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Timothy Stoltzfus Jost

Washington and Lee University School of Law, [jostt@wlu.edu](mailto:jostt@wlu.edu)

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# Oversight of Marketing Relationships Between Physicians and the Drug and Device Industry: A Comparative Study

Timothy Stoltzfus Jost<sup>†</sup>

## ABSTRACT

*Throughout the world, complex mutually-dependent relationships exist between physicians and pharmaceutical and medical device companies. This article focuses on one particular aspect of these relationships—payments made by drug and device companies to physicians and their organizations and institutions to market drugs and devices. It is widely believed that drug and device company marketing to physicians creates conflicts of interest that corrupt physician judgment and increase the cost of medical care. This article examines first the economic basis of physician/industry relationships that causes conflicts to arise. It next considers the measures that a number of developed countries have taken to respond to these relationships. Finally, it proposes an approach that would comprehensively address the problems caused by drug and device company marketing to physicians.*

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## I. PROFESSIONAL INDUSTRY RELATIONSHIPS

Throughout the world, complex mutually-dependent relationships exist between physicians and pharmaceutical and medical device companies.<sup>1</sup> These relationships are found in research, education, and clinical practice. They include, for example, drug and device company sponsorship of research, fellowships, and continuing professional education; industry payments to physicians for consulting; gifts of meals, pens, and coffee mugs to physicians, their office staffs, and medical students; and industry involvement in the formulation of clinical practice guidelines. Some physicians also hold equity interests in drug or device companies or intellectual property interests in their products. Physician-industry relationships present conflicts of interest because the physician's primary commitment to patients in clinical practice, students in education, and science (and patients) in research comes into conflict with a secondary commitment to a drug or device company that offers the physician an opportunity for financial gain.<sup>2</sup>

The literature on physician-industry conflicts of interest has generally viewed these relationships negatively. There is a concern that industry funding of research may bias research findings; obscure the source of information on research results or their interpretation; or at least delay or limit the release of research findings and sharing of data.<sup>3</sup> Industry support of undergraduate, graduate, or continuing education may bias presentations to favor the products of sponsors. Physicians in clinical practice may order drugs and devices produced by firms that offer them consulting contracts or gifts or in which they hold an equity interest rather than the products that are most appropriate for a particular patient or most cost effective.<sup>4</sup> Conflicts of interest may even infect clinical practice guidelines.<sup>5</sup> Biases resulting from industry-physician relationships may result in bad research, patient injury, and high health care system costs.

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<sup>1</sup> See CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 170-75 (Bernard Lo & Marilyn Field eds., 2008) (documenting these relationships); Eric Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 NEW ENG. J. MED. 1742, 1746-47 (2007) (94% of physicians in a recent survey in the United States had some type of relationship with the pharmaceutical industry).

<sup>2</sup> See Ezekiel J. Emanuel & Dennis F. Thompson, *The Concept of Conflicts of Interest*, in THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 758, 760-61 (Ezekiel J. Emanuel et al. eds., 2008).

<sup>3</sup> See Lo & Field, *supra* note 1, at 102-09; Justin E. Bekelman, Yan Li & Cary P. Gross, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289(4) JAMA 454, 456-59 (2004); Trudo Lemmens, *Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene*, 32 J. L. MED. & ETHICS 641, 644-45 (2004); Brian C. Martinson, Melissa S. Anderson & Raymond de Vries, *Scientists Behaving Badly*, 435 NATURE 737, 737 (2005); Robert Steinbrook, *Gag Clauses in Clinical-Trial Agreements*, 352 NEW ENG. J. MED. 2160, 2160 (2005).

<sup>4</sup> Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283(3) JAMA 373, 378 (2000).

<sup>5</sup> See Lo & Field, *supra* note 1, at 189-210; Niteesh K. Choudhry, Henry Thomas Stelfox & Allan S. Detsky, *Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry*, 287(5) JAMA 612, 615 (2002); Peter Q. Eichacker, Charles Natanson & Robert L. Danner, *Surviving Sepsis-Practice Guidelines, Marketing Campaigns, and Eli Lilly*, 355 NEW ENG. J. MED. 1640, 1640 (2006).

But there are also arguments in favor of close working relationships between industry and physicians.<sup>6</sup> In most countries, industry support for research is necessary if medical research is to continue. Support from government and from non-profit foundations is far from adequate to support continued medical progress, and is in any event usually focused on basic science rather than on clinical trials and product development. Industry support for medical education may provide much needed funds to make up for short-falls educational institutions would face if they had to depend solely on public support and on student tuition. Industry marketing and support for continuing professional education helps busy doctors in practice learn about new products that may prove very beneficial to their patients, but that they may not otherwise have learned about. Moreover, doctors are scientists trained to think critically—it should not be assumed that a gift of a meal or pen will distort their judgment, which a life-time of training tells them should consider only the welfare of their patients. Conflicts of interest do not necessarily result in bias.

But they may. Common sense tells us that financial interests do affect judgment, or are likely to. Indeed, there is considerable empirical evidence that even small gifts, even when given without any strings attached, create an expectation of reciprocity on both sides that distorts judgment and result in bias.<sup>7</sup> Tellingly, physicians who are skeptical that pharmaceutical representatives influence their own prescribing believe that the behavior of their colleagues is influenced by industry relationships.<sup>8</sup> Indeed, a systematic review of the medical literature on gifting found that gifts had a negative effect in most instances.<sup>9</sup> There is reason, therefore, to be cautious in encouraging, or even permitting, financial relationships between industry and physicians.

This article considers why physician-industry conflicts of interest exist, how developed countries regulate them, and how they should be regulated. It examines first the economic basis of physician-industry relationships that causes conflicts to arise. It next considers the measures that a number of developed countries have taken to respond to these relationships. The article focuses primarily on industry activities best described as “marketing.” It specifically does not address in any detail industry sponsorship of research. Industry sponsorship of research is perhaps unavoidable, and is generally accepted as making a positive contribution, despite the concerns it raises. Most (although not all) commentators agree that industry research funding should be regulated rather than banned.<sup>10</sup> It is less clear that industry

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<sup>6</sup> See Thomas P. Stossel, *Regulation of Financial Conflicts of Interest in Medical Practice and Medical Research: A Damaging Solution in Search of a Problem*, 50 *BIO. & MED.* 54, 55-56 (2007).

<sup>7</sup> Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290(2) *JAMA* 252, 252 (2003); Dana Katz, Arthur L. Caplan & Jon F. Merz, *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving*, 3 *AM. J. BIOETHICS* 39, 42-43 (2003).

<sup>8</sup> Dana & Loewenstein, *supra* note 7, at 254.

<sup>9</sup> Wazana, *supra* note 4, at 373.

<sup>10</sup> See, e.g., AAMC-AAU ADVISORY COMM., *PROTECTING PATIENTS, PRESERVING INTEGRITY, ADVANCING HEALTH: ACCELERATING THE IMPLEMENTATION OF COI POLICIES IN HUMAN SUBJECTS RESEARCH* 1-4 (2008); FASEB, *CALL TO ACTION: MANAGING FINANCIAL*

marketing efforts aimed at medical education and clinical practice are necessary. The argument for banning them, or at least for regulating them, is stronger. This article concludes with a proposal that would ban most industry payments to physicians for marketing, while continuing to allow drug and device companies to advertise their products freely and providing a substitute stream of funding for the legitimate activities that drug and device companies now finance.

## II. THE MARKET FOR DRUGS AND DEVICES

The market for drugs and devices is quite distinctive. The supply side, demand side, and regulation of the market are each unlike those found in typical markets.

On the supply side, the market is characterized by very high fixed costs with relatively low variable production costs.<sup>11</sup> This is particularly true with small molecule drugs, where research and development can cost hundreds of millions of dollars, while manufacturing costs are comparatively small. Second, manufacturers often have considerable market power. Drugs and devices are usually protected by patents (or sometimes trade secrets), and in some countries by market exclusivity periods that supplement patent rights. Intellectual property rights give breakthrough products sole dominance over the market. Because of the high cost of developing innovator products, companies often find it more profitable to produce new products that offer only marginal improvements over existing products (longer lasting slow release products, for example) or products that are therapeutically similar to competing products that dominate lucrative markets.<sup>12</sup> But even products that have therapeutic equivalents often retain some market power until they face competition from multiple generics.<sup>13</sup> Many countries regulate in one way or another the prices of drugs and devices, but regulated prices are often a function of prices paid by other countries, and throughout most of the developed world, prices are high and not radically different from country to country.<sup>14</sup>

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RELATIONSHIPS BETWEEN ACADEMIA AND INDUSTRY IN BIOMEDICAL RESEARCH 1-4 (2007); Lo & Field, *supra* note 1, at 110-21.

<sup>11</sup> The cost of developing a new drug has been estimated at over \$800 million, though this estimate is quite controversial. See Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is it Really \$802 Million?*, 25 HEALTH AFF. 420, 427 (2006). Only about a quarter of drug company revenues are spent on production costs. Uwe E. Reinhardt, *Perspectives on the Pharmaceutical Industry*, 20 HEALTH AFF. 136, 141 (2001).

<sup>12</sup> See Lenny H. Pattikawa, *Longitudinal Study on the Performance of U.S. Pharmaceutical Firms: The Increasing Role of Marketing*, in RESEARCH IN MANAGEMENT 2007, at 1, 1-3 (Erasmus Research Inst. of Mgmt. Series Ref. No. 20, 2007).

<sup>13</sup> See Nina Pavcnik, *Do Pharmaceutical Prices Respond to Insurance?* 16-19 (Nat'l Bureau of Econ. Research, Working Paper No. 20, 2000).

<sup>14</sup> See Antonio Cabrales & Sergi Jiménez-Martín, *The Determinants of Pricing in Pharmaceuticals: Are U.S. Prices Really Higher Than Those of Canada?* 12-13 (Dept. of Econ. and Business, Universitat Pompeu Fabra, Econ. Research, Working Paper No. 1032, 2007); Patricia M. Danzon & Michael F. Furukawa, *International Prices and Availability of Pharmaceuticals*, in 2005, 27 HEALTH AFF. 221, 222-23 (2008).

On the demand side, drugs and devices usually face relatively low price elasticity of demand.<sup>15</sup> Health is of great value and sick patients are often willing to pay handsomely for the restoration of health and well-being or for protection against a worsening of their condition. An even more important factor influencing demand is moral hazard. In developed countries, most patients are covered by public or private insurance, or both. Patients rarely pay the full cost of drugs and devices. Patients often face some cost-sharing obligations, but most of the cost of a drug or device is usually borne by insurance. Insurance coverage allows pharmaceutical companies to keep prices high.<sup>16</sup> Moreover, purchasing decisions are often not made by the patient, but rather by an agent – in the first instance by the physician who must write a prescription, and beyond that by institutional formulary committees or by national coverage determination entities that decide which drugs and devices are available. In short, the demand mechanisms that normally control prices are fundamentally distorted with respect to drugs and devices.

Medicinal products are also heavily regulated. While drugs and devices offer great value to society, they also often have serious side effects and can cause serious injury if they malfunction or are used excessively or inappropriately. Moreover, if harmless or ineffective products are relied upon when effective alternatives are available, patients may suffer serious health consequences. Developed countries, therefore, usually require that drugs and potentially harmful devices be proven safe and effective through rigorous testing.<sup>17</sup> This testing is usually done through clinical trials. However, clinical trials are limited in their length, the scope of the population that participates, and the indications that are considered. Yet drug and device approval agencies do not control the prescribing or use of the products themselves, and prescribing in practice is usually not limited to the indications for which a product is tested—off-label use is common.<sup>18</sup> There is a strong incentive, therefore, for drug companies to conduct clinical trials and to get approval for a relatively narrow indication and then to encourage use of the product for a whole range of other treatments without further clinical trials.<sup>19</sup>

These characteristics of drug and device markets often result in troubling relationships between manufacturers and professionals. In particular, drug and device companies face a host of incentives to spend a great deal of money marketing their products. As noted above, their variable production costs tend to be low, but they are able to keep prices high because of low elasticity of demand, moral hazard, and relative lack of competition as long as a product is

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<sup>15</sup> See JEANNE S. RINGEL ET AL., NAT'L DEFENSE RESEARCH INST., THE ELASTICITY OF DEMAND FOR HEALTH CARE, 35-36 (2002).

<sup>16</sup> Pavcnik, *supra* note 13, at 20.

<sup>17</sup> This is usually done on a national basis, although in Europe it is also done at the European level by the European Medicines Agency. For a brief description and history of the drug approval process, see History and Future of ICH, <http://www.ich.org/cache/compo/276-254-1.html> (last visited Apr. 11, 2010).

<sup>18</sup> See Sharon Conroy et al., *Survey of Unlicensed and Off Label Drug Use in Paediatric Wards in European Countries*, 320 BMJ 79, 79 (2000); David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1021 (2006).

<sup>19</sup> See Michael A. Steinman et al., *Characteristics and Impact of Drug Detailing for Gabapentin*, 4 PLoS MED. 743, 747 (2007).

covered by a patent or market exclusivity period. Even when products are therapeutically equivalent, there is an incentive for aggressive marketing as manufacturers try to differentiate their products from competitor products or to break into a market dominated by other manufacturers.

The money that companies receive because of the difference between low production costs and high prices can be devoted to research and development, profit, or marketing. Companies that wish to stay in business must spend some money, often a great deal, on research and development. But companies also face in particular a great incentive to spend heavily on marketing. Economic theory generally predicts that market power will result in decreased supply of goods and in increased prices compared to what would be found in competitive market. But in drug and device markets low elasticity of demand means that increased demand does not necessarily result in reduced price, thus the optimal strategy of drug and device companies is to engage in aggressive marketing to shift the demand curve.<sup>20</sup> As long as a dollar, pound, yen, or euro spent on marketing brings in more than an additional dollar, pound, yen, or euro after variable costs (including marketing and production costs) are covered, marketing makes sense. In fact, while the average manufacturing industry spends less than one percent of its sales income on marketing, drug companies spend ten to twenty percent.<sup>21</sup>

The fact that drugs and devices are prescribed or ordered by physicians rather than purchased directly by consumers also has a profound effect on the nature of marketing. In most developed countries, direct-to-consumer brand advertising of prescription drugs is prohibited. Even where direct-to-consumer advertising is permitted, however, it does not really sell the product to consumers, who cannot legally buy it without a prescription. Rather direct-to-consumer advertising enlists consumers to pressure their doctors to order the product.<sup>22</sup> Most marketing is in fact directed at physicians, the real decision-makers with respect to drug and device purchases, and is aimed at persuading them to order or prescribe a particular product.<sup>23</sup> In 2004, pharmaceutical companies in the United States spent almost \$4.3 billion on marketing to physicians, \$61,000 for every physician in the United States.<sup>24</sup> Marketing can also be aimed less directly at formulary committees, guideline committees, or at others who decide whether or not a particular product will be covered or available to patients. The prevalence of off-label prescribing

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<sup>20</sup> See Alan M. Garber et al., *Insurance and Incentives for Medical Innovation* 16 (Nat'l Bureau of Econ. Research, Working Paper No. 12080, 2006).

<sup>21</sup> Charles King III, *Marketing, Product Differentiation, and Competition in the Market for Anticancer Drugs 2* (Harvard Bus. Sch., Working Paper No. 01-014, 2002), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=891128](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=891128). This marketing is often aimed at getting physicians to switch from one drug to another rather than to expand a market. *Id.* at 23-24.

<sup>22</sup> Barbara Mintzes et al., *Influence of Direct to Consumer Pharmaceutical Advertising and Patients' Requests on Prescribing Decisions: Two Site Cross Sectional Survey*, 324 *BMJ* 278, 278-79 (2002).

<sup>23</sup> See Sridhar Narayanan et al., *The Informative Versus Persuasive Role of Marketing Communication in New Product Categories: An Application to the Prescription Antihistamines Market 4* (Univ. Chicago Graduate Sch. of Bus., Working Paper, 2003) available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=472881](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=472881).

<sup>24</sup> Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 *PLoS MED.* 29, 32 (2008).

increases the incentives faced by manufacturers to market their products aggressively, since they cannot depend on physicians or formulary or guideline committees discovering all of the indications for which products may be used through approved labeling.

Drug and device marketing takes place through a wide variety of channels. First, companies advertise in professional and scientific journals. This strategy allows drug companies to disseminate information about their products directly to their most important audience. It also, however, makes journals financially dependent upon them and thus vulnerable to their influence when a journal must decide whether or not to publish an article favorable to a product or critical of the industry.<sup>25</sup>

Second, companies sponsor medical education, including continuing medical education which physicians may need to attend to maintain their licensure or specialty certification. In 2000, industry sponsored 314,000 educational events for physicians in the United States.<sup>26</sup> Traditionally drug companies in the United States could pick the speakers for continuing education symposia and even provide them with the text and slides for their presentations. Although drug companies are no longer supposed to be as directly involved in CME in the United States, they still fund over half of continuing education, usually indirectly through commercial CME providers.<sup>27</sup> Industry CME funding amounts to over one billion dollars a year and compliance with requirements is far from universal.<sup>28</sup> In some other countries, companies continue to be more directly involved in CME.<sup>29</sup> In the past, continuing professional education programs were often held at resorts or other recreational destinations and companies covered travel costs for physicians and sometimes even for their families. Most countries now limit payments for physician entertainment, but continuing education still takes place in attractive settings and companies can still fund travel costs for speakers (who sometimes do little to earn their pay) and even for CME attendees in many countries. While most professions finance continuing education by paying fees, the medical profession seems to believe that continuing education is only possible if it is funded by drug and device companies.

Third, companies play a major role in funding medical specialty societies and even patient disease organizations.<sup>30</sup> Companies help sponsor specialty society annual meetings and journals and pay fees for space in exhibition halls at society meetings. Companies often offer their own marketing programs in tandem with specialty association meetings. Specialty societies in turn often

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<sup>25</sup> See Richard Smith, *Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies*, 2 PLoS MED. 364, 364 (2005).

<sup>26</sup> Troyen A. Brennan et al., *Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 295 JAMA 429, 430 (2006).

<sup>27</sup> Arnold S. Relman, *Defending Professional Independence: ACCME's Proposed New Guidelines for Commercial Support of CME*, 289 JAMA 2418, 2418 (2003).

<sup>28</sup> STAFF OF S. FIN. COMM., 110TH CONG., *USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS* 9 (Comm. Print 2007); Lo & Field, *supra* note 1, at 143-49.

<sup>29</sup> Ray Moynihan, *Doctor's Education: The Invisible Influence*, 336 BMJ 416, 416 (2008).

<sup>30</sup> See, e.g., Gardiner Harris, *Drug Makers Scrutinized Over Grants*, N.Y. TIMES, Jan. 11, 2006, at C1; Christopher Rowland, *Doctors Fight Over Drug Firm Influence*, BOSTON GLOBE, June 16, 2005, at E1.



play an active role in formulating practice guidelines, which can favor particular products or approaches to the treatment of diseases. Companies also fund patient disease organizations, which in turn pressure government and insurers to cover particular products or procedures.<sup>31</sup>

Fourth, companies often pay medical opinion leaders to market their products to other doctors through consulting or “speaker’s bureau” contracts.<sup>32</sup> These arrangements not only have the potential to distort the judgment of the physician hired as a consultant or speaker, but can also be quite effective in affecting the prescribing behavior of physicians with whom opinion leaders interact. These operations can be quite sophisticated where companies have access to physician prescribing data, allowing them to target their efforts on “switching” doctors who are low prescribers of their products and to track changes in prescribing behavior after physicians have been exposed to a company presentation.<sup>33</sup>

Physicians also receive payments for participating in post-marketing research. While this research can be a legitimate effort to discover longer-term side effects of drugs or to study the safety and effectiveness of drugs in new populations or for new indications, it is sometimes little more than a ploy to pay doctors for prescribing a particular drug or using a particular device.<sup>34</sup> Doctors participating in sham research collect little useful data, which is in any event not effectively reviewed.

Finally, companies engage in detailing. Britain has 8000 drug company representatives, while the United States had 83,000 in the year 2000.<sup>35</sup> It is the responsibility of detailers to personally contact physicians or their offices to distribute information about drugs. Detailers provide food for the office staff and leave behind mementos of their visit.<sup>36</sup> These are often trivial items – coffee mugs, pens, pads of paper--but they assure that drug and drug company names and logos are pervasively present in medical practices.<sup>37</sup> Historically, moreover, gifts included much more expensive items such as sports equipment or tickets to sports or entertainment events, and these practices may continue in some countries. Drug companies also frequently offer food, entertainment, and small gifts to doctors in training – undergraduate or graduate medical students. These can include practice-related gifts, such as stethoscopes or reference books. These gifts are useful to students as they prepare for medical practice, but they also establish a bond

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<sup>31</sup> See Thomas Ginsberg, *Donations Tie Drug Firms and Nonprofits: Many Patient Groups Reveal Few, if Any, Details on Relationships with Pharmaceutical Donors*, PHILA. INQUIRER, May 28, 2006, at A1.

<sup>32</sup> Richard Smith, *Curbing the Influence of the Drug Industry: A British View*, 2 PLoS MED. 821, 822 (2005).

<sup>33</sup> See Daniel Carlat, *Dr. Drug Rep*, N. Y. TIMES, Nov. 25, 2007, at 64.

<sup>34</sup> See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

<sup>35</sup> Smith, *supra* note 32, at 821; EMILY CLAYTON, ‘TIS ALWAYS THE SEASON FOR GIVING 3 (2004), *available at* <http://www.calpirg.org/uploads/Le/LW/LeLWJ1Gv4Nwd9MVJapxdkQ/TistheSeasonForGiving04.pdf>.

<sup>36</sup> See Ray Moynihan, *Who Pays for the Pizza? Redefining the Relationships Between Doctors and Drug Companies. 1: Entanglement*, 326 BMJ 1189 (2002).

<sup>37</sup> Christopher Sikora, *Whose Pen is In Your Pocket?*, 52 CANADIAN. FAM. PHYSICIAN. 394, 394 (2006).

between the company and the future professional. Moreover, industry largess can create dependence on the part of institutions and their leadership as well as individual physicians.<sup>38</sup> Finally, drug companies often give physicians samples or vouchers for the purchase of drugs, thus encouraging physicians to get patients started on their products rather than on less expensive products.

Products that doctors prescribe in response to marketing may or may not be the most appropriate for particular patients. Patients who are prescribed inappropriate drugs may, of course, suffer side effects or experience no remediation or even an aggravation of their medical conditions. Marketing tends to focus on newer products, which may be safer or more effective than older products, but which also may not have been fully tested for long term side-effects. Several widely-publicized incidents in recent years have involved heavily marketed drugs such as VIOXX that turned out to be dangerous or ineffective.<sup>39</sup> Heavily advertised products also tend to be more costly than alternatives. Marketing also increases the cost of health care by leading to overprescribing of drugs and probably over-diagnosis of illnesses.<sup>40</sup> In this way marketing drives up health care costs, which are often not directly borne by the patient because of public or private insurance.

To sum up the argument thus far: developed countries have attempted to encourage drug and device innovation by granting intellectual property rights and market exclusivity and by setting prices quite high where prices are regulated. Markets, on the other hand, generally fail to keep prices low because of low elasticity of demand driven by moral hazard. Because high prices are often coupled with low production costs, drug and device companies can expand their income by expanding their markets. They do so primarily by marketing their products to physicians, either directly through detailing, marketing trials, or consulting payments or indirectly through influencing medical and scientific journals, specialty societies, disease advocacy groups, and guidelines panels. These marketing practices effectively transfer large sums of money from patients, governments, and insurers to drug companies, who in turn spread it throughout the health care industry, but primarily to doctors and their organizations. Doctors, who often believe themselves to be underpaid, have come to expect this largess, and indeed many believe that they are entitled to it.<sup>41</sup> The entire arrangement, however, has the potential to corrupt medical judgment and thus to be contrary to the interest of patients, as well as to drive up health care costs.

The question then becomes, how do various countries respond to this situation, and what is the most appropriate response?

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<sup>38</sup> See Charles Mather, *The Pipeline and the Porcupine: Alternate Metaphors of the Physician-Industry Relationship*, 60 SOC. SCI. MED. 1323 (2005).

<sup>39</sup> See Jeanne Lenzer, *Secret US Report Surfaces on Antidepressants in Children*, 329 BMJ 307, 307 (2004); Eric J. Topol, *Failing the Public Health—Rofecoxib, Merck, and the FDA*, 351 NEW ENG. J. MED. 1707, 1707 (2004).

<sup>40</sup> See Ray Moynihan, Iona Health & David Henry, *Selling Sickness: The Pharmaceutical Industry and Disease Mongering*, 324 BMJ 886 (2002).

<sup>41</sup> Frederick Sierles et al., *Medical Students' Exposure to and Attitudes About Drug Company Interactions: A National Survey*, 294 JAMA 1034, 1035 (2005).

### III. COMPARATIVE APPROACHES TO REGULATION OF INDUSTRY/PROFESSIONAL RELATIONSHIPS

One of the most common responses is industry self-regulation through codes of conduct. The International Federation of Pharmaceutical Manufacturer and Associations (IFPMA) Code of Pharmaceutical Marketing Practices lays down a baseline for pharmaceutical promotion worldwide. In Europe, the *Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals* of the European Federation of Pharmaceutical Industries and Associations (EFPIA), adopted in 1991 and revised most recently in 2007, establishes a self-regulatory framework for the thirty pharmaceutical-producing countries of Europe. The major pharmaceutical producing countries of Europe each also have their own independent codes, including the recently revised Association of the British Pharmaceutical Industry (ABPI) Code of Practice and the Code of Conduct of the Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V in Germany. In the United States, the Pharmaceutical Research and Manufacturing Association (PhRMA) Code governs interactions between pharmaceutical companies and professionals while the AdvaMed code governs device manufacturers.

These codes vary from country to country in their stringency. At a minimum they proscribe or limit the least defensible forms of marketing. The EFPIA Code, which sets out a minimum standard for European codes, permits companies to host promotional events and pay travel costs for professionals to attend, but cautions companies to avoid venues that are “renowned” for their entertainment facilities or are ‘extravagant’.<sup>42</sup> It also prohibits companies from offering gifts to professionals as an inducement to prescribe a particular product, but allows “inexpensive” gifts that are “relevant to the practice of medicine.”<sup>43</sup> European national codes tend to reinforce the EFPIA Code, but contain national variations. The German Code, for example, provides that; “Healthcare professionals shall not be unreasonably molested by advertising,” including faxes and e-mails without prior permission.<sup>44</sup> National codes can also be more specific and detailed. The British Code prohibits gifts with a value in excess of £6. The Japanese code is quite permissive, allowing pharmaceutical companies to pay for transportation for doctors attending conferences and to engage in unlimited assistance to providers in connection with their own products.<sup>45</sup>

In general, industry codes are vague and open to interpretation. It is also often not clear that any serious consequences follow from violating industry codes. The EFPIA Code suggests that national associations require offending companies to cease unpermitted activities and sanction offending companies with a combination of publication and fines.<sup>46</sup> Complaints of violations of the

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<sup>42</sup> EUR. FED’N OF PHARM. INDUS. & ASS’N, CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS, §§ 9.01, 9.07.

<sup>43</sup> *Id.* at §§ 10.01, 10.02.

<sup>44</sup> FARM SERV. AGENCY, CODE OF CONDUCT ON THE COLLABORATION WITH HEALTHCARE PROFESSIONALS, § 13(1) (2004).

<sup>45</sup> Marc. Rodwin, *Physicians’ Conflicts of Interest in Japan and the United States: Lessons for the United States*, 25 J. HEALTH POL., POL’Y & L. 343, 354 (2000).

<sup>46</sup> EUR. FED’N OF PHARM. INDUS. & ASS’N, *supra* note 42, at art.18.

ABPI Code in Britain are investigated by the Prescription Medicines Code of Practice Authority (PMCPA), which investigated 127 complaints in 2007, although many of these had to do with advertisements and a number were brought by competing pharmaceutical companies.<sup>47</sup> I know of no independent research as to the extent to which companies are in fact complying with marketing codes.

A second common approach to regulating these relationships is professional association codes of conduct, which focus on the professionals who are the targets of marketing. The World Medical Association's 2004 *Statement Concerning the Relationship Between Physicians and Commercial Enterprises* is weaker than the statements of many national professional or regulatory bodies, but at least provides a baseline for countries in which regulation does not exist or is minimal.<sup>48</sup> The American Medical Association has issued an ethical opinion addressing gifts to physicians from industry and a lengthy set of questions and answers explicating that opinion.<sup>49</sup> It permits, for example, gifts that are primarily for the benefit of patients and not of substantial value (defined as around \$100) and "modest" dinners, but does not permit gifts of cash or sweepstakes offering expensive prizes. Significantly, it does not allow pharmaceutical companies to pay for travel, lodging, or meal expenses for physicians to attend conferences or meetings, although it does allow funding for social events during conferences and for travel expenses for "bona fide faculty." The Canadian Medical Association policy on physicians and the pharmaceutical industry prohibits industry funding of travel expenses for physicians attending CME. It also prohibits "receipt of personal gifts of any significant monetary or other value," and notes that gifts of any value have been shown to have the potential to influence clinical decisions.<sup>50</sup> Finally, the Canadian policy prohibits doctors from charging a fee to see manufacturing representatives.<sup>51</sup>

In all developed countries physicians must be licensed (or in a few countries, registered). A number of countries have professional licensure regulations limiting industry-physician relationships. Regulatory guidance is often quite vague. A General Medical Council Opinion of 2006, for example, states, "You must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe for, treat, or refer patients." The German *Muster Berufsordnung* likewise prohibits gifts that are not "geringfügig" (negligible).<sup>52</sup> It also prohibits doctors from participating in pharmaceutical advertising and requires doctors to file any contracts between them and pharmaceutical companies with the physician licensure

<sup>47</sup> PRESCRIPTION MED. CODE OF PRACTICE AUTH., ANNUAL REPORT 2 (2007).

<sup>48</sup> See World Medical Association, WMA Statement concerning the Relationship between Physicians and Commercial Enterprises, <http://www.wma.net/en/30publications/10policies/r2/index.html> (last visited Apr. 2, 2010).

<sup>49</sup> See American Medical Association, Ethical Opinion E-8.061, Gifts to Physicians from Industry, available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml> (last visited Apr. 2, 2010).

<sup>50</sup> CANADIAN MEDICAL ASSOCIATION POLICY, GUIDELINES FOR PHYSICIANS IN INTERACTIONS WITH INDUSTRY § 44 (2007).

<sup>51</sup> *Id.* § 49.

<sup>52</sup> Hans-Dieter Lippert & R. Ratzel, Kommentar zur Musterberufsordnung der deutschen Ärzte, § 33(2)-(3) (2006) [hereinafter MBO].

agency.<sup>53</sup> It does permit, however, pharmaceutical companies to pay travel costs for doctors to attend continuing education programs.<sup>54</sup> In France, the *Code de la Santé Publique* (Article L.4113-6) prohibits doctors from receiving gifts worth more than 30€. <sup>55</sup> In the Netherlands both drug companies and doctors have been fined for providing and receiving “excess hospitality.”<sup>56</sup> Again, however, it is hard to know how widespread noncompliance with regulatory requirements is, or how frequently disciplinary actions are brought.

In a few countries continued licensure status depends on fulfilling continuing medical education (CME) requirements.<sup>57</sup> In other countries, CME is not required, but physicians’ fees may be increased or decreased based on continuing education credits. In most countries, continuing education is voluntary and is handled through specialty associations or colleges and faculties.<sup>58</sup> Industry funding of CME seems pervasive, yet it does not seem to be addressed by government regulation in most countries.<sup>59</sup>

Industry sponsorship of CME is addressed in some countries, however, through private accreditation agencies. In the United States, the Accreditation Council for Continuing Medical Education accredits continuing medical education. Accreditation is in turn required by state regulatory boards for CME credit. The ACCME attempts to limit the control that drug and device companies exert over continuing education that they finance. Its standards, for example, prohibit commercial interests from dictating the content or choosing the speakers for accredited CME activities, or for paying travel costs for doctors receiving CME.<sup>60</sup>

Marketing practices can also be addressed by government regulation of advertising. Title VIII of the European Council Directive 2001/83/EC addresses advertising of medicinal products, including advertising to health care professionals. Articles 94 and 95 permit drug and device companies only to offer inexpensive gifts and hospitality to professionals. Article 97 obligates member states to enforce the directive. In the U.K, pharmaceutical marketing is regulated by the Healthcare Products Regulatory Agency (HPRA), in cooperation with the self-regulatory PMCPA.<sup>61</sup> The HPRA publishes *The Blue*

<sup>53</sup> MBO §§ 33-34. See also Hans-Dieter Lippert & Rudolph Ratzel, *Arzt und Industrie nach den Beschlüssen des 106. Deutschen Ärztetags* 46 NJW 3301 (2003).

<sup>54</sup> MBO § 33(4).

<sup>55</sup> Elizabeth Wager, *How to Dance with Porcupines: Rules and Guidelines on Doctor's Relations With Drug Companies*, 326 BMJ 1196, 1197 (2003).

<sup>56</sup> Ann McGuaran, *Royal College Issues New Guidelines on Gifts from Drug Companies*, 325 BMJ 511, 511 (2003).

<sup>57</sup> See Cathy Peck et al., *Continuing Medical Education GMC, Guidance on Continuing Professional Development, International Comparisons*, 320 BMJ 432, 432-33 (2000); See also General Medical Council, *Guidance on Continuing Professional Development*, [http://www.gmc-uk.org/education/continuing\\_professional\\_development/cpd\\_guidance.asp](http://www.gmc-uk.org/education/continuing_professional_development/cpd_guidance.asp) (last visited Apr. 1, 2010).

<sup>58</sup> Peck et al., *supra* note 57, at 433.

<sup>59</sup> Moynihan, *supra* note 29, at 416.

<sup>60</sup> See ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, ACCME STANDARDS FOR COMMERCIAL SUPPORT-STANDARDS TO ENSURE THE INDEPENDENCE OF CME ACTIVITIES, 1-3 (2007).

<sup>61</sup> See Memorandum of Understanding between the Ass'n of the British Pharm. Indus., the Prescription Medicines Code of Practice Auth., and the Medicines and Healthcare Prod. Regulatory Agency, (Nov. 3, 2005) available at

*Guide: Advertising and Promotion of Medicines* in the UK, which explains the UK Medicines Regulations, which in turn implement the EC Directive. It contains specific interpretation of the regulations, for example, defining “inexpensive” as not costing more than £6 (excluding VAT), and items “relevant to the practice of medicine” as including coffee mugs.<sup>62</sup> The United States Food and Drug Administration (FDA) has statutory authority to regulate drug and device labeling and advertising.<sup>63</sup> The FDA does not attempt to control industry supported educational programs as long as the programs are independently administered, as outlined in an industry guidance.<sup>64</sup> Finally, while the Patient Protection and Affordable Care Act, recently adopted in the United States does not limit gifts from industry to doctors, it does require manufacturers of drugs, devices, biologics, and medical supplies to disclose in a public, searchable database all “Payments or other transfers of value” that they make to physicians and teaching hospitals, subject to limited exceptions.<sup>77</sup>

Professional school faculty and employees must also abide by the policies that govern their institution. Some medical schools in the United States have adopted policies greatly limiting pharmaceutical promotion on campus, for example. The Association of American Medical Colleges is currently in the process of considering recommendations for greater restrictions on interactions between industry and academic medical centers and their students.<sup>65</sup> In countries where professional schools are state run, laws governing the institutions may require that the administration approve payments that faculty receive from industry.<sup>66</sup>

Finally, relationships between industry and physicians may also raise criminal law issues. This is particularly likely in countries where physicians are public employees. In Germany and Japan, for example, doctors employed by public hospitals or public educational institutions are civil servants. Gifts or payments to them could be considered to be attempts to bribe or corrupt public officials, which is in turn potentially a serious offense. Section 331 of the German Civil Code prohibits a public official from accepting a benefit for discharge of an official duty, while section 332 prohibits an official from accepting a benefit in return for violating the officer’s official duties.<sup>67</sup> In a recent decision, the Bundesgerichtshof (Germany’s highest nonconstitutional court) refused to find a university professor guilty of violating section 331

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[http://www.abpi.org.uk/links/assoc/PMCPA/Memo\\_understanding\\_nov3.pdf](http://www.abpi.org.uk/links/assoc/PMCPA/Memo_understanding_nov3.pdf) (last visited Apr. 15, 2010).

<sup>62</sup> MEDICINE AND HEALTHCARE PRODUCTS REGULATORY AGENCY, *THE BLUE GUIDE: ADVERTISING AND PROMOTION OF MEDICINES IN THE UK 30* (TSO 2005).

<sup>63</sup> 21 U.S.C. §§ 352(f),(n),(q) & (r), 353 (2006).

<sup>64</sup> See FED. DRUG ADMINISTRATION, *GUIDANCE FOR INDUSTRY: INDUSTRY-SUPPORTED SCIENTIFIC AND EDUCATIONAL ACTIVITIES* 1, 3 (1997), <http://www.gwumc.edu/cehp/pdf/CMEPolicies/FDAguidance.pdf>.

<sup>77</sup> Pub. L. No. 111-148, § 6002

<sup>65</sup> See ASS’N AM. MED. C., *INDUSTRY FUNDING OF MEDICAL EDUCATION* vi-xi (2008), [http://services.aamc.org/publications/showfile.cfm?file=version114.pdf&prd\\_id=232](http://services.aamc.org/publications/showfile.cfm?file=version114.pdf&prd_id=232).

<sup>66</sup> See, e.g., *Beamtenstatusgesetz [BeamtStG] [Civil Service Law]* Feb. 5, 2009, § 42 (F.R.G.).

<sup>67</sup> *Strafgesetzbuch [StGB] [Penal Code]* §§ 331, 332 (F.R.G.). See ERWIN DEUTSCH & ANDREAS SPICKHOFF, *MEDIZINRECHT*, ¶¶ 491, 492 ((6th ed. 2008); Lippert & Ratzel, *supra* note 53, at 3304-05.

where the doctor had received payments from a pacemaker manufacturer for services but where there was no evidence that the services were not approved by the university or that they had influenced treatment decisions. The court went on to observe that prosecutions for payments received by officials from third parties in connection with their official duties were certainly possible, and that it was very important that university faculty disclose industry relationships to the university administration, and receive approval where necessary.<sup>68</sup> In Japan, a *National Public Official Moral Code*, adopted in 2000 imposes much the same constraints on doctors working at university hospitals as are found in the German law.<sup>69</sup>

Physician-industry relationships are also problematic if they increase the costs of public insurance programs. For this reason, it is illegal in the United States for an entity such as a pharmaceutical or device company to offer or pay “remuneration” to a physician in exchange for the referral of a patient or the ordering of a service, or for a physician to solicit or receive such a payment.<sup>70</sup> Additionally, a physician may not refer a patient for a “designated health service,” including outpatient pharmaceuticals and durable medical equipment, if the physician has an investment or compensation arrangement with the entity providing the services.<sup>71</sup> Both laws cover all forms of remuneration, direct and indirect, in cash and in kind. It is, of course, always possible for physicians or companies to argue that a payment from a company was for something other than a referral, for example for genuine consulting services, but if “one purpose” for a payment is to secure a referral, it violates the law.<sup>72</sup>

The sanctions for violation of the antikickback and self-referral laws in the United States are potentially very serious. Violation of the antikickback law is a felony, punishable by up to five years in prison. Violation of the self-referral law results in the service for which the patient is referred not being covered by public insurance, but intentional violation of either law can potentially result in administrative sanctions or civil fines. Civil fraud cases brought against companies for violation of the law in recent years have been settled for amounts in the hundreds of millions of dollars.

The Office of Inspector General of the Department of Health and Human Services has issued compliance guidance for pharmaceutical companies identifying a number of questionable practices, including: payments to doctors for switching patients from competing products; illegitimate consulting or advisory payments; payments to physicians for listening to detailers or the provision of entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations; gifts, gratuities, and other business courtesies; and compensation relationships with physicians for services connected directly or

<sup>68</sup> See *Bundesgerichtshof [BGH]* [Federal Court of Justice] Feb. 25, 2003, 5 StR [Strafsenat] 363/02 (F.R.G.).

<sup>69</sup> Akira Akabayashi, Brian Taylor Slingsby & Yoshiyuki Takimoto, *Conflict of Interest: A Japanese Perspective*, 14 *CAMB. Q. HEALTHCARE ETH.* 277, 278 (2005).

<sup>70</sup> 42 U.S.C. § 1320a-7b(b) (2010).

<sup>71</sup> 42 U.S.C. § 1395nn(a)(1)(A) (2010).

<sup>72</sup> *United States v. Greber*, 760 F.2d 68, 69 (3<sup>rd</sup> Cir. 1985). Actually, there isn't at this time. There are older cases that conflict with Greber but they are based on the statute before it was amended.

indirectly to a manufacturer's marketing and sales activities, such as speaking, certain research, or preceptor or "shadowing" services.<sup>73</sup>

Pharmaceutical manufacturers have been a primary focus of fraud and abuse enforcement in recent years. In 2007, Purdue Pharma and Purdue Frederick agreed to pay \$600 million for illegal marketing of Oxycontin, while three of its chief executives pled guilty to criminal charges. In 2006, Serono agreed to pay a fine of \$704 million for illegal promotion of Serostim. Among other illegal practices, Serono had paid for a number of physicians to attend an AIDS conference in Cannes at its expense. The Department of Justice has also recently entered into "deferred prosecution agreements" with a number of medical device companies in which they have agreed to pay over 300 million dollars for violations of the fraud and abuse laws, and to agree to a number of practices in the future and continuing monitoring of their marketing practices by an independent monitor.<sup>74</sup> It is possible that in other countries, receipt of payments from pharmaceutical companies could be seen as fraud as well, but in Germany, the fact that physicians have no direct relationships with social insurers because payments are made to the *Kassenärztlichen Vereinigungen* (the insurance doctors' association), which in turn pays doctors, makes this unlikely.<sup>75</sup> In other countries, the potential of conflicts to affect medical costs is recognized but not criminalized. In Scotland, for example, financial relationships between physicians and drug companies are simply subject to public disclosure.<sup>76</sup>

In sum, regulation of marketing relationships between physicians and the drug and device industry are universally addressed by regulation, self-regulation, or criminal prohibition. Countries vary in the extent to which they rely on each of these approaches. Countries also vary in the stringency of their regulation. Some, for example, allow drug companies to finance physician travel to educational events sponsored by drug companies, others do not, and some even prohibit direct drug company funding of continuing education. Countries also vary in the specificity and clarity of their requirements. It is easier to evade and harder to enforce a requirement that gifts not be "excessive" than one that they not exceed £6. All countries permit some financial benefits to flow from industry to physicians, none of the countries examined here permit them without limitation. But the international trend is toward stricter limits on these relationships.

#### IV. HOW SHOULD INDUSTRY PROFESSIONAL RELATIONSHIPS BE REGULATED?

Drug and device companies should be prohibited from giving any gifts to professionals who have the authority to prescribe or order their products, to the families or employees of such professionals, or to undergraduate or graduate professionals in training. Where drug or device companies contract

<sup>73</sup> See OIG, *supra* note 34, at 23733.

<sup>74</sup> U.S. Dep't of Justice, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* 1, 2 (Sept. 27, 2007), <http://www.usdoj.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf>.

<sup>75</sup> See Deutsch & Spickhoff, *supra* note 67, at ¶ 493.

<sup>76</sup> See Bryan Christie, *Scottish Doctors Will Have to Register Financial Links to Drug Companies*, 328 BMJ 69, 69 (2004).



with a professional to provide a service for remuneration, compensation should be for a service of real value to the company for some purpose other than marketing (or assistance in marketing to others) and the compensation should be for the fair market value of the services and not be based on the volume and value of referrals. Drug samples should only be made available for patients who cannot afford the drugs, and then only when they are appropriate and when an ongoing source of the drug is assured for chronic cases. Drug and device companies should be absolutely prohibited from funding medical education, including continuing medical education, directly or indirectly. These recommendations are basically consistent with those made recently by a committee of the Institute of Medicine (on which I served), except that the committee, recognizing that industry funding of CME could not be eliminated overnight, called for the development of a new system of funding for CME to replace the current industry-funded system.<sup>78</sup>

Drug and device companies must, of course, be allowed to continue to market their products—in print media, electronically, through presentations by company employees, and through face-to-face contact with physicians. Limitation of their right to do so may be unconstitutional in several countries as an abridgement of freedom of expression.<sup>79</sup> But freedom of expression does not include the right to pay professionals to use a product, or even for their attention. Such payments should be stopped.

Ending payments from drug companies to professionals will, however, upset the financial balance that currently exists in health systems in developed nations. The basic thesis of this article is that drug and device companies have been overpaid for their products and have passed on some of the excess payments they have received to others in the health care industry through marketing. The continuing medical education industry in particular, but also specialty societies and even patient disease organizations and medical schools (not to mention the office staff of doctors in clinical practice) have come to depend on funding from the drug and device industry. In most developed countries physicians are generously paid and should be able to afford their own lunches without drug industry assistance, but real shortfalls may appear in the funding of medical education and practice guideline development. Also, physicians may face diminished access to information about new drugs and devices.

This funding shortfall should be made up by a tax imposed on the drug and device industry to raise funds for education and for practice guideline development. This money could be distributed through a government agency or through one or more nonprofit foundations formed for this purpose. Part of this money should be used to fund new “academic detailing” programs that would disseminate to doctors accurate, evidence-based, and unbiased information on drugs and devices. There is a long and successful track record for such programs in Canada, England, the Netherlands, Australia, and a number of American states.<sup>80</sup> The rest of the funding would be passed on to

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<sup>78</sup> Lo & Field, *supra* note 1.

<sup>79</sup> See *RJR-MacDonald Inc. v. Canada* [1995] 3 S.C.R. 199 (Can.) (commercial speech protected in Canada); Aaron Kesselheim & Jerry Avorn, *Pharmaceutical Promotion to Physicians and First Amendment Rights*, 358 *NEW ENG. J. MED.* 1727, 1728 (2008).

<sup>80</sup> See Statement of Jerry Avorn, <http://aging.senate.gov/events/hr190ja.pdf>.

continuing medical education providers for CME, specialty societies and patient groups for guidelines development and patient education, and perhaps to medical schools for fellowships.<sup>81</sup>

Drug and device manufacturers will protest that limitations on their marketing practices will diminish physician knowledge of new products (or new uses of existing products), and thus harm patient care. Limits on marketing may also reduce sales and thus the income that the industry depends on to do research and product development. It is not obvious that these results would follow. Drug companies will still be able to advertise their products through traditional channels, as do other successful industries. An adequately funded drug information agency should be able to get information out quickly to physicians about innovative products. It is demeaning to physicians to believe that they will inform themselves about products that will benefit their patients only if the information comes with free pizza. Truly superior products should thrive as their benefits are revealed by unbiased, evidence-based information. The creators of superior products will prosper, allowing them to pursue further innovative research. Drug companies, on the other hand, will find little profit in “me too” products that offer no comparative advantages to existing products unless they decide to compete seriously on price. Educational institutions – undergraduate, graduate, and continuing – will be able to focus their efforts on education, not on dealing with marketing. Unbiased practice guidelines and formularies will improve medical practice and patient care.

In the end, the goal of our health care systems is the care of patients. Patients are not well served by current systems for marketing of drugs and devices, the goal of which seems to be the distortion, indeed the corruption, of medical judgment through financial inducements. Vague and easily evaded prohibitions of particular practices are unlikely to improve the situation. On the other hand, the total prohibition of marketing inducements is not alone the optimal solution. Prohibition must be coupled with redirection of financial flows so that the educational functions currently served by marketing practices could be carried on, but in an objective and unbiased fashion. The proposal put forth by this article would make this possible.

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<sup>81</sup> See Brennan, *supra* note 26, at 431-432 (calling for funding of CME through voluntary pooling of funding by drug companies).