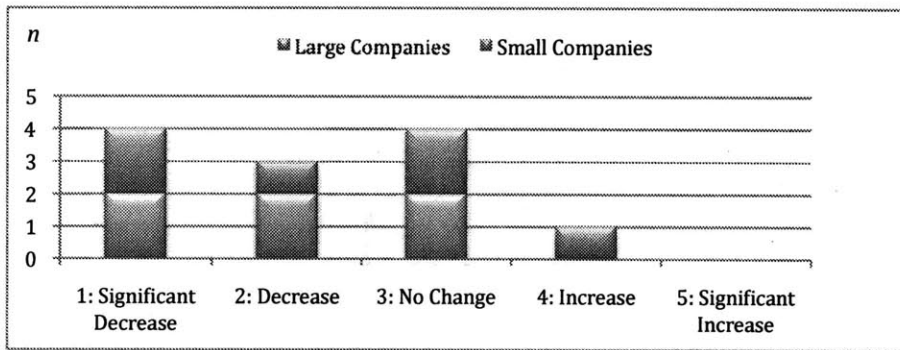
Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

*Has there been an impact on the decisions of company representatives and physicians to collaborate on post-market research?*

Over half (58.3 percent) of company representatives cited a decrease in their interest to collaborate with physicians on development research for already approved and marketed products (Figure 23). Of these, 57.1 percent claimed a “significant decrease.” Surprisingly, 33.3 percent company representatives claimed “no change” in their interest level. This is surprising, given the results of pre-market research and the fact that physician payments for post-market research are not exempt from disclosure, whereas payments for pre-market research are exempt. Similar to the pre-market results, the majority of physicians claimed

no change or an increase in their interest to collaborate with industry on post-market research (Figure 24).

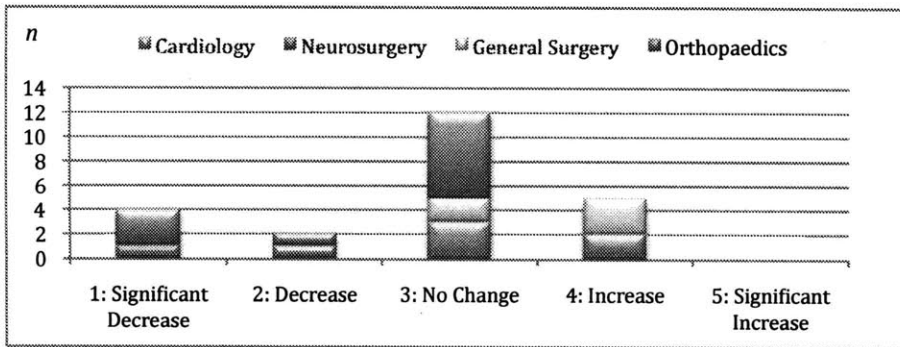
**Figure 23: Impact on industry interest in collaborating with Massachusetts-licensed physicians on post-market R&D**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Small Companies	6	2.3	1.2	33.3%	16.7%	33.3%	16.7%	0.0%
Large Companies	6	2.0	0.9	33.3%	33.3%	33.3%	0.0%	0.0%
<b>All Companies</b>	<b>12</b>	<b>2.2</b>	<b>1.1</b>	<b>33.3%</b>	<b>25.0%</b>	<b>33.3%</b>	<b>8.3%</b>	<b>0.0%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

**Figure 24: Impact on physician interest in collaborating with industry on post-market R&D**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	11	2.4	0.9	27.3%	9.1%	63.6%	0.0%	0.0%
General Surgery	5	3.6	0.5	0.0%	0.0%	40.0%	60.0%	0.0%
Neurosurgery	1	1.0	NA	100.0%	0.0%	0.0%	0.0%	0.0%
Cardiology	6	3.2	0.8	0.0%	16.7%	50.0%	33.3%	0.0%
<b>All Physicians</b>	<b>23</b>	<b>2.8</b>	<b>1.0</b>	<b>17.4%</b>	<b>8.7%</b>	<b>52.2%</b>	<b>21.7%</b>	<b>0.0%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

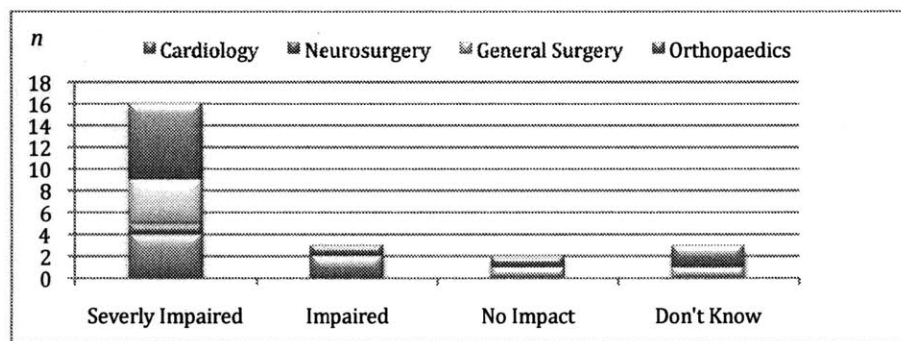
### Physician Education

*Have physician education and patient care been impacted by the Massachusetts regulations?*

Physicians were asked their initial impressions of the law's impact on physician education, exposure to medical device therapy options, training on new devices procedures, and

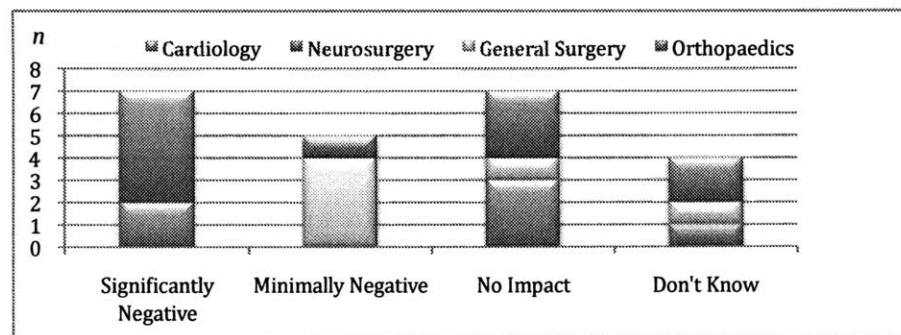
ultimately patient care. A significant majority (79.2 percent) claimed that physician education has been impaired or severely impaired as a direct result of the Massachusetts regulations (Figure 25). 66.7 percent of these physicians claimed severe impairment. Causes of this impairment were cited as the various restrictions placed on interactions with industry and the withdrawal of industry support from various forms of educational events and financial support for Massachusetts-licensed physicians. Approximately half (52.2 percent) of physicians believed that the Massachusetts regulations would have a negative impact on patient care in the long term, through impaired physician education and a decreased ability to stay updated on new therapies (Figure 26).

**Figure 25: Impact on physician education, as perceived by physicians**



	n	Severely Impaired	Impaired	No impact	Don't Know
Orthopaedics	11	63.6%	9.1%	9.1%	18.2%
General Surgery	6	66.7%	0.0%	16.7%	16.7%
Neurosurgery	1	100.0%	0.0%	0.0%	0.0%
Cardiology	6	66.7%	33.3%	0.0%	0.0%
<b>All Physicians</b>	<b>24</b>	<b>66.7%</b>	<b>12.5%</b>	<b>8.3%</b>	<b>12.5%</b>

**Figure 26: Impact on patient care, as perceived by physicians**



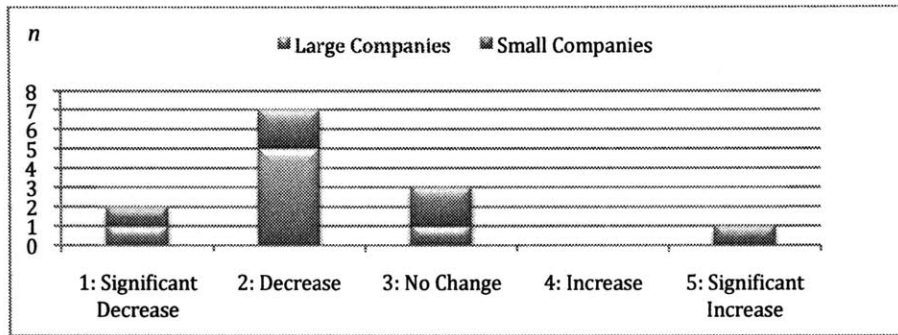
	n	Significantly Negative	Minimally Negative	No Impact	Don't Know
Orthopaedics	11	45.5%	9.1%	27.3%	18.2%
General Surgery	6	0.0%	66.7%	16.7%	16.7%
Neurosurgery	1	0.0%	0.0%	0.0%	100.0%
Cardiology	5	40.0%	0.0%	60.0%	0.0%
<b>All Physicians</b>	<b>23</b>	<b>30.4%</b>	<b>21.7%</b>	<b>30.4%</b>	<b>17.4%</b>

*Have physician exposure to new and existing devices decreased since the law's adoption?*

A majority (69.2 percent) of company representatives claimed a decrease in the number of opportunities to expose physicians to new device therapy options (Figure 27) and a roughly half (47.8 percent) of physicians claimed a decrease in their exposure to new device therapy options (Figure 28). 45.5 percent of these physicians were orthopaedic surgeons and 36.4 percent were general surgeons. 21.7 percent of physicians claimed an increase in their exposure to new therapy options. 30.8 percent of company representatives cited a decrease in the number of their company's sales representatives carrying new devices (marketed for less than one year) into the hospital and 75.0 percent of these respondents were from small companies (Figure 31). These small companies also cited a decrease in the number of sales representative carrying existing devices (marketed for more than one year), however the large company citing a decrease for new devices claimed "no change" for existing devices (Figure 29).

Approximately half (52.2 percent) of physicians claimed a decrease in their exposure to sales representatives carrying new devices (Figure 32). This ratio was higher (56.5 percent) for existing devices, supporting the findings obtained from company representatives that exposure to existing devices was impacted more than that for new devices (Figure 30). However, 43.5 percent of physicians claimed a decrease in their ability to introduce new devices to other physicians within their own institution, through formal committees or informal conversations (Figure 33).

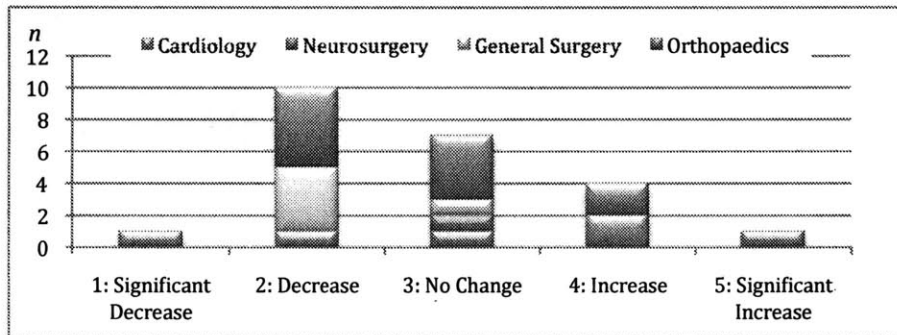
**Figure 27: Number of opportunities to expose physicians to new device therapy options, as perceived by company representatives**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Small Companies	6	2.7	1.4	16.7%	33.3%	33.3%	0.0%	16.7%
Large Companies	7	2.0	0.6	14.3%	71.4%	14.3%	0.0%	0.0%
<b>All Companies</b>	<b>13</b>	<b>2.3</b>	<b>1.0</b>	<b>15.4%</b>	<b>53.8%</b>	<b>23.1%</b>	<b>0.0%</b>	<b>7.7%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

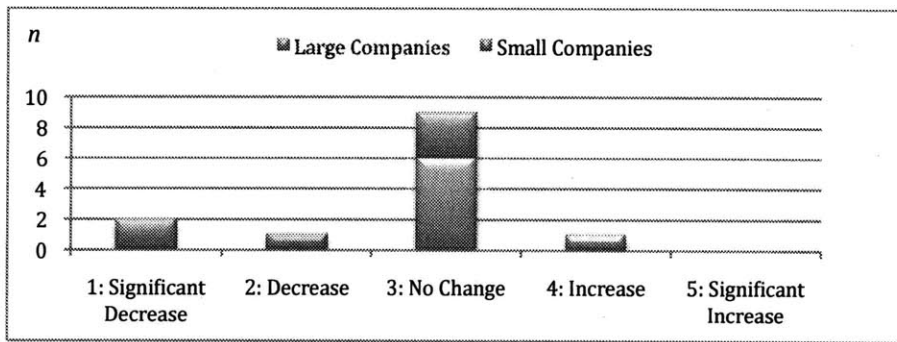
**Figure 28: Number of opportunities to gain exposure to new device therapy options, as perceived by physicians**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	11	2.7	0.8	0.0%	45.5%	36.4%	18.2%	0.0%
General Surgery	5	2.2	0.4	0.0%	80.0%	20.0%	0.0%	0.0%
Neurosurgery	1	3.0	NA	0.0%	0.0%	100.0%	0.0%	0.0%
Cardiology	6	3.2	1.5	16.7%	16.7%	16.7%	33.3%	16.7%
<b>All Physicians</b>	<b>23</b>	<b>2.7</b>	<b>1.0</b>	<b>4.3%</b>	<b>43.5%</b>	<b>30.4%</b>	<b>17.4%</b>	<b>4.3%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

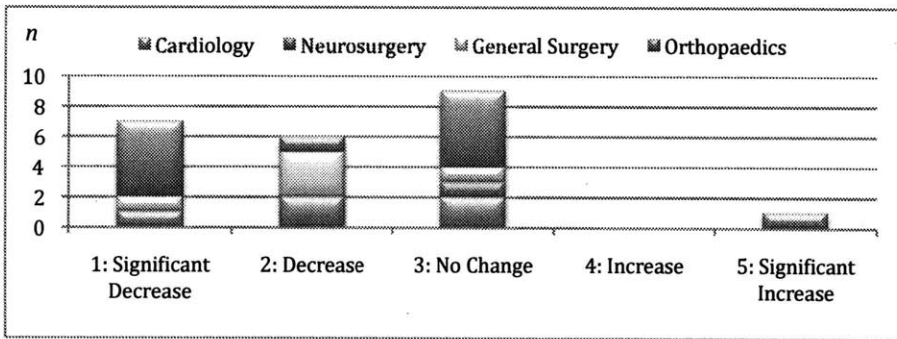
**Figure 29: Impact on number of sales representatives carrying existing devices in the hospital, as perceived by companies**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Small Companies	6	2.2	1.0	33.3%	16.7%	50.0%	0.0%	0.0%
Large Companies	7	3.1	0.4	0.0%	0.0%	85.7%	14.3%	0.0%
<b>All Companies</b>	<b>13</b>	<b>2.7</b>	<b>0.9</b>	<b>15.4%</b>	<b>7.7%</b>	<b>69.2%</b>	<b>7.7%</b>	<b>0.0%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

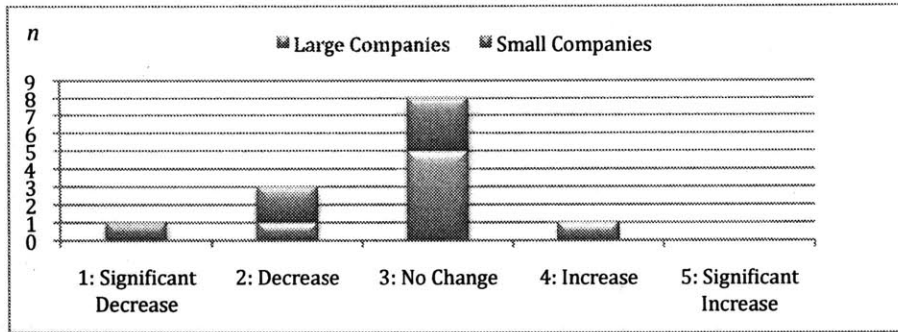
**Figure 30: Impact on number of sales representatives carrying existing devices in the hospital, as perceived by physicians**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	11	2.0	1.0	45.5%	9.1%	45.5%	0.0%	0.0%
General Surgery	5	2.0	0.7	20.0%	60.0%	20.0%	0.0%	0.0%
Neurosurgery	1	3.0	NA	0.0%	0.0%	100.0%	0.0%	0.0%
Cardiology	6	2.7	1.4	16.7%	33.3%	33.3%	0.0%	16.7%
<b>All Physicians</b>	<b>23</b>	<b>2.2</b>	<b>1.0</b>	<b>30.4%</b>	<b>26.1%</b>	<b>39.1%</b>	<b>0.0%</b>	<b>4.3%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

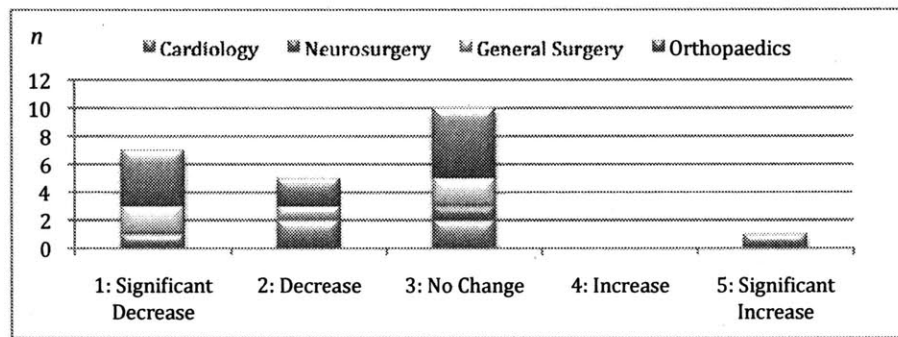
**Figure 31: Impact on number of sales representatives carrying new devices in the hospital, as perceived by companies**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Small Companies	6	2.3	0.8	16.7%	33.3%	50.0%	0.0%	0.0%
Large Companies	7	3.0	0.6	0.0%	14.3%	71.4%	14.3%	0.0%
<b>All Companies</b>	<b>13</b>	<b>2.7</b>	<b>0.8</b>	<b>7.7%</b>	<b>23.1%</b>	<b>61.5%</b>	<b>7.7%</b>	<b>0.0%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

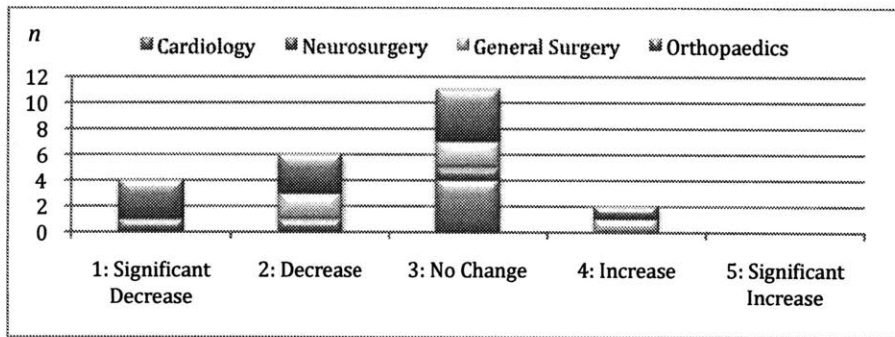
**Figure 32: Impact on number of sales representatives carrying new devices in the hospital, as perceived by physicians**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	11	2.1	0.9	36.4%	18.2%	45.5%	0.0%	0.0%
General Surgery	5	2.0	1.0	40.0%	20.0%	40.0%	0.0%	0.0%
Neurosurgery	1	3.0	NA	0.0%	0.0%	100.0%	0.0%	0.0%
Cardiology	6	2.7	1.4	16.7%	33.3%	33.3%	0.0%	16.7%
<b>All Physicians</b>	<b>23</b>	<b>2.3</b>	<b>1.1</b>	<b>30.4%</b>	<b>21.7%</b>	<b>43.5%</b>	<b>0.0%</b>	<b>4.3%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

**Figure 33: Impact on physician ability to introduce new device therapies to other physicians, as perceived by physicians**



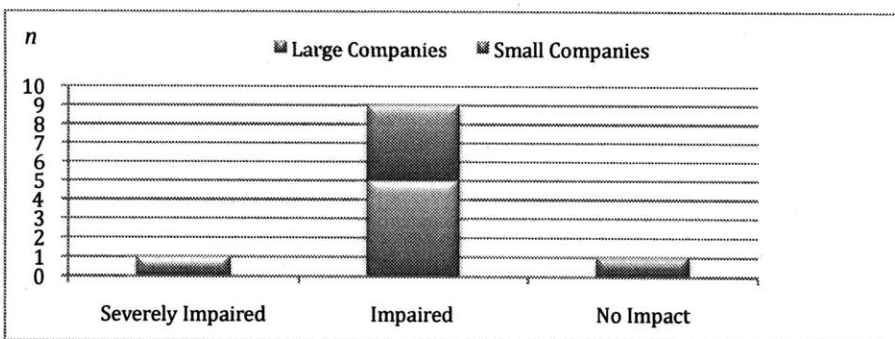
	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	11	2.3	1.0	27.3%	27.3%	36.4%	9.1%	0.0%
General Surgery	5	2.8	0.8	0.0%	40.0%	40.0%	20.0%	0.0%
Neurosurgery	1	3.0	NA	0.0%	0.0%	100.0%	0.0%	0.0%
Cardiology	6	2.5	0.8	16.7%	16.7%	66.7%	0.0%	0.0%
<b>All Physicians</b>	<b>23</b>	<b>2.5</b>	<b>0.9</b>	<b>17.4%</b>	<b>26.1%</b>	<b>47.8%</b>	<b>8.7%</b>	<b>0.0%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

*Has the law impacted the ability of physicians to stay updated on new device therapies?*

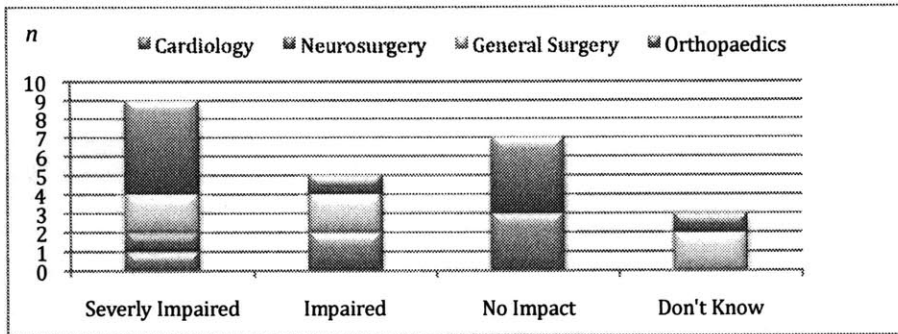
A majority of company representatives (90.9 percent) stated that their ability to keep physicians updated had been impaired or severely impaired as a result of the law (Figure 34), whereas 58.3 percent of physicians supportively claimed that their ability to stay updated on new device therapies had been impaired or severely impaired (Figure 35). 29.2 percent of physicians stated no impact.

**Figure 34: Impact on company's ability to keep physicians updated on new device therapy options, as perceived by companies**



	n	Severely Impaired	Impaired	No impact
Small Companies	5	0.0%	80.0%	20.0%
Large Companies	6	16.7%	83.3%	0.0%
<b>All Companies</b>	<b>11</b>	<b>9.1%</b>	<b>81.8%</b>	<b>9.1%</b>

**Figure 35: Impact on physician’s ability to stay updated on new device therapy options, as perceived by physicians**

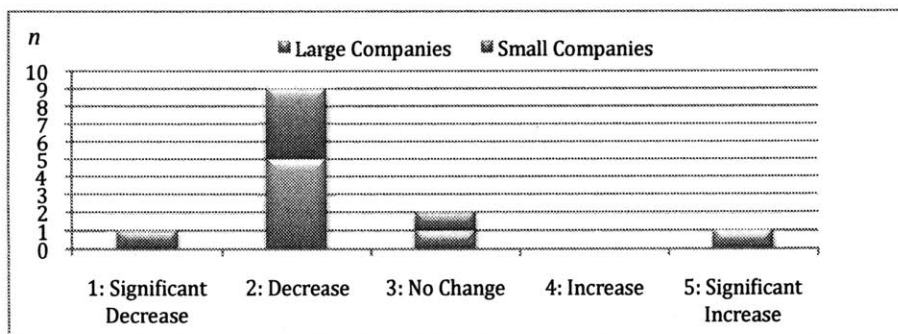


	n	Severely Impaired	Impaired	No impact	Don't Know
Orthopaedics	11	45.5%	9.1%	36.4%	9.1%
General Surgery	6	33.3%	33.3%	0.0%	33.3%
Neurosurgery	1	100.0%	0.0%	0.0%	0.0%
Cardiology	6	16.7%	33.3%	50.0%	0.0%
<b>All Physicians</b>	<b>24</b>	<b>37.5%</b>	<b>20.8%</b>	<b>29.2%</b>	<b>12.5%</b>

*Has physician training on new devices been impacted since the law's adoption?*

A majority (76.9 percent) of company representatives claimed a decrease in training opportunities with new devices for Massachusetts-licensed physicians (Figure 36) and a majority (80.0 percent) of company representatives also claimed a decrease with existing device training opportunities. Similarly, a majority (56.5 percent) of physicians cited a decrease in opportunities to train in new device procedures (Figure 37). These results support anecdotal evidence of industry withdrawal from training engagements with Massachusetts-licensed physicians, as described in interviews.

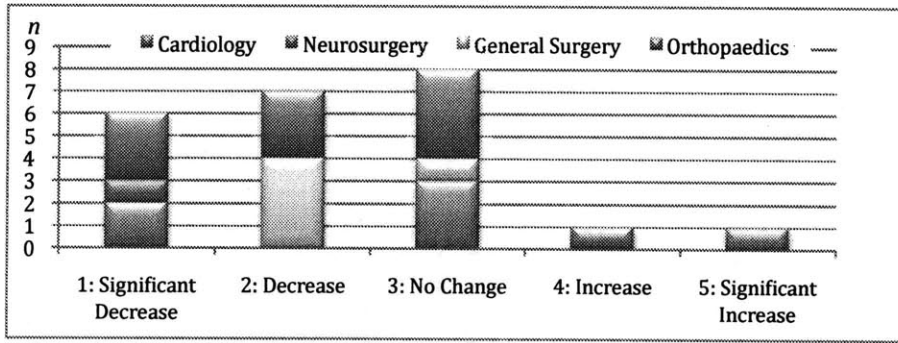
**Figure 36: Impact on number of physician training opportunities for new device procedures, as perceived by companies**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Small Companies	6	2.0	0.6	16.7%	66.7%	16.7%	0.0%	0.0%
Large Companies	7	2.6	1.1	0.0%	71.4%	14.3%	0.0%	14.3%
<b>All Companies</b>	<b>13</b>	<b>2.3</b>	<b>0.9</b>	<b>7.7%</b>	<b>69.2%</b>	<b>15.4%</b>	<b>0.0%</b>	<b>7.7%</b>

Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

**Figure 37: Impact on number of physician training opportunities for new device procedures, as perceived by physicians**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	11	2.3	1.0	27.3%	27.3%	36.4%	9.1%	0.0%
General Surgery	5	2.2	0.4	0.0%	80.0%	20.0%	0.0%	0.0%
Neurosurgery	1	1.0	NA	100.0%	0.0%	0.0%	0.0%	0.0%
Cardiology	6	2.7	1.5	33.3%	0.0%	50.0%	0.0%	16.7%
<b>All Physicians</b>	<b>23</b>	<b>2.3</b>	<b>1.1</b>	<b>26.1%</b>	<b>30.4%</b>	<b>34.8%</b>	<b>4.3%</b>	<b>4.3%</b>

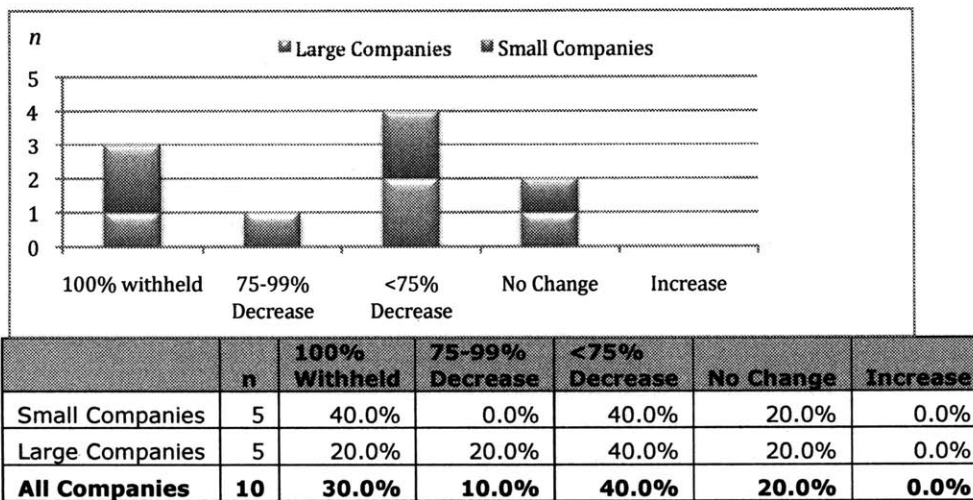
Scale 1-5: 1=significant decrease, 3=no change, 5=significant increase

*Has industry-supported physician education been impacted by the law?*

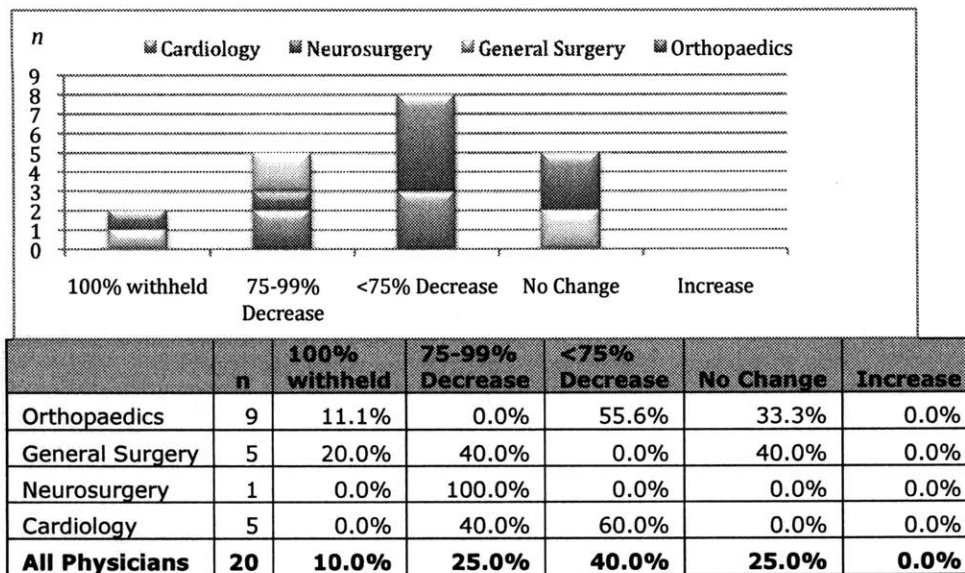
Results obtained from company representatives and physicians imply a significant impact of the law on industry-supported physician education. 80% of companies decreased the number of event invitations to Massachusetts-licensed physicians, relative to last year. Of these companies, 37.5 percent withheld 100% of their event invitations. A significant number of educational events have been canceled in Massachusetts as a direct result of the regulations (Figure 38).

A majority (75.0 percent) of physicians surveyed stated a significant annual decrease in the number of their event invitations, relative to last year, with 35.0 percent claiming a greater than 75 percent decrease (Figure 39). A majority (66.7 percent) of the companies that responded claimed at least one educational event being canceled in Massachusetts as a direct result of the law (Figure 40). Most (82.6 percent) physicians also claimed a decrease in industry funding for their academic department in the form of fellowships, informal non-CME educational events, and research since the law's adoption (Figure 41).

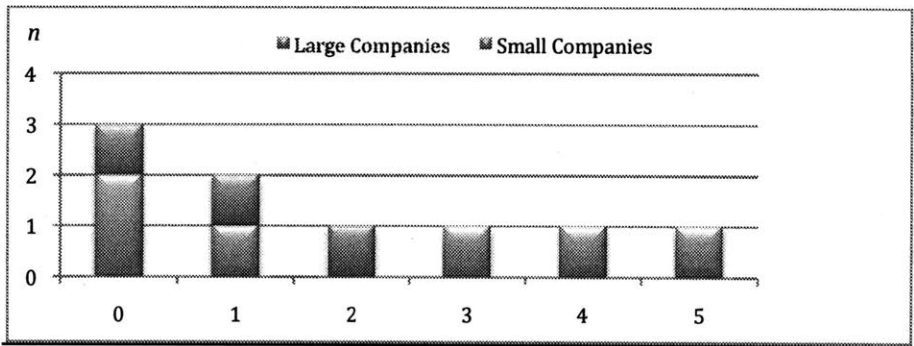
**Figure 38: Annual impact on number of event invitations to Massachusetts-licensed physicians**



**Figure 39: Annual impact on number of event invitations to Massachusetts-licensed physicians, as perceived by physicians**

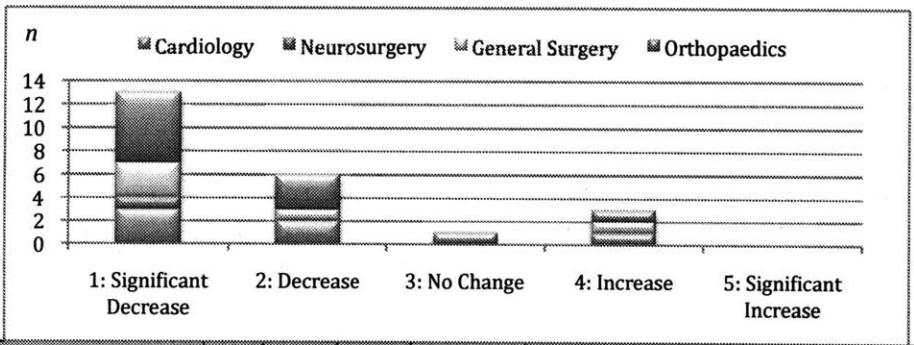


**Figure 40: Number of events canceled by nine companies in past year, as a direct result of Massachusetts regulations**



	n	$\bar{x}$	$\sigma$	0	1	2	3	4	5
Small Companies	3	0.5	0.5	33.3%	33.3%	33.3%	0.0%	0.0%	0.0%
Large Companies	6	1.0	0.6	33.3%	16.7%	0.0%	16.7%	16.7%	16.7%
<b>All Companies</b>	<b>9</b>	<b>1.5</b>	<b>0.8</b>	<b>33.3%</b>	<b>22.2%</b>	<b>11.1%</b>	<b>11.1%</b>	<b>11.1%</b>	<b>11.1%</b>

**Figure 41: Impact on industry funding for academic departments, as perceived by physicians**



	n	$\bar{x}$	$\sigma$	1	2	3	4	5
Orthopaedics	11	1.7	1.0	54.5%	27.3%	9.1%	9.1%	0.0%
General Surgery	5	3.6	1.3	60.0%	20.0%	0.0%	20.0%	0.0%
Neurosurgery	1	1.0	NA	100.0%	0.0%	0.0%	0.0%	0.0%
Cardiology	6	1.8	1.2	50.0%	33.3%	0.0%	16.7%	0.0%
<b>All Physicians</b>	<b>23</b>	<b>1.7</b>	<b>1.1</b>	<b>56.5%</b>	<b>26.1%</b>	<b>4.3%</b>	<b>13.0%</b>	<b>0.0%</b>

### Market Dynamics

*What is the total annual cost of compliance to the Massachusetts regulations?*

Large companies, on average, estimated their annual cost of compliance to the Massachusetts regulations at several million US dollars. The minimum number cited by a large company was \$1.5 million. This cost included training employees, additional FTEs, legal fees, disclosure reporting information systems, the annual \$2000 fee to the DPH, and all other associated costs. A significant portion of these costs were claimed to be solely dedicated to the Massachusetts regulations and not associated with other corporate reporting systems. However, one large company expected to be able to leverage the

Massachusetts reporting resources for Vermont's disclosure requirements. Large, public companies claimed an advantage in their ability to leverage some of their 404 infrastructure for financial reporting. As part of the law, manufacturers are required to have an employee dedicated to ensuring compliance of the law. Larger companies can leverage their in-house general counsel or 404 compliance employees as discrete full-time employees. Large, decentralized companies that had grown through acquisition with several business units expected to face higher costs of compliance, with some companies requiring a FTE dedicated to disclosure tracking within each business unit in addition to business unit-specific software systems for tracking data.

Small companies, on average, estimated their annual cost of compliance at between \$2,000 and \$100,000. The small companies surveyed did not require as sophisticated methods for tracking and reporting, significant training budgets, and could flexibly assign existing employees with additional compliance duties rather than hire FTEs solely dedicated to compliance. Although there are some economies of scale to compliance, there is a considerable fixed cost portion and small companies are still faced with significant costs on a state-by-state basis.

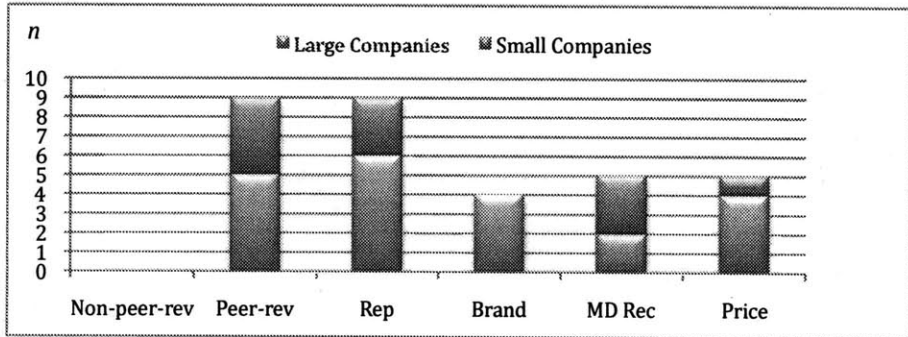
Although the statute requires a \$2000 annual registration fee to the DPH, this cost is only a small fraction of the annual costs of compliance, monitoring, and training required of device manufacturers selling to Massachusetts-licensed HCPs. The disclosure and reporting requirement is a costly issue for companies, because the reporting systems currently in place even at large companies do not match this need. Companies are required to train their sales representatives, and many companies are doing so with online training infrastructure or training seminars. Many companies are monitoring their compliance to the regulations through regional sales managers and monitoring their compensation controls through their accounts payable function [22]. The compliance officer at the company must certify with the state, and some companies are requiring proof from sales representatives of compliance to the law. All companies will need to make an investment in the reporting infrastructure, and since there is still some ambiguity with respect to preemption by the federal law occurring in 2013, companies are forced to invest in multiple reporting systems for various states.

*Has the basis of competition changed, since the law's adoption?*

Company representatives and physicians were asked which factors were most important in the sale of a medical device, before and after the Massachusetts law's adoption. Prior to the

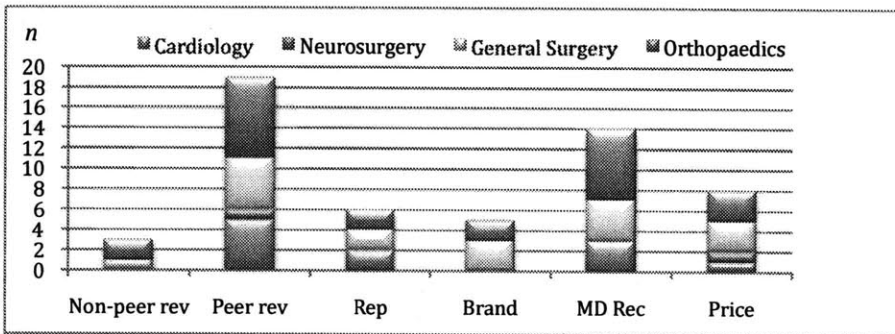
law, company representatives weighted the sales representative's support, reliability, and stocking function and peer-reviewed data as the most important factors influencing their ability to sell a medical device (Figure 42). These were followed by recommendation by a physician colleague, price, and manufacturer brand. Physicians claimed peer-reviewed data as most important, followed by a physician colleague recommendation, price, sales representative, brand, and non-peer-reviewed data (Figure 43).

**Figure 42: Driving market adoption factors enabling the sale of a medical device, as perceived by companies**



	n	Non-peer-rev	Peer-rev	Rep	Brand	MD Rec	Price
Small Companies	5	0.0%	80.0%	60.0%	0.0%	60.0%	20.0%
Large Companies	6	0.0%	83.3%	100.0%	66.7%	33.3%	66.7%
<b>All Companies</b>	<b>11</b>	<b>0.0%</b>	<b>81.8%</b>	<b>81.8%</b>	<b>36.4%</b>	<b>45.5%</b>	<b>45.5%</b>

**Figure 43: Driving market adoption factors enabling the sale of a medical device, as perceived by physicians**



	n	Non-peer rev	Peer rev	Rep	Brand	MD Rec	Price
Orthopaedics	10	20.0%	80.0%	20.0%	20.0%	70.0%	30.0%
General Surgery	6	16.7%	83.3%	33.3%	50.0%	66.7%	50.0%
Neurosurgery	1	0.0%	100.0%	0.0%	0.0%	0.0%	100.0%
Cardiology	5	0.0%	100.0%	40.0%	0.0%	60.0%	20.0%
<b>All Physicians</b>	<b>22</b>	<b>13.6%</b>	<b>86.4%</b>	<b>27.3%</b>	<b>22.7%</b>	<b>63.6%</b>	<b>31.8%</b>

Company representatives and physicians were in accordance in claiming that manufacturer brand has become relatively more important and that the role of the sales representative has

become relatively less important as a factor influencing the sale or use of a medical device. With the decreasing role of the sales representatives, physicians may have less procedural support and inventory readily available in the operating room. Companies with more technologically complex devices and fewer competitors claimed they were not affected by this shift in market adoption factors. One sales representative in this subset of company representatives cited no change in his ability to interact with physicians and patients.

*Has the law affected small and large companies equally, i.e. has it leveled the playing field?*

In general, the regulations were found to impair small companies more than large companies since 1) large companies are already largely compliant with AdvaMed and have existing reporting infrastructure that they can leverage for compliance to Massachusetts regulations and 2) manufacturer brand has become more important in the sale of medical devices to physicians. As noted, the large company brand advantage was less valuable in more technically complex markets with fewer competitors, in which physicians required the support of sales representatives, regardless of company size, to properly utilize devices.

Several large companies claimed a more level playing field, since small companies were forced to play by the same conduct and disclosure rules with which large companies have been compliant, according to AdvaMed guidelines. Surprisingly, several small companies representatives also claimed a more level playing field, since they no longer felt obligated to compete on extravagant events, meals, or excessive payments to gain the attention of physicians.

## **Chapter 5: Discussion**

In this pilot study, we examined several of the potential negative consequences of the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct, adopted and implemented by the Massachusetts Department of Public Health in July 2009. We focused on the medical device industry because of the higher level of interaction between physicians and companies in technology development, physician education, and new device procedure training.

The anecdotal concerns of industry stakeholders were gathered through a number of informal interviews with representatives from medical device manufacturers, product distributors, academic medical centers, venture capital firms, law firms, consulting firms, MassMedic, and the DPH. These concerns focused on the law's impairment of physician-industry collaboration related to technology development and physician education. Additional concerns highlighted a potential impact on medical device innovation through a shift in the market adoption factors and market dynamics of large and small companies. Our hypothesis that the Massachusetts regulations have impaired physician-industry collaboration in the Massachusetts medical device industry was confirmed through an interview- and survey-based analysis.

In order to assess our hypothesis and evaluate the anecdotal concerns described, an extensive review of the existing literature on the role of sales and marketing in the medical device industry was conducted and a variety of surgical procedures were observed at MGH. A formal survey was developed to solicit physician and industry perspectives. Survey questions were designed to assess the potential impacts in four interaction categories: understanding of the regulations, technology development relationships, physician education, and market dynamics.

### ***Limitations***

The selection of survey participants was intended to enable this study to serve as a roadmap for future research, not necessarily to reach statistically significant conclusions. Companies were selected with target markets in the clinical areas of cardiovascular, orthopaedic, and neurosurgical. A fourth category of companies included all other clinical markets, but primarily comprised of devices targeting general surgeons. This diversity of target markets

served to broaden the study's scope and gain insight into a variety of device companies and physician relationships, but simultaneously limited the strength of our conclusions given the variability of other factors between different markets. Since the study's intention was to provide a roadmap for future work, we felt a broader scope was a more important objective. Companies were also selected on the basis of size, as measured by annual revenue, in order to ensure both large and small companies were represented in the sample and to assess potential impacts on the market dynamics between large and small firms.

The selection of physicians was limited to academics, in order to focus the results. This has implications for our results, since the majority of physician-industry collaboration related to procedure training and physician education occurs with non-academic physicians and community hospital physicians would most likely offer different perspectives. However, many of the new device therapies are initially adopted at academic hospitals, where physicians who collaborate with industry on clinical research often reside. Academic physicians thus served as an appropriate starting point for our research. Physicians at University of Massachusetts, Tufts University, and Partners Healthcare were selected based on their area of clinical specialty: cardiology, orthopaedic surgery, neurosurgery, and general surgery. Selection of academic physicians from these specific institutions may have created selection bias, since these physicians may be unrepresentative of the academic physician population in Massachusetts or unrepresentative of the broader population of community hospital physicians in Massachusetts.

Of the 143 company representatives and physicians selected to participate in the survey, 40 eventually participated comprising 16 company representatives and 24 physicians. These results were supported by 36 informal interviews. The survey response rate of 28% highlights the possibility of selection bias in our results. Additional selection bias may have been induced given the unequal proportions of clinical specialties. The majority of physician respondents were orthopaedic surgeons, followed by general surgeons and cardiologists, and of these cardiologists all were interventional cardiologists working in the catheterization lab. This distribution of physicians is unrepresentative of the population of academic physicians.

Additionally, the company representatives that responded primarily represented orthopaedic companies, followed by cardiovascular companies selling to a broader population of cardiologists and vascular surgeons. No significant disparities could be drawn

between clinical specialties. However, an even distribution of large and small companies was collected and these two groups were appropriately compared.

The result that academic physicians had greater familiarity with their own institutional policies than with the Massachusetts law has potential implications for our results. This finding implies that physician responses regarding the law's impact may be more reflective of their institutional policy's impact on physician-industry collaboration, rather than the direct impact of the regulations. However, their institutional policies have been developed and refined in tandem with the Massachusetts regulations and it is difficult to argue that the institutional policies are independent from the regulations. Physician anecdotes and perspectives should not be overly discounted for this reason. This finding was expected and incorporated into the survey questions, since the legal liability and cost burdens falls on companies, not physicians under the Massachusetts statute.

Company representative understanding is still diverse regarding disclosure of physician payments for clinical research and training on new devices. What constitutes "clinical research" and whose name becomes disclosed may be misunderstood by some individuals. Payments to physicians for clinical research on an already marketed device is not exempt from public disclosure, however payments for preclinical or pre-market clinical research are exempt. However, if the company pays the institution directly and the institution compensates the physician indirectly, then the physician's name is not disclosed. Institutions are exploring this payment strategy for new device training events, which could theoretically avoid the individual names of physicians being publicly disclosed.

Our work also attempted to summarize the anecdotal perspectives and impressions of company representatives and physicians of the law's impact, and to separate these perceptions from the actual impact of the law on the decisions made by these individuals relating to collaborative relationships. We found that company representatives and physicians expected a significant impact of the Massachusetts regulations across the spectrum of medical device innovation. The actual impact still remains to be seen, but we found that the regulations have impacted the actual decisions of medical device companies to collaborate with Massachusetts-licensed physicians in technology development and physician education. Companies have decreased the number of their relationships with Massachusetts-licensed physicians in clinical research, product development, scientific advisory boards, new device procedure training events, non-CME accredited educational

events, CME accredited educational events, and promotional events, regardless of the statute's exemptions and allowances.

One possible explanation for the widespread industry withdrawal from Massachusetts is that the regulations had an overall chilling effect on collaboration by creating excessive legal liabilities and compliance costs for already resource constrained companies. This effect may erode as companies gain a more intimate understanding and awareness of the state regulations. We found that a majority of the current company misunderstandings and ambiguities with the regulations are regarding disclosure requirements and allowances under the marketing code of conduct. As the DPH continues to interact closely with the medical device industry as a separate entity from the pharmaceutical industry and address frequently asked questions, these ambiguities should disappear in time for the first required disclosures in July 2010.

We speculate that the noted decrease in clinical research relationships results from this chilling effect and will improve over time as companies gain a better grasp of the regulations and build the appropriate compliance and reporting infrastructure. Massachusetts is home to several of the world's premier academic institutions and it is unlikely that medical device companies will avoid research relationships with physicians at these institutions, even with the added compliance costs. Although our results provide evidence of company and physician withdrawal from these relationships, it is possible that these findings are exaggerated since the disclosure rules specifically exempts clinical research. However, a withdrawal in post-market approval research may not be exaggerated.

### ***Negative Consequences of the Massachusetts Regulations***

The most restrictive aspects of the law, however, may not disappear even with the partial federal preemption by the Sunshine provisions. As shown, companies are most impaired by the marketing code of conduct in their inability to interact with physicians in a variety of educational environments. A strong majority of physicians claimed that medical education, new device procedure training, and their ability to stay updated on new therapy options have been impaired by the Massachusetts regulations. This was strongly supported by data showing that device companies have decreased the number of events available to Massachusetts-licensed physicians in the past year as a direct result of the law and have decreased financial support for educational events with Massachusetts-licensed physicians.

Companies similarly claimed a decrease in the number of training opportunities available for Massachusetts-licensed physicians, which was confirmed by physician data.

This decrease in new device procedure training opportunities was likely a result of the disclosure requirements on expense reimbursement and compensation prohibition of meals outside of a hospital setting. Faced with disclosure requirements on all “sales and marketing” expenditures, companies would rather not deal with the added costs of inviting Massachusetts-licensed physicians. In theory, companies could invite physicians without providing any financial reimbursement or compensation. However, as our results imply, we would not expect most physicians to attend training events without expense reimbursement or other forms of compensation for their time. This is surprising, since physicians ultimately benefit financially by learning new device procedures. Similarly, we would not expect the majority of physicians to attend non-CME accredited educational events, promotional events, or participate in research without expense reimbursement or compensation. We would expect most physicians to continue to attend CME-accredited events without expense reimbursement, since they gain required credits and gain updated medical information.

The concept of transparency and relationship disclosure was agreed upon as benefiting patient care by a majority of industry and physician stakeholders. Although a large minority of physicians believed that the Massachusetts disclosure requirements were not helpful and disrespectful, a majority didn't mind them or supported them. Similarly, a majority of company representatives supported relationship transparency as a mechanism to level the playing field between small and large companies. Industry opponents of disclosure rules suggested that companies could lose their competitiveness by disclosing the confidential identities of their collaborative physicians or that the disclosure of relationships could bias research results. These concerns have some merit; however, the identities of individual physicians would not necessarily be disclosed if the physician's institution receives the payment from a company. Some institutions are exploring the expansion of this practice to engagements beyond research, like new device procedure training events, in an effort to mitigate company and physician concerns.

All companies perceived the reality of disclosure requirements on a state-by-state basis as overly restrictive and responsible for excessive costs. Federal Sunshine disclosure requirements will only govern a small subset of the interactions within the scope of the Massachusetts regulations, but will broaden the scope of covered interactions in other ways. For example, the Sunshine regulations will not exempt clinical research relationships from

disclosure, but will establish limited disclosure protection for pre-approved products undergoing clinical trials. A federal law that preempts all state laws and institutional conduct policies governing the interaction of companies with physicians could serve to benefit medical device innovation by reducing the repetitive and excessive costs of institutional and state compliance for companies.

The annual costs of compliance were found to be largely variable costs and did not regressively impact small companies more than they did large companies. The compliance costs were higher for large companies that had grown through acquisition, since these companies were faced with having to create duplicative reporting infrastructures and software systems. However these same large companies had some of the information architecture in place and were already AdvaMed compliant or compliant with other states' reporting requirements so could share some of these resources for Massachusetts compliance activities. This enabled large companies with an advantage relative to small companies that did not have the reporting infrastructure in place.

The Massachusetts law was also found to impair small companies more than large companies by altering the role of the sales representative in clinical adoption. Our results showed that companies and physicians were in agreement in claiming that the sales representative's traditional role of technical and procedural support has become less important in selling a new medical device to a physician, especially in less technically complex markets and more crowded markets. These markets are often characteristic of cheaper and faster product development. The lower barriers to entry in these markets (e.g. spine and orthopaedics) have historically enabled smaller companies easier access to physicians through relationships with sales representatives.

In these more crowded markets, manufacturer brand has increased in relative importance for companies and Massachusetts-licensed physicians since the law's adoption. As the basis of competition becomes more heavily weighted on existing manufacturer brands and less on the role of the sales representative, small companies will face greater challenges in selling devices to physicians. This shift in market dynamics may enable large companies to gain market share from small companies and may increase the buying power of large companies seeking to continue to grow through acquisitions. In more technologically complex markets with fewer competitors (e.g. deep brain stimulation), the role of the sales representative was found to be less impacted by the regulations, since physicians and patients continue to require technical support from the sales representatives to maintain optimal patient care.

### ***Future Research***

Our pilot, survey-based assessment of the impact of the Massachusetts regulations on physician-industry collaboration has implications for future research and should serve as a roadmap for follow-up studies with greater resources. The law's impact will be more readily accessible in the months following the first required reporting date in July 2010, at which points companies will have greater comfort with the law's compliance requirements.

Future studies after this time should consider a larger sample of physicians and companies across different clinical specialties. With a larger sample size, companies can be compared more robustly across different markets and related to the results obtained from their direct physician customers. This work should retrospectively explore the change in the number of pre-market and post-market approval research relationships following the law's adoption.

Future work should also explore the impact on physicians at non-academic hospitals, where the majority of clinical adoption occurs. This work might also establish negative controls by comparing the sales and market adoption differences of new and existing medical devices in states adjacent to Massachusetts with less aggressive regulations. Future results could have significant public policy implications for state and federal regulators, since our study results suggest that medical device companies, when faced with increased regulatory challenges, are withdrawing from relationships with Massachusetts-licensed physicians with respect to technology development and physician education.

## **Chapter 6: Conclusions**

The results obtained highlight that physician-industry collaboration in the medical device industry has been negatively impacted as a result of the Massachusetts regulations, specifically among some of the most collaborative device-oriented physicians and companies in the industry. Company representatives and physicians contended that the Massachusetts regulations do influence their decisions to interact across the broad spectrum of medical device innovation, from research to product promotion. Even with knowledge of the law's disclosure and conduct exemptions, company representatives claimed an impact on their decisions to collaborate with physicians with regard to research, scientific advisory boards, new device procedure training, non-CME accredited educational events, CME accredited educational events, and promotional events.

### ***Impact on Physician Education, Technology Development, and Patient Care***

1. The regulations had a greater impact on physician education than on technology development collaboration, although both were significantly affected as measured by physician and company representative surveys and interviews.
2. Within physician education, new device procedure training, non-CME-accredited education, and promotional events experienced the most significant impact.
3. A significant majority of physicians claimed that physician education has been impaired as a direct result of the Massachusetts regulations and a majority of company representatives stated that their ability to keep physicians updated had been impaired as a result of the law.
4. Over half of all physicians believed that the Massachusetts regulations would have a negative impact on patient care in the long term, through impaired physician education and ability to stay updated on new therapies.
5. A majority of physicians would not participate in industry interactions related to physician education, without expense reimbursement or compensation. Since travel, compensation, and honoraria related to physician education are reportable under the regulations, our results showed that a majority of companies have decided to avoid these interactions with Massachusetts-licensed physicians.

### ***Stakeholder Understanding of the Massachusetts Regulations***

1. Companies were most familiar with the AdvaMed Code, relative to their customers' institutional policies and the Massachusetts regulations; however, Massachusetts regulations and customer institution policies disproportionately favored large companies.
2. Physicians were most familiar with their own institutional policies, relative to the AdvaMed Code and the Massachusetts regulations.
3. Ambiguities still exist in the Massachusetts regulations as they are currently implemented. The majority of these ambiguities regard disclosure and the marketing code of conduct, specifically which company representative behaviors are allowable and which interactions are exempt from disclosure.

### ***Most Restrictive Aspects of the Massachusetts Regulations***

1. The most restrictive aspects of the law as perceived by company representatives reside in the marketing code of conduct and disclosure requirements.
2. Company representatives cited one of the most restrictive components of the marketing code as the prohibition of interactions with Massachusetts-licensed physicians in certain environments, for example holding modest receptions for physicians at trade shows and meals outside of hospital-like facilities.
3. This restriction impaired companies' abilities to attract physicians and legitimately interact at these events. It also incited companies to significantly reduce event invitations to Massachusetts-licensed physicians and in some cases dismiss Massachusetts-licensed physicians from scientific advisory board positions.
4. Disclosure requirement challenges include the maintenance of a robust reporting system. This was described as less of an issue for small companies, but a significant challenge for large companies that have grown through acquisition and have amassed a decentralized information architecture. Large companies may be forced to build a different disclosure reporting system for each of their business units, which could lead to issues with centralized reporting to the Massachusetts DPH and federal HHS.
5. Disclosure requirements on a state-by-state level were believed to be excessive and created unnecessary costs for companies, diverting limited resources that could be spent on research, development, and physician education.

### ***Change in Market Dynamics: Regressive Tax on Innovation***

1. The regulations impair small companies more than large companies since 1) large companies are already largely compliant with the AdvaMed Code and have existing reporting infrastructure that they can leverage for compliance to Massachusetts regulations and 2) manufacturer brand has become relatively more important and the role of the sales representative has become relatively less important as a factor influencing the sale or use of a medical device.
2. This shift was more readily discernable in less technologically complex markets with fewer competitors, in which physicians required the support of sales representatives, regardless of company size, to properly utilize devices.
3. With the decreasing role of the sales representatives, physicians will have less procedural support, inventory, and updated knowledge of therapy options readily available in the operating room.
4. Since the early development of medical devices is often accomplished by small, venture capital-backed entrepreneurial companies, the larger negative impact of the regulations on small firms may hinder innovation in Massachusetts.

## **Chapter 7: Implications**

### ***Need for Broader Federal Preemption***

As noted earlier, beginning in 2013, the federal Sunshine provisions will only preempt the Massachusetts regulations within the scope of the Sunshine provisions, with regard to relevant payments to physicians and individuals at academic institutions. The federal law will not establish a federal marketing code of conduct, so the most restrictive aspects of the Massachusetts regulations, as shown in our results, will not be preempted by federal law. These conduct, implementation, and disclosure challenges will still reside at the state and institutional levels for companies selling to Massachusetts-licensed physicians and other healthcare providers.

Our work suggests the strong public need for broader preemption by federal provisions, which might preempt all state and institutional policies governing the marketing behaviors of medical devices and disclosure requirements related to physician-industry engagements. Our results also suggest the need to more deliberately separate medical devices from pharmaceuticals with regard to all future legislation, given the differences in technology development, clinical adoption, and physician research relationships. Without broader federal preemption, individual states and institutions are saddling medical device companies with excessive costs that could be dedicated to research, development, and physician education. Additionally, overreaching institutional policies may be impairing physicians from engaging in research and educational activities, with negative consequences for medical device innovation, physician exposure, and ultimately patient care.

## **Appendix A: Physician Survey**

# Physician Survey for MIT Student Research

Date:   
Name:   
Position:   
Phone:

Dan W. Wolf  
Biomedical Enterprise Program  
Harvard-MIT Health Sciences & Technology  
m: 617-803-1225  
dwolf@mit.edu

The **Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct** (105 CMR 970.000) was enacted July 1, 2009. The state law requires pharmaceutical and medical device manufacturers to: (1) comply with a marketing code of conduct developed by the MA Department of Public Health; (2) undertake specific compliance activities (training, auditing, and corrective action); and (3) disclose payments to providers with a value of \$50 or more in connection with sales and marketing activities.

Please answer the following questions based on your own experiences, perceptions, and opinions. Your responses will be kept strictly confidential and anonymous and will be used solely in connection with my research as a graduate student at the Harvard-MIT Division of Health Sciences and Technology.

## Background Information:

Please rate your familiarity with the following (1 = extremely unfamiliar; 5 = extremely familiar)

1. What is your medical specialty?

12. AdvaMed Code of Ethics, effective July 2009:

1     2     3     4     5

2. How many procedures do you perform annually?

13. Your institution's policy regarding physician interaction with industry (research, development, training, promotion):

1     2     3     4     5

3. How many years have you been in practice?

14. Exact differences between your institution's policy and the MA law (105 CMR 970.000):

1     2     3     4     5

4. How would you describe your medical practice? (private, academic medical center, community hospital, etc.)

Please rate your *perceptions* of the change in the following in the past 12 months.

(1 = significant decrease; 3 = no effect; 5 = significant increase)

5. Please list any committees on which you serve. (IRB, new device, reimbursement, etc.)

15. Number of device sales representatives in the OR carrying existing devices (marketed for more than one year):

1     2     3     4     5

6. How many times have you contractually engaged with industry in a consulting capacity for a new device technology?

16. Number of device sales representatives in the OR carrying new devices (marketed for less than one year):

1     2     3     4     5

7. Are you involved in academic research? Please include number of peer-reviewed articles, if applicable.

17. Your or your colleagues' exposure to new device technologies:

1     2     3     4     5

8. Are you involved in physician education? Please describe your role.

18. Physician training opportunities with new devices:

1     2     3     4     5

9. Are you involved in the purchase of medical devices for your hospital or institution? Please describe your role.

19. Your interest in participating in company-sponsored research for a device not yet marketed:

1     2     3     4     5

10. Do you believe that there is value to your patients or future patients in working with industry in some capacity?

20. Your interest in participating in company-sponsored research for a device already marketed:

1     2     3     4     5

11. Do you believe that there is conflict in working with industry in this capacity?

21. Industry funding for your department (fellowships, educational events, research, etc.)

1     2     3     4     5

# Physician Survey (Continued)

Dan W. Wolf  
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 Harvard-MIT Health Sciences & Technology  
 m: 617-803-1225  
 dwolf@mit.edu

**22. Your or your colleagues' ability to introduce new devices to other physicians in your hospital (committees or informally):**

1     2     3     4     5

Please provide your opinion to the following questions:

**23. How has the MA law influenced medical education or physician training on new devices?**

**24. How has the MA law influenced your ability to collaborate with industry on technology development?**

**25. How has the MA law influenced your or your colleagues' ability to stay updated on new device technologies?**

**26. How has the MA law influenced patient care?**

Please estimate the following to the best of your ability:

**27. In the past 12 months, how many industry-supported events were you invited to?**

**28. In the year prior, how many industry-supported events were you invited to?**

**29. In the past 12 months, how many times have you canceled plans to attend an industry-sponsored event?**

**30. Since July 2009, have you noticed a decrease in the number of excessive gifts or meals? Please describe.**

**31. If you are the recipient of \$50 or more in value from a company in connection with "sales and marketing" of a device, how would you feel about your name, transaction value, and transaction purpose made publicly available on both the company website and Department of Public Health website? Includes compensation/reimbursement for services and expenses associated with training, promotion, and product development for an already marketed device.**

(1=not helpful and disrespectful; 3=don't mind; 5=improves patient care)

1     2     3     4     5

**32. Would you attend the following industry-supported events on your own expense and without compensation for your time? Please check all that apply.**

- Preclinical or clinical research
- New device procedure demonstration or training
- Non-CME educational event
- CME educational event
- Promotional event for new device

**33. Prior to the law, what were the most important factors influencing your decision to use a new medical device? Please check all that apply.**

- Non-peer-reviewed clinical evidence
- Peer-reviewed clinical evidence
- Knowledge, support, or reliability of sales rep
- Brand or reputation of device manufacturer
- Recommendation of physician colleague
- Relative price
- Other (please explain)

Comments:

**34. Has the MA law changed the importance of any of these factors? Please check all that apply.**

- Non-peer-reviewed clinical evidence
- Peer-reviewed clinical evidence
- Knowledge, support, or reliability of sales rep
- Brand or reputation of device manufacturer
- Recommendation of physician colleague
- Relative price
- Other (please explain)

Comments:

**Submit by Email**

Thank you very much for your time. If you have any questions or comments, please contact me at 617-803-1225 or dwolf@mit.edu.

**Dan W. Wolf**  
 Biomedical Enterprise Program  
 Harvard-MIT Health Sciences & Technology, MS Class of 2010  
 Harvard Business School, MBA Class of 2009

Additional Comments:

**Appendix B: Industry Survey**

# Industry Survey for MIT Student Research

Date:   
Name:   
Position, Company:   
Phone:

Dan W. Wolf  
Biomedical Enterprise Program  
Harvard-MIT Health Sciences & Technology  
m: 617-803-1225  
dewolf@mit.edu

The **Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct** (105 CMR 970.000) was enacted July 1, 2009. The state law requires pharmaceutical and medical device manufacturers to: (1) comply with a marketing code of conduct developed by the MA Department of Public Health; (2) undertake specific compliance activities (training, auditing, and corrective action); and (3) disclose payments to providers with a value of \$50 or more in connection with sales and marketing activities.

Please answer the following questions based on your own experiences, perceptions, and opinions. Your responses will be kept strictly confidential and anonymous and will be used solely in connection with my research as a graduate student at the Harvard-MIT Division of Health Sciences and Technology.

## Background Information:

**1. What is your company's target market(s)?**

**2. What is your role and which products are you responsible for?**

**3. Which physician speciality or specialties do you target?**

**4. How many years have you been in your current role? In the medical device industry?**

**5. What is your company's approximate annual revenue?**

- Less than \$10M     \$100M - \$500M  
 \$10M - \$50M     \$500M - \$1B  
 \$50M - \$100M     Greater than \$1B

**6. What is your company's expected yoy sales growth in MA?**

- Less than 2%     10% - 15%  
 2% - 5%     15% - 20%  
 5% - 10%     Greater than 20%

**7. What is your company's expected yoy sales growth ex-MA?**

- Less than 2%     10% - 15%  
 2% - 5%     15% - 20%  
 5% - 10%     Greater than 20%

Please rate your familiarity with the following (1=extremely unfamiliar; 5=extremely familiar and completely fluent in details/exceptions)

**8. AdvaMed Code of Ethics, effective July 2009:**

1     2     3     4     5

**9. The MA law (105 CMR 970.000), effective July 2009:**

1     2     3     4     5

**10. Your customers' institutional policies regarding physician interaction with industry (research, training, promotion, etc.):**

1     2     3     4     5

**11. Exact differences between the MA law (105 CMR 970.000), the AdvaMed recommendations, and your customers' policies?**

1     2     3     4     5

Please rate your *perceptions* of the change in the following in Massachusetts, resulting from 105 CMR 970.000:

(1=significant decrease; 3=no effect; 5=significant increase):

**12. Number of your company's sales representatives in the hospital carrying existing devices (marketed for > one year):**

1     2     3     4     5

**13. Number of your company's sales representatives in the hospital carrying new devices (marketed for < one year):**

1     2     3     4     5

**14. Your or your colleagues' ability to expose MA physicians to new device technologies:**

1     2     3     4     5

**15. Number of physician training opportunities with existing devices from your company:**

1     2     3     4     5

**16. Number of physician training opportunities with new devices from your company:**

1     2     3     4     5

**17. Your interest in conducting research or development with MA physicians for a device technology not yet marketed:**

1     2     3     4     5

**18. Your interest in conducting product development with MA physicians for a device already marketed (disclosure required):**

1     2     3     4     5

**19. Your or your colleagues' ability to introduce new devices to your target hospital customers:**

1     2     3     4     5

# Industry Survey (Continued)

Dan W. Wolf  
Biomedical Enterprise Program  
Harvard-MIT Health Sciences & Technology  
m: 617-803-1225  
dwolf@mit.edu

Please provide your opinion to the following questions:

**20. How has the MA law influenced your ability to collaborate with physicians on product development?**

**21. How has the MA law influenced your or your colleagues' ability to update physicians on new device technologies?**

**22. Beyond the \$2000 fee, how much will compliance to the MA law cost your company annually?** Please include costs of training employees, additional FTEs, legal fees, disclosure tracking, etc.

**23. Will the MA law have an impact on your company's performance (sales, income, market share)? Please explain.**

Please provide an estimate to the following:

**24. In the past 12 months, what proportion of physicians that your company invited to sponsored events were from MA?**

**25. In the year prior, what was this proportion?**

**26. In the past 12 months, how many sponsored events has your company canceled as result of the MA law?**

**27. Have you noticed a meaningful change in your company's relationships with physicians? Please describe.**

**28. What are the most restrictive aspects of the law to your company? Please check all that apply and explain.**

- Marketing code of conduct (restricted meals, events, payments)
- Implementation of compliance activities and training programs
- Disclosure requirements

Comments:

**29. What ambiguities still exist in the law, if any, as it is written? Please check all that apply and explain.**

- Marketing code of conduct (restricted meals, events, payments)
- Implementation of compliance activities and training programs
- Disclosure requirements

Comments:

**30. Does the law influence your company's decision to interact with MA physicians in any of the following categories? Please check all that apply.**

- Preclinical or clinical research
- Scientific advisory boards
- New device procedure demonstrations
- Non-CME educational events
- CME educational events
- Promotional events

**31. Prior to the law, what were the most important factors influencing your ability to sell a new medical device? Please check all that apply.**

- Non-peer-reviewed clinical evidence
- Peer-reviewed clinical evidence
- Knowledge, support, or reliability of sales rep
- Brand or reputation of your company
- Recommendation from physician colleague
- Relative price
- Other (please explain)

Comments:

**32. Since July 2009, have any of these factors changed in importance? Please check all that apply.**

- Non-peer-reviewed clinical evidence
- Peer-reviewed clinical evidence
- Knowledge, support, or reliability of sales rep
- Brand or reputation of your company
- Recommendation from physician colleague
- Relative price
- Other (please explain)

Comments:

**Submit by Email**

Thank you very much for your time. If you have any questions or comments, please contact me at 617-803-1225 or dwolf@mit.edu.

**Dan W. Wolf**  
Biomedical Enterprise Program  
Harvard-MIT Health Sciences & Technology, MS Class of 2010  
Harvard Business School, MBA Class of 2009

Additional Comments:

## **Appendix C: 105 CMR 970.000 Statute**

### CHAPTER 111N

#### PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT

Section 1. As used in this chapter, the following words shall have the following meanings:-

"Department", the department of public health.

"Health care practitioner", a person who prescribes prescription drugs for any person and is licensed to provide health care, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals.

"Marketing code of conduct" practices and standards that govern the marketing and sale of prescription drugs or medical devices by a pharmaceutical or medical device manufacturing company to health care practitioners.

"Medical device", an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which is: (1) recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (3) intended to affect the structure or function of the body of a person or animal, and which does not achieve its primary intended purposes through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

"Person", a business, individual, corporation, union, association, firm, partnership, committee or other organization.

"Pharmaceutical or medical device manufacturer agent", a pharmaceutical or medical device marketer or any other person who for compensation or reward does any act to promote, oppose or influence the prescribing of a particular prescription drug, medical device, or category of prescription drugs or medical devices; provided, however, that "pharmaceutical or medical device manufacturer agent" shall not include a licensed pharmacist, licensed physician or any other licensed health care practitioner with authority to prescribe prescription drugs who is acting within the ordinary scope of the practice for which he is licensed.

"Pharmaceutical or medical device manufacturing company", any entity that participates in a commonwealth health care program and which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs or medical devices, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that "pharmaceutical or medical device manufacturing company" shall not include a wholesale drug distributor licensed under section 36A of chapter 112 or a retail pharmacist registered under section 37 of said chapter 112.

"Pharmaceutical or medical device marketer", a person who, while employed by or under contract with a pharmaceutical or medical device manufacturing company that participates in a commonwealth health care program, engages in detailing, promotional

activities or other marketing of prescription drugs or medical devices in the commonwealth to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs; provided, however, that the "pharmaceutical or medical device marketer" shall not include a wholesale drug distributor licensed under section 36A of chapter 112, a representative of such a distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug or a retail pharmacist registered under section 37 of said chapter 112 if such person is not engaging in such practices under contract with a manufacturing company.

"Physician", a person licensed to practice medicine by the board of registration in medicine under section 2 of chapter 112 who prescribes prescription drugs, or the physician's employees or agents.

"Prescription drugs", drugs upon which the manufacturer or distributor has placed or is required by federal law and regulations to place the following or a comparable warning: "Caution federal law prohibits dispensing without prescription".

Section 2. Notwithstanding any general or special law to the contrary, the department shall adopt a standard marketing code of conduct for all pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth. The marketing code of conduct shall be based on applicable legal standards and incorporate principles of health care including, without limitation, requirements that the activities of the pharmaceutical or medical device manufacturer agents be intended to benefit patients, enhance the practice of medicine and not interfere with the independent judgment of health care practitioners. In promulgating regulations for a marketing code of conduct, the department adopt regulations that shall be no less restrictive than the most recent version of the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America and the Code on Interactions with Healthcare Professionals developed by the Advanced Medical Technology Association. The marketing code of conduct adopted by the department shall not allow:

- (1) the provision of or payment for meals for health care practitioners that:
  - (a) are part of an entertainment or recreational event;
  - (b) are offered without an informational presentation made by pharmaceutical marketing agent or without the pharmaceutical marketing agent being present;
  - (c) are offered, consumed, or provided outside of the health care practitioner's office or hospital setting; or
  - (d) are provided to a healthcare practitioner's spouse or other guest;
- (2) the provision or payment of entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any health care practitioner who is not a salaried employee of the company;
- (3) sponsorship or payment for continuing medical education, in this section referred to as CME, also known as independent medical education, that does not meet the Accreditation Council for Continuing Medical Education Standards For Commercial Support, or that provides payment directly to a health care practitioner;
- (4) financial support for the costs of travel, lodging or other personal expenses of non-

faculty healthcare practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor, except in cases as determined by the department.

(5) funding to compensate for the time spent by health care practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;

(6) the provision of or payment for meals directly at any CME event, third-party scientific or educational conferences, or professional meetings;

(7) payments in cash or cash equivalents to healthcare practitioners either directly or indirectly, except as compensation for bona fide services;

(8) any grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a healthcare practitioner in exchange for prescribing prescription drugs or using medical devices or for a commitment to continue prescribing prescription drugs or using medical devices.

The marketing code of conduct adopted by the department shall allow:

(1) the provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;

(2) the purchase of advertising in peer reviewed academic, scientific or clinical journals;

(3) prescription drugs provided to a health care practitioner solely and exclusively for use by the health care practitioner's patients;

(4) compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or a clinical trial;

(5) payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device.

The department shall update the marketing code of conduct no less than every two years.

The department may promulgate regulations or other guidelines as necessary to implement this section.

Section 3. No pharmaceutical or medical device manufacturer company or pharmaceutical or medical device manufacturer agent shall knowingly and willfully violate the marketing code of conduct as adopted by the department.

Section 4. (a) A pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, or medical device in the commonwealth shall adopt and comply with the most recent marketing code of conduct as adopted by the department.

(b) A pharmaceutical or medical device manufacturing company that employs a person to sell or market prescription drugs or medical devices in the commonwealth shall adopt a training program to provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the marketing code of conduct.

(c) A pharmaceutical or medical device manufacturing company that employs a person to sell or market prescription drugs or medical devices in the commonwealth shall conduct annual audits to monitor compliance with the marketing code of conduct.

(d) A pharmaceutical or medical device manufacturing company that employs a person

to sell or market a prescription drugs or medical devices in the commonwealth shall adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct and take corrective action in response to noncompliance and the reporting of instances of noncompliance to the appropriate state authorities.

(e) A pharmaceutical or medical device manufacturing company that employs a person to sell or market prescription drugs or medical devices in the commonwealth shall identify a compliance officer responsible for operating and monitoring the marketing code of conduct.

Section 5. A pharmaceutical or medical device manufacturing company that employs a person to sell or market prescription drugs or medical devices in the commonwealth shall annually submit to the department: (i) a description of its training program; (ii) a description of its investigation policies; (iii) the name, title, address, telephone number and electronic mail address of its compliance officer; and (iv) certification that it has conducted its annual audit and is in compliance with the marketing code of conduct.

Section 6. (1) By July 1 of each year, every pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, chemical, device or appliance in the commonwealth shall disclose to the department of public health the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or other person in the commonwealth authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the commonwealth. The disclosure shall be accompanied by the payment of a fee, to be determined by the department, to pay the costs of administering this section.

(2) The department of public health shall make all disclosed data publicly available and easily searchable on its website.

(3) The department of public health shall report to the attorney general any payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value provided in violation of the market code of conduct as adopted by the department of public health.

Section 7. This chapter shall be enforced by the attorney general, the district attorney with jurisdiction over a violation or the department of public health. A person that violates this chapter shall be punished by a fine of not more than \$5,000 for each transaction, occurrence or event that violates this chapter.

## **Appendix D: 105 CMR 970.000 Regulations**

### 105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct

#### Section

970.001: Purpose

970.002: Regulatory Authority

970.003: Citation

970.004: Definitions

970.005: General Requirements

970.006: Provision of Meals

970.007: CME, Third-party Scientific or Educational Conferences, or Professional Meetings

970.008: Other Payments to Health Care Practitioners

970.009: Disclosure of Payments

970.010: Penalties

970.011: Enforcement

#### 970.001: Purpose

105 CMR 970.000 is set forth to implement M.G.L. c. 111N, Pharmaceutical and Medical Device Manufacturer Conduct, as enacted under Chapter 305 of the Acts of 2008, An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care. 105 CMR 970.000 is intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and health care practitioners not interfere with the independent judgment of health care practitioners. Pursuant to M.G.L. c. 111N, the regulation seeks to accomplish these objectives without compromising companies' legitimate confidentiality interests in protecting trade secrets and other intellectual property rights associated with genuine medical research, clinical trials, and the discovery of new treatments and medical devices.

#### 970.002: Regulatory Authority

105 CMR 970.000 is adopted under the authority of M.G.L. c.111, s.3 and M.G.L. c.111N.

#### 970.003: Citation

105 CMR 970.000 shall be known, and may be cited, as The Pharmaceutical and Medical Device Manufacturer Code of Conduct or the Marketing Code of Conduct.

#### 970.004: Definitions

The following terms as used in 105 CMR 970.000 shall have the following meanings, unless the context or subject matter clearly require a different interpretation:

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"Authorized entity," the attorney general, the district attorney with jurisdiction over a violation, or the department of public health.

"Biologic," a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, immunoglobulin product, or analogous product, as defined by Section 351 of the Public Health Service Act applicable to the prevention, treatment, or cure of a disease or condition of human beings and regulated as a drug under the Federal Food, Drug, and Cosmetic Act.

"Bona fide services," an arrangement for services including, but not limited to, research, participation on advisory boards, collaboration with 501(c)(3) organizations dedicated to the promotion of health and the prevention of disease, and presentations at pharmaceutical or medical device manufacturing company-sponsored medical education and training including U.S. Food and Drug Administration ("FDA") required education and training involved in producing safe and effective medical devices, provided such an arrangement is formalized in a written agreement specifying the services to be provided, based on the fair market value of the services and characterized by the following factors:

- a legitimate need for the services clearly identified in advance;
- a connection between the competence and expertise of the health care practitioner and the purpose of the arrangement;
- the number of health care practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the health care practitioner;
- the venue and circumstances of any meeting with the health care practitioner is conducive to the services and activities related to the services are the primary focus of the meeting; and
- the decision to retain a health care practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company's sales personnel.

"Charitable donation," the provision of financial support to a 501(c)(3) or the in-kind provision of drugs, biologics or medical devices for charity care of patients.

"Clinical trial," a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board ("IRB") after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or equivalent standards of another federal agency.

"Covered recipient," A person authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the commonwealth, including a hospital, nursing

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home, pharmacist, health benefit plan administrator, or a health care practitioner. A person who otherwise meets this definition but is a bona fide employee of a pharmaceutical or medical device manufacturing company shall not be a covered recipient. Additionally, consumers who purchase prescription drugs or medical devices are not covered recipients.

"Conference or Meeting," any convening where responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the event's organizers in accordance with their guidelines, held in a venue that is appropriate and conducive to informational communication and training about medical information, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented.

"Department," the department of public health.

"Genuine Research Project," a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry.

"Health care practitioner", a person who prescribes prescription drugs for any person and is licensed to provide health care in the commonwealth, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals. Hospitals are not healthcare practitioners. Additionally, full time employees and boardmembers of pharmaceutical or medical device manufacturers are not health care practitioners.

"Hospital Setting," (a) a hospital (b) academic medical center or (c) 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.

"Medical device," an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which is: (1) recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (3) intended to affect the structure or function of the body of a

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person or animal, and which does not achieve its primary intended purposes through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

"Non-faculty," a health care practitioner who does not serve as a speaker or provide actual and substantive services as a faculty organizer or academic program consultant for a continuing medical education ("CME") event, third-party scientific or educational conference, or professional meeting.

"Person," a business, individual, corporation, union, association, firm, partnership, committee or other organization.

"Pharmaceutical or medical device manufacturer agent," a person who, while employed by or under contract with a pharmaceutical or medical device manufacturing company, engages in detailing, promotional activities or other marketing of prescription drugs, biologics, or medical devices in the commonwealth to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices ; provided, however, that "pharmaceutical or medical device manufacturer agent" shall not include a licensed pharmacist, licensed physician or any other licensed health care practitioner with authority to prescribe prescription drugs, biologics or medical devices who is acting within the ordinary scope of the practice for which he or she is licensed, a wholesale drug distributor licensed under section 36A of chapter 112, a representative of such a distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug or a retail pharmacy registered under section 37 of said chapter 112 if such person is not engaging in such practices under contract with a manufacturing company.

"Pharmaceutical or medical device manufacturing company," any entity that:

- (a) is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics, or medical devices, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or
- (b) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices;

provided, however, that "pharmaceutical or medical device manufacturing company" shall not include a health care practitioner, physician practice, home health agency, hospital licensed under M.G.L. c. 111, s. 51, a wholesale drug distributor licensed under M.G.L. c. 112, s. 36A or a retail pharmacy registered under M.G.L. c. 112, s. 37-39C.

"Prescription drugs," drugs upon which the manufacturer or distributor has

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placed or is required by federal law and regulations to place the following or a comparable warning: "Caution federal law prohibits dispensing without prescription."

"Sales and marketing activities," for the purposes of disclosure under 105 CMR 970.009, sales and marketing activities include advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Sales and marketing activities also include any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose.

Sales and marketing activities also include the provision of any fee, payment, subsidy or other economic benefit with a value of at least \$50 to a covered recipient except as follows: Sales and marketing activities do not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or "new use" or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on [clinicaltrials.gov](http://clinicaltrials.gov) will be deemed exempt from disclosure. Sales and marketing activities also shall not include the provision of prescription drugs to a covered recipient solely and exclusively for use by patients, demonstration or evaluation units, in-kind items used for the provision of charity care, or confidential price concessions established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of drugs, biologics or medical devices or the management of a health plan's formulary.

### 970.005: General Requirements

1. By July 1, 2009, each pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall:
  - a. adopt a marketing code of conduct in compliance with the requirements of 105 C.M.R. 970.000.
  - b. adopt and submit to the Department a description of a training program to provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the marketing code of conduct. The training program must:

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- i. ensure that all representatives who are employed by or acting on behalf of the company and who visit health care practitioners have sufficient knowledge of:
    - 1. the marketing code of conduct,
    - 2. general science, and
    - 3. product-specific information to provide accurate, up-to-date information, consistent with state law and FDA requirements; and
  - ii. provide for regular assessments of persons who are employed by or acting on behalf of the companies to ensure that they comply with the requirements of 105 C.M.R. 970.000 and other relevant company policies.
  - c. certify to the Department to the best of the company's knowledge, information and belief that it is in compliance with 105 C.M.R. 970.000;
  - d. adopt and submit to the Department policies and procedures for investigating non-compliance with 105 C.M.R. 970.000, taking corrective action in response to noncompliance and reporting instances of non-compliance to the appropriate state authorities; and
  - e. submit to the Department the name, title, address, telephone number and electronic mail address of the compliance officer it has identified as responsible for certifying compliance with 105 C.M.R. 970.000 and implementing, monitoring, and enforcing the company's marketing code of conduct.
2. Each pharmaceutical manufacturing company that uses non-patient identified prescriber data to facilitate communications with health care practitioners shall:
- a. maintain the confidential nature of prescriber data;
  - b. develop policies regarding the use of the data;
  - c. educate employees and agents about these policies;
  - d. designate an internal contact person to handle inquiries regarding the use of the data;

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- e. identify appropriate disciplinary actions for misuse of the data; and
  - f. comply with the request of any health care practitioner not to make his or her prescriber data available to company sales representatives.
  - g. Before utilizing health care practitioner prescriber data for marketing purposes, manufacturers must give health care practitioners the opportunity to request that their prescriber data :
    - i. be withheld from company sales representatives, and ii. not be used for marketing purposes.
  - h. Nothing in 105 CMR 970.005(2) shall prohibit pharmaceutical manufacturing companies from using prescriber data to:
    - i. impart important safety and risk information to prescribers of a particular drug or device;
    - ii. conduct research;
    - iii. comply with FDA mandated risk management plans that require manufacturers to identify and interact with health care practitioners who prescribe certain drugs or devices; or
    - iv. track adverse events of marketed dugs, biologics or devices.
3. In all speaker and commercial consultant contracts, pharmaceutical manufacturing companies shall require any health care practitioner who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the nature and existence of his or her relationship with the company. This disclosure requirement must extend for at least two years beyond the termination of any speaker or consultant arrangement.
4. Beginning on July 1, 2010, and annually on or before July 1 of each year thereafter, each pharmaceutical and medical device manufacturing company must certify to the Department that it has conducted annual audits to monitor compliance with 105 C.M.R. 970.000.

970.006:        Provision of Meals

1. Except as otherwise provided in 105 CMR 970.000, no pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide or pay for meals for health care practitioners that:

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- a. are part of an entertainment or recreational event;
  - b. are offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present;
  - c. are offered, consumed, or provided outside of the health care practitioner's office or a hospital setting; or
  - d. are provided to a healthcare practitioner's spouse or other guest.
2. Meals provided to health care practitioners in compliance with 105 CMR 970.006 must be modest and occasional in nature.

970.007: CME, Third-Party Scientific or Educational Conferences, or Professional Meetings

1. No pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide:
  - a. financial support for the costs of travel, lodging, or other personal expenses of non-faculty health care practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor.
  - b. funding to compensate for the time spent by health care practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;
  - c. payment for meals directly to a health care practitioner at any CME event, third-party scientific or educational conferences, or professional meetings, although a CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a pharmaceutical or medical device manufacturing company for the event to provide meals for all participants
  - d. sponsorship or payment for CME, also known as independent medical education, that does not meet the Standards For Commercial Support as established by the Accreditation Council for Continuing Medical Education ("ACCME") or equivalent commercial support standards of the relevant continuing education accrediting body, or that provides payment directly to a health care practitioner.

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2. A pharmaceutical manufacturing company shall separate its CME grant-making functions from its sales and marketing departments.
3. A pharmaceutical manufacturing company shall not provide any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by the company.
4. Nothing in 105 CMR 970.000 shall prohibit:
  - a. compensation or reimbursement made to a health care practitioner serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting, provided that the payment:
    1. is reasonable;
    2. is based on fair market value; and
    3. complies with the standards for commercial support as established by the relevant accreditation entity.
  - b. sponsorship or payment for any portion of a third-party scientific or educational conference, charitable conference or meeting, or professional meeting, where the payment is made directly to the conference or meeting organizers.
  - c. the use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific, educational or professional meetings or conferences.

### 970.008: Other Payments to Health Care Practitioners

1. No pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide:
  - a. entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips, to any health care practitioner who is not a salaried employee of the pharmaceutical or medical device manufacturing company;
  - b. payments of any kind including cash or cash equivalents, equity, "in kind" or tangible items including any "complimentary" items such as

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pens, coffee mugs, gift cards, etc. to health care practitioners either directly or indirectly, except as compensation for bona fide services;

- c. any grants, scholarships, subsidies, supports, consulting contracts, or educational or practice related items in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing, or using prescription drugs, biologics or medical devices;
- d. any other payment or remuneration, in cash or in kind, directly or indirectly, including any rebate or "kickback" that is prohibited under applicable federal or state "fraud and abuse" laws or regulations including the federal "Anti-Kickback Statute" (42 U.S.C. 1320a-7b) and equivalent Massachusetts laws such as M.G.L. c. 118E, s. 41 and M.G.L. c. 175H, s. 3.

2. Nothing in 105 CMR 970.008 shall prohibit the following:

- a. Reasonable compensation for bona fide services, or the reimbursement of other reasonable out-of-pocket costs incurred by the health care practitioner directly as a result of the performance of such services, where the compensation and reimbursement is specified in, and paid for under, a written agreement;
- b. 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 a medical device if the 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;
- c. The provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;
- d. The purchase of advertising in peer reviewed academic, scientific or clinical journals;
- e. The provision of prescription drugs to a health care practitioner solely and exclusively for use by the health care practitioner's patients;
- f. The provision of reasonable quantities of medical device demonstration and evaluation units provided to a health care practitioner to assess the appropriate use and functionality of the product and determine whether or not and when to use or recommend the product in the future.

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- g. The provision of price concessions, such as rebates or discounts, in the normal course of business;
- h. Provision of reimbursement information regarding products, including identifying appropriate coverage, coding, or billing of products, or of procedures using those products and information, in support of accurate and responsible billing to Medicare and other payors and provision of information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of products, provided, however, that this technical or other support shall not be offered or provided for the purpose of inducing health care practitioners to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of products; or
- i. The provision of payments, or the provision of free outpatient prescription drugs, to health care practitioners for the benefit of low income individuals, through established "patient assistance programs" ("PAPs"), provided the program meets the criterion for a permissible program in accordance with the relevant published guidance available from the U.S. Department of Health and Human Services Office of the Inspector General, or is otherwise permitted under applicable federal laws and regulations including the "Anti-Kickback Statute" (42 USC 1320a-7b).
- j. The provision of charitable donations provided that the donation:
  - 1. is not provided in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using prescription drugs, biologics or medical devices, and
  - 2. does not otherwise violate the provisions of 105 C.M.R. 970.000.

### 970.009

#### Disclosure of Payments

- 1. Beginning July 1, 2010, and annually on or before July 1 of each year thereafter, every pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall disclose to the Department the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities.

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2. Each annual disclosure report shall be accompanied by a fee of \$2,000. The first annual payment of \$2,000 shall be due to the Department on July 1, 2009.
3. Disclosures shall be made for the previous calendar year using a standardized reporting format developed by the Department. The first required disclosure report shall cover the period from July 1, 2009 through December 31, 2009. Each annual disclosure report may be submitted to the Department electronically.
4. Pharmaceutical or medical device manufacturing companies shall certify that to the best of the company's knowledge, information and belief, the report is true and accurate.
5. For the purposes of computing the \$50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated. Pharmaceutical or medical device manufacturing companies shall not structure fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements of M.G.L. c. 111N, §6 and 105 C.M.R. 970.009.

### 970.010      Penalties

1. A person who knowingly and willfully violates 105 CMR 970.000 shall be punished by a fine of not more than \$5,000 for each transaction, occurrence or event.
2. No pharmaceutical or medical device manufacturing company, shall discharge, refuse to hire, refuse to serve or in any manner retaliate or take any adverse action against any employee, applicant, health care practitioner or covered recipient because such employee, applicant, health care practitioner, or covered recipient takes or has taken any action in furtherance of the enforcement of 105 CMR 970.000.

### 970.011      Enforcement

1. Fines pursuant to 105 CMR 970.000 shall be issued by an authorized entity.
2. Ten days prior to the issuance of any fine pursuant to 105 C.M.R. 970.000, the authorized entity shall provide notice and an informal opportunity to dispute the issuance of the fine in person or by counsel or other representative as to the proposed action.

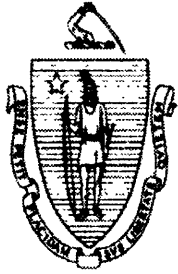
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3. Notice shall be provided by mail, postage prepaid, to the person's usual place of business or, if unavailable, to the person's last known address.
4. A person aggrieved by the issuance of a fine by an authorized entity pursuant to 105 CMR 970.000 may seek judicial review in the Superior Court.
5. An authorized entity may file a civil complaint in Superior Court following the failure of any person to pay a fine issued by the authorized entity

REGULATORY  
AUTHORITY

105 CMR 970.000: M.G.L. c. 111, § 3  
and c. 111

**Appendix E: 105 CMR 970.000 Compliance Form**



**Massachusetts Department of Public Health  
 Pharmaceutical and Medical Device Manufacturer Marketing  
 Code of Conduct  
 Compliance Filing Form for Manufacturers in Accordance  
 with M.G.L. Chapter 111N**

\_\_\_\_\_  
 Manufacturer's Name Address, including zip code

\_\_\_\_\_  
 Contact Name Title Address, including zip code Telephone Number Email Address

- Our company has a marketing code of conduct in compliance with 105 C.M.R. 970.000.
- Our company has adopted a program to routinely train appropriate employees, including, without limitation, all sales and marketing staff regarding the marketing code of conduct, as described in 105 C.M.R. 970.000. A copy of the training program is available to the Department of Public Health on request (DO NOT SEND COPIES).
- Our company has policies and procedures in place for conducting investigations into any and all non-compliance with 105 C.M.R. 970.000, taking corrective actions in response to all non-compliance, and reporting instances of non-compliance to the appropriate state authority. A copy of these policies and procedures is available to the Department of Public Health on request (DO NOT SEND COPIES).
- The Manufacturer expects that beginning July 1, 2010, and annually thereafter as required, the company will be required to submit to the Department of Public Health a disclosure report detailing all payments made to 'covered recipients.' The disclosure report is due by July 1, 2010 and shall cover the period from July 1, 2009 through December 31, 2009. Your manufacturing company should adopt a system to record this information beginning on July 1, 2009 in order to be able to submit this information to the Department by July 1, 2010. Details on this reporting requirement can be found in 105 C.M.R. 970.009 and on the Department of Public Health website at [www.mass.gov/dph/dhcq](http://www.mass.gov/dph/dhcq).
- An annual fee of \$2,000 is included with this form. Please make checks payable to the Commonwealth of Massachusetts.

<i>Compliance</i>	<i>Officer's</i>
Name _____ Title _____ Tel.# _____	
Address _____ Email Address _____ Fax# _____	
<p>I hereby certify to the Massachusetts Department of Public Health to the best of the company's knowledge, information, and belief that _____ is in compliance with 105 C.M.R. 970.000.</p> <p align="center">[Manufacturer's Name]</p>	
<p>Signed under the pains and penalties of perjury.</p>	
<p>_____  <i>Signature of the Manufacturer's Compliance Officer</i></p>	<p>Massachusetts Department of Public Health                  Division of Health Care Quality                  99 Chauncy St., 2<sup>nd</sup> floor                  Boston, MA 02111</p>
<p>Please submit completed form and check to: _____</p>	
<p>Sheila Faiella                  Financial Manager</p>	<p>_____  <i>Date</i></p>

## Appendix F: References

1. Adams, Christopher, and Van Brantner. "Spending on New Drug Development." *Health Economics* 19.2 (2009): 130-41. Web.
2. "AdvaMed Revises Code of Conduct." *Ebglaw.com*. EpsteinBeckerGreen. Web. 30 Mar. 2010.
3. *Advanced Medical Technology Association*. Web. 30 Mar. 2010. <<http://www.advamed.org/>>.
4. Bentley, Linda. "Voluntary Codes: Are You Ready to Comply with Massachusetts? New Pharmaceutical and Medical Device Code of Conduct Law?" MassMedic Meeting. 23 Jan. 2009. Web.
5. Bonoma, Thomas. "Major Sales: Who Really Does the Buying?" *Harvard Business Review* 1 July 2006. Print.
6. Cain, Mary, and Robert Mittman. *Diffusion of Innovation in Health Care*. Rep. California Healthcare Foundation, Institute for the Future, May 2002. Web.
7. Campbell, PhD, Eric, Russel Gruen, MD, and James Mountford, MD. "A National Survey of Physician-Industry Relationships." *New England Journal of Medicine* 356.17 (2007): 1742-750. Web.
8. Cerundolo, Pat. Lecture. *Proposed 105 CMR 970.000 - Pharmaceutical and Medical Device Manufacturer Conduct Impact on the Massachusetts Medical Device Industry*. Foley Hoag LLP, MassMedic. Web. 30 Mar. 2010.
9. Clayton-Matthews, Alan. *The Medical Device Industry in Massachusetts, Executive Summary*. Rep. Boston: MassMedic, University of Massachusetts, 2001. Print.
10. Cornell, Rupa. "Preparing for Compliance with the New MA Pharmaceutical and Medical Device Code of Conduct Law." Lecture. *MassMEDIC*. Boston Scientific. Web. 30 Mar. 2010.
11. Coye, MD, MPH, Molly, Wade Aubry, MD, and Wil Yu. *The ?Tipping Point? and Health Care Innovations: Advancing the Adoption of Beneficial Technologies*. Rep. Washington DC: National Institute for Health Care Management Foundation, National Committee for Quality Health Care, 2003. Print.
12. Depena, Barbara, and Laura Mirviss. "Partners' Conflict of Interest Policy's Reach Concerns Docs." *The Harvard Crimson*. 19 Feb. 2010. Web. <<http://www.thecrimson.com/article/2010/2/19/policy-medical-partners-drug/>>.
13. Ellis, Sam. *Biotechnology in the US*. IBISWorld, 2010. Print.
14. "Federal Anti-kickback Law and Regulatory Safe Harbors." Office of Inspector General | U.S. Department of Health and Human Services. Web. 09 Apr. 2010. <<http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm>>.
15. Fleuren, Margot, Karin Wiefferink, and Theo Paulussen. "Determinants of Innovation within Health Care Organizations." *International Journal for Quality in Health Care* 16.2 (2004): 107-23. Web.
16. *Going to Market*. Publication. Harvard Business School. Print.
17. Gonzalez-Campoy, MD, PhD, FACE, J. Michael. "The Physician-Industry

- Relationship: Lessons from the Minnesota Experience." *Endocrine Practice* 15.4 (2009): 292-96. [Http://www.acreonline.org/](http://www.acreonline.org/). Web.
18. Gelijns, Annetine, and Ethan A. Halm. *The Changing Economics of Medical Technology*. Washington, D.C.: National Academy, 1991. Print.
  19. *Global Biotechnology*. Issue Brief. IBISWorld, 2010. Print.
  20. *Global Pharmaceuticals and Medicine Manufacturing*. Issue Brief. IBISWorld, 2010. Print.
  21. Goodman, Ph.D., Michael. "The Medical Device Industry in Massachusetts: An Updated Profile." Presentation to MassMedic's 11th Annual Meeting by Dir of Economic and Public Policy Research, Office of the President. Massachusetts. 1 May 2007. Web.
  22. Goodwin Proctor. Zemlin, Raymond. "Compliance Strategies." One Year Later: Complying with the Massachusetts Gift Ban Law. MassMedic. 26 Feb. 2010. Web.
  23. Grice, Judith. *Global Pharmaceutical Marketing: a Practical Guide to Codes and Compliance*. London: Pharmaceutical, 2008. Print.
  24. *Integrated Marketing Communications*. Publication. Harvard Business School. Print.
  25. Kidson, Angela. *Medical Instrument & Supply Manufacturing in the US*. Issue Brief no. 33911a. IBISWorld, 2010. Print.
  26. Levitt, Theodore. "Marketing Myopia." *Harvard Business Review* 1 July 2004. Print.
  27. Lopes, Melissa. "Pharmaceutical and Medical Device Manufacturer Conduct." *MassMEDIC*. Department of Public Health. Web.
  28. *Market Segmentation, Target Market Selection, and Positioning*. Publication. Harvard Business School. Print.
  29. *Marketing Promotions*. Publication. Harvard Business School. Print.
  30. "Massachusetts Enacts Final Rules Governing Pharmaceutical and Medical Device Manufacturer Conduct: Manufacturers Must Prepare for a New Regime of State Law Compliance." McDermott Will & Emery, 28 May 2009. Web. <<http://www.mwe.com/info/news/wp0509c.pdf>>.
  31. "Massachusetts Enacts New Law, Chapter 111N "Pharmaceutical And Medical Device Conduct"." Massachusetts Enacts New Law, Chapter 111N "Pharmaceutical And Medical Device Conduct". Nutter McClennen & Fish LLP. Web. 6 Apr. 2010. <[http://www.nutter.com/publications\\_events.php?NewsID=748](http://www.nutter.com/publications_events.php?NewsID=748)>.
  32. Massachusetts. Health and Human Services. Department of Public Health. *Pharmaceutical and Medical Device Manufacturer Conduct Statute*. Web. 30 Mar. 2010. <<http://www.mass.gov/dph/pharmamed>>.
  33. "Massachusetts Hospitals - Board of Registration in Medicine." Page - Board of Registration in Medicine. Web. 28 Apr. 2010. <[http://www.massmedboard.org/links/hospital\\_list.shtm](http://www.massmedboard.org/links/hospital_list.shtm)>.
  34. "Massachusetts Medical Society Study Records Shortages of Primary Care Physicians for the First Time." Massachusetts Medical Society. 27 June 2006. Web. 28 Apr. 2010. <[http://www.massmed.org/AM/Template.cfm?Section=News\\_Releases&CONTE](http://www.massmed.org/AM/Template.cfm?Section=News_Releases&CONTE)

- NTID=15224&TEMPLATE=/CM/ContentDisplay.cfm>
35. *MassMEDIC*. Web. 30 Mar. 2010. <<http://www.massmedic.com/>>.
  36. *Medtronic, the World Leader in Medical Technology and Pioneering Therapies*. Web. 30 Mar. 2010. <<http://www.medtronic.com/>>.
  37. Mehta, Shreefal S. *Commercializing Successful Biomedical Technologies: Basic Principles for the Development of Drugs, Diagnostics, and Devices*. Cambridge: Cambridge UP, 2008. Print.
  38. Montgomery, K., and ES Schneller. "Hospitals? Strategies for Orchestrating Selection of Physician Preference Item." *Milbank Q* 85.2 (2007): 307-35. Print.
  39. Myers, Chris, and Todd Burchill. "The Short Life of a Medical Device." *Health Forum Journal* 45.5 (2002): 34-39. Web.
  40. Napodano, Jason. "Biotech Companies Face the Key Question—Deal or No Deal?" *Genetic Engineering & Biotechnology News*, 5 June 2009. Web. Mar. 2010. <<http://www.genengnews.com/specialreports/sritem.aspx?oid=55672254>>.
  41. "New Vermont Law Expands Ban, Adds Biological Firms to Scope." *Pharmaceutical Law & Industry Report*, 12 June 2009. Web.
  42. *Note on Marketing Strategy*. Publication. Harvard Business School. Print.
  43. *Note on Pricing*. Publication. Harvard Business School. Print.
  44. *Personal Selling and Sales Management*. Publication. Harvard Business School. Print.
  45. "Physicians Payments Sunshine Provisions in Health Care Reform." *Pew Prescription Project*. Web. 30 Mar. 2010. <<http://www.prescriptionproject.org/>>.
  46. *PricewaterhouseCoopers: Global: Insights & Solutions: MoneyTree Survey Report*. Web. 30 Mar. 2010. <<https://www.pwcmoneytree.com/MTPublic/ns/index.jsp>>.
  47. *Principles of Product Policy*. Publication. Harvard Business School. Print.
  48. *Product Policy*. Publication. Harvard Business School. Print.
  49. Reeves, Nikki. "Revised AdvaMed Code of Ethics and Massachusetts Marketing Code of Conduct Comparison Chart." *The American Health Lawyers Association*. Web. 30 Mar. 2010. <<http://www.healthlawyers.org/>>.
  50. Roback, Kerstin. *Medical Device Innovation: The Integrated Processes of Invention, Diffusion and Deployment*. Rep. Sweden: Linkoping University, Institute of Technology, 2006. Print.
  51. S. 301: Physician Payments Sunshine Act of 2009 (GovTrack.us)." *GovTrack.US: Tracking the U.S. Congress*. Web. 30 Mar. 2010. <<http://www.govtrack.us/congress/bill.xpd?bill=s111-301>>.
  52. *Strategic Issues in Distribution*. Publication. Harvard Business School. Print.
  53. Tornelli, MD, MA, FCCP, Mark. "Conflict of Interest in Clinical Practice." *CHEST* 132 (2007): 664-70. Web.
  54. Update on Massachusetts Pharmaceutical and Device Manufacturer Conduct Law: Massachusetts Department of Public Health Issues Proposed Regulations." *Ropes & Gray LLP*. 11 Dec. 2008. Web. 30 Mar. 2010. <<http://www.ropesgray.com/masspharmaanddevicelaw/>>.
  55. Ventola, Lee. "Challenges in Evaluating and Standardizing Medical Devices in Health Care Facilities." *P&T* 33.6 (2008): 348-59. Web.
  56. Weber, Leonard J. Profits before People?: Ethical Standards and the Marketing of

- Prescription Drugs. Bloomington: Indiana UP, 2006. Print.
57. Windhover Healthcare Business Intelligence. Web. 28 Apr. 2010.  
<<http://sis.windhover.com.libproxy.mit.edu/searchform.php?mode=deals&key=current&>>.
58. Zwicker, Joseph, and Dara Kesselheim. "Stringent Requirements for Pharmaceutical and Medical Device Companies in Massachusetts." Choate, 1 Oct. 2008. Web.