

AN INSIDER'S PERSPECTIVE: DEFENSE OF THE PHARMACEUTICAL INDUSTRY'S MARKETING PRACTICES

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I. INTRODUCTION

A sharply dressed, attractive female walks into the waiting room of an office. All eyes turn and look at this young lady, who looks quite out of place amongst the throngs of elderly, young, and sick patients waiting long periods to see their doctor. This person, carrying meals, gifts, and free drugs, skips the line of patients waiting to be seen and walks right into the back, embracing a friendly handshake with the physician. The patients are all wondering how much longer they will now have to wait because a "drug rep" has walked in just as their appointments are to begin. The patients eventually see their doctor, late because of the drug rep, and are wondering if they have been prescribed a drug that the rep was just promoting to their doctor. These same patients eventually go home and turn on the television in the evening to enjoy sports, the evening news, or a sitcom. The evening news may even be airing a special on the marketing tactics of "big pharma." Each commercial break is full of ads by drug companies promoting their products . . .

It is no wonder that negative perceptions surround the pharmaceutical industry.¹ The woman described above represents a pharmaceutical company, and for many, is an image of what is wrong with today's healthcare industry. The perception that the

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¹ See generally LEONARD J. WEBER, PROFITS BEFORE PEOPLE? 1–8 (2006) (discussing the root of many perceptions surrounding the pharmaceutical industry).

pharmaceutical industry is market-driven² arguably conflicts with the hope that it is a research-driven,³ lifesaving industry.⁴ I would argue that it could be all three.

The right to affordable healthcare for all members of society is a burning topic—cheaper medications are at the forefront of the debate.⁵ Although pharmaceuticals only make up about ten percent of all healthcare costs,⁶ the pharmaceutical industry falls into the heart of the healthcare debates because of its conflicting role as a provider and profit maker.⁷ The companies are providers of essential, yet expensive, medicines that are partially financed by high out-of-pocket costs, and such costs are justified by the industry as the expenses incurred in researching and developing the lifesaving and life-improving medicines of the future.⁸ The high profits in the pharmaceutical industry certainly do not help the image.⁹ Some believe that pharmaceutical companies have a social contract with society to provide cheap, lifesaving medicines and that the government should be regulating pricing.¹⁰ Others believe that lifesaving medicines only come from innovation, which will be eradicated by heavy regulation of prices if the government were to get involved, thereby leaving companies with little incentive to invest towards research and development.¹¹

This paper is a benefits analysis to the services provided by the

² *Id.* at 14 (“Whether it is desirable to have for-profit industry occupy key roles in the healthcare system is a legitimate question . . .”).

³ See discussion *infra* Part II.A.

⁴ Michael A. Santoro, *Introduction to Charting a Sustainable Path for the Twenty-First Century Pharmaceutical Industry*, in *ETHICS AND THE PHARMACEUTICAL INDUSTRY* 1, 1 (Michael A. Santoro & Thomas M. Gorrie eds., 2005).

⁵ See David Leonhardt, *Dr. James Will Make it Better*, N.Y. TIMES MAG., Nov. 8, 2009, at 30, 32 (“The health care debate of 2009 has had so many moving parts that it has sometimes seemed impossible to follow. The crisis behind the debate, though, is about one thing above all: the scattershot nature of American medicine.”). See generally Leonard J. Nelson, III, *Rationing Health Care in Britain and the United States*, 7 J. HEALTH & BIOMEDICAL L. 175, 181–88 (2011) (discussing the recent heated debates with regard to healthcare reform in the United States, from the viewpoints of bioethicists, politicians, and healthcare experts).

⁶ NAT’L HEALTH STATISTICS GRP., OFFICE OF THE ACTUARY, CTRS. FOR MEDICARE & MEDICAID SERVS., THE NATION’S HEALTH DOLLAR (\$2.5 TRILLION), CALENDAR YEAR 2009: WHERE IT WENT, available at <https://www.cms.gov/Research-Statistics-Data-and-Reports/NationalHealthExpendData/downloads/PieChartSourcesExpenditures2009.pdf>.

⁷ WEBER, *supra* note 1, at 13.

⁸ *Id.* at 152–53.

⁹ *Id.* at 152.

¹⁰ See Santoro, *supra* note 4, at 1–4.

¹¹ See Sidney Taurel, *The Campaign Against Innovation*, in *ETHICS AND THE PHARMACEUTICAL INDUSTRY* 326, 328–29 (Michael A. Santoro & Thomas M. Gorrie eds., 2005).

pharmaceutical industry and aims to address and clarify a few of the many misperceptions about the industry. The pharmaceutical industry is often portrayed as having unethical business practices, and the industry fails to fall into a positive light—more often than not—becoming a target amongst the media, the general public, and politicians.¹² I would like to expose readers to the pharmaceutical world I knew in my former career as a pharmaceutical representative¹³ and provide one viewpoint from the other side—the story that is often not told by those who are quick to blame pharmaceutical companies for the problems affecting the healthcare industry.¹⁴

More specifically, I plan on addressing the practices that are the most widely criticized by opponents: direct-to-consumer marketing,¹⁵ physician-directed marketing,¹⁶ and the so-called lack of regulations governing the pharmaceutical industry's practices.¹⁷ Part II of this paper will begin the discussion by providing relevant background information in order to gain insight into the pharmaceutical industry's world. The background will cover the drug development process from Petri dish to pharmacy, the economic effect of the pharmaceutical industry, and what pharmaceutical marketing entails. Part III will continue an exploration of the pharmaceutical industry by discussing several laws and regulations that govern the industry's research, development, and marketing. The research and development

¹² See Gardiner Harris, *Drug Makers Seek to Mend Their Fractured Image*, N.Y. TIMES, July 8, 2004, at C1 (“The share of Harris Poll respondents . . . [with] a positive attitude about the pharmaceutical industry has fallen 35 points since 1997, more than any other industry. Drug makers now share the bottom of the rankings with oil, managed care and tobacco companies. . . . [with only] 13 percent of poll respondents describ[ing] pharmaceutical companies as generally honest and trustworthy.”).

¹³ After graduating with a B.S. in Biology, I began a career as a pharmaceutical sales representative for Pfizer in upstate New York. For three years, I worked with physicians in the fields of primary care, urology, neurology, cardiology, pain management, pulmonology, obstetrics and gynecology, and rheumatology. I remained with Pfizer Inc. until I began law school.

¹⁴ See Scott Velasquez, *There Ain't No Such Thing as a Free Lunch: A Look at State Gift Disclosure Laws and the Effect on Pharmaceutical Company Marketing*, 41 J. MARSHALL L. REV. 563, 563–64 (2008) (describing how the “free lunches” provided to doctors create a conflict of interest for recipient healthcare providers); see also Amanda L. Connors, Comment, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73 ALB. L. REV. 243, 243 (2009) (“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.”).

¹⁵ See discussion *infra* Part IV.B.1.

¹⁶ See discussion *infra* Part IV.B.2.

¹⁷ See discussion *infra* Part III.

("R&D") process can span decades, and many times the profit generated barely covers the expense of R&D.¹⁸ In fact, many drugs, even after years of research, will fail once they reach the Food and Drug Administration ("FDA") process, and by then, millions of dollars have already been spent by the pharmaceutical company, only to see no return.¹⁹ Part IV will argue that the industry's highly criticized marketing practices are distorted perceptions and will provide a balanced discussion in favor of many pharmaceutical practices. Many of the industry's practices have voluntarily evolved²⁰ and the industry is now a good citizen trying to do the right thing. Part V will conclude with a discussion of how the industry can continue to evolve in the right direction, both for the average consumer and industry insiders.

II. BACKGROUND INFORMATION

A. *Research and Development*

Drug development is both a "lengthy and costly process."²¹ Pharmaceutical companies are spending tremendous amounts of money on research and development ("R&D") and not necessarily seeing an equal rate of return.²² In 2010, according to Pharmaceutical Research and Manufacturers of America ("PhRMA"), the pharmaceutical industry spent an estimated \$67.4 billion on R&D alone and, importantly, over twenty percent of sales went directly to R&D.²³ According to a study from 2003 ("DiMasi study"), which analyzed sixty-eight randomly selected new drugs from ten pharmaceutical companies in 1997, the expense of bringing a *single* new drug to the market was estimated to cost pharmaceutical companies \$802 million.²⁴ As of 2005, it was estimated that the expense of bringing a new drug to the market

¹⁸ See discussion *infra* Part II.A.

¹⁹ STEPHEN J. CECCOLI, PILL POLITICS: DRUGS AND THE FDA app. at 165 (2004) ("Estimates suggest that the average duration of the drug development process . . . is approximately fifteen years.").

²⁰ See WEBER, *supra* note 1, at 66.

²¹ Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 152 (2003).

²² See *id.* at 182.

²³ PHARM. RESEARCH & MFRS. OF AMERICA, PHARMACEUTICAL INDUSTRY: 2011 PROFILE, KEY FACTS 11, http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf (last visited Jan. 8, 2013) [hereinafter KEY FACTS].

²⁴ DiMasi et al., *supra* note 21, at 157, 157 n.15, 166.

had increased to \$1.3 billion.²⁵ The authors of the DiMasi study previously considered profitability and return rates versus pharmaceutical R&D, and they had “not found evidence of significant and sustained excess profits.”²⁶ Surprisingly to many, only two out of ten marketed drugs return revenues that match or exceed R&D costs.²⁷

What makes bringing a new drug to the market expensive? There are several factors to consider, including the gamble that drug companies make in drug development, the amount of time R&D takes, and most importantly, the FDA's approval process.²⁸ A significant aspect of developing a new drug is meeting the FDA's standards for safety, efficacy, and marketing.²⁹ The federal government's involvement requires FDA approval at two stages of the drug development process.³⁰

The initial phases of development, called pre-clinical testing, take place in the pharmaceutical laboratory where experiments are conducted between the new drug and the disease that is being researched for a cure to see if the drug has any effect on the disease.³¹ During these experiments the research is concerned with safety, toxicity, and biological activity and the experiments are only performed on animals and/or involve other laboratory studies, which do not include humans.³² This period alone, for a single compound, can take, on average, three to four years to complete, and typically 5000 compounds are evaluated at a given time.³³ Once the pre-clinical testing is finished, the company will file an investigational new drug application (“IND”) with the FDA.³⁴

Once the IND application is approved, clinical testing can begin on humans.³⁵ There are three stages to clinical testing: Phase I, Phase II, and Phase III.³⁶ Phase I involves twenty to eighty healthy

²⁵ KEY FACTS, *supra* note 23, at 2.

²⁶ DiMasi et al., *supra* note 21, at 182.

²⁷ KEY FACTS, *supra* note 23.

²⁸ *See generally* CECCOLI, *supra* note 19, app. at 165–71 (explaining that as a result of the numerous factors and “increasing complexities,” the drug development process is approximately an average of fifteen years—nearly double the average length of the process during the 1960s).

²⁹ *Id.* app. at 165.

³⁰ *Id.*

³¹ *Id.* app. at 166.

³² *Id.*

³³ *Id.* app. at 166–67.

³⁴ *Id.* app at 166; *see also* 21 C.F.R. § 312.20 (2012) (outlining the requirements for an IND).

³⁵ CECCOLI, *supra* note 19, app. at 166.

³⁶ 21 C.F.R. § 312.21 (2012).

volunteers, and the goals are to determine the safety and toxicity of the compound, its *in vivo* behavior, and preliminary dosage requirements or potential indications for the drug.³⁷ Phase II consists of 100 to 300 volunteers who are afflicted with the disease being researched and the potential compound to combat it.³⁸ This phase lasts around two years and the goal is to determine effectiveness and side effects of the compound.³⁹ Typically, only 5 of the original 5000 compounds will enter Phase II.⁴⁰ Phase III involves controlled experiments with 1000 to 3000 volunteers whom physicians monitor during a trial period.⁴¹ At this stage, which lasts about three years, the goal is to verify effectiveness and monitor effects of long-term use.⁴² Here, dosage can be more accurately defined, and the FDA requires adverse reactions that were reported early on to be further monitored during this phase.⁴³ Typically, the studies are controlled, following a form of randomized, double-blind, placebo-controlled investigation so that neither the investigator nor the patient knows who is taking a placebo.⁴⁴

After the clinical testing phase is over, the company submits a

³⁷ CECCOLI, *supra* note 19, app. at 166; *see also* 21 C.F.R. § 312.21(a) (“Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug’s pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80. . . Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.”)

³⁸ CECCOLI, *supra* note 19, app. at 166; *see also* 21 C.F.R. § 312.21(b) (“Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.”).

³⁹ CECCOLI, *supra* note 19, app. at 167.

⁴⁰ *Id.*

⁴¹ CECCOLI, *supra* note 19, app. at 166; *see also* 21 C.F.R. § 312.21(c) (“Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects.”).

⁴² *See* 21 C.F.R. § 312.21(c); CECCOLI, *supra* note 19, app. at 167.

⁴³ *See* CECCOLI, *supra* note 19, app. at 168.

⁴⁴ *Id.*

new drug application (“NDA”) to the FDA, which includes the data and analyses of safety and efficacy of the compound from all the phases of clinical investigation.⁴⁵ The FDA review phase is performed by three FDA centers consisting of physicians, pharmacologists, chemists, microbiologists, and statisticians.⁴⁶ In addition to FDA reviewers, there are also advisory committees making decisions with regard to the compounds.⁴⁷

FDA review is followed by Phase IV, which consists of post-marketing testing, where the FDA will use adverse reactions reported by the public to educate physicians, pharmacists, and patients when safety concerns arise.⁴⁸ There are several methods used by the FDA to educate consumers, including: (1) providing “Dear Healthcare Professional” letters which contain product safety information to the aforementioned individuals; (2) directing the pharmaceutical company to alert consumers with brochures and advertising themselves; (3) instructing the pharmaceutical company to change labeling on the product and restrict the use of the drug further; or (4) requiring that the company to withdraw the product entirely from the market.⁴⁹

B. Industry Profits

Despite the high stakes involved in drug R&D, the pharmaceutical industry has most definitely prospered. For instance, in 2001, it was “ranked first in . . . return on revenues.”⁵⁰ However, as of 2011, only two pharmaceutical companies were ranked in the top fifty of Fortune 500 companies with regards to revenue, and neither of these two pharmaceutical companies ranked in the top twenty-five.⁵¹ Additionally, the profits tend to be “overstated” because R&D is counted as an expense rather than as an investment, which is untraditional as compared to most other business models.⁵² This skews the ratio of profits to total

⁴⁵ 21 C.F.R. § 310.303 (2012).

⁴⁶ See CECCOLI, *supra* note 19, app. at 168.

⁴⁷ *Id.* at 169.

⁴⁸ See *id.* at 171.

⁴⁹ 21 C.F.R. § 310.305 (2012).

⁵⁰ CECCOLI, *supra* note 19, at 130 (citations omitted).

⁵¹ Fortune 500 2011, CNN MONEY, http://money.cnn.com/magazines/fortune/fortune500/2011/full_list (last visited Jan. 8, 2013). Pfizer was ranked thirty-first with \$67.809 million in revenue, and Johnson & Johnson was ranked fortieth with revenue of \$61.587 million. *Id.*

⁵² 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

investment by creating a smaller denominator, making the return on investment seem larger than it really is.⁵³ While the industry is certainly profitable, profits may be incorrectly perceived by the general public as grossly higher than they really are, thus further fueling criticism of the industry.⁵⁴

C. Economic Impact of the Pharmaceutical Industry and the Value of Medicines

Health economists have studied the economic impact of medical advances for years. Although the United States has been criticized for spending more on healthcare than other countries, with no obvious improvement in life expectancy,⁵⁵ a recent study which examined five major disease states⁵⁶ found that returns on investment in medical improvements in these conditions “substantially outweigh[ed] the costs for four of these diseases.”⁵⁷ The study concluded that the increase in costs was, overall, worth the medical care that was provided.⁵⁸ Similarly, another study “estimate[d] the returns on investment for medical research at greater than 100:1.”⁵⁹ This same study found that an “increase in U.S. population longevity between just 1970 and 2000 was worth an additional \$75 *trillion* to the U.S. economy, and that further

11, 11 (Jillian Clare Cohen et al. eds., 2006) (“Because R&D is left out of investment, the ratio of profits to total investment is distorted; the denominator is artificially small.”).

⁵³ *Id.* See also DAVID H. AUSTIN ET AL., CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 4 (2006) [hereinafter CBO STUDY], available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugrd.pdf> (“By standard accounting measures, the pharmaceutical industry consistently ranks as one of the most profitable industries in the United States. Those measures, however, treat most R&D outlays as expenditures rather than as investments that add to the value of a firm. Thus, they omit from a firm’s asset base the value of its accumulated stock of knowledge. For R&D-intensive industries, such as pharmaceuticals, that omission can significantly overstate profitability. Adjusted for the value of its R&D assets, the drug industry’s actual profitability still appears to be somewhat higher than the average for all U.S. industries, but not two to three times higher, as standard measures of profitability indicate.”).

⁵⁴ See Lexchin, *supra* note 52, at 11.

⁵⁵ Joel W. Hay, *The Application of Cost-Effectiveness and Cost-Benefit Analysis to Pharmaceuticals*, in ETHICS AND THE PHARMACEUTICAL INDUSTRY 225, 232–33 (Michael A. Santoro & Thomas M. Gorrie eds., 2005) (footnotes omitted).

⁵⁶ See generally David M. Cutler & Mark McClellan, *Is Technological Change in Medicine Worth It?* 20 J. HEALTH AFF., Sept. 2001, at 11, 19, available at <http://content.healthaffairs.org/content/20/5/11.full> (examining five conditions, including heart attacks, low-birth-weight infants, depression, cataracts, and breast cancer).

⁵⁷ Hay, *supra* note 55, at 233, 233 tbl.14.1 (finding that a one-year increase in life expectancy provided a \$70,000 value, and after \$10,000 in treatment costs was spent, a net benefit of \$60,000).

⁵⁸ *Id.* at 233–34.

⁵⁹ *Id.* at 234 (footnote omitted).

reducing heart disease mortality by just 10 percent would be worth an additional \$5 trillion to Americans.”⁶⁰ Since the approval of antiretroviral drugs for HIV/AIDS treatments, the AIDS death rate in the United States has dropped by more than seventy-five percent since 1995, and according to the American Heart Association, cardiovascular disease death rates have dropped by twenty-eight percent between 1997 and 2007.⁶¹

Pharmaceutical companies have lent a supportive hand to the economy, and their contributions to society's health, as discussed above, are notable. From an employment perspective, as of 2005, the pharmaceutical industry directly provided 655,025 jobs, and when indirect or induced jobs were taken into consideration, 3.1 million jobs were created by the pharmaceutical industry.⁶²

Although Europe spends sixty percent less than the United States on R&D—and other countries have been able to obtain life expectancies and disease reductions similar to those in the United States—some health economists suggest that the international community is likely “free-riding” on the advances made by the United States.⁶³ Also, it is undeniable that U.S. citizens are paying more than their European counterparts for medicines, mostly because these drugs are greatly subsidized in these countries.⁶⁴ However, if the same subsidies were to occur in the United States, it is likely that the decrease in revenue for the pharmaceutical companies would affect R&D first, which in turn suggests an increase in costs to the international community who is currently “free-riding.”⁶⁵

⁶⁰ *Id.*

⁶¹ KEY FACTS, *supra* note 23, at 21–22.

⁶² *Id.* at 5.

⁶³ Hay, *supra* note 55, at 234–35.

In 2002, Germany saved \$19 billion because it spent much less per head than America on [prescription] drugs. On the other hand . . . in the same year, Germany lost out on \$4 billion from R&D, patents and related benefits that went elsewhere. It lost \$8 billion because high-value jobs went somewhere else . . . German drug firms would have made \$3 billion more profit if they had kept pace with rivals elsewhere. A further \$2 billion was lost as the country shed corporate headquarters and the benefits they bring. The cost of poorer-than-necessary health was \$5 billion. . . . In sum, it reckons that Germany's \$19 billion saving is in fact a \$3 billion net loss.

Id. at 235 (final alteration in original) (quoting *The Trouble with Cheap Drugs*, ECONOMIST (Jan. 29, 2004), <http://www.economist.com/node/2388708>).

⁶⁴ See AM. ASS'N OF RETIRED PERSONS, AARP EUROPEAN LEADERSHIP STUDY: EUROPEAN EXPERIENCES WITH PRESCRIPTION DRUG PRICING 3, 8 (2006), available at http://assets.aarp.org/www.aarp.org/_cs/gap/ldrstudy_prescdrugs.pdf (discussing the higher costs in the United States due to the lack of price limits and differing payment systems).

⁶⁵ See *id.* (describing how favorable drug prices drive R&D).

D. Marketing

1. Direct-to-Consumer Advertising

After spending millions to get their lifesaving or life-improving product on the market, the pharmaceutical industry employs a wide-array of procedures to assure that their drugs are made available to the public. Marketing by the industry consists of direct-to-consumer advertising (“DTCA”) and physician-directed marketing.⁶⁶ DTCA is a pharmaceutical company’s way of presenting prescription drugs and/or information about diseases to the general public through various forms of media.⁶⁷ DTCA can range from the advertisements displayed on television, to advertisements in magazines, and more recently, online websites.⁶⁸ In 2003, the industry spent \$25.6 billion on drug promotions, and of that amount, 87.5% went to free samples and representative visits to physicians, and 12.5% went to DTCA.⁶⁹

In my experience, the goal of DTCA is to increase market share for the new drug by bringing awareness to a particular disease that the drug treats.⁷⁰ The industry employs three different types of ads to promote awareness.⁷¹ Full-product advertisements will name the drug and its indications, and discuss the benefits of the medication along with risks associated with the drug.⁷² Reminder advertisements will only name the drug, such as displaying its logo, but will not discuss any of the drug’s benefits or risks.⁷³ Help-seeking advertisements will present a disease state, like overactive bladder, for example, and persuade patients to talk to their physician about treatment options for that condition, such as an anti-cholinergic medication to reduce visits to the bathroom.⁷⁴

When *Chantix*, a smoking-cessation medication, was released, several of the pharmaceutical company’s commercials consisted of

⁶⁶ See Thomas Abrams, *The Regulation of Prescription Drug Promotion*, in ETHICS AND THE PHARMACEUTICAL INDUSTRY 153, 154–55 (Michael A. Santoro & Thomas M. Gorrie eds., 2005) (detailing the shift from a focus on the practitioner as the customer to the individual consumer as the customer).

⁶⁷ SHAILI JAIN, UNDERSTANDING PHYSICIAN-PHARMACEUTICAL INDUSTRY INTERACTIONS 59 n.1 (2007).

⁶⁸ *Id.* at 59.

⁶⁹ Santoro, *supra* note 4, at 127–28.

⁷⁰ See *infra* Part IV.B.1.

⁷¹ Abrams, *supra* note 66, at 156.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

help-seeking advertisements which brought awareness to the public about the health risks involved with smoking cigarettes and the importance of quitting sooner rather than later.⁷⁵ These commercials did not name *Chantix* in their particular ads, and instead aimed to increase awareness about smoking and the benefits of quitting.⁷⁶ The pharmaceutical company, as well as the sales representatives, hoped that the viewer or reader would bring up quitting smoking with their physician at their next doctor's visit, and the physician might prescribe the product that the pharmaceutical company had created.⁷⁷ Essentially, the company informed sales representatives at training that it is increasing treatment of a disease state, and thus increasing overall profits for a particular class of drugs used to treat the disease, of which it hopes some of the benefit will funnel to the company's drug.⁷⁸

2. Physician-Directed Marketing

Physician-directed marketing consists of "detailing" by pharmaceutical representatives and publishing ads in medical journals read by physicians.⁷⁹ "Detailing" is considered to be the most effective way of promoting medicines in the pharmaceutical industry.⁸⁰ On average, a pharmaceutical representative will contact eight to ten medical offices in a day⁸¹ with the goal of distributing samples, providing information on new medicines, or updating physicians on medications with which they are already familiar.⁸²

"Detailing" the physician occurs when a representative discusses medications with a physician.⁸³ Traditionally, in my experience,

⁷⁵ Pfizer's non-branded commercials lead consumers, who are interested in quitting smoking, to a Pfizer website. See A PLAN FOR QUITTING SMOKING: MY TIME TO QUIT, <http://www.mytimetoquit.com> (last visited Jan. 8, 2013). The website does not mention Pfizer's quit-smoking medication, *Chantix*, but does name Pfizer Inc. as the copyright holder. See *id.*

⁷⁶ See *id.*

⁷⁷ Whenever a new product commercial was launched, district managers of sales representatives would guide their representatives to converse with physicians about the commercials.

⁷⁸ For instance, when an erectile dysfunction drug was to be advertised during the Super Bowl, the company would inform the sales representatives of the millions of potential viewers who may respond to the advertisement by visiting their physician shortly thereafter.

⁷⁹ JAIN, *supra* note 67, at 12.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² See *id.*

⁸³ *Id.*

“detailing” consisted of a brief presentation about a medication to a doctor with the use of a sales brochure or “detail aid” which contained details of clinical studies, side effects, and efficacy rates versus competitors. Next, the representative was trained to answer the doctor’s questions and try to “close” the sales call by getting the doctor to commit to prescribing the drug.

However, based on my actual experiences in doctors’ offices, the practice of detailing has evolved to meet multiple new challenges. Representatives now find themselves trying to assist the doctors in prescribing their product by describing not only efficacy and side effects, but also costs. In a world of “me-too” drugs,⁸⁴ sometimes the competition between companies is no longer focused on which drug works better, or has the least side effects, because the efficacy and side effects are fairly comparable. Instead, in my encounters, the cost of the medication and availability to patients dominated most discussions between physicians and representatives.

The cost of medications to patients is based on a variety of things including what, if any, type of health insurance coverage they may have (Medicaid, Medicare, or private payor).⁸⁵ Many states have adopted price measures and access controls to reduce Medicaid drug costs, and pharmaceutical companies are required to provide their drugs to Medicaid and Medicare with immense rebates to which there is little, if any, profitability.⁸⁶ Insurance companies, much like Medicare and Medicaid, each have their own “formularies” at which branded and generic drugs are priced based on a tier level.⁸⁷ This may be one reason why “detailing” by representatives, in my experience, has become cost-focused. It is nearly impossible for a doctor to know every insurance company’s formulary status, for each patient she sees a day, for every drug she prescribes. Often, during a “detail,” the representative will provide the tier information for the physician about a drug they commonly prescribe, as the formularies change each year. As a

⁸⁴ See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1773 (1996).

⁸⁵ See William C. Weldon, *A Future Agenda for Government-Industry Relations*, in ETHICS AND THE PHARMACEUTICAL INDUSTRY 282, 284 (Michael A. Santoro & Thomas M. Gorrie eds., 2005); *Health Insurance*, USA.GOV, <http://www.usa.gov/Citizen/Topics/Health/HealthInsurance.shtml> (last updated Jan. 02, 2013).

⁸⁶ Weldon, *supra* note 85, at 288.

⁸⁷ Charles L. Bardes, *Ethics and Prescribing: The Clinician’s Perspective*, in ETHICS AND THE PHARMACEUTICAL INDUSTRY 136, 147 (Michael A. Santoro & Thomas M. Gorrie eds., 2005).

pharmaceutical representative, knowledge of formularies is more likely to assist the physician in a discussion about a product and help patients in the long run, which is the goal of both physicians and most sales representatives.⁸⁸

There are many different types of details that can be employed by representatives.⁸⁹ When I was a representative, I found that if the doctor only had a few minutes, the representative would ask the doctor if they needed samples for a particular product, especially if they were already familiar with the drug. They would ask the doctor to sign for the samples and remind them about a safety or efficacy point with the medication. If, however, there was more time to speak to a doctor, the representative was provided with an opportunity to find out what the physician's concerns were with prescribing a drug for a particular disease state which the representative is familiar with. This required the representative to be knowledgeable about cost, efficacy, side effects, contraindications, and more.

Having gone through training with a large pharmaceutical company, I remember being told that representatives must know "a lot about a little," in terms of the few disease states that they are going to represent, because doctors know "a little about a lot." A representative for a large pharmaceutical company may, for example, provide information to physicians about four particular disease states, and be an expert in those four diseases, while a counterpart representative with the same company may be an expert in three to four other disease states.

Based on the conversations I had with physicians about medications, a representative must be able to speak with the physician at their educational and clinical experience level.⁹⁰ This is why the training for pharmaceutical representatives can be long and tedious. In training to become a pharmaceutical representative, I had to learn the entire disease state for a particular product (for example the Urinary System) before I learned about the product used to treat the condition. There would

⁸⁸ See GEOFFREY HEAL, *WHEN PRINCIPLES PAY: CORPORATE SOCIAL RESPONSIBILITY AND THE BOTTOM LINE* 96–97 (2008).

⁸⁹ JAIN, *supra* note 67, at 13.

⁹⁰ See Andrea Santiago, *Pharmaceutical Sales Representative—Career Profile and Jobs for Pharma Reps*, ABOUT.COM HEALTH CAREERS, <http://healthcareers.about.com/od/healthcareerprofiles/p/PharmaRep.htm> (last visited Jan. 8, 2013) (“[R]eps must have the ability to memorize vast amounts of medical terminology and detailed information about the medication they represent, and be able to intelligently relay the information to physicians.”).

be a disease state examination where one had to attain an eighty-five percent passage rate and there was an additional examination on the product itself, requiring the same passage rate.⁹¹ The disease state examination consisted of questions regarding the anatomy of that particular part of the human body, the systems involved, and the disease itself. The product examination consisted of questions about the science of the product, how it worked in the body, adverse reactions, side effects, package insert details, and studies used to obtain product approval by the FDA or to gain additional indications for the product. Furthermore, the representatives would have to learn about competitor products to understand the differences between their product and other companies' competing products. The "modules" used to study for these tests consisted of books which were hundreds, if not thousands, of pages long for each medication.⁹²

An additional service provided by pharmaceutical companies, via their representatives, is product sampling.⁹³ During the years I was a representative, the physician was required to sign for receipt of the samples on a form, and later a computer screen, acknowledging the number of samples they received from the company, for each product. By signing the form, the physician also agreed not to use the sample for personal reasons for herself or others, and agreed not to resell the samples. Many companies, including Pfizer, do not call the products distributed to offices "samples," but are instead called "starters" because the purpose of the "starters" is to allow a patient to "start" treatment by trying a product for its efficacy and safety before they are committed to purchasing a thirty-day to ninety-day supply of the product.⁹⁴ The practice at Pfizer for pharmaceutical representatives was to leave formulary information (based on that office's population), rebates or coupons that were available, and information on financial assistance programs for those who needed help paying for their medicines.⁹⁵

⁹¹ Once a representative was hired at Pfizer they underwent seven phases of training. The first phase involved taking multiple-choice tests on diseases and Pfizer medications.

⁹² Prior to orientation at Pfizer, sales representatives would receive a box of books for each drug they would eventually promote to physicians. Each box contained individual books on the disease, the product, the side effects, and studies used to establish the product with the FDA.

⁹³ See JAIN, *supra* note 67, at 45–49.

⁹⁴ *Id.* at 46.

⁹⁵ When Pfizer became aware that discussions between representatives and physicians were becoming increasingly focused on cost, they initiated a directive to distribute formulary information to physicians.

III. LAWS AND REGULATIONS GOVERNING PHARMACEUTICAL PRACTICES

The pharmaceutical industry is one of the most highly regulated industries in the world.⁹⁶ The rules that pharmaceutical companies follow can span anywhere from those required by law, such as federal regulations, to those that are formed by either public interest groups or pharmaceutical companies themselves.⁹⁷ There are three main statutes that govern pharmaceutical companies: the Medicare and Medicaid Anti-Kickback Statute,⁹⁸ the civil False Claims Act,⁹⁹ and the Prescription Drug Market Act ("PDMA") of 1987, which governs the distribution of drug samples.¹⁰⁰ Additionally, the Office of the Inspector General of the U.S. Department of Health and Human Services issues guidelines to pharmaceutical companies for developing programs to ensure legal compliance.¹⁰¹

In terms of marketing, the FDA's Center for Drug Evaluation and Research ("CDER") not only evaluates drugs for safety and effectiveness before they are approved, but also monitors them once they are on the market.¹⁰² Their efforts include monitoring the drug for unexpected side effects that might arise, and informing the public and healthcare professionals of any updates.¹⁰³ Additionally, the CDER oversees advertising of prescription drugs to both consumers and physicians to ensure that the drug advertisement "contain[s] a truthful summary of information about its effectiveness, side effects and circumstances when its use should be

⁹⁶ See Bryan D. Sullivan, *Reconciling the Terms and Spirit of the Law: Pharmaceutical Sales Representatives and the FLSA Outside-Sales Exemption*, 96 IOWA L. REV. 1429, 1448 (2011).

⁹⁷ See PHARM. RESEARCH & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS 1, 5, 11 (2008) [hereinafter PhRMA Code], available at http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf.

⁹⁸ 42 U.S.C. § 1320a-7b (2006).

⁹⁹ 31 U.S.C. § 3729 (2006).

¹⁰⁰ 21 U.S.C. §§ 331(t), 333(b) (2006).

¹⁰¹ See Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions under the Anti-Kickback Statute, 64 Fed. Reg. 63,518 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001); see also OIG Compliance Program Guidance for Pharm. Mfrs., 68 Fed. Reg. 23,731 (May 5, 2003) (setting forth views on principles of compliance programs and what pharmaceutical manufacturers should consider when implementing compliance programs).

¹⁰² 2007 Update: *Improving Public Health Through Human Drugs*, CTR FOR DRUG EVAL. & RESEARCH, FOOD & DRUG ADMIN., U.S. DEPT OF HEALTH & HUMAN SERVS., 1, 7 (2007), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/WhatWeDo/UCM121704.pdf> [hereinafter CDER REPORT].

¹⁰³ *Id.* at 37.

avoided.”¹⁰⁴

On September 27, 2007 the FDA Amendments Act of 2007, which modified the Food, Drug, and Cosmetic Act, became law and began the official supervision of the pharmaceutical industry’s advertising for the first time.¹⁰⁵ The Act specifically addresses DTCA regulations.¹⁰⁶ The FDA was given authority to require pharmaceutical companies to submit all DTC television advertisements for FDA review, before the ads are made public.¹⁰⁷ If a company runs “false or misleading direct-to-consumer prescription drug advertisements” the FDA has the authority to seek civil monetary penalties,¹⁰⁸ and even pull the ad entirely from running.¹⁰⁹ The Act “requires that the statement of risks in . . . advertisements . . . be presented in a clear, conspicuous and neutral manner, and that print [advertisements] include information on how to report adverse drug events to FDA.”¹¹⁰

In addition to civil monetary penalties, the FDA also issues two types of letters to companies in order to ensure compliance with drug advertising and promotion regulations.¹¹¹ The first is called a “Regulatory Action Letter” which is sent to companies whose advertisements were not “truthful, fairly balanced, and not misleading.”¹¹² One of these letters is usually sent as either an “untitled letter” for general violations, or as a “warning letter” for more serious violations.¹¹³ A second type of letter is usually issued to companies during the “launch” or introduction of a new product to the market.¹¹⁴ These “Campaign Advisory Letters” are usually sent after the FDA reviews promotional materials, before the drug is launched.¹¹⁵ The number of letters issued by the FDA to pharmaceutical companies has dropped from 254 letters in 2003, to 188 letters in 2007, and the increase in regulation may be a reason

¹⁰⁴ *Id.* at 7.

¹⁰⁵ *Id.* at 46.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Prescription Drug Advertising: Questions and Answers*, FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/UCM076768.htm> (last updated Sept. 13, 2012).

¹¹⁰ CDER REPORT, *supra* note 102, at 46.

¹¹¹ *Id.* at 44.

¹¹² *Id.*

¹¹³ Abrams, *supra* note 66, at 162.

¹¹⁴ See CDER REPORT, *supra* note 102, at 44.

¹¹⁵ *Id.*

for the reduction in letters.¹¹⁶

The Consumer-Directed Broadcast Advertisements guide issued by the FDA provides direction on how to meet regulatory requirements with DTCA.¹¹⁷ The goal of the guide is to provide package insert (“PI”)¹¹⁸ access to consumers who are watching or hearing about the ads.¹¹⁹ The four items an advertisement may contain to provide access to a PI include: (1) listing a phone number where consumers can find the PI; (2) a Web site where consumers can view the PI; (3) a reference to a print ad where consumers could read a brief summary, without reading the entire PI; and (4) a reference to a healthcare professional where one can obtain additional information about the product, that is not answered by the PI.¹²⁰

In terms of self-regulation, the Pharmaceutical Research and Manufacturers of America (“PhRMA”) developed a code of conduct in 2002 that applies mostly to pharmaceutical representatives.¹²¹ The focus of the PhRMA Code is on marketing activities and it “prohibit[s] companies from giving doctors inducements to prescribe their products in the form of payments, lavish gifts or extravagant hospitality.”¹²² Although adherence to the Code is voluntary, forty-six pharmaceutical companies are members of PhRMA, including some of the largest pharmaceutical companies in the world: Johnson & Johnson, Pfizer, Abbott Laboratories, Merck, and Eli Lilly.¹²³ The year I was employed by Pfizer—2007—the company was already effectuating PhRMA’s “guidelines” in full force as the governing, and *mandatory*, rules for all representatives to follow.

The PhRMA Code governs many topics including: the

¹¹⁶ *Id.* at 47.

¹¹⁷ Abrams, *supra* note 66, at 157.

¹¹⁸ A package insert is a package of information that is provided with each prescription or sample for consumers to educate themselves on the risks, benefits, and usage of the particular medication that they will consume. See *The FDA Announces New Prescription Drug Information Format*, FOOD & DRUG ADMIN., U.S. DEPT OF HEALTH & HUMAN SERVS., <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm188665.htm> (last updated Nov. 2, 2009) (explaining the purpose and advantages of the package insert).

¹¹⁹ See Abrams, *supra* note 66, at 157.

¹²⁰ *Id.*

¹²¹ See PhRMA Code, *supra* note 97, at 3.

¹²² JAIN, *supra* note 67, at 37.

¹²³ KEY FACTS, *supra* note 23, at 36–38; NICOLE GRAY, CHANGING LANDSCAPES: A SPECIAL REPORT ON THE WORLD’S TOP 50 PHARMA COMPANIES, PHARM. EXEC. 80–82 (2006), available at <http://www.pharmexec.com/pharmexec/data/articlestandard/pharmexec/272006/354138/article.pdf>.

informational presentations given by pharmaceutical representatives to physicians and their accompanying meals, continuing medical education support, consultants, speaker training and programs, scholarships and educational funds, educational items that are given to healthcare professionals, and training and conduct of representatives.¹²⁴

The Code specifically prohibits entertainment and recreation:

To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, companies should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items; (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.¹²⁵

The Code goes on to say that meals may only be provided to a healthcare professional if they are both “modest” and “occasional.”¹²⁶ A “modest” meal at Pfizer, in my experience, was generally defined as eight to ten dollars per healthcare professional, per meal.

The Code also prohibits pharmaceutical companies from providing non-educational and practice-related items:

Providing items for healthcare professionals’ use that do not advance disease or treatment education—even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar ‘reminder’ items with company or product logos)—may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues. Such non-educational items should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials.

Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) likewise should not be

¹²⁴ PhRMA Code, *supra* note 97, at 1.

¹²⁵ *Id.* at 5.

¹²⁶ *Id.*

offered.

Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

It is appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.¹²⁷

In addition to self-regulation, there is a federal regulation—21 C.F.R. § 203.1—governing drug samples provided by pharmaceutical companies.¹²⁸ Although many critics will argue that the PhRMA Code is a voluntary and arbitrary set of guidelines,¹²⁹ in my former company the Code was taken very seriously. As soon as PhRMA would update its guidelines, Pfizer was one of the first companies to immediately implement the new policy changes. For example, the prohibition on free gifts by PhRMA began about a year after I was employed at Pfizer. Immediately we were asked to ship all “gifts” amounting to pens, notepads, tissue boxes, etc., back to the company warehouses and to discontinue distribution, effective immediately. Pfizer was not alone; the week that the policies were implemented, the vast majority of other pharmaceutical companies had also immediately ceased providing any “gifts.”

IV. ETHICAL ISSUES

The pharmaceutical industry has been demonized for the manner in which it markets its products after the products have cleared the FDA approval process and become available to the public.¹³⁰ Many critics point out how much money is spent on marketing to consumers and physicians, and that this money could be put towards research and development (“R&D”) instead of marketing.¹³¹

¹²⁷ *Id.* at 11–12.

¹²⁸ *See* 21 C.F.R. § 203.1 (2012).

¹²⁹ Connors, *supra* note 14, at 244.

¹³⁰ *See* Matthew F. Hollon, *Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand*, 281 JAMA 382, 382 (1999) (describing the negative effects of DTCA and calling for stricter FDA guidelines surrounding DTCA approval). *See generally* JAIN, *supra* note 67, at 13, 48–49 (criticizing drug sampling and interactions between pharmaceutical representatives and physicians).

¹³¹ *See* Connors, *supra* note 14, at 246–47.

Critics also argue that consumers and physicians are vulnerable, unable to make decisions for themselves, and are being brainwashed by the pharmaceutical industry.¹³² However, studies have demonstrated that physicians can remain uninfluenced¹³³ and are able to make informed decisions for their patients and consumers, who are vigilant and highly informed in today's day and age.¹³⁴

Consumers, today, are much more educated about the healthcare system, and take accountability for their well-being.¹³⁵ Thanks to the abundance of Internet access for most members of society, people have developed an information-seeking addiction that allows them to search for almost any question or concern that they may have.¹³⁶ Patients are able to take control of their health and look into symptoms and treatments available for diseases that they have been diagnosed with.¹³⁷ Pharmaceutical companies simply recognized the trend towards information seeking, and responded by providing information in areas where information was being sought.¹³⁸ This section will provide both the critics' arguments of marketing practices, and an industry-insider's insight, on the positive effects of the pharmaceutical industry's marketing practices, more specifically: (1) DTCA and (2) physician-directed marketing.

A. *Adverse Reactions: Critical Opinions of the Pharmaceutical Industry*

Recent headlines in major newspapers read: “\$8B Fines, but Drug Fraud Continues,”¹³⁹ “Fees to Doctors by Drugs Makers to be

¹³² See *id.* at 276.

¹³³ 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, 1479 (2004) (finding that only five percent of physicians said that “[his or her] prescribing practices [were] affected by gifts”).

¹³⁴ See Alan F. Holmer, *Direct-to-Consumer Prescription Drug Advertising Builds Bridges Between Patients and Physicians*, 281 JAMA 380, 381 (1999) (describing “participatory health care” and how consumers are “assuming more responsibility for their own health”).

¹³⁵ See Abrams, *supra* note 66, at 155.

¹³⁶ *Id.*

¹³⁷ *Id.* (noting that the percentage of consumers who are seeking information from the Internet about medications grew from eighteen percent in 1999 to thirty-eight percent in 2002).

¹³⁸ *Id.*

¹³⁹ Kelly Kennedy, *\$8B Fines, but Drug Fraud Continues*, USA TODAY, Mar. 6, 2012, at A1.

Disclosed,”¹⁴⁰ “*Useless Studies, Real Harm*.”¹⁴¹ So what are the critics saying and what exactly is behind the mass media coverage of the industry? Valid criticisms do exist, for sure. For example, fraud in the pharmaceutical industry has been in the news quite frequently, and for good cause.¹⁴² Collectively, the largest pharmaceutical companies have paid at least \$8 billion in fines for Medicare and Medicaid fraud over the last ten years.¹⁴³ Pfizer alone paid \$3 billion in fines during this time period for improperly promoting the use of drugs for purposes other than for what they were approved by the FDA.¹⁴⁴ Merck has paid \$1.6 billion in fines since 2008 for not providing the mandated lowest rebates to the government for medications being taken by Medicare and Medicaid beneficiaries.¹⁴⁵

The criticism lies mostly with the penalties imposed for such fraud. Typically, in addition to the severe monetary penalties that are imposed, the companies' only other penalties are requirements to sign “corporate integrity agreements” with the Office of Inspector General (“OIG”), a division of the U.S. Department of Health and Human Services (“HHS”).¹⁴⁶ Corporate integrity agreements (“CIAs”) are created as a part of a settlement between providers and other entities when there are allegations of violations of civil false claims statutes.¹⁴⁷ Usually, the agreements are imposed on companies for five years, and require companies to implement procedures to prevent them from defrauding the government again.¹⁴⁸ However, many see these “promises” not to defraud as “not sufficient to deter further misconduct” because many of the larger companies are signing, not one, but multiple CIAs for various

¹⁴⁰ Robert Pear, *Fees to Doctors by Drug Makers to be Disclosed*, N.Y. TIMES, Jan. 17, 2012, at A1.

¹⁴¹ Carl Elliot, Op-Ed., *Useless Studies, Real Harm*, N.Y. TIMES, Jul. 29, 2011, at A27.

¹⁴² See *supra* notes 139–41 and accompanying text.

¹⁴³ Kennedy, *supra* note 139.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ See *Corporate Integrity Agreements*, OFFICE OF INSPECTOR GENERAL, U.S. DEPT OF HEALTH & HUMAN SERVS., <http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp> (last visited Jan. 8, 2013).

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* (“[Companies are required to] hire a compliance officer/appoint a compliance committee; develop written standards and policies; implement a comprehensive employee training program; retain an independent review organization to conduct annual reviews; establish a confidential disclosure program; restrict employment of ineligible persons; report overpayments, reportable events, and ongoing investigations/legal proceedings; and provide an implementation report and annual reports to OIG on the status of the entity’s compliance activities.”).

violations, suggesting that the CIAs are not acting as sufficient deterrents to fraud.¹⁴⁹

The government has suggested new tactics to control fraud, such as going after individuals as opposed to the company.¹⁵⁰ Individuals have been prosecuted before in this manner. In 2008, a district manager for Pfizer was charged with obstruction of justice for altering and deleting documents from his own computer, and for directing his representatives to delete e-mails from their computers about the off-label promotion.¹⁵¹ However, in this case, Pfizer reported the employee to the federal government when they learned of the employee's conduct, and they cooperated in the investigation and prosecution of the case.¹⁵² Other tactics, such as preventing companies from providing medications to Medicare and Medicaid beneficiaries, would hurt companies' sales, however this type of penalty would have deeper negative impacts on the Medicare and Medicaid beneficiaries, who would be unable to get the medications that they are prescribed.¹⁵³

In addition to fraud, critics also point to the marketing by pharmaceutical companies as an area where reform is needed.¹⁵⁴ Legislation calling for stricter guidelines on marketing to consumers is based on evidence that advertising lowers "price sensitivity" and raises the price of medications.¹⁵⁵ Pharmaceutical companies employ heavy promotions of their medications and on average twenty to thirty percent of sales are spent on marketing to consumers.¹⁵⁶ Spending on pharmaceutical promotional materials is only growing. Between 1996 and 2005, DTCA increased by 330%.¹⁵⁷ With increasing costs of medications, the growing elderly population, and a declining economy, the prices of branded medications have come under scrutiny, and many claimed that the expenses spent on marketing could be reduced thereby reducing

¹⁴⁹ See Kennedy, *supra* note 139 (quoting Gregory Demske, Assistant Inspector General for Legal Affairs in HHS) (internal quotation marks omitted).

¹⁵⁰ *Id.*

¹⁵¹ Jim Edwards, *Pfizer District Sales Manager Guilty of Altering Off-Label Celebrex Documents*, CBS NEWS, Mar. 19, 2009, http://www.cbsnews.com/8301-505123_162-42840956/pfizer-district-sales-manager-guilty-of-altering-off-label-celebrex-documents.

¹⁵² *Id.*

¹⁵³ See Kennedy, *supra* note 139.

¹⁵⁴ See Connors, *supra* note 14, at 256–57.

¹⁵⁵ See John A. Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drugs*, 42 J. L. & ECON. 89, 91 (1999).

¹⁵⁶ *Id.* at 90.

¹⁵⁷ Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED., 673, 673, 675 (2007).

drug prices.¹⁵⁸

Studies have shown that payments to doctors for speaking engagements, research, and consulting, influence doctors' decisions, and raise costs by causing more branded medications to be prescribed.¹⁵⁹ Under the newly passed Affordable Care Act, pharmaceutical companies will be required to report all payments to healthcare providers, including lunches brought to offices, research, and any financial contributions to healthcare institutions.¹⁶⁰ These payments will be posted on a federal website and the accuracy of the payment reporting will be audited by the government.¹⁶¹ If a company fails to make a payment disclosure, the company will be fined \$10,000.¹⁶² Many companies have already undertaken the practice of full disclosure and have been reporting payments on their websites for years.¹⁶³ However, the new health law will make it mandatory for all companies to comply.¹⁶⁴ This attempt at transparency aims to reconcile the conflict of interest that may present itself when physicians form working relationships with pharmaceutical companies and their representatives.¹⁶⁵

B. Mislabeled: Why the Pharmaceutical Industry's Marketing Practices are Actually Beneficial

1. Direct-to-Consumer Advertising ("DTCA")

Critics of DTCA argue that the advertisements have more negative consequences than positive consequences.¹⁶⁶ However, the benefits to DTCA are plentiful, proven, and can outweigh many of the negative effects. While there may be evidence that medications cost more due to marketing, the very same advertising may provide benefits such as: (1) an increase in awareness and reduction in the stigma (for example, depression) behind certain conditions that keep people from seeking care, thus encouraging treatment; (2) adherence to medication regimens; (3) can make consumers more

¹⁵⁸ *Id.* at 678.

¹⁵⁹ *See* Pear, *supra* note 140.

¹⁶⁰ *See id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *See infra* notes 235–37 and accompanying text.

¹⁶⁴ *See* Pear, *supra* note 140.

¹⁶⁵ *See generally* Velasquez, *supra* note 14, at 584–85 (describing the public mistrust of the pharmaceutical industry and how almost half the states' legislatures have seen "gift disclosure legislation" proposals).

¹⁶⁶ *See* Hollon, *supra* note 130, at 382.

attentive to diagnoses and potential treatments; (4) improve communication between physicians and consumers who are increasingly knowledgeable; and (5) increase patient autonomy because patients are better able to weigh the risks and benefits of treatment choices.¹⁶⁷ Whether patients benefit from DTCA, or whether they are harmed by marketing, remains the ultimate question.

Critics argue that the advertisements do not accurately or fairly provide the risks and benefits of the medication being advertised,¹⁶⁸ and that the general consumer “lack[s] the expertise to assess the quality of the content of the advertisements.”¹⁶⁹ However, proponents of DTCA argue that physicians serve as a “safety net, preventing the inappropriate use of prescription drugs.”¹⁷⁰ One could also argue that patients are not as incompetent as they seem, and that patients are aware that the advertising is not to be confused with complete and unbiased health information.¹⁷¹ These are not public information advertisements supplied by the government.¹⁷² Consumers are more informed today, more than they ever were,¹⁷³ and many understand that pharmaceutical companies’ desire for profits are driving these advertisements.¹⁷⁴ Presently, and historically, these profits have led to new lifesaving treatments and have improved the quality of life for many.¹⁷⁵

¹⁶⁷ See Meredith B. Rosenthal & Julie M. Donohue, *Direct-to-Consumer Advertising of Prescription Drugs: A Policy Dilemma*, in *ETHICS AND THE PHARMACEUTICAL INDUSTRY* 169, 169 (Michael A. Santoro & Thomas M. Gorrie eds., 2005); see also JAIN, *supra* note 67, at 60 (discussing some of the advantages of DTCA).

¹⁶⁸ JAIN, *supra* note 67, at 60.

¹⁶⁹ Alan Lyles, *Direct Marketing of Pharmaceuticals to Consumers*, 23 ANN. REV. PUB. HEALTH, 73, 78 (2002).

¹⁷⁰ Hollon, *supra* note 130, at 383; see also Rosenthal & Donohue, *supra* note 167, at 179 (“The key difference . . . is that a doctor or other licensed prescriber must participate in the purchasing decision.”).

¹⁷¹ But see Michael S. Wilkes et al., *Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, and Implications*, 19 J. HEALTH AFF., 110, 117 (2012), available at <http://content.healthaffairs.org/content/19/2/110.full.pdf>. (“[F]ew consumers have the clinical and pharmacologic background to properly understand and evaluate DTC advertisements. These advertisements thus may lead to confusion and inaccurate perceptions of a drug’s effectiveness and safety.”).

¹⁷² See Hollon, *supra* note 130, at 383.

¹⁷³ Julia Pennbridge et al., *Questionnaire Survey of California Consumers’ Use and Rating of Sources of Health Care Information Including the Internet*, 171 W. J. MED. 302, 302 (1999), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1308740/pdf/westjmed00315-0016.pdf>.

¹⁷⁴ Hollon, *supra* note 130, at 382–83 (“The pharmaceutical industry’s interest in the bottom line is legitimate. The industry, which has made important medical contributions, exists because it is profitable.”).

¹⁷⁵ See *supra* notes 55–62 and accompanying text.

The FDA's regulations on DTCA are designed to make sure that the advertisements are fair and balanced, in order to avoid causing harm to the public.¹⁷⁶ Consumers can view the advertising with an understanding of the risks and benefits and couple it with the expertise of their physician during diagnoses to receive the best medication for their ailment. With highly-regulated advertisements, vigilant consumers, and physicians, a mutually symbiotic relationship can exist between pharmaceutical companies and consumers if companies are allowed to continue advertising their new treatments.

The argument that physicians' expertise will help consumers sort through the risks and benefits of medications that they view in DTCA, lends credence to an additional argument by critics that a physician's precious time with a patient is already constrained enough without having to talk patients out of a medication that they have seen on television that is not suitable for them.¹⁷⁷ Yet, it can be argued that doctors are provided with an opportunity to help consumers figure out any potential misguidance from an advertisement when a patient approaches them, without the expertise to comprehend the advertisement, and in fact the majority of doctors view these discussions with patients as constructive.¹⁷⁸

Critics also argue that "DTC advertising . . . cultivate[s] the belief among the public that there is a pill for every ill and contribute[s] to the medicalization of trivial ailments, leading to an even more medicated society . . ." ¹⁷⁹ However, consumer surveys suggest that DTCA actually motivates consumers to discuss their "untreated conditions with their physicians."¹⁸⁰ In one study, half of all consumers who talked to their physicians about a drug were seeking treatment for the condition for the first time, and of those, only eight percent asked for a prescription,¹⁸¹ suggesting that under-diagnosed conditions are being treated more often because of DTCA, and patients are not necessarily being "brain-washed" by asking for a drug;¹⁸² instead, patients are simply seeking treatment after becoming educated on a condition that may be afflicting them.¹⁸³

¹⁷⁶ See discussion *supra* Part III.

¹⁷⁷ See Carol Rados, *Truth in Advertising: Rx Drug Ads Come of Age*, 38 FDA CONSUMER, Aug. 2004, at 20, 23.

¹⁷⁸ Rosenthal & Donohue, *supra* note 167, at 180.

¹⁷⁹ Rados, *supra* note 177, at 23 (internal quotation marks omitted).

¹⁸⁰ Rosenthal & Donohue, *supra* note 167, at 173 (emphasis added).

¹⁸¹ *Id.* at 174 (citations omitted).

¹⁸² See *id.*

¹⁸³ See *id.*

The physician can then determine if the condition is “trivial” or not.

Adherence to treatment therapy also increases with DTCA, especially in areas where considerable improvement in adherence is needed, such as diabetes, depression, and high cholesterol.¹⁸⁴ One study found that following a period of high advertising, those who were diagnosed with depression were more likely to fill the prescription they were prescribed for depression, than those following a period of low advertising.¹⁸⁵ Another study found that DTCA for hyperlipidemia did reduce gaps between filling prescriptions, while another study found that DTCA for antidepressants increased the probability that someone with depression received treatment for the appropriate duration of time.¹⁸⁶ The reason for the increased treatment adherence may be that those who have seen advertisements have been educated about the disease, drugs and other therapy, and their benefits and risks.¹⁸⁷

Another criticism of DTCA is that “consumers must bear . . . costs in the form of higher [drug] prices” because of the amount of money that is spent on DTCA.¹⁸⁸ However, one study suggested that “changes in marketing costs are unlikely to have a direct effect on pharmaceutical prices.”¹⁸⁹ The studies and data on this point are mixed.

Critics argue that the advertisements are geared towards increasing a particular brand’s market share over its competitors.¹⁹⁰ However, that would lead one to believe that expanding treatment, as discussed earlier, is not one of the industry’s goals. Several studies have been performed to determine whether DTCA expands treatment for under-diagnosed conditions.¹⁹¹ This further enhances the argument in favor of DTCA, because once again, DTCA is encouraging the patient to discuss a condition with their doctor and the doctor is able to have a candid discussion with them. Most studies have demonstrated that DTCA has a considerable impact on total class sales of any given condition, but a slight influence over individual product market share.¹⁹² Therefore, a particular disease

¹⁸⁴ *Id.* at 177.

¹⁸⁵ *Id.* (citations omitted).

¹⁸⁶ *Id.* (citations omitted).

¹⁸⁷ *Id.* at 177–78.

¹⁸⁸ Donohue et al., *supra* note 157, at 678.

¹⁸⁹ *Id.*

¹⁹⁰ Rosenthal & Donohue, *supra* note 167, at 173.

¹⁹¹ *Id.*

¹⁹² *Id.* (“A recent study of the impact of DTCA on aggregate sales of prescription drugs in

state, like depression for example, may be treated at a higher rate due to DTCA, but no one single anti-depressant will gain from the increase in diagnoses.

Additionally, DTCA is not the only driver in what type of medication a patient will be prescribed, and eventually continue therapy on. Health plans and formularies will largely control which medications the patient receives, based on what is available on the patient's individual plan.¹⁹³ Although the doctor will write the prescription, many times the prescription will change from what was prescribed by the doctor, to what will actually be covered by the insurance company.¹⁹⁴ Ultimately, it is not the advertisement that is driving the sale of the prescription, but instead the insurance company.¹⁹⁵ The pharmaceutical companies can only hope that if the treatment the doctor intends to prescribe is the best option for the patient, that the doctor, patient, and pharmaceutical company will together find a solution to the formulary's denial and get the best prescription in the patient's hands.

2. Physician-Directed Marketing

Critics of physician-directed marketing argue that the strategy employed by pharmaceutical companies to impact doctors' prescribing habits is unethical.¹⁹⁶ Many of the valuable services provided by pharmaceutical representatives have been criticized for being "forceful and deceptive."¹⁹⁷ Yet interestingly, ninety-five percent of physicians surveyed indicated that the distribution of free samples, detailing, and modest meals did not affect their prescribing practices.¹⁹⁸ However, other studies suggest that patients believe there is an improper influence¹⁹⁹ whether doctors

five therapeutic classes . . . found that although DTCA was associated with an increase in sales to the therapeutic class as a whole, it had no impact on market share.").

¹⁹³ Bardes, *supra* note 87, at 147.

¹⁹⁴ *See id.*

¹⁹⁵ *See* Holmer, *supra* note 134, at 381 ("There's no detail man or pharmaceutical company or patient that puts a gun to a doctor's head to write a prescription. Ultimately, it isn't the patient's signature on the prescription—it's the doctor's.") (internal quotation marks omitted) (citing Elyse Tanouye, *Drug Ads Spur Patients to Demand More Prescriptions*, WALL ST. J., Dec. 22, 1997, at B1).

¹⁹⁶ *See generally* Connors, *supra* note 14, at 256–57 (criticizing free samples, gift distribution, and other marketing tactics by pharmaceutical sales representatives).

¹⁹⁷ *Id.* at 256.

¹⁹⁸ *See* Halperin, *supra* note 133, at 1479 (finding that ninety-six percent of physicians who responded to a survey admitted to accepting at least one gift from pharmaceutical manufacturers).

¹⁹⁹ EMILY CLAYTON, CALPIRG, 'TIS ALWAYS THE SEASON FOR GIVING: A WHITE PAPER ON

admit it or not.²⁰⁰

There is legitimacy to the concerns about influence, and these concerns were behind the changes to the PhRMA Code.²⁰¹ The pharmaceutical industry's change of procedures made major headway by addressing the issues of unethical marketing practices to physicians, and the common negative perceptions by patients about marketing tactics, by doing away with pens, notepads, lavish meals, and trips.²⁰² Most companies' goals are to promote interactions between pharmaceutical representatives and physicians, which provide physicians with an opportunity to learn about cost of medications, new formulations, new dosages, and drug combinations.²⁰³

Critics argue that free samples are usually the most expensive of the options available to treat a condition, and when patients are provided these samples they are encouraged to use the medication for longer periods of time, which leads to higher healthcare expenses.²⁰⁴ However, based on my discussions with physicians, sampling provides a way to evaluate effectiveness and tolerability of the medication for a patient before they invest in a prescription.²⁰⁵ For example, looking at one common ailment, overactive bladder ("OAB")²⁰⁶—there are several anti-cholinergic agents (OAB treatments) on the market with varying efficacy and side effects. A physician who diagnoses a patient with OAB has the flexibility to start the patient on a medication for three months without any expense to the patient (the amount of samples recommended to get an idea for tolerability and efficacy with OAB agents) and then bring the patient back for a follow-up after three months to see how

THE PRACTICE AND PROBLEMS OF PHARMACEUTICAL DETAILING 4 (2004), available at <http://www.wcl.american.edu/pijip/documents/CALPIRG-September2004.pdf> (finding that approximately seventy percent of patients believe that gifts to their physicians impact prescribing habits).

²⁰⁰ See Connors, *supra* note 14, at 266 (finding that sixty-one percent of physicians believed that they were immune to pharmaceutical marketing tactics); see also Halperin, *supra* note 133, at 1479 (indicating that thirty-three percent of physicians believed that they were not affected by pharmaceutical marketing tactics, but other physicians were).

²⁰¹ See Clayton, *supra* note 198, at 6.

²⁰² See *supra* text accompanying notes 121–29.

²⁰³ See JAIN, *supra* note 67, at 46.

²⁰⁴ *Id.* at 48.

²⁰⁵ *Id.* at 46.

²⁰⁶ OAB is "a condition in which the bladder muscle cannot be controlled, squeezes too often or squeezes without warning." Press Release, U.S. Food & Drug Admin., FDA Approves Myrbetriq for Overactive Bladder (June 28, 2012), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310096.htm> (reporting on the approval of a new drug to treat OAB).

the patient is doing.²⁰⁷ This is done at no expense to the patient,²⁰⁸ and the doctor is able to play with the various treatment options to find the one that best suits the patient at hand. This is an invaluable way to save both the patient and physician time, money and frustration. Furthermore, medication samples are a way of providing free medications to indigent patients,²⁰⁹ and their use can promote goodwill between the patient and physician.²¹⁰ The drug samples that the representative leaves behind are incredibly valuable and are, arguably, the best service a representative can provide to patients.

Further, skeptics argue that the interactions between representatives and physicians are imbalanced and provide skewed data with regards to the efficacy and side effects of the medications that they are promoting against their competitors.²¹¹ In my experience, pharmaceutical representatives' interactions with physicians consisted of providing balanced information about the company's products and the corresponding disease state. The training that representatives go through, again in my personal experience, strictly prohibits omission of important information about the medication and other details. Naturally, representatives tend to be one sided; however their assertions are substantiated with scientific facts.²¹² The discussions can span anywhere from new studies about the disease state itself to new studies about the medications used to treat the disease. Interestingly, but not surprisingly, most discussions always began or ended with doctors' questions about the cost of the medications that I was providing.

I would argue that cost is the reason why the interactions between pharmaceutical representatives and providers have become even more prominent and necessary. Take the typical interaction: the representative stops by a urology office to discuss Detrol LA and how it can improve the quality of life for someone who is suffering from an OAB.²¹³ The representative will most likely start off by

²⁰⁷ Urologists often conveyed to representatives that patients responded to anti-cholinergic agents over a period of three months, and this is why they preferred to distribute three months' worth of samples to OAB patients.

²⁰⁸ Drug samples are provided to patients at no out-of-pocket cost.

²⁰⁹ JAIN, *supra* note 67, at 46.

²¹⁰ *Id.*

²¹¹ Bardes, *supra* note 87, at 148; Connors, *supra* note 14, at 261.

²¹² Bardes, *supra* note 87, at 148.

²¹³ Although OAB has been criticized by some as a disease-state that is not really as bad as the commercials make it seem, it is such a prevalent and debilitating condition that primary care physicians are unable to treat it well, and most patients suffering from OAB are seeing a specialist (a urologist) for relief. See Press Release, Food & Drug Admin., *supra* note 206.

asking the doctor if they are having any trouble prescribing the medication or if they or their patients have come across any obstacles, such as prior-authorizations.²¹⁴ Prior authorizations are a tactic used by insurance companies to keep costs down by requiring a physician to fill out masses of paper work only for branded medications that the insurance company does not want to pay for.²¹⁵ The representative can educate the physician on the availability of the medication that he is trying to prescribe using formulary information, and help get the medication in the patient's hands quicker.²¹⁶

Once the doctor shares whether or not she has been having any difficulty, the representative will remind the doctor of benefits and risks.²¹⁷ In my experience, most of the time, the interaction between the representative and the physician will end here, with the physician signing for samples. The representative will then distribute patient brochures with the samples, or place brochures in the waiting rooms (many that are unbranded) to increase awareness about different disease states.²¹⁸

Further, critics argue that the meals provided by pharmaceutical representatives to healthcare professionals and their staff are intended to get the physician to prescribe more of their company's medication.²¹⁹ However, in my experience, the interaction would consist of a modest, occasional lunch—the only time of day that the physician could see the representative occurred when the physician's office would normally take a break for meals. This is why representatives often visit at the lunch hour and provide lunch

²¹⁴ See John M. Grohol, *Prior Authorization: The Bane of Doctors*, PSYCHCENTRAL, <http://psychcentral.com/blog/archives/2008/04/03/prior-authorization-the-bane-of-doctors> (last updated Apr. 3, 2008) (“Prior authorization means that a doctor can't prescribe a particular medication (or type of medication) without . . . prior authorization from the insurance company.”).

²¹⁵ *Id.*

²¹⁶ See *supra* notes 87–89 and accompanying text.

²¹⁷ For example, I would try to convince the physician by stating: “Detrol LA may reduce the number of trips your patient has to make to the bathroom, but a common side effect is dry mouth and the product is contraindicated in patients with urinary retention” or “this insurance company is covering Lipitor at third-tier now so your patients will have to pay forty-five to fifty dollars a month, instead of the fifteen to twenty dollars that they were paying. Here is a coupon for those patients to take some of the extra cost off of their co-pay.”

²¹⁸ Many of these pamphlets not only contained coupons, but also contained ways to make lifestyle changes to further increase the likelihood of reducing or eliminating symptoms that the patient might be having. For example, the quit-smoking drug, *Chantix*, had a pamphlet with a smoker's log where smokers could write down what triggered their desire to smoke, in order to help them avoid those triggers.

²¹⁹ See Connors, *supra* note 14, at 243–44.

while they are there. Only healthcare providers were allowed to join the meal, during which a representative would discuss the benefits and risks of the company's medications.²²⁰ There was absolutely zero *quid pro quo*²²¹ in my experiences providing modest meals to physicians. That would be a violation of federal law.²²² Additionally, the expenses incurred during the day were closely monitored and randomly audited by the pharmaceutical company for accuracy and compliance to ensure that representatives and physicians were not taking advantage of the system with bribes or excess spending. Following the interaction with the physician, the pharmaceutical representative would make sure that there were enough drug samples and patient-centric literature for distribution, should the physician choose to prescribe the medication that day.²²³

Opponents contend that physicians receive misinformation from pharmaceutical companies and the physician is not fully informed when he is making a decision about which drug to prescribe.²²⁴ I would argue that it is not the pharmaceutical representative's role to ensure proper use of all medications provided to patients, but instead it is the prescribing physician's responsibility, along with pharmacists who dispense the medications. Physicians are highly educated individuals, arguably more so than people in most other occupations. It is unlikely that physicians are prescribing medications without an understanding of the medication itself. However, if they are prescribing a medication wrongly, the pharmacist is a good safety net in those occasions.

Additionally, most physicians are now equipped with tablet PC's and palm-sized devices where they can type in a medication and quickly retrieve side effects and contraindications at the touch of a button. These types of technological advances can also protect against incorrect prescribing. And, thanks to electronic medical records ("EMR"), it will become impossible to prescribe drugs that interact with one another because the EMR will not allow the physician to prescribe drugs incorrectly.²²⁵

²²⁰ Following each meal, a receipt from the meal along with a signed roster of who attended the lunch was submitted to the company.

²²¹ "This for that." See also BLACK'S LAW DICTIONARY 1367 (9th ed. 2009) ("An action or thing that is exchanged for another action or thing of more or less equal value . . .").

²²² See *supra* Part III.

²²³ Often times, the patient-centric literature would provide information on lifestyle changes that one could make in order to ease their symptoms. For example, with OAB, the pamphlet would suggest avoiding caffeine and drinking too many fluids before bedtime.

²²⁴ See Bardes, *supra* note 87, at 148; Connors, *supra* note 14, at 261.

²²⁵ Kenny Lin, *Electronic Medical Records: No Cure-All for Medical Errors*, US NEWS &

Skeptics argue that physicians believe that they are immune to a representative's sales detail but in reality they are "engaged in a corrupted, symbiotic relationship with [pharmaceutical companies], where they personally benefit in exchange for writing prescriptions."²²⁶ Because of this ethical dilemma—or perception of a dilemma—non-educational gift giving is completely prohibited by the PhRMA Code.²²⁷ Additionally, in my experience, physicians are not going to prescribe drugs for any other reason than to assure that their patient receives the best treatment. This is required for doctors by medical ethics²²⁸ and the fear of medical malpractice is a constant reminder to practice medicine with the patient's best interest in mind, first and foremost.²²⁹

Interactions between physicians and representatives can be positive, informative, balanced, and provide information that will help patients. The spotlight on the interactions by critics of the industry has led to making the interactions stronger and better in the public's best interests. The pharmaceutical representative has become an asset for physicians who are trying to find their way through a maze of private insurance, Medicaid, Medicare Part D, and the constant changes that occur in the pharmaceutical sciences. The fact that the pharmaceutical industry voluntarily changed its practices by eradicating the generous gifts, trips, and any gift giving of pens or other items, supports the idea that the industry is a good citizen trying to do the right thing and is recognizing its prior missteps.

V. HOW TO IMPROVE NEGATIVE PERCEPTIONS

Getting to the root of the negative perceptions and understanding where the negative perceptions are coming from is probably the best way to address the perceptions and try to correct them. One viewpoint with regard to where the criticism stems from is that the pharmaceutical industry became immensely prosperous during a

WORLD REP. (Dec. 23, 2010), <http://health.usnews.com/health-news/blogs/healthcare-headaches/2010/12/23/electronic-medical-records-no-cure-all-for-medical-errors> (“[Electronic systems] offer safeguards against accidental prescriptions of drugs patients are on record as being allergic to, and drugs that may not mix safely with others patients are taking . . .”).

²²⁶ Connors, *supra* note 14, at 265.

²²⁷ See *supra* notes 121–30 and accompanying text (discussing the PhRMA Code).

²²⁸ MARC D. HILLER, *MEDICAL ETHICS AND THE LAW: IMPLICATIONS FOR PUBLIC POLICY* 5 (1981).

²²⁹ See Ryan T. Emery, *Unwise and Unnecessary: Statutory Caps on Non-Economic Damages in Medical Malpractice Cases and the Appellate Review Alternative*, 69 ALB. L. REV. 913, 916 (2006).

period where lifesaving and life-enhancing drugs were changing millions of lives for the first time.²³⁰ From this perspective, many viewed the profits by pharmaceutical companies as justified because so many lives were being saved and improved.²³¹ Since the start of the twenty-first century, however, the public is beginning to feel as if the industry's profits are not "sufficiently matched by contributions to the common good."²³² Herein lies the animosity towards pharmaceutical companies. The economy is faltering, and the issue of uninsured citizens being deprived of lifesaving medicines is at the forefront of the healthcare reform debate.²³³ Companies are less steadily producing the same lifesaving drugs in comparison to when the industry first began to thrive.²³⁴

The path to improving perceptions has begun by the self-regulations imposed by pharmaceutical companies in requiring a patient-centric focus in all interactions with healthcare professionals. Despite the notion that pens and other odds and ends likely did not change prescribing behavior of physicians, the perception amongst the public was one of bribery by pharmaceutical companies.²³⁵ The prohibition of gifts was a major step in the right direction.

Additionally, full disclosure by pharmaceutical companies will also help to address some of the unfounded allegations of what benefits physicians are receiving from pharmaceutical companies. In January 2010, voluntary healthcare provider disclosures went into effect for all physicians in the United States for several pharmaceutical companies.²³⁶ Pfizer joined the transparency movement and created a website where anyone can search the name of a physician to see what, if anything, they are receiving from Pfizer.²³⁷ For example, if a physician were to receive a lunch from a representative, the cost of this lunch would be divided amongst the number of providers in attendance at the lunch. If the meal were seventy-five dollars and there were ten people in attendance,

²³⁰ See Santoro, *supra* note 4, at 1.

²³¹ *Id.*

²³² *Id.* at 1–2.

²³³ See DiMasi et al., *supra* note 21, at 152.

²³⁴ See CBO STUDY, *supra* note 53, at 1.

²³⁵ See discussion *supra* Part II.D.2 (physician-directed marketing).

²³⁶ See Pfizer's Disclosure of Payments to HCPs Frequently Asked Questions, PFIZER, INC., http://www.pfizer.com/responsibility/working_with_hcp/faqs_hcp.jsp (last visited Jan. 8, 2012).

²³⁷ See Sheryl Williams, *HCP Disclosure: A False Sense of Transparency?*, MED. MARKETING & MEDIA (Nov. 13, 2009), <http://www.mmm-online.com/hcp-disclosure-a-false-sense-of-transparency/article/158840>.

including six nurses and four doctors, the seventy-five dollars would be divided by the four doctors and listed on the website if the doctor was searched by name. This initiation of transparency was started by Eli Lilly and Merck²³⁸ and should increase transparency of other companies. This will hopefully lead many to realize the true extent of the interactions between providers and the industry, instead of exaggerations created by some critics.

One last method to improve perceptions would be to address the real and serious problem that is at the heart of the pharmaceutical controversy: drug costs that arise from the high-risk nature of research and development (“R&D”) of new drugs.²³⁹ One viewpoint in addressing this issue is a suggestion that the R&D costs be mitigated by the government in a way that will continue to encourage innovation but also provide medications at more affordable prices for more people.²⁴⁰ As discussed earlier, because the cost of medications reflects the cost of producing the next generation of drugs, and not the actual direct cost of producing the drug being paid for,²⁴¹ the government could step in to assist in the R&D of future drugs.

The viewpoint on government involvement suggests that “[a] potential solution to the problem of rewarding drug innovation . . . would be to have the government establish . . . patent buy-outs, or guaranteed government drug purchases payable to successful innovators in return for putting drug patent rights into the public domain.”²⁴² This argument is thought-provoking because it preserves innovation by leaving R&D to the pharmaceutical companies, but also reduces their overhead, thereby placing drugs in the hands of more people at a more affordable price.²⁴³ This theory suggests that the government would buy the patents from the pharmaceutical companies after the FDA approves the medication.²⁴⁴ Otherwise, the government could purchase the compound prior to its approval by the FDA, and after its discovery by the industry, and the government could do the rest of the studies required for approval.²⁴⁵

²³⁸ *Id.*

²³⁹ *See supra* Part II.A.

²⁴⁰ Hay, *supra* note 55, at 244.

²⁴¹ Weldon, *supra* note 85, at 284.

²⁴² Hay, *supra* note 55, at 244.

²⁴³ *Id.*

²⁴⁴ *Id.*

²⁴⁵ *See id.*

There are a few important points in this argument that preserve innovation. First, the patent system would remain in effect and the companies would not be forced to sell their compounds.²⁴⁶ The companies could proceed and compete individually as before, especially if the company feels as if it has developed two drugs: one that is a blockbuster drug and the other is a less marketable drug (less financially-incentivizing), which could be sold to the government.²⁴⁷ The price of the compound buyout by the government would be based on a cost-effectiveness and cost-benefit analysis.²⁴⁸

Ensuring that innovation survives is the key to guaranteeing that future lifesaving medications will be produced; however, the industry will be forced along with the government to address the issue of millions of people without adequate medications. Collaboration by the two entities, while ensuring a free market, would be a step in the right direction.

VI. CONCLUSION

Perception and reality are often confused; especially in times when people are looking to point a finger of blame for all that has gone wrong within the healthcare crisis. The pharmaceutical industry can continue to thrive and remain profitable so long as it is willing to be transparent with its practices. My years as a pharmaceutical representative gave me perspective on the great deal of value that pharmaceutical companies provide to physicians and patients, especially when a company and its representatives share a common goal with physicians: to provide the best options for patients. There is merit to many critics' arguments, however, the industry is well on its way to correcting many of the ethical dilemmas it imposes with its drive for new medicines and profits to sustain research and development.

The path towards the industry improving and providing even greater benefits does not lie with the industry itself but with all partners of the industry, including the government and the medical community. Once all of the players in the healthcare community align, solutions to the negative perceptions of the industry, and solutions for the future can be discussed and implemented. In the

²⁴⁶ *Id.*

²⁴⁷ *See id.*

²⁴⁸ *Id.* at 245.

334

Albany Law Review

[Vol. 76.1

meantime, pointing fingers at one industry will not resolve any issues.