COMMENTS

BIG BAD PHARMA: AN ETHICAL ANALYSIS OF PHYSICIAN-DIRECTED AND CONSUMER-DIRECTED MARKETING TACTICS

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I. INTRODUCTION

"We try never to forget that medicine is for the people. It is not for the profits. The profits follow."[1] This noble mantra is long-forgotten in today's world of extreme pharmaceutical marketing tactics, which are frequently deceptive and supported by biased information. Pharmaceutical manufacturers often appear to forget their moral purpose and instead engage in the hard sell, stopping at nothing to reach their goals. If that means providing false or misleading data to physicians and consumers, then so be it. Pharmaceutical sales teams are a force to be reckoned with, comparable to an army prepared to enter a battle, equipped with powerful tools to take down anyone who stands in their way.

Through distribution of free drug samples, skewed marketing materials, meals, and more, the industry engages in deception hidden by a veil of flattery and free gifts.[2] Although free sample distribution does present some benefits to patients, it is

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[1] Shannon Brownlee, *Big Pharma's Golden Eggs; Marketing, Not Research, Is Now the Core of the Drug Industry*, WASH. POST, Apr. 6, 2008, at BW03 (reviewing MELODY PETERSEN, OUR DAILY MEDS:HOW THE PHARMACEUTICAL COMPANIES TRANSFORMED THEMSELVES INTO SLICK MARKETING MACHINES AND HOOKED THE NATION ON PRESCRIPTION DRUGS (2008) (quoting George Merck, President, Merck & Co.)).

[2] *See infra* Part III.A.

uncontrolled and accompanied by distorted data and gifts.[3] Physicians often stand to benefit a great deal from this symbiotic relationship with brand name pharmaceutical manufacturers ("big pharma"), and are unwilling to sacrifice the free gifts and luxurious trips for patients' best interest. Distribution of gifts by the pharmaceutical industry has formed a rift between what physicians are morally obligated to do and what physicians personally desire, creating a breach of fiduciary duty owed to patients.[4] Upon entering the medical profession, a physician agrees to always act in his or her patients' best interest. A physician who accepts bribes puts his own personal interests ahead of his patients' best interest. The medical profession remains one of the few professions trusted by the public. Thus, practices affecting the medical profession must be held to a stricter standard of behavior to maintain that trust.

Big pharma's marketing efforts are not limited to physicians. In fact, a great deal of money and effort is spent every day completely bypassing physicians and appealing directly to consumers, through television, print, and internet advertisements.[5] These direct-to-consumer ("DTC") advertisements are frequently filled with covert, deceptive, and confusing messages. DTC ads are particularly dangerous, as lay persons are not trained with the medical know-how to discern fact from fiction.

In its current form, the pharmaceutical industry is virtually free of regulation, aside from a few voluntary guidelines.[6] In addition to guidelines created by the American Medical Association ("AMA") and other professional groups, the industry has promulgated self-imposed guidelines with respect to both physician-directed and consumer-directed marketing. These guidelines, however, are all highly arbitrary, discretionary, and unenforceable. Although the United States Food and Drug Administration ("FDA") does impose limited parameters by which the industry must abide, the current regulations entrust an excessive level of power and discretion to manufacturers. Furthermore, despite the amending of previous Pharmaceutical Research and Manufacturers of America ("PhRMA") guidelines, it is unclear if the new regulations will be enough to protect patients. The current system appears to remain inefficient and dangerous to consumers.

This paper argues that pharmaceutical manufacturers are

[3] *See infra* Part III.B.
[4] *See infra* Part III.C.
[5] *See infra* Parts IV, V.
[6] *See infra* Parts II, VI.

exploiting both physicians and patients. The United States is in dire need of more stringent regulation with respect to brand name pharmaceutical company marketing.[7] The current recommended guidelines and relaxed FDA regulations are not sufficient. Regulation should be increased through the enactment of laws. Specifically, direct contact between pharmaceutical sales representatives and physicians should be minimized or eradicated entirely, and televised drug advertisements should be prohibited. In order to maintain an incentive for big pharma to continue investing in research and development, safeguards should be implemented, such as allowing manufacturers to mail samples to physicians and permitting printed drug advertisements directed toward consumers.

Part II of this paper will discuss background information regarding: (1) the phases of drug development, with a focus on the marketing phase; (2) the profit margins of big pharma; (3) the history and current form of the FDA; and (4) the current guidelines regulating physician-directed marketing.

Part III will discuss the ethical issues surrounding physician-directed marketing including: (1) the tricks of the trade, specifically with respect to how big pharma lands the sale; (2) the positive and negative impacts of free sample distribution; and (3) the impact of physician-directed gifts.

Part IV will provide background on DTC advertising, along with the current U.S. standards for DTC advertisements. Part V will discuss the ethical issues and consequences of DTC ads, including: (1) the manufacture of disease by big pharma; (2) the "me-too drug" phenomena; and (3) the consequences of DTC advertising.

Part VI will discuss the problems with the existing state of the law. Part VII will suggest methods for attacking these problems.

II. BACKGROUND

A. Phases of Drug Development

Pharmaceutical manufacturers generally undertake several phases during drug development, two of which are particularly relevant. The first phase, research and development, is the process of discovering and extensively testing new compounds.[8] Research

[7] *See infra* Part VII.

[8] *See generally* STEPHEN J. CECCOLI, PILL POLITICS: DRUGS AND THE FDA 165–67 (2004) (describing the process of developing drugs).

and development can take years; very few newly discovered compounds make it through to FDA approval.[9] The second phase that is relevant for this paper is drug marketing, which has developed into a controversial topic in recent years with the advent of the "blockbuster drug."[10]

"Blockbuster drugs are superior selling drugs whose" profits exceed all other drugs, ensuring continual profit streams for a pharmaceutical manufacturer.[11] Generally, annual sales of each individual blockbuster drug exceed one billion dollars.[12] Typically, the most aggressive pharmaceutical sales tactics are reserved for blockbuster drugs under patent protection.[13] After a patent monopoly expires on a product, a pharmaceutical manufacturer has no remaining incentive to market that product because generic manufacturers can quickly obtain approval to sell generic versions of the brand name drug.[14] Generic drugs send the market value of the once-patented drug plummeting.[15] In addition, generic versions are usually much less expensive and equally as effective as the brand name version.[16]

Big pharma has recently come under attack, with many experts claiming that marketing costs substantially outweigh funds put into research and development.[17] Critics claim that this discrepancy compromises the ultimate duty of the drug manufacturer, which is to find cures to the world's most deadly diseases.[18] In 2001, nine out of nine leading pharmaceutical companies spent more money on marketing and advertising than on research and development, with eight out of nine spending two times as much on marketing and

[9] *Id.* at 165 (citation omitted).

[10] *Id.* at 2.

[11] *Id.*

[12] *Id.*

[13] *See* Joel Lexchin, *The Pharmaceutical Industry and the Pursuit of Profit*, *in* THE POWER OF PILLS: SOCIAL, ETHICAL AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING, AND PRICING 11, 16–17 (Jillian Clare Cohen et al. eds., 2006).

[14] *Id.* at 20 ("Brand-name companies have also developed tactics to delay the entry of generic drugs [into the marketplace].").

[15] *Id.* at 19 (citation omitted).

[16] *Id.*

[17] *See* CECCOLI, *supra* note 8, at 133; FAMILIES USA, PROFITING FROM PAIN: WHERE PRESCRIPTION DRUG DOLLARS GO 1, 3–5 (2002), *available at* http://www.familiesusa.org/assets/pdfs/PPreport89a5.pdf.; *see also* WILLIAM H. SORRELL, VT. ATT'Y GEN., PHARMACEUTICAL MARKETING DISCLOSURES 1 (2005), *available at* http://www.atg.state.vt.us/assets/files/2005%20Pharmaceutical%20Marketing%20Disclosures%20Report.pdf ("[Between July 1, 2003 and June 30, 2004,] pharmaceutical manufacturers spent $3.11 million on fees, travel expenses, and other direct payments . . . for the purpose of marketing their products in Vermont.").

[18] *See* CECCOLI, *supra* note 8, at 133–35.

advertising.[19] On average, big pharma employs 81% more people in marketing and advertising than it does in research and development.[20]

B. Profits by Big Pharma

A lack of intrinsic limits on the pharmaceutical industry has led to high profits.[21] It is estimated that big pharma makes between "a 15 to 20 percent annual profit,"[22] which is well above most industries in the U.S.[23] In the 1990s, the profit gap for big pharma was 15.1%, compared to 4.1% for other *Fortune* 500 companies.[24] Big pharma "ranked first in 2001 . . . [for] return on revenues, return on assets, and return on shareholders' equity."[25] This hefty profit margin can be at least partially attributed to a free-market economy and deregulation of the pharmaceutical industry.[26]

The U.S. holds the position of being "the most highly medicated [country] in the world," with over three billion prescriptions dispensed in 2002 alone.[27] "[P]rescription drugs . . . account[] for approximately 9.4 percent of all health care expenditures in the United States. . . . [O]utpatient prescription drugs in retail outlets in the United States exceeded $154 billion in 2001."[28]

High profit margins translate into high paying salaries for pharmaceutical executives. One report compiled a list of the top ten highest paid pharmaceutical executives in the industry for 2001.[29] Average annual compensation for the ten highest paid executives was over $23 million.[30] The former Bristol-Meyers Squibb Co. Chairman and CEO, C.A. Heimbold, Jr., earned $74.89 million in 2001.[31]

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[19] FAMILIES USA, *supra* note 17, at 3–5.

[20] *Id.* at 13.

[21] *See* CECCOLI, *supra* note 8, at 130–31 ("*Fortune* 500 drug companies were twice as profitable as the median company for all industries during the 1970s and 1980s, and almost four times as profitable (as the median company) during the 1990s.").

[22] DANIEL CALLAHAN & ANGELA A. WASUNNA, MEDICINE AND THE MARKET: EQUITY V. CHOICE 165 (2006) (citation omitted).

[23] *Id.*; CECCOLI, *supra* note 8, at 130–31.

[24] Lexchin, *supra* note 13, at 11 (citation omitted).

[25] CECCOLI, *supra* note 8, at 130 (citation omitted).

[26] CALLAHAN & WASUNNA, *supra* note 22, at 165 (explaining the consequences of a market driven, laissez-faire pharmaceutical industry).

[27] CECCOLI, *supra* note 8, at 1 (citation omitted).

[28] *Id.* (citation omitted).

[29] FAMILIES USA, *supra* note 17, at 7–9.

[30] *Id.* at 7 (including the highest paid executives from Bristol-Meyers Squibb Co., Wyeth, Pfizer Inc., Allergan, Inc., Schering-Plough Corp., and Abbott Laboratories).

[31] *Id.*

C. FDA—Historical Roots and Current Form

The pharmaceutical industry is primarily regulated by the FDA, which was constructed in the mid-nineteenth century[32] in order "to protect consumers from the dangers of fraudulent, impure, or mislabeled substances."[33] Given its "regulatory functions" in the passage of the Pure Food and Drugs Act, the FDA was the first formal agency in the U.S. with the sole responsibility of regulating the food and drug industry.[34] In 1938, the Federal Food, Drug and Cosmetic Act ("FDCA")[35] was passed in response to a "public outcry" for more stringent safety regulations on food and drugs throughout the U.S.[36] This Act required drug manufacturers to demonstrate drug safety prior to market sale.[37] This Act remains the foundation of the FDA to this day.[38]

In 1962, the Kefauver-Harris Amendments were enacted, requiring drug manufacturers to demonstrate efficacy in addition to safety for each of a drug's intended uses.[39] The amendments were a reaction to the thalidomide disaster across Europe in the 1950s.[40] It also signaled a new era in the FDA, one in which broader control would be exercised over food and drug production.[41] In its current form, the FDCA also regulates drug advertising and labeling.[42]

Throughout the 1980s, the FDA began to exercise more stringent scrutiny over new drug applications and currently approved drugs.[43] For example, the Prescription Drug Marketing Act of 1987, along

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[32] John P. Swann, *Food and Drug Administration*, *in* A HISTORICAL GUIDE TO THE U.S. GOVERNMENT 248–49 (George Thomas Kurian et al. eds., 1998).

[33] CECCOLI, *supra* note 8, at 3.

[34] Swann, *supra* note 32, at 248–51.

[35] Federal Food, Drug and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§ 301–99 (2006)).

[36] Swann, *supra* note 32, at 251. In 1937, the Elixir Sulfanilamide "disaster" occurred, killing "over one-hundred people . . . most of whom were children." *Id.* The Elixir was distributed as a "sulfa wonder drug," without safety testing, and contained a poisonous chemical analogue of anti-freeze. *Id.*

[37] CECCOLI, *supra* note 8, at 3.

[38] *Id.*

[39] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780. These amendments are also known as the Kefauver-Harris Amendments, after the prominent Senator and Representative who worked on them. *See* S. Rep. No. 87-1744 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2887, 2898, 2915; H.R. Rep. No. 87-2526 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2927, 2936 (Conf. Rep.); *see also* CECCOLI, *supra* note 8, at 93 (noting that Kefauver was a "key actor").

[40] CECCOLI, *supra* note 8, at 7, 93 (describing how thalidomide was distributed to pregnant mothers as a sleep aid in Europe, resulting in birth defects in their children).

[41] *Id.* at 92–93.

[42] 21 U.S.C. § 352 (2006).

[43] CECCOLI, *supra* note 8, at 92–93.

with its 1992 Amendments, was created to further ensure that drug products purchased by consumers were safe and effective.[44] This Act prohibits counterfeit, misbranded, substandard, subpotent, ineffective, or expired drugs, by regulating the distribution of drug samples.[45] Also, in 1984, the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, was passed.[46] This gave the FDA authority to accept new drug applications for generic drugs.[47] Hatch-Waxman was intended to reduce the cost of generic drug manufacturing and marketing, while simultaneously increasing the term of patent protection for patented drugs.[48]

The Code of Federal Regulations contains FDA rules that further control the practice of drug advertising by prohibiting false and misleading advertisements.[49] The FDA has the power to take action against companies that use false or misleading advertisements, as well as to prohibit advertising that lacks a balance between side-effect information and effectiveness information.[50]

In 1997, the Food and Drug Administration Modernization Act ("FDAMA") was enacted, permitting physicians to prescribe drugs for off-label use.[51] The FDAMA, however, prohibits drug manufacturers from promoting FDA approved drugs for any purpose other than that for which they are approved unless the manufacturer resubmits the drug to the FDA for testing and approval.[52]

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[44] Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988) (codified as amended at 21 U.S.C. §§ 301–99 (2000 & Supp. IV 2004)); Prescription Drug Amendments of 1992, Pub. L. No. 102-353, 106 Stat. 941.

[45] Prescription Drug Marketing Act of 1987 §§ 4–7; Prescription Drug Amendments of 1992 §§ 2–4.

[46] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; *see, e.g.*, *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act": Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 124–26 (2003) [hereinafter *Examining*] (statement of Daniel E. Troy, Chief Counsel, U.S. Food and Drug Administration) (discussing the Hatch-Waxman Act).

[47] *See Examining*, *supra* note 46, at 125–26; CECCOLI, *supra* note 8, at 129–30.

[48] *See Examining*, *supra* note 46, at 124–25; CECCOLI, *supra* note 8, at 129–30.

[49] 21 C.F.R. § 202.1 (2009).

[50] *Id.*

[51] Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2358 (1997) (repealed 2006).

[52] *Id.*; *see also* United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 44 (D. Mass. 2001). Off-label drug use occurs when a physician prescribes a particular drug for use that was not approved by the FDA. *Id.*

D. Guidelines Regulating Physician-Directed Marketing

In addition to regulation by the FDA, pharmaceutical manufacturers face a plethora of guidelines, all aimed at regulating manufacturers' presence in the medical community. These guidelines are promulgated by various groups, such as the Office of the Inspector General,[53] AMA,[54] the American Board of Internal Medicine Foundation,[55] PhRMA,[56] the Advanced Medical Technology Association ("AdvaMed"),[57] and Harvard University.[58] The guidelines were created in response to the medical industry's concern with impropriety by pharmaceutical manufacturers and their sales representatives.

The Department of Health and Human Services Office of the Inspector General created a Program Guidance for Pharmaceutical Manufacturers in 2003.[59] Drug manufacturers should consider this voluntary, aspirational set of guidelines "when developing and implementing a compliance program or evaluating an existing one."[60] For example, "[a]ny time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals."[61] This set of guidelines is concerned primarily with anti-kickback statutes, which may be implicated by gifts, gratuities, recreation, travel, and meals to physicians by drug manufacturers, if the sole purpose of the

[53] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,731 (May 5, 2003).

[54] *See* COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, AM. MED. ASS'N, CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION, § 8.061 (2008–2009 ed.) [hereinafter CODE OF MEDICAL ETHICS].

[55] *See* ABIM Found. et al., *Medical Professionalism in the New Millennium: A Physician Charter*, 136 ANNALS INTERNAL MED. 243, 245 (2002).

[56] PHARM. RESEARCH & MFRS. OF AM. (PHRMA), CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (2008), *available at* http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf [hereinafter PHRMA CODE].

[57] ADVANCED MED. TECH. ASS'N (ADVAMED), CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS (2003), *available at* http://www.advamed.org/NR/rdonlyres/D96644D9-7FA9-4DCC-B944-F00A8351FE57/0/AdvaMedCodeofEthicswithFAQ.pdf [hereinafter ADVAMED CODE].

[58] FACULTY OF MED., HARVARD UNIV., *Policy on Conflicts of Interest and Commitment*, (2004), *available at* http://www.hms.harvard.edu/integrity/conf.html.

[59] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,731 (May 5, 2003).

[60] *Id.*

[61] *Id.* at 23,737.

arrangement is to generate business.[62] The Program further recommends that a drug manufacturer "spot check[]" its sales force to ensure compliance with these guidelines.[63] Manufacturers can minimize risks associated with sample distribution by "[t]raining their sales force to inform sample recipients in a meaningful manner that samples may not be sold or billed . . . and conspicuously labeling individual samples as units that may not be sold."[64]

The AMA enacted its own set of guidelines to regulate gifts to physicians from the pharmaceutical industry.[65] The primary goal of these guidelines is to protect the physician-patient relationship by eliminating potential conflicts of interest.[66] First, gifts "should primarily . . . benefit [the] patients and should not be of substantial value."[67] "Individual gifts of minimal value," such as "pens and notepads," are allowed if they "are related to the physician's work."[68] Under the AMA guidelines, "[s]ubsidies to underwrite the costs of continuing medical education" ("CME") to physicians are permissible, so long as the medical conferences have a primary objective of education.[69] Importantly, the AMA guidelines explicitly state that "[n]o gifts should be accepted if there are strings attached."[70]

ABIM has also promulgated a set of guidelines, called a "Charter on Medical Professionalism" for the medical profession.[71] ABIM places a premium on professionalism, defining it as "placing the interests of patients above those of the physician."[72] In maintaining an ethical medical practice, physicians must never exploit patients or compromise patient care for their own personal financial gain, and "[r]elationships between industry and opinion leaders should be disclosed."[73]

One group within the pharmaceutical industry itself, PhRMA, has adopted a Code on Interactions with Healthcare Professionals.[74]

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[62] *Id.* at 23,738.
[63] *Id.* at 23,739.
[64] *Id.*
[65] CODE OF MEDICAL ETHICS, *supra* note 54, § 8.061.
[66] § 8.061
[67] § 8.061, ¶ 1.
[68] § 8.061, ¶ 2.
[69] § 8.061, ¶ 4.
[70] § 8.061, ¶ 7.
[71] ABIM Found. et al., *supra* note 55, at 243.
[72] *Id.* at 244.
[73] *Id.* at 245.
[74] PHRMA CODE, *supra* note 56.

One provision of the PhRMA Code provides that "[i]nteractions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical [research and] education."[75] The PhRMA Code's most recent amendments, which became effective in January 2009,[76] for the first time limited industry-sponsored gifts to those educational in nature.[77] Similar to the AMA guidelines, the PhRMA Code allows physicians to be speakers and consultants, but discourages direct payment.[78] The PhRMA Code also requires that gifts be under $100 according to fair market value and that gifts primarily benefit patients.[79] The Code makes a distinction between gifts for patient education, which are allowed, and gifts for patient treatment, which are prohibited.[80] "[M]odest" meals are acceptable, if offered in connection with scientific or educational value.[81] In addition, financial assistance for scholarships or other educational funds allowing medical students or residents to attend conferences may be offered, with the condition that the academic or training institution chooses who attends.[82]

Another industry guideline, promulgated by AdvaMed, aims to regulate gift acceptance in the medical technology industry[83] and is similar to the PhRMA Code. For example, the AdvaMed guidelines state that the industry may provide medical professionals with "modest" hospitality, in the form of meals and receptions at meetings, if the focus of meeting is on education or training.[84] Medical professionals may also accept pay from AdvaMed for "reasonable travel and modest lodging."[85] In addition, "modest gifts" under $100 are permitted for educational purposes.[86] Gifts

[75] *Id.* at 4.

[76] *Id.* at 3.

[77] *Id.* at 11.

[78] *Id.* at 6, 10–11. The PhRMA Code allows pharmaceutical manufacturers to fund CMEs by giving money to the CME provider. *Id.* at 6.

[79] *Id.* at 12. Under the new PhRMA guidelines, drug manufacturers cannot give out pens or other non-educational items, such as mugs. *Id.* at 11–12.

[80] *Id.* at 12. ("[A]n anatomical model for use in an examination room is intended for the education of the patients and is therefore appropriate, whereas a DVD or CD player may have independent value to a healthcare professional outside of his or her professional responsibilities, even if it could also be used to provide education to patients, and therefore is not appropriate."). Furthermore, stethoscopes may not be offered under the PhRMA Code because they are designed for patient treatment, not education. *Id.*

[81] *Id.* at 4.

[82] *Id.* at 11.

[83] ADVAMED CODE, *supra* note 57, at 1, 4.

[84] *Id.* at 2.

[85] *Id.*

[86] *Id.* at 14.

are also allowed at an industry member's discretion for "significant life event[s]" of medical professionals.[87] Food gifts, however, are allowed only when used in conjunction with education or training.[88]

Harvard University also disseminated guidelines for conflicts of interest with respect to faculty members and students of its medical school.[89] The guidelines are not mandatory, but provide some guiding principles on ethical boundaries and ways to avoid placing personal interests before professional ethical interests. For example, student training must be objective and trustworthy, and faculty should be "concerned about the content and quality of the training experience for students whose research is sponsored by a for-profit business and whose preceptors have a personal interest in that business."[90] Harvard Medical School has recently been criticized, after receiving an F grade from the American Medical Student Association in 2008,[91] a group that rates the ability of medical schools to control and limit funding from the drug industry.[92] In response to Harvard's excessive entanglement with big pharma, Harvard students began an initiative, now four years old, to eliminate big pharma's influence on their medical education.[93]

Some states have passed laws requiring drug manufacturers to disclose and report gifts made to medical professionals.[94] Specifically, Vermont enacted the Pharmaceutical Marketing Gift Disclosure Law in 2008 that requires pharmaceutical manufacturers to disclose "the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical

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[87] *Id.* at 13.

[88] *Id.*

[89] FACULTY OF MED., *supra* note 58. This policy was enacted to demonstrate a commitment to reducing conflicts of interest in academia, and is not mandatory, but "enable[s] faculty members to recognize situations that may be subject to question." *Id.*

[90] *Id.*

[91] Duff Wilson, *Harvard Medical School in Ethics Quandary*, N.Y. TIMES, Mar. 3, 2009, at B1. A grade of F is the lowest, and is also given to non-reporting institutions. Am. Med. Student Ass'n, ASMA PharmFree Scorecard 2009, Conflict of Interest Policies at Academic Medical Centers, http://www.amsascorecard.org/institutions/112 (last visited Nov. 13, 2009). Currently, Harvard Medical School has a grade of B. Harvard did not report in 2008 and therefore received an F. Wilson, *supra*.

[92] Wilson, *supra* note 91.

[93] *Id.* This initiative requires faculty to disclose any ties they have to the drug industry in class. FACULTY OF MED., *supra* note 58.

[94] *E.g.*, VT. STAT. ANN. tit. 18, § 4632 (2008 & Supp.).

marketers, to any physician."[95] Under this law, drug manufacturers are not required to report gifts under twenty-five dollars, the distribution of free samples, or scholarships given to medical students and residents.[96]

Massachusetts also joined in the fight, with Governor Deval Patrick signing into law, in January 2009, the Pharmaceutical and Medical Device Manufacturer Code of Conduct in January 2009.[97] This code, among other things, prohibits manufacturers from providing meals and other gifts to health care practitioners in many instances.[98] The Massachusetts law also places intensive regulations on manufacturers' ability to fund CMEs, educational conferences, other professional meetings, and curtails manufacturers' ability to make payments to health care practitioners.[99] For example, the law bans manufacturers from providing entertainment, recreational items of any value, sporting equipment, and leisure trips, along with any cash equivalents.[100] Tangible items like pens, coffee mugs, and gift cards are also barred under the Massachusetts regulation, and any gift worth more than fifty dollars must be disclosed.[101]

Government representatives have recognized the need for heightened regulation as well. For example, Congressman Fortney Pete Stark, a member of the House of Representatives from California's Thirteenth District, introduced the Prescription Drug Safety and Affordability Act in 2006.[102] Under current laws regarding big pharma's interaction with the medical profession, Congressman Stark explained, pharmaceutical marketing promotions directed at physicians are tax deductible, and gifts to physicians often undercut a physician's ability to act in his patients' best interest.[103] Under Representative Stark's proposal, big pharma would no longer have tax-deductions, and therefore no incentive to

[95] § 4632 (a)(1).

[96] § 4632 (a)(4).

[97] Press Release, Office of the Governor of Massachusetts, Governor Patrick Signs Bill Enhancing Quality, Cost-Effectiveness and Transparency of Health Care (Aug. 11, 2008), *available at* http://www.mass.gov/?pageID=gov3pressrelease&L=1&L0=Home&sid=Agov3&b=pressrelase&f=080811_dr_gifts&Csid=Agov3.

[98] 105 MASS. CODE REGS. 970.006–.008 (2009).

[99] *Id.* at 970.007–.008. Under this Code, manufacturers must also disclose to the Massachusetts state government any payments made to health care practitioners by July 2010. *Id.* at 970.009.

[100] *Id.* at 970.008.

[101] *Id.* Any person who knowingly and willfully violates this Massachusetts law is subject to a fine of up to $5,000 for each occurrence. *Id.* at 970.010.

[102] 152 CONG. REC. E76 (daily ed. Feb. 7, 2006) (statement of Rep. Fortney Pete Stark).

[103] *Id.*

provide gifts to physicians.[104] In turn, that money could be "redirect[ed] . . . toward [productive activity, such as] research and development."[105]

U.S. Senators have also followed suit, introducing legislation to regulate big pharma's physician-directed marketing practices. The Physician Payment Sunshine Act, introduced by U.S. Senators Chuck Grassley and Herb Kohl, would require drug manufacturers to disclose the value of any gifts to physicians worth $100 or more.[106] Under this proposal, the penalty for not reporting or under-reporting would range from $10,000 to $100,000 fines.[107]

These legislative and educational initiatives all indicate a desire and willingness to increase regulation among the pharmaceutical industry. The passage of state laws that prohibit lavish gifts and require reporting those gifts, as well as student-run initiatives at medical schools, mark a significant leap toward solving the ethical issues surrounding questionable marketing techniques of big pharma. These proposals, however, are not pervasive enough to eradicate the larger ethical problems within the drug industry.

III. ETHICAL ISSUES OF PHYSICIAN-DIRECTED MARKETING

The sales force of the pharmaceutical industry is vast, and 84% of that marketing force is directed at physicians.[108] For every five "office-based physicians," there is approximately one pharmaceutical sales representative, totaling between 80,000 and 100,000 sales representatives in the industry, and approximately $25,000 is spent annually per physician.[109] "Promotions targeting physicians account for the majority of drug industry spending on marketing and promotion. In 2003, pharmaceutical companies

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[104] *Id.* at E76–77.

[105] *Id.* New York State Governor David Paterson proposed similar legislation in 2008 and again in 2009—neither of which passed—that would require disclosure of any gift with over fifty dollars in value. Press Release, Governor of New York, Governor Paterson Proposes Legislation to Reduce Improper Influence in Drug Prescription (May 15, 2008), *available at* http://www.state.ny.us/governor/press/press_0515085.html; Michelle Mancusi et al., Nixon Peabody LLP, *Health Law Alert*, *Legal and political developments affecting the health care industry*, *Gift Bans* (July 2, 2009), http:www.nixonpeabody.com/linked_media/publications/Health)law)Alert_-_07_02_2009_.pdf.

[106] Physician Payments Sunshine Act of 2009, S. 301, 111th Cong. (2009), *available at* http://thomas.loc.gov/cgi-bin/query/z?c111:S.301:.

[107] *Id.*

[108] Catherine A. Marco et al., *Gifts to Physicians from the Pharmaceutical Industry: An Ethical Analysis*, 48 ANNALS EMERGENCY MED. 513, 513–14 (2006).

[109] Kenneth V. Iserson et al., *Politely Refuse the Pen and Note Pad: Gifts from Industry to Physicians Harm Patients*, 84 ANNALS THORACIC SURGERY 1077, 1079 (2007).

spent $9 billion on marketing and promotion. Of this amount, $5.7 billion (over 60%) was aimed at physicians."[110] This section will discuss the ethical implications of physician-directed marketing, including: (1) the forceful and deceptive sales techniques used by big pharma; (2) the impact of free sample distribution; and (3) the impact of gift distribution.

A. Tricks of the Trade: Landing the Sale

The industry uses several techniques, including targeting vulnerable groups, tailoring its sales pitches for individual physicians, tracking high-volume prescribing physicians,[111] and ensuring that its representatives are always good-looking, overly-friendly, and stylish. Physician-directed marketing techniques also include practices such as distributing free samples,[112] enticing physicians with offers of gifts,[113] and providing meals to physicians and office staff.[114]

Medical students and residents are particularly susceptible to marketing tactics, as these individuals are in a submissive position—often being overworked, without experience or practical knowledge of ethics rules, and with respect to residents, severely underpaid.[115] One "study found that 56% of medical students had three or more . . . conversations with pharmaceutical representatives during medical school."[116] Another study found that "97% of the 164 [resident physicians] studied carried at least [one] item with pharmaceutical insignia" on their person.[117] "Policies

[110] Memorandum from Rep. Henry A. Waxman, Ranking Minority Member, H. Comm. on Gov't Reform, The Marketing of Vioxx to Physicians, to the Democratic Members of the Gov't Reform Comm. 6 (May 5, 2005), *available at* http://oversight.house.gov/images/stories/documents/20050505114932-41272.pdf. [hereinafter Waxman Memorandum] (citation omitted) .

[111] IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163, 170 (D. N.H. 2007), *rev'd*, 550 F.3d 42 (1st Cir. 2008).

[112] *Compare* Waxman Memorandum, *supra* note 110, at 6 n.15 (explaining that in 2003, the industry spent $16.3 billion on free sample distribution (citation omitted)), *with* Sara Selis, *Study Calculates Outlay of Pharmaceutical Marketing: Drug Companies Promote Through Multiple Channels*, STAN. REP., May 21, 2003, http://news.stanford.edu/news/2003/may21/pharma.html (explaining that, in 1998, only $6.6 billion was spent on free sample distribution).

[113] *See* David W. McFadden et al., *The Devil Is in the Details: The Pharmaceutical Industry's Use of Gifts to Physicians as Marketing Strategy*, 140 J. SURGICAL RES. 1, 2 (2007) (explaining that big pharma spends approximately $12–15 billion each year on gifts and payments to physicians).

[114] *Id.*

[115] *Id.*

[116] *Id.* (citation omitted).

[117] Marco et al., *supra* note 108, at 514 (citation omitted).

restricting contacts with pharmaceutical company representatives during residency training have been shown to result in fewer contacts after training and a less positive attitude towards the information from such contacts."[118] This data is especially significant, "because [long-term] prescribing habits develop during [medical] training."[119] This data also paints a vivid picture that big pharma has tapped into a world of virtually free marketing, as medical residents are walking drug advertisements throughout hospitals nationwide. There are now associations in place that discourage gift-giving, free meals, and sponsored education to medical students and residents.[120]

With respect to specific physician-directed strategies, sales representatives are given detailed instructions on how to persuade physicians through use of verbal and non-verbal cues.[121] "It's positioning yourself to match the person talking. It subconsciously raises his [or] her level of trust by building a bridge of similarity."[122] For example, representatives are instructed to shake a doctor's hand for three seconds and when dining with physicians, to eat "one small bitesize piece at a time. Break off and butter bread one single piece at a time. Bread dipped in olive oil should also be broken off and eaten one single piece at a time."[123] Sales representatives become masters of nonverbal communication, using it to take advantage of physicians.[124] Representatives are taught to "[n]od [your] head," "[maintain] [e]ye contact," "[s]mile (if appropriate)," "[d]on't interrupt," "[t]ake notes," and "[use] [o]penness in gestures."[125] They are further instructed to use vocal cues to land a sale, by "[s]ound[ing] interested," "[m]imic[ing] or match[ing] vocal behavior of [the] speaker," "[using] voice inflection and energy," and using an "empathetic voice."[126] In order to compliment those vocal cues, representatives also use verbal cues, such as "'Hmmm, Yes, Okay, I see,'" "[a]cknowledg[ing]," "[a]sk[ing] questions,"

[118] Morris A. Fisher, *Physicians and the Pharmaceutical Industry: A Dysfunctional Relationship*, 46 PERSP. BIOLOGY & MED. 254, 258 (2003) (citation omitted).

[119] Lisa D. Chew et al., *A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior*, 15 J. GEN. INTERNAL MED. 478, 483 (2000).

[120] *See* AMSA PharmFree Campaign Best Practice Policies, http://www.pharmfree.org/campaign?id=0003 (last visited Nov. 13, 2009); No Free Lunch, http://www.nofreelunch.org/aboutus.htm (last visited Nov. 13, 2009).

[121] Waxman Memorandum, *supra* note 110, at 7–13.

[122] *Id.* at 9 (citation omitted).

[123] *Id.* at 12 (citation omitted).

[124] *Id.* at 7.

[125] *Id.* at 8 fig. 1.

[126] *Id.*

"[s]ummariz[ing]," and allowing for "[s]hort periods of silence."[127] Sales representatives are even instructed on how to exploit a physician's personality type, and how to stage discussions.[128]

Physicians respond well to this behavior. The Kaiser Foundation determined that in 2001, "92% of physicians had received free drug samples, 61% had received meals, free access to entertainment, sporting events or travel, and [approximately 14%] had received financial benefits."[129] Another study, published in the New England Journal of Medicine in 2007, put a spotlight on physician-directed pharmaceutical sales techniques.[130] In this study of approximately 3,000 physicians, researchers found that 83% of physicians accepted food or drink from big pharma, 78% accepted drug samples, 35% accepted reimbursement for meeting expenses, 28% accepted money for lectures, and 7% accepted free tickets.[131]

This data shows the controversial phenomenon in today's medical industry, which is the use of bribes to increase pharmaceutical profits. Many physicians admit to seeing pharmaceutical representatives daily,[132] and many feel they are entitled to gifts and samples, considering it a sign of status.[133] Although most of those physicians claim gifts and samples have no impact on their practice, studies have shown that free sample distribution, along with other big pharma sales techniques, do affect physician prescribing patterns.[134] A suggested standard to physicians "is to ask yourself whether you would mind seeing an article on the front page of your hometown newspaper describing [your] behavior."[135] If you would

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[127] *Id.*

[128] *Id.* at 9–10. Sales representatives were told how to approach particular personality types: "For a . . . 'technical' personality . . . 'use figures [and] percentages' in [sales] pitches; for a . . . 'supportive personality' . . . 'focus on benefits to patients'; and for a[n] . . . 'expressive personality' . . . 'show enthusiasm; appeal to his/her ego.'" *Id.* (citation omitted). Sales reps were also taught how to stage discussions to make a physician sympathetic and willing to listen. *Id.* at 10.

[129] McFadden et al., *supra* note 113, at 2 (citation omitted).

[130] E.G. Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 NEW ENG. J. MED. 1742, 1742 (2007). Data was taken from 2003 through 2004. *Id.* The survey was sent to 3,167 physicians, and 52% responded. *Id.*; *see also* Joe Fahy, *Most Doctors Still Take Gifts From Drug, Device Firms*, PITTSBURGH POST-GAZETTE, Apr. 26, 2007, at A1.

[131] Campbell et al., *supra* note 130, at 1742; Fahy, *supra* note 130.

[132] Iserson et al., *supra* note 109, at 1078 (citation omitted).

[133] Dana Katz et al., *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving*, 3 AM. J. BIOETHICS 39, 40 (2003).

[134] Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 373 (2000).

[135] *See* Joseph S. Alpert, *Doctors and the Drug Industry: How Can We Handle Potential Conflicts of Interest?*, 118 AM. J. MED. 99, 100 (2005); *see also* Marco et al., *supra* note 108, at 518.

not mind, then it is likely ethical. On the other hand, if the thought of publicizing your behavior makes you cringe, that is a good sign that you are violating the rules of ethics.[136]

B. Impact of Free Sample Distribution

A physician's primary concern should be patient care and serving his or her patients' best interests,[137] whereas the pharmaceutical industry's primary concern is encouraging product use and maximizing shareholder profits.[138] This discrepancy presents a conflict of interest, and the distribution of free samples to physicians further complicates this conflict. Although there are some positive consequences of sample distribution, research shows that the negative consequences greatly outweigh the limited benefits.

There are three main arguments that sample distribution benefits consumers and physicians more than it harms them. First, free samples provide drug access to poor and uninsured patients, particularly the sick and elderly who often need many expensive drugs.[139] In 2001, over $154 billion was spent in the U.S. on prescription drugs.[140] Estimates show the total retail value of sampled drugs in 2004 was $15.9 billion.[141] This is no small number by any means, and samples provide otherwise unavailable medication to patients who are in need. Second, samples allow consumers to experiment with prescription drugs without commitment, while simultaneously providing immediate relief without the need to wait for a pharmacy to fill a prescription.[142] Third, samples are often accompanied by company-sponsored educational material, which provides physicians, and therefore patients, with increased knowledge about specific drugs.[143]

These alleged positive impacts must be weighed against the

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[136] *See* Marco et al., *supra* note 108, at 518.

[137] *See* ABIM Found. et al., *supra* note 55, at 244.

[138] Ian E. Marshall, *Physicians and the Pharmaceutical Industry: A Symbiotic Relationship?*, *in* THE POWER OF PILLS: SOCIAL, ETHICAL AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING, AND PRICING 57, 57 (Jillian Clare Cohen et al. eds., 2006).

[139] Sarah L. Cutrona et al., *Characteristics of Recipients of Free Prescription Drug Samples: A Nationally Representative Analysis*, 98 AM. J. PUB. HEALTH 284, 284 (2008).

[140] McFadden et al., *supra* note 113, at 1 (citation omitted).

[141] The Henry J. Kaiser Family Foundation, Trends and Indicators in the Changing Health Care Marketplace, http://www.kff.org/insurance/7031/ti2004-1-20.cfm (last visited Nov. 13, 2009) (displaying the "Trends in Promotional Spending for Prescription Drugs, 1996–2004" in Exhibit 1.20).

[142] Chew et al., *supra* note 119, at 482.

[143] Waxman Memorandum, *supra* note 110, at 4.

negative consequences of the use of free samples. First, with respect to the argument that samples provide indigent patients with access to otherwise unaffordable drugs, it has been demonstrated that poor and uninsured patients are in fact less likely to receive drug samples than wealthy and insured patients.[144] Research has also shown that white patients are more likely to receive samples than minority patients, and that race, ethnicity, and age are defining factors related to drug sample distribution.[145] It appears to researchers that "free drug samples serve as a marketing tool, not as a safety net" for indigent patients.[146]

Second, although samples allow for experimentation and immediate relief, samples actually encourage consumers to seek out brand name products, thereby creating long-term dependency on brand name drugs. Studies have also found that after being provided free samples, physicians are likely to dispense and then subsequently prescribe drugs that differ from their preferred drug choice.[147] Physicians claim that they do this to save patients money; however, because the samples are for more expensive drugs than generic and older versions, samples will often increase the cost to patients in the long term.[148] Despite the "short-term cost savings" to patients, overall "societal costs" will increase because patients become dependent on drugs that are prescribed for indefinite lengths of time.[149] For example, consider Crestor, a popular cholesterol reducing drug which is manufactured by AstraZeneca and currently in the midst of an extensive marketing campaign.[150] Crestor is likely to be dispensed to physicians for free sample distribution while it remains under patent protection. In fact, AstraZeneca is currently offering a program where consumers may log onto Crestor's website and personally order a "Take Action Kit," which contains an exclusive "30-day free trial offer."[151] Although this thirty-day sample supply will provide a patient with free and immediate short-term relief, it may simultaneously create a subconscious dependence and trust in Crestor. A patient who

144 Cutrona et al., *supra* note 139, at 287.

145 *Id.*

146 *Id.*

147 Chew et al., *supra* note 119, at 482.

148 *Id.*

149 *Id.*

150 *See* Crestor Home Page, http://www.crestor.com/c/home.aspx (last visited Nov. 13, 2009).

151 *See* Crestor Free Take Action Kit, https://www.crestor.com/c/take-action-kit/index.aspx (last visited Nov. 13, 2009).

receives free samples of Crestor may be more apt to pay to use Crestor once his or her sample supply is depleted, as opposed to switching to a less expensive generic equivalent. Once the patient has developed an affinity to Crestor, he or she may continue using the drug for indefinite periods of time.

Third, in response to the argument that samples provide educational tools, a glance into the marketing of Merck's Vioxx makes it painfully clear that this "educational material" is highly biased.[152] Industry sponsored "educational material" often suppresses unfavorable research results, allowing physicians to rely on incomplete and sometimes false information.[153] This technique is known as selective disclosure, and is commonly found throughout the industry.[154] Big pharma is skilled in hiding promotional material within seemingly unbiased information, and has historically engaged in deceptive practices just to make a profit.[155] This material frequently appears to be independently gathered, but is actually skewed and used as subconscious promotional marketing material.[156]

In 2000, Merck was undergoing an extensive marketing scheme for its drug Vioxx, which was used to treat osteoarthritis.[157] Vioxx was heavily advertised to physicians; however, an internal study by Merck ("VIGOR study") showed a five times increased risk of heart

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[152] *See* Waxman Memorandum, *supra* note 110, at 3–4.

[153] See Lexchin, *supra* note 13, at 14 ("GlaxoSmithKline did not publish results that showed that paroxetine (Paxil™) was ineffective . . . in children and adolescents . . . .").

[154] According to one study cited in a recent district court decision, "11 percent of the in-person statements made to physicians by pharmaceutical sales representatives contradicted information that was readily available to them." IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163, 167 (D. N.H. 2007), *rev'd* 550 F.3d 42 (1st Cir. 2008) (citation omitted); *see also* Elisabeth L. Backer et al., *The Value of Pharmaceutical Representative Visits and Medication Samples in Community-Based Family Practices*, 49 J. FAM. PRAC. 811, 811 (2000) (explaining that researchers have found little to no organization or structure in the distribution of patient educational materials); Katz et al., *supra* note 133, at 40 (citing several scientific studies that found information provided by pharmaceutical sales representatives is "often biased, and sometimes . . . misleading").

[155] United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 48–49 (D. Mass. 2001). Parke-Davis was engaged in an aggressive and highly deceptive marketing campaign for the promotion of off-label use of the drug Neurontin. *Id.* Neurotonin was approved by FDA for epilepsy, yet Parke-Davis marketed it in unapproved doses, and for other uses, such as pain control, bipolar disease, and Attention Defecit Disorder ("ADD"). *Id.* at 45. Franklin created misleading reports, without any supporting data, touting that Neurontin was effective at treating bipolar disorder, that it was safe in higher than approved doses, and that it was effective for ADD treatment. *Id.* at 48–49. Franklin was also trained and instructed to purposefully deceive physicians with fake data, "falsified 'leaks' from clinical trials, scientifically flawed reports, or 'success stories.'" *Id.* at 48.

[156] Iserson et al., *supra* note 109, at 1079.

[157] Waxman Memorandum, *supra* note 110, at 18.

attack to patients who took Vioxx.[158] In response to these results, the FDA issued cautionary discussions of the cardiovascular risks of Vioxx in 2001, stating that physicians should be informed of the risk of heart attack.[159] Rather than bring the results of the VIGOR study to prescribing physicians' attention, however, Merck instructed its sales force to show physicians a document entitled the "Cardiovascular Card."[160] This card incorrectly claimed that Vioxx could be between eight to eleven times safer than other anti-inflammatory drugs.[161] Merck directly instructed its sales force, through a bulletin, not to "INITIATE DISCUSSIONS ON THE FDA ARTHRITIS ADVISORY COMMITTEE . . . OR THE RESULTS OF THE . . . VIGOR STUDY."[162] Merck further instructed sales representatives to respond to doctor's questioning by saying "I cannot discuss the study with you" or by telling doctors to submit any questions in writing, and to never leave the "Cardiovascular Card" with physicians.[163] But it gets worse. Despite warnings by FDA scientific research, "Merck launched Project Offense, a major marketing campaign," which claimed that Vioxx was safe and effective.[164] The most disturbing aspect of this case was that Vioxx prescriptions remained common among physicians, in spite of evidence that it was a killer.[165] Merck had no qualms about putting thousands of patients' lives at risk of a deadly heart attack because it had one goal in mind: make money. This example shows not only that "educational material" is biased, but also that big pharma has an immense level of control over the medical industry, and it uses that control however it deems necessary to reap the maximum possible profit.

In addition to the above negative impacts of sample distribution, patients are negatively affected in various other ways. A patient whose physician is unduly influenced by free samples loses the benefit of speaking with an impartial physician looking out for his or her best interests. Additionally, when pharmaceutical companies provide misinformation to a physician, the physician's patients lose the benefit of speaking with a fully informed physician who knows a particular patient's prescriptions and can gauge how drugs will

[158] *Id.* at 3.
[159] *Id.*
[160] *Id.* at 4.
[161] *Id.* at 17–19.
[162] *Id.* at 22 (alteration in original).
[163] *Id.*
[164] *Id.* at 25–26.
[165] *Id.*

interact with one another when taken at or around the same time. This could result in fatal complications for unwary patients.

C. Impact of Gift Distribution

> For the past several months, a drug rep has been bringing coffee to our office on Tuesday mornings. We have never asked her to continue doing this since we have a coffee pot, and we routinely make coffee for our staff and our patients. But she does it anyway, which is very nice of her. She calls this "Two for Tuesday." The problem is that every week she also says to me, "If you don't write 2 more prescriptions for my brand today, I'm not going to be able to continue bringing coffee." I prescribe her drug when it is right for my patients. There are many times when it is not right.
>
> We feel pressure from her to prescribe her product even though we have never asked her to bring coffee. This may sound like a small thing, but I feel that since she knows exactly how many prescriptions I write each week for her drug versus the competition, she is expecting a quid pro quo.[166]

Gifts are frequently brought to physicians by pharmaceutical representatives in order to induce physicians into seeing representatives and to "encourage receptivity."[167] Numerous physicians admit that the main reason they see pharmaceutical sales representatives is for the free gifts.[168] There are three main types of gifts given to physicians.[169] "'[R]eminder' items" are small gifts of minimal value, such as pens, notepads, and coffee mugs.[170] "Moderately priced items" typically value between twenty to one-hundred dollars, and include reference tools, books, and meals.[171] "Expensive" items are less common, but run afoul of all modern standards of medical ethics and integrity.[172] These include "tickets, trips, and large honoraria for participation in pharmaceutical-

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[166] IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163, 173 (D. N.H. 2007), *rev'd*, 550 F.3d 42 (1st Cir. 2008). In addition to sales reps' personal knowledge of doctors' prescribing patterns, prescribing habits are tracked by data mining companies who sell data, allowing companies to determine which sales tactics are most effective. *Id.* at 172.

[167] *Id.* at 167.

[168] Katz et al., *supra* note 133, at 40 (citations omitted).

[169] Marco et al., *supra* note 108, at 514.

[170] *Id.*

[171] *Id.*

[172] *Id.*

sponsored activities."[173] In the past, some pharmaceutical manufacturers have sponsored trips to "lap-dancing clubs" and given "cash awards" to prescribing physicians.[174] The leakage of this behavior has brought to light practices that have taken place for years, but remained hidden beneath a cloak of secrecy.[175]

There are several ethical issues implicated by the practice of gift-giving to physicians, and the effect of gifts on physicians is often far greater than the monetary value of the gift itself. First, gift distribution places a rift in the trust patients place in their physician. Second, gifts create feelings of reciprocity and indebtedness, regardless of their worth. Third, physicians often believe they are immune to big pharma's bribes, but research has shown that gifts do affect prescribing habits. Fourth, physicians are frequently engaged in a symbiotic relationship with big pharma, and are unwilling to admit influence, because they would lose the perks accompanied with expensive gifts. Fifth, pharmaceutical manufacturers' gifts are truly not gifts at all, and are in fact marketing expenses.

First, although gifts are common throughout the business world, gifts to physicians in exchange for prescriptions compromises the fiduciary duty physicians owe to their patients.[176] Approximately 70% of patients believe that gifts to their physicians significantly impact prescribing habits, and up to "two thirds [of patients] believe [gifts to their physician] increase[s] the overall cost of medications."[177] Patients place insuperable levels of trust in their physicians, relying on their doctors to act in their best interest and exercise care in making treatment decisions. Physicians who accept gifts from the industry fracture that necessary level of patient trust.

Furthermore, gifts create feelings of reciprocity and indebtedness, no matter the size of the gift.[178] "Feelings of obligation are not related to the size of the initial gift or favor."[179] Even small gifts

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[173] *Id.*

[174] McFadden et al., *supra* note 113, at 2.

[175] *See* United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (describing how doctors were provided luxurious travel expenses and tickets to the 2000 Olympics in exchange for writing Neurontin prescriptions).

[176] Iserson et al., *supra* note 109, at 1078.

[177] EMILY CLAYTON, CALPIRG, 'TIS ALWAYS THE SEASON FOR GIVING: A WHITE PAPER ON THE PRACTICE AND PROBLEMS OF PHARMACEUTICAL DETAILING 4 (2004), *available at* http://www.calpirg.org/uploads/Le/LW/LeLWJ1Gv4Nwd9MVJapxdkQ/TistheSeasonForGiving04.pdf (quoting Michael A. Steinman, *Gifts to Physicians in the Consumer Marketing Era*, 284 JAMA 2243, 2243 (2000)).

[178] Katz et al., *supra* note 133, at 41.

[179] *Id.*

can open the door to a physician prescribing other drugs produced by a particular manufacturer. One classic example of the power of small gifts is the practice of "the Disabled American Veterans organization[, which] appeals for donations through direct-mail solicitation."[180] When envelopes contain an unsolicited gift, such as customized address labels, the donation response rate is 35%, as compared to without a gift, when the response rate is only 18%.[181] This simple example supports the idea that accepting a gift without reciprocating is "socially uncomfortable"[182] and creates subconscious feelings of guilt. Big pharma is well aware that gifts create feelings of indebtedness, and takes full advantage by exploiting physicians.[183]

Many physicians mistakenly believe they are educated and critical enough to remain immune to any improper influence by big pharma's sales pitches. For example, many physicians deny that small gifts "undermine their . . . objectivity."[184] Yet research has shown that as the number of gifts to a physician increases, "the more likely [that physician] is to believe that [those gifts] do not influence [his or her] behavior."[185] Logically, the physicians who are most likely to be influenced are those who claim they are immune to gifts, because their "defenses are down."[186] The industry has tapped into the three most powerful "tools of persuasion"—"[f]ood, flattery, and friendship"—making it difficult for physicians to resist the temptation of attractive gifts, meals, and sales representatives.[187] The success of past pharmaceutical marketing, for drugs such as Vioxx, displays that physicians are in fact influenced by this behavior, regardless of what they may believe.

In addition, physicians are often engaged in a corrupted, symbiotic relationship with big pharma, where they personally benefit in exchange for writing prescriptions. Many physicians

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[180] *Id.* (citation omitted).

[181] *Id.* (citation omitted).

[182] *Id.*

[183] One big pharma executive's e-mail, published in the *New York Times*, underscores this notion of indebtedness. Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny*, N.Y. TIMES, Jan. 28, 2006, at A14 ("[O]ur goal is 50 or more scripts per week . . . . If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs, and past preceptorships that you have provided or paid for and get the business!! You can do it!!").

[184] Katz et al., *supra* note 133, at 40 (citations omitted).

[185] *Id.* (citation omitted).

[186] *Id.* at 41.

[187] *Id.*

claim they are immune to influence, but are suspicious that their peers are susceptible to it.[188] One study demonstrated that 61% of physicians believed they were immune to big pharma's sales tactics, but believed that only 16% of their colleagues remained uninfluenced.[189] Another study showed similar results, with only 5% of physicians admitting that "[his or her] prescribing practices [were] affected by gifts," yet 33% believed that "'other' physicians' [prescribing practices] were affected" by gifts.[190] This data indicates a placement of blame, and a lack of willingness to admit influence but an eagerness to implicate cohorts. There is also "a correlation between the willingness of [a] physician to accept gifts of high value" and his or her perspective of sales representatives.[191] The more the physician benefits, the less likely he or she is in favor of restricting regulations.[192] Physicians who accept large gifts were more likely to disagree with statements such as "professional societies should actively discourage pharmaceutical companies . . . from hosting parties and providing free meals or giving gifts to physicians attending the annual meeting,"[193] and were more likely to agree that "[c]linical information provided to [physicians] by pharmaceutical companies . . . provides a useful continuing medical education service."[194]

Lastly, big pharma's "gifts" are truly not gifts at all. In the U.S., charitable gifts are those that exhibit a "detached and disinterested generosity," and are tax deductible.[195] Big pharma's "gifts," on the other hand, are marketing expenses which are not given for charitable purposes, and should not be tax deductible.[196] "[C]alling small tokens given as part of the sales activity of pharmaceutical

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[188] Edward C. Halperin et al., *A Population-Based Study of the Prevalence and Influence of Gifts to Radiation Oncologists from Pharmaceutical Companies and Medical Equipment Manufacturers*, 59 INT'L J. RADIATION ONCOLOGY BIOLOGY PHYSICS 1477, 1482 (2004).

[189] McFadden et al., *supra* note 113, at 2 (citing Mary-Margaret Chren, *Interactions Between Physicians and Drug Company Representatives*, 107 AM. J. MED. 182 (1999)).

[190] Halperin et al., *supra* note 188, at 1479.

[191] *Id.* at 1477.

[192] *Id.* at 1482.

[193] *Id.* at 1480.

[194] *Id.* at 1479; *see also* Elizabeth Ellen, *Visits from Pharmaceutical Reps*, PSYCHIATRIC TIMES, Vol. 18, Jan. 1, 2001, http://www.psychiatrictimes.com/display/article/10168/51086 ("Here you are, working for a company that wants to abide by the guidelines, and you can't compete with a guy who's giving away tickets . . . . Money is the big resource. The pads and pens are great for access, but the dinners and what costs money-CDs, handheld computers, everything given in the name of research-this is what's thrown at docs to get them to change their minds." (quoting a former pharmaceutical sales representative)).

[195] *See* Katz et al., *supra* note 133, at 42 (citation omitted).

[196] *Id.*

firms 'gifts' is disingenuous and a transparent attempt to be nonjudgmental. These 'gifts' should be recognized for what they are: marketing wares."[197] Gifts from the pharmaceutical industry are being offered to obtain business and, therefore, should not be considered tax deductible. Although the newly promulgated PhRMA guidelines prohibit drug makers from distributing pens, mugs, and other non-educational items, these guidelines leave a loophole. As long as a drug maker can tie its gifts to an educational purpose, those gifts are expressly allowed. Although PhRMA did make limited headway with respect to physician-directed marketing, in reality PhRMA took the least action possible, just enough to avoid increased governmental regulation.

IV. GUIDELINES REGULATING DIRECT-TO-CONSUMER MARKETING

In addition to targeting physicians, big pharma also engages in a plethora of DTC advertisements on television, in magazines, and on the internet. Televised DTC advertisements have been growing in popularity in the U.S. in recent years, a phenomenon of which anyone who watches television is acutely aware. Historically in the U.S. and virtually all other countries, televised DTC advertisements were banned and DTC advertising in general was limited.[198] In 1997, however, the FDA revised its rules and allowed product-specific DTC advertisements to be broadcast on television.[199]

The U.S. and New Zealand are the only two countries that allow pharmaceutical companies to market with television ads.[200] The FDA currently allows drug advertisements through "television or radio, communicated over the telephone, or printed in magazines and newspapers."[201] In addition, "[a]dvertisements cannot be false

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[197] *Id.*

[198] *Direct-to-Consumer Advertising: Marketing, Education or Deception? Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2008) [hereinafter Dingell Statement] (statement of Rep. John D. Dingell, Chairman, H. Comm. on Energy and Commerce), *available at* http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1235&catid=18:platforms&Itemid=58.

[199] *Id.*; *see* Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43171, 43172 (Aug. 12, 1997).

[200] *See Direct-to-Consumer Advertising: Marketing, Education or Deception? Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. 2 (2008) [hereinafter Stupak Statement] (statement of Rep. Bart Stupak, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce), *available at* http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/Testimony/OI/050808.OI.hrg.DTC.pdf.; Natasha Singer, *Citing Risks, Lawmakers Seek to Curb Drug Commercials*, N.Y. TIMES, July 27, 2009, at B1.

[201] Carol Rados, *Truth in Advertising: Rx Drug Ads Come of Age*, 38 FDA CONSUMER 20, 24

or misleading and cannot omit material facts."[202] The regulation of DTC advertisement is controlled by the FDA's division of Drug Marketing, Advertising, and Communications ("DDMAC").[203]

There are several types of DTC advertisements used in today's market to reach consumers. The first type—product-claim ads—are the most common.[204] These ads mention the drug name, represent the drug, include a "brief summary" of the drug that describes both the benefits and risks, and present a "fair balance" of risks and benefits.[205] The FDA allows an exception for televised ads, due to short time constraints, that may include information about risks instead of a brief summary.[206] Televised ads must also give consumers access to more information—usually satisfied by a "toll-free telephone number, a Web site address, or a link to a concurrently running print ad" with the information, or referral to a health care provider.[207] The second type of drug advertisement is a "reminder ad," which provides a drug name, accompanied by other minimal information—dosage, form, and cost.[208] Reminder ads are not required to provide information about risks or the clinical role of the product.[209] The third type of DTC ad is a "help-seeking ad," which educates consumers about a disease or condition, tells consumers that there are treatments available, and encourages consumers to consult a physician to determine whether the drug would be suitable.[210] Help-seeking ads do not name specific drugs and no risk information is required.[211] "Drug companies are required to submit [a copy] of their ad[]" when it is ready to be aired or published; however, no preclearance approval by the FDA is necessary.[212] If, after airing, the FDA determines that an ad violates an FDA provision, it can issue letters for violations. The FDA, however, cannot impose fines other than "through an administrative hearing."[213]

PhRMA has promulgated a set of guidelines for DTC marketing,

(2004).

[202] *Id.*; 21 C.F.R. § 202.1(e)(1) (2009).

[203] Rados, *supra* note 201, at 24.

[204] *Id.*

[205] *Id.*

[206] 21 C.F.R. § 202.1(e)(1).

[207] Rados, *supra* note 201, at 24.

[208] *Id.*

[209] *Id.* at 24–25.

[210] *Id.*

[211] *Id.* at 25.

[212] *See* Stupak Statement, *supra* note 200, at 2.

[213] *Id.*

similar to those that guide physician-directed marketing.[214] PhRMA claims that an important benefit of DTC advertisements is that they encourage "informed conversation about health, disease, and treatments" between physicians and patients.[215] PhRMA further claims its guidelines "increas[e] awareness," "educat[e] patients about treatment options," "motivat[e] patients to contact their physicians," "increas[e] the likelihood that patients will receive appropriate care for . . . frequently under-diagnosed [conditions]," and "encourag[e] compliance with prescription drug treatment regimens."[216] The PhRMA guidelines explain that drug makers should spend "an appropriate amount of time" on physician education prior to running DTC ads.[217] The guidelines further recommend that "[c]ompanies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast."[218] Additionally, PhRMA recommends that DTC ads should contain "information about the availability of other options such as diet and lifestyle changes where appropriate,"[219] and that DTC ads "should be presented in clear, understandable language, without distraction from the content."[220]

In response to a great deal of recent controversy regarding particular DTC ads, a congressional hearing was held on May 8, 2008, to evaluate the existing state of law.[221] The hearing was held regarding questionable advertising practices of three pharma giants—Pfizer's Lipitor ads featuring Mr. Robert Jarvik, Merck & Schering-Plough's "Food and Family" ads for Vytorin, and Johnson & Johnson's "cancer fatigue" ads for Procrit.[222]

First, with respect to the Jarvik ads for Lipitor, Mr. Jarvik was not a medical doctor and had no license to practice or prescribe medicine.[223] In the commercial, Jarvik claimed to take Lipitor, but later admitted that he did not take Lipitor until months after

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[214] *See* PHRMA, PHRMA GUIDING PRINCIPLES: DIRECT TO CONSUMER ADVERTISEMENTS ABOUT PRESCRIPTION MEDICINES 1–2 (2005), *available at* http://www.roche.com/files/dtcguidingprinciples.pdf.

[215] *Id.* at 1.

[216] *Id.*

[217] *Id.* at 1, 3 (Principle 6 leaves the "amount of time" to the discretion of the company to independently decide).

[218] *Id.* at 4, ¶ 8.

[219] *Id.* at 4, ¶ 9.

[220] *Id.* at 4, ¶ 11.

[221] *See, e.g.*, Stupak Statement, *supra* note 200, at 1.

[222] *Id.*

[223] *Id.* at 1–2.

commercials began filming.[224] Jarvik also received $1.35 million for his participation in the commercials from Pfizer, which was never disclosed.[225] Second, the Vytorin "Food and Family" ads falsely claimed to reduce cholesterol after studies showed that it had no effect on cholesterol build up and "an equally effective generic [version], Zocor, was already available."[226] Merck & Schering-Plough knew of the lack of effect on cholesterol by Vytorin, but suppressed results for two years and continued marketing to consumers.[227] Third, Johnson & Johnson's Procrit was approved to treat chemotherapy and dialysis-induced anemia, but Johnson & Johnson marketed it as a way to improve patients' quality of life.[228]

Michigan democrat Bart Stupak said DTC ads on television use "deceptive techniques to push products to potential patients and increase sales."[229] Big pharma "should consider it a privilege to be allowed to air DTC ads in this country. As with all privileges, there comes responsibility," Stupak went on to say.[230] Other Committee speakers agreed with Stupak, stating that big pharma uses "fast speech" and "visual effects" to downplay risks and emphasize benefits.[231]

In response to this ethical quandary, other government representatives have proposed legislation. For example, New York Democrat Jerrold Nadler introduced the Say No to Drug Ads Act in June 2009 in the United States House of Representatives.[232] This Act would amend the Internal Revenue Code and thereby prevent drug manufacturers "from [withholding] the cost of [DTC] advertisements as a business expense."[233] Other representatives, from states like Virginia and Illinois, have introduced legislation

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[224] *Id.* at 1.

[225] *Id.* The Jarvik ads were voluntarily withdrawn following the committee hearings. *Id.* at 2.

[226] *Id.*

[227] *Id.* The Vytorin ad was voluntarily withdrawn as well, and in February 2009, Merck and Schering-Plough settled with attorneys general from thirty-five states. *Id.*; Singer, *supra* note 200, at B1. In its settlement agreement, "Merck agreed to submit all new television commercials to the F.D.A. for approval before they are broadcast." *Id.*

[228] Stupak Statement, *supra* note 200, at 2. This type of off-label marketing is not permitted. *Id.*

[229] Susan Heavey, *Drugmakers Need to Rein in Ads, Hearing Told*, REUTERS, May 8, 2008, http://www.reuters.com/article/idUSN0837948820080508.

[230] Stupak Statement, *supra* note 200, at 3.

[231] Heavey, *supra* note 229 (reiterating statements made by Ruth Day, head of Duke's University Medical Cognition Laboratory).

[232] Say No to Drug Ads Act, H.R. 2966, 111th Cong. (2009) (as introduced to the House of Representatives by Rep. Jerrold Nadler on June 19, 2009), *available at* http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.2966:.

[233] Singer, *supra* note 200, at B1.

similar to Nadler's.[234]

V. ETHICAL ISSUES SURROUNDING CONSUMER-DIRECTED MARKETING

"Americans will watch an average of nine [drug advertisements] a day."[235] In 2002, an FDA survey found that "81 percent of respondents . . . reported seeing or hearing" a prescription drug advertisement.[236] In 2005, DTC spending reached an astounding $4.2 billion.[237] This spending has increased exponentially since 1997, when the FDA relaxed its rules to permit product-specific, televised drug ads. In 1998, shortly after the revision, only 10.5% of all drug promotion expenditures, totaling $1.3 billion, were used in DTC advertisements.[238] By 2005, there was an approximate 325% increase in spending in comparison to 1998.[239] Research indicates that for "[e]very [dollar] spent on DTC advertising[, there is] up to a [six dollar] increase in [drug] sales."[240]

A great deal of confusion among consumers has resulted from airing these DTC drug ads. According to one FDA survey, "75 percent of physicians surveyed believe that DTC ads cause patients to think that [a] drug" is more effective than it truly is.[241] That same survey indicated physicians often felt pressured to prescribe a particular drug when a patient mentioned a DTC advertisement.[242] Other research has shown that patients frequently have misunderstandings with respect to DTC advertising.[243] In particular, one survey indicated that half of consumers "thought [drug ads] were approved by the government, 43% thought only 'completely safe' medic[ines were] advertised, and 22% believed

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[234] *Id.* (explaining the background of two bills, one introduced by Illinois Democrat Daniel Lipinski and the other by Virginia Democrat James P. Moran, that would prohibit tax deductions for DTC advertising, and ban DTC advertisements for sexual aids like Levitra and Viagra from primetime television, respectively).

[235] Nicole Perlroth, *Pharma Oversold?*, FORBES.COM, Sept. 1, 2008, http://www.forbes.com/healthcare/2008/08/29/pharmaceuticals-advertising-television-biz-healthcare-cz_np_0901drugads.html.

[236] Carol Lewis, *The Impact of Direct-to-Consumer Advertising*, 37 FDA CONSUMER 9, 9 (2003).

[237] *See* Stupak Statement, *supra* note 200, at 1.

[238] Selis, *supra* note 112.

[239] *See* Stupak Statement, *supra* note 200, at 1. During this time period, however, research and development increased by only 103 percent. *Id.*

[240] *Id.*; *see also* Dingell Statement, *supra* note 198.

[241] Lewis, *supra* note 236, at 9.

[242] *Id.*

[243] Jeffrey T. Berger, *Pharmaceutical Industry Influences on Physician Prescribing: Gifts, Quasi-Gifts, and Patient-Directed Gifts*, 3 AM. J. BIOETHICS 56, 56–57 (2003).

that . . . drugs with serious side effects could not appear in advertisements."[244] The research shows that consumers are confused and do not understand big pharma's ploy. Consumers are not in a knowledgeable position to evaluate the complexity of DTC advertisements, and often place unwarranted trust in advertisements. There are several problematic issues relating to DTC advertising, including: (1) big pharma's manufacture of disease; (2) the mass production of "me-too" drugs; and (3) the unintended consequences of DTC ads.

A. Manufacturing Disease

The pharmaceutical industry is highly criticized for creating disease by widening its productivity net to target "lifestyle diseases."[245] For example, Pharmacia & Upjohn, the maker of Detrol—an over-active bladder medication—marketed its product "to people annoyed by . . . frequent urges to use the bathroom" in order to increase its market.[246]

> "To expand the number of potential customers . . . marketers . . . [targeted p]eople who 'mapped toilets' . . . [meaning those who] would not leave their homes . . . until they knew the location of every clean facility in the vicinity of their planned travels. A person who used 'defensive voiding' . . . never passed a restroom without stopping in."[247]

Through this marketing campaign, Pharmacia attempted to make people who perhaps had been mildly disturbed by bladder problems in the past believe that they were irritated with an overactive bladder and go to their physicians for help, which could lead to the prescription of Detrol.[248]

GlaxoSmithKline[249] ("GSK") also engaged in marketing a lifestyle disease with respect to its antidepressant, Paxil.[250] Paxil was approved by the FDA "for the treatment of social phobia," which

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[244] *Id.* at 57 (citation omitted).

[245] Lexchin, *supra* note 13, at 17.

[246] MELODY PETERSEN, OUR DAILY MEDS: HOW THE PHARMACEUTICAL COMPANIES TRANSFORMED THEMSELVES INTO SLICK MARKETING MACHINES AND HOOKED THE NATION ON PRESCRIPTION DRUGS 20 (2008).

[247] *Id.*

[248] *Id.*

[249] Lexchin, *supra* note 13, at 17 (GlaxoSmithKline was formerly known as SmithKlineBeecham).

[250] *Id.* at 17–18.

affected only a small percentage of the population.[251] GSK extended the definition of social phobia to include "shyness" and played upon people's fears in order to enlarge its market.[252] Only a month after 9/11, GSK aired "an advertisement of a woman walking on a crowded street, her face strained, in a crowd otherwise blurred. The caption read '[m]illions suffer from chronic anxiety. Millions could be helped.'"[253] This advertisement appeared to be an attempt to unfairly take advantage of a paralyzing nationwide fear experienced by millions of people post-9/11.[254] Through its advertising, it appears that GSK tried to make viewers subconsciously believe that even shyness could potentially be treated with Paxil.[255]

Yet another familiar example of big pharma's creation of lifestyle diseases is the plethora of erectile dysfunction ("ED") drugs currently on the market. Studies have indicated that only 10% of American males experience a "complete [and total] inability to achieve [an] erection."[256] This leads to the conclusion that many males who take ED drugs are a product of a "socially constructed condition" that offers all males a heightened sexual experience.[257] "[T]he more anxiety a corporation can produce, the larger its market. In other words, worrying about ED may in fact cause ED."[258]

This creation of disease by drug makers has led to an overly medicated society that depends on drugs to cure even the smallest of ailments. This is not just good marketing—it is a threat to public health. As a society, are we willing to accept this type of behavior by drug makers? Where will we draw the line, and will we be too late?

B. Me-Too Drugs

"*Webster's* defines disease as any deviation of a body from its

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[251] *Id.*

[252] *Id.*

[253] *Id.* at 18 (citation omitted).

[254] *Id.*

[255] *Id.* at 17–18.

[256] Adam Mannan & Alan Story, *Abolishing the Product Patent: A Step Forward for Global Access to Drugs*, *in* THE POWER OF PILLS: SOCIAL, ETHICAL AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING, AND PRICING 179, 179 (Jillian Clare Cohen et al. eds., 2006) ("[I]t is certainly true that, in some cases, ED is the consequence of organic causes, including peripheral vascular disease, hypertension, drug side-effects, hormonal imbalance, and diabetes." (citation omitted)).

[257] *Id.*

[258] *Id.* (quoting MEIKA LOE, THE RISE OF VIAGRA: HOW THE LITTLE BLUE PILL CHANGED SEX IN AMERICA 54 (2004)).

normal or healthy state. But what is normal? And how does one define health, for that matter?"[259] Because there is no universal definition of disease,[260] manufacturers are free to "sell[] expensive drugs with marginal benefits . . . over older" and cheaper versions.[261] These drugs are coined "me-too drugs" or "copycat" drugs.[262] In order to combat the drastic price reduction on brand name drugs upon patent expiration, a drug maker will often make minor modifications on a drug compound to extend its patent monopoly.[263] The minor modifications on drug formulas do not necessarily increase the effectiveness of the drug, yet do keep drug prices high.[264] Studies have found that big pharma sinks a great deal of money into new dosage forms or combinations of existing drugs, yet does not make such a hefty investment in researching "new molecular entities."[265] These new but similar combinations often have little or no therapeutic benefit to patients, yet patients pay a pretty penny to get them.[266] "Non-governmental [studies] indicate[] . . . that 65 percent of new drugs introduced between 1989 and 2000 used active ingredients already on the market, and 76 percent offered no significant benefit over already available products."[267] These numbers are striking, and may indicate an inefficient use of research and development by big pharma.

In addition to creating me-too drugs, big pharma has developed techniques that delay the onslaught of generic competition on its patented drugs.[268] By 2012, eight of the world's top pharma products, in addition to Pfizer's Lipitor, will face generic competition.[269] The stakes are high, as generic production will cause the market price of brand name drugs to nosedive.

In November 2008, the European Commission announced that "Big Pharma [has] systematically rigged the market to squeeze out

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[259] PETERSEN, *supra* note 246, at 23.

[260] *Id.*

[261] CALLAHAN & WASUNNA, *supra* note 22, at 165–66.

[262] *See* Leo Cendrowicz, *Big Pharma Faces a Crackdown in Europe*, TIME, Nov. 28, 2008, http://www.time.com/time/printout/0,8816,1862791,00.html.

[263] *Id.*; Lexchin, *supra* note 13, at 19–20; McFadden et al., *supra* note 113, at 1 ("76% of 'new' drugs represent [only minor] changes in existing drugs despite [two]-fold increases in price.").

[264] Fisher, *supra* note 118, at 256 (citation omitted).

[265] *Id.* at 256.

[266] *Id.*

[267] *Id.* (citation omitted).

[268] Cendrowicz, *supra* note 262; Lexchin, *supra* note 13, at 20.

[269] Linda A. Johnson, *Generic Drug Prices Falling in U.S.*, BLUE CROSS BLUE SHIELD ASS'N, Dec. 9, 2008, http://www.bcbs.com/news/national/generic-drug-prices-falling-in-us.html.

copycat medicines."[270] The Commission further found that big pharma uses patent lawsuits to bankrupt smaller competitors and delay tactics to prevent generics from entering the market.[271] "The most common tactic allegedly involves filing multiple patent applications for the same medicine—so-called patent clusters—that stake out an extremely broad claim for a drug's intended use and physical form . . . ."[272]

C. Consequences of DTC Marketing

Industry members and other proponents of DTC ads support the use of product-specific televised ads for several reasons. First, proponents claim that DTC advertisements advance public health by encouraging patients to talk with their physicians about health conditions.[273] Second, proponents assert that DTC ads remove the stigma accompanied by diseases, "such as erectile dysfunction [and] depression."[274] Industry members claim that patients can now take charge of their health,[275] because the ads contain "educational information."[276] Furthermore, some proponents claim that televised ads "stimulate[] competition," "result[ing] in lower [drug] prices."[277] One FDA survey found that 53% of physicians said DTC ads lead to "[b]etter discussion[s] with patients," but only 10% believed that DTC ads have an informational or educational component for patients.[278]

DTC ads have many negative consequences, however, which threaten to curtail patients' trust in their physicians and create the risk of an over-medicated society. First, and most obviously, DTC ads may threaten public health if they contain any inaccurate or

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[270] Cendrowicz, *supra* note 262.

[271] *See id.*; Lexchin, *supra* note 13, at 20. These observations were noted in an "interim Commission report based on evidence collected during January raids at the headquarters" of Johnson & Johnson, GlaxoSmithKline, AstraZeneca, Pfizer, and Sanofi-Aventis. Wyeth, Merck, Bayer Schering Pharma and Roche, Teva and Sandoz were also raided. Cendrowicz, *supra* note 262.

[272] Cendrowicz, *supra* note 262.

[273] Rados, *supra* note 201, at 22.

[274] *Id.*

[275] Ronald J. Vogel et al., *A 3-Stage Model for Assessing the Probable Economic Effects of Direct-to-Consumer Advertising of Pharmaceuticals*, 25 CLINICAL THERAPEUTICS 309, 312 (2003).

[276] Alan Lyles, *Direct Marketing of Pharmaceuticals to Consumers*, 23 ANN. REV. PUB. HEALTH 73, 78 (2002).

[277] *Id.*

[278] Rados, *supra* note 201, at 23.

misleading information.[279] Although false and misleading ads are prohibited by the FDA, drug makers still find ways to conceal critical information and divert consumers' attention away from risky side effects.[280] The problem lies in the fact that most "consumers lack the expertise to assess the quality of the content of the ad[s]."[281] An additional problem with DTC ads cited by critics is that patients may withhold information from physicians to fit a particular profile based on what they observe in a commercial, and patients may try to diagnose and cure themselves.[282] "DTC advertising may cultivate the belief among the public that there is a pill for every ill and contribute to the medicalization of trivial ailments, leading to an even more medicated society . . . ."[283]

Many physicians oppose DTC advertising for additional reasons, including that it is a difficult and time-consuming task to attempt "to talk [patients] out of [a drug] they [already] have their hearts set on [taking]."[284] This places physicians in a moral bind, as they want to please their patients and retain the business, yet they do not want to compromise their fiduciary duty in doing so.[285] Groups that oppose DTC advertisements argue that televised drug ads will lead to increased drug prices and increased litigation and liability.[286]

VI. PROBLEMS WITH THE EXISTING STATE OF LAW

There are several critical legal issues that confront today's highly unregulated pharmaceutical industry.[287] First, big pharma is playing deceptive mind games with physicians and consumers through psychological trickery. These efforts often create patient dependency and subconsciously put the idea of prescribing a particular drug into physicians' heads.[288]

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[279] *Id.*

[280] *See* Lyles, *supra* note 276, at 78.

[281] *Id.*

[282] Rados, *supra* note 201, at 23.

[283] *Id.*

[284] *Id.*

[285] CALLAHAN & WASUNNA, *supra* note 22, at 170.

[286] Lyles, *supra* note 276, at 86–87 (describing the "learned intermediary" doctrine, in which courts have held that physicians are the intermediary between big pharma and patients). Therefore, big pharma does not need to directly provide patients with product warnings—this has shielded drug makers from liability to consumers. *Id.*

[287] With the exception of Vermont's Pharmaceutical Marketing Gift Disclosure Law, VT. STAT. ANN. tit. 18, § 4632 (2008 & Supp.), and Massachusetts's Pharmaceutical and Medical Device Manufacturer Conduct, 105 MASS. CODE REGS. 970.006 (2009), many of these issues have yet to be formally addressed by state legislatures. *See supra* Part II.D.

[288] *See* Rados, *supra* note 201, at 23; *see also* Deepa Seetharaman, *New U.S. Drug*

Another vital problem is the grave state of affairs for those physicians who have forgotten the Hippocratic Oath, which requires physicians to always put their patients' interests first, even before their own personal interests.[289] The physician who engages in a symbiotic relationship with drug manufacturers acts against the best interest of his or her patients, and engages in a breach of his or her fiduciary duty to patients.

In addition, with the advent of DTC advertising, the patient-physician relationship is compromised. Consumers are diagnosing themselves based on limited or no knowledge, which has led the U.S. to become an overmedicated society. Because of the constant and unending consumer exposure to televised DTC ads, physicians are frequently put in the uncomfortable position of following the demands of their patient and prescribing some expensive and unnecessary brand-name drug, or withholding a prescription and risking the loss of a patient.

The laws governing the pharmaceutical industry must be reformed. The hidden agendas contained within the industry's marketing techniques severely undercut a physician's ability to effectively do his or her job. The distribution of drug samples, marketing materials, and free gifts creates conflict between physicians and patients. The dissemination of superfluous marketing and promotional materials, to both physicians and patients, is not cost-effective and deters big pharma from its ultimate, altruistic, and often-forgotten purpose—to prevent and cure disease. The utter domination and control of the health care industry by a sales force is unethical. Medicine should be dominated by scientific evidence, not secretive marketing techniques. The dissemination of marketing propaganda takes the burden off physicians to maintain competence by independently researching issues, and allows them to rely on biased and skewed information.[290] It also confuses consumers by misleading them to believe that a drug can cure even the most insignificant ailment. This creation of disease by drug makers has led to an overmedicated society that pays too much money and too little attention.

Marketing Code Draws Line at Gift Pens, REUTERS, July 10, 2008, http://www.reuters.com/articlePrint?articleId=USN1138423320080711. ("[T]he policy will probably not hurt drug makers' marketing efforts because their approach has shifted to more direct-to-consumer methods and relying on pitches by sales representatives.").

[289] STEVEN H. MILES, THE HIPPOCRATIC OATH AND THE ETHICS OF MEDICINE xiii (2004).

[290] ABIM Found. et al., *supra* note 55, at 245 (encouraging a "[c]ommitment to scientific knowledge").

The lack of intrinsic limitations on the pharmaceutical industry invites external regulation and control, yet there is virtually no regulation or control in place.[291] Despite the advent of professional and industry guidelines, the ethical issues implicated by physician-directed marketing remain unresolved.[292] Most problematic, the guidelines are all highly discretionary, arbitrary, and voluntary. As one Wyeth spokesman explained, "the [AMA] guidelines are not specific enough to be a practical guide for everyday practice in our industry."[293] Furthermore, the PhRMA and AdvaMed guidelines are promulgated by lobbyist groups within the industry, leaving the neutrality of these guidelines highly questionable.[294]

With respect to DTC advertisement regulations, the current FDA standards are too relaxed. Rather than anticipating and preventing DTC violations, the FDA regulations allow drug makers to violate the rules. Only if the FDA happens to catch the violation is big pharma subject to liability. As one researcher pointed out, post-broadcast amendments to DTC ads won't make consumers forget what they saw in the original ad.[295] In addition, the PhRMA guidelines are similar to the physician-directed guidelines, and are highly discretionary, voluntary, and unenforceable.

VII. PROPOSED SOLUTIONS

Is there any way to solve the problem of big pharma's domination and control over physician prescribing habits? One thing is for sure: it will not be solved overnight, as several steps must be taken in order to return to ethical behavior. First, the suggested sets of voluntary guidelines currently in place should be rewritten by an independent group, absent of any conflict of interest. At the very least, the group should consist of members of the industry, members of the medical profession, and ethics experts in order to provide input from each side of the controversy. A group of industry lobbyists, whose sole interest is in preserving and extending big pharma's current stronghold over U.S. physicians and consumers,

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[291] CALLAHAN & WASUNNA, *supra* note 22, at 166–67.

[292] *See* Iserson et al., *supra* note 109, at 1080. For example, several gifts remain: meals, drug samples, and educational items. *Id.*

[293] Bill Brubaker, *Drug Firms Still Lavish Pricey Gifts on Doctors; Ethics Debated as Freebies Flow*, WASH. POST, Jan. 19, 2002, at E1.

[294] *See* CALLAHAN & WASUNNA, *supra* note 22, at 169 (explaining PhRMA's self- interest in the industry, and that PhRMA is the leading professional group for the pharmaceutical industry, spending millions of dollars on lobbying annually).

[295] Lyles, *supra* note 276, at 81, 88.

should not be the ones who decide industry standards. Even the AMA guidelines that were created by medical professionals are vague and highly discretionary. The new standards must be clearer, less discretionary, and less arbitrary. Once a set of guidelines is agreed upon, those guiding principles should be mandated by law. This would provide incentive for the industry and physicians to follow, even if for no other reason than to avoid liability. For example, rather than allowing big pharma to teach continuing medical education, provisions of CMEs should be left to independent researchers and scientists, who have no monetary interest. Big pharma should be prohibited from contacting medical students and residents. In addition, because the exchange of even negligible gifts creates feelings of indebtedness, industry sponsored gifts, meals, and other honoraria should be banned.

Because drug samples do provide some benefit, although minor, the new rules should allow their continuance, but with added safeguards. For example, that rules could require that samples be mailed to physicians without accompanying promotional materials, instead of personally delivered by sales representatives. This would not solve the major concern of long-term patient dependency on expensive drugs that is a result of free sample distribution. It would, however, eliminate deceptive sales tactics and skewed marketing, while allowing patients free access. It would also give big pharma an incentive to participate, as products would still reach patients. It would at least be a step toward reforming the pharmaceutical industry.

The doctor-patient relationship is not a simple business transaction. Rather, it implicates life and death issues, as well as the fiduciary duty of the doctor to his patient. Physicians behold "public trust," as opposed to typical corporate salespersons who engage in standard arms-length business transactions.[296] Physicians should not have the option to disregard their public duty, and should be held to a higher standard because of their position of public trust.[297]

One suggestion is to follow Vermont and Massachusetts, by requiring full disclosure by pharmaceutical manufacturers

[296] Katz et al., *supra* note 133, at 43.

[297] *Id.* (reasoning that physicians should be held to the same standard as journalists, university professors, judges, National Basketball Association referees, and Major League Baseball umpires, who are all in positions of public trust and are therefore prohibited from accepting gifts).

regarding payments and gifts to medical professionals.[298] This would be a step in the right direction. Another suggestion is to create "a national Internet-based registry of transactions between [physicians] and [the industry, accompanied by] market values" to which patients would have access.[299] Although an internet registry would be an improvement on our current state of affairs, it would not be effective unless patients took initiative to research and compare their own physician's behavior with that of other physicians. This would erroneously misplace the burden onto the patient, when it should remain with the physician. At the very least, records of pharmaceutical manufacturer marketing activity should be available for "public inspection."[300]

Furthermore, any scientific research secretly conducted by big pharma and disguised as objective must be eliminated. Research funds should be granted by agencies at full arm's length from the drug industry, and pharmaceutical manufacturers should be required to present peer-reviewed research along with their own marketing materials.[301]

With respect to DTC advertisements, the PhRMA guidelines promote industry progress by restricting the use of actors and physicians in DTC ads and prohibiting DTC ads that market off-label use.[302] The PhRMA guidelines, however, do not require long-term testing or evidence of valid clinical trials prior to DTC advertising. In addition, there is no waiting period for newly approved drugs to be advertised on television, nor is there a required preclearance requirement by the FDA prior to airing DTC ads.[303]

Critics of DTC advertising have suggested several methods to protect consumers. First, some argue that product-specific DTC advertisements should be stopped entirely.[304] Other groups argue

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[298] *Id.*; 105 MASS. CODE REGS. 970.006 (2009); *see also* Marco et al., *supra* note 108, at 516 (describing Vermont's statute).

[299] Alpert, *supra* note 135, at 99–100.

[300] CALLAHAN & WASUNNA, *supra* note 22, at 201.

[301] McFadden et al., *supra* note 113, at 5.

[302] Press Release, H. Comm. on Energy and Commerce, Dingell, Stupak React to PhRMA's DTC Policy Revisions: Lawmakers Commend Progress, Call for Further Action to Protect Consumers (Dec. 10, 2008), *available at* http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1457.

[303] *Id.*

[304] Lyles, *supra* note 276, at 74. The Academy of Managed Care Pharmacy takes this approach. *Id.* Lyles further proposes that printed advertisements are ineffective in reaching consumers. *Id.* at 88. Lyles argues that if television ads are banned, it will lead to an abundance of internet ads, most of which are out of the FDA's reach, and therefore, would not need to meet the FDA risk/benefit balance requirement. *Id.*

that the FDA should regulate and ensure accuracy of DTC ads.[305] For example, the FDA could conduct a "mandatory pre-broadcast clearance" on all DTC ads.[306]

With respect to the idea of increasing regulation among the marketing activities of big pharma, free speech issues are invariably implicated. Because most drug industry marketing is conducted by sales representatives in doctors' offices or by privately owned television companies[307]—both private property—a deeper analysis is required, including whether the regulations would be content-neutral, and therefore require a time, place, and manner restriction.[308] This paper does not address those issues as they require further analysis, however, sources suggest that increased regulation on drug makers could survive constitutional scrutiny.[309]

Perhaps the U.S. should follow the trend of many European countries that have imposed a tremendous amount of regulations on pharmaceutical manufacturers. Regulations in Europe include the cutting of drug costs, cost-sharing, abiding by lists of subsidized drugs, allowing parallel imports, and banning direct-to-consumer advertisements.[310] Pharmaceutical manufacturers continue to make profits in Europe, yet many are leaving Europe for the U.S., where there are no rules or regulations and profits are seemingly without limit.[311] Virtually all developed countries have at least some control over drug prices, yet somehow drug prices in the U.S.

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[305] *Id.* at 74. The American Associations of Retired Persons (AARP) takes this approach.

[306] *Id.* at 81.

[307] *See id.* at 80–81 (evidencing that both television and office promotional expenditures are the highest among other media and other uses).

[308] To meet the content-neutral test, a law must be truly content-neutral, there must be a significant government interest (such as protecting consumers and respecting the medical profession), the law must be narrowly tailored (affecting only practices whose harm outweighs its benefit), and the act must "leave open ample alternative channels of communication." Frisby v. Schultz, 487 U.S. 474, 481 (1988) (quoting Perry Educ. Ass'n v. Perry Local Educators' Ass'n, 460 U.S. 37, 45 (1983)).

[309] *See* Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 97 (2002) ("[I]njured consumers may make negligent marketing claims in cases where there is evidence that pharmaceutical companies have pressured physicians to over-prescribe their products or where these companies have failed to exercise some control over doctors or pharmacists who facilitate abuse of prescription drugs."); Timothy S. Hall, *The Promise and Peril of Direct-to-Consumer Prescription Drug Promotion on the Internet*, 7 DEPAUL J. HEALTH CARE L. 1, 33–36 (2003) (discussing various ways the FDA can enhance regulations on industry marketing without disregarding the fair balance requirement, including by balancing the levels of promotion and warning to both viewers and customers).

[310] CALLAHAN & WASUNNA, *supra* note 22, at 182–83.

[311] *Id.* at 179 (taking into account the European price control and the decreasing profitability of European markets).

remain higher than anywhere else.[312] For example, Lipitor's wholesale price in the U.S. for a 10 mg pill is $1.88, almost double the cost of the drug in Europe, which is under $1. In addition, AstraZeneca's Prilosec has a wholesale price of $3.69 per 20 mg pill in the U.S., but under $1.50 in Europe.[313]

Drugs are still effectively marketed and sold throughout Europe,[314] so it is clear that big pharma can still make substantial profits despite the increased regulation. If drug makers can remain profitable in Europe in spite of government control, they could also survive and even prosper with lower U.S. prices.[315] Perhaps Congress or state legislatures should consider increasing regulation to make drugs more accessible to patients, rather than be concerned about the profit margins of big pharma.[316] If U.S. regulators followed the lead of European counterparts, it would ideally lead to the creation of a universal standard for drug manufacturers. A universal standard would eliminate the safe haven for big pharma that currently exists in the U.S. and would potentially solve the ethical concerns of big pharma's current stronghold over the medical profession.

[312] *See* Lexchin, *supra* note 13, at 15 (noting that drugs are 30–40% more expensive in the U.S. than in Canada and Europe).

[313] CALLAHAN & WASUNNA, *supra* note 22, at 179.

[314] *Id.*

[315] *Id.* at 200.

[316] *Id.* at 201–02.