

NOTE

Medical Marketing in the United States: A Prescription for Reform

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INTRODUCTION: DRUG AND DEVICE MARKETING

Each year, physicians in the United States write more than three billion prescriptions, or about twelve prescriptions per American.¹ In 2009 alone, the United States spent some \$300 billion on prescription drugs.² Similarly, the medical device market accounts for around \$200 billion in annual sales.³ With so much money at stake, it should come as no surprise that drug and device companies invest massive sums in aggressive marketing.

Estimates vary,⁴ but the pharmaceutical and medical device industries spend around \$30 billion per year on marketing efforts de-

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¹ Janet Lundy, *Prescription Drug Trends*, HENRY J. KAISER FAM. FOUND. (Sept. 2008), http://www.kff.org/rxdrugs/upload/3057_07.pdf.

² Duff Wilson, *Drug Companies Increase Prices in Face of Change*, N.Y. TIMES, Nov. 16, 2009, at A1.

³ Peter Stone, *Take Two Kickbacks . . .*, MOTHER JONES, Nov. 2, 2009, at 18.

⁴ See MARCIA ANGELL, *THE TRUTH ABOUT DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 120 (2004) (estimating \$54 billion in marketing expenditures for 2001); Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription*

signed to maximize market share, and doctors are one of their main targets.⁵ On average, the drug and medical device industries spend over \$20,000 per doctor each year on marketing efforts that include gifts, meals, travel, consultancy fees, and continuing medical education programs.⁶ The reach of medical marketing has grown so broad that one recent survey reported that ninety-four percent of physicians have received some form of benefit or payment from the drug and device industries.⁷ For example, on any given day, pharmaceutical companies pay to deliver lunch to the twenty or so doctors and employees of Nassau Queens Pulmonary Associates in New York.⁸ Moreover, the practice of paying for meals is alarmingly widespread. Indeed, “some [doctors’] offices get breakfast and lunch every day” courtesy of drug and device companies.⁹

Pharmaceutical outreach, however, is not limited to bagels and brunch. Drug companies flood doctors’ offices with branded trinkets—everything from paper and pens to mugs and mousepads—in an effort to push the latest prescription medicines.¹⁰ Under an educational guise, paid and highly trained¹¹ sales representatives en-

Drugs, 357 NEW ENG. J. MED. 673, 675 (2007) (estimating \$29.9 billion in marketing expenditures for 2005); Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 29, 30 (2008), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2174966/pdf/pmed.0050001.pdf> (estimating \$57.5 billion in marketing expenditures for 2004); Verispan Year in Review—2007 (June 12, 2008) (presentation by Tara Hamm) (on file with author) (estimating \$20.4 billion in marketing expenditures for 2007). Estimates vary widely due to inconsistent data availability, varying metrics, and excluding payments made to doctors for speaking engagements and consulting fees from marketing estimates. See Andrew Miner & Alan Menter, *The Ethics of Consulting with Pharmaceutical Companies*, 27 CLINICS DERMATOLOGY 339, 340 (2009) (“The total amount of money presently spent on physician consulting is unknown.”).

⁵ Andrew Pollack, *Stanford to Ban Drug Makers’ Gifts to Doctors, Even Pens*, N.Y. TIMES, Sept. 12, 2006, at C2 (noting that “[a]bout 90 percent of the pharmaceutical industry’s \$21 billion marketing budget is directed at physicians”).

⁶ A recent study estimated that the United States has 788,000 active doctors. Douglas O. Staiger et al., *Comparison of Physician Workforce Estimates and Supply Projections*, 302 JAMA 1674, 1678 (2009). Pharmaceutical companies spend \$18.9 billion on them every year, amounting to some \$23,984.77 per doctor. See Pollack, *supra* note 5.

⁷ Eric G. Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 N. ENG. J. MED. 1742, 1746 (2007).

⁸ Stephanie Saul, *Drug Makers Pay for Lunch as They Pitch*, N.Y. TIMES, July 28, 2006, at A1.

⁹ *Id.*

¹⁰ See Dana Katz et al., *All Gifts Large and Small*, AM. J. BIOETHICS, Summer 2003, at 39, 40 (describing the industry’s use of “reminder items,” such as pens and notepads).

¹¹ One former sales representative described the training of pharmaceutical sales representatives as focusing on how to “present our products in the best possible light, . . . trivialize problems associated with them and . . . emphasize the shortcomings of our competitors’ prod-

courage physicians to prescribe more products by bringing food and freebies to doctors' offices, a practice known as "detailing."¹² And drug companies know their marketing works. One former marketing representative called free meals an "incredibly effective" tool for boosting drug sales.¹³ The true cost of medical marketing, however, is ultimately paid by taxpayers and private insurance customers who foot the bill for industry-induced overspending.

In the face of cheaper generic medicines or more effective alternative treatments, doctors who meet with marketers prescribe more drugs overall and more frequently prescribe the medicine advertised.¹⁴ Because costs can vary dramatically between branded medicines and their generic alternatives, the extra spending adds up.¹⁵ Insurance companies raise the price of coverage to compensate for higher costs, and "[s]ince the Federal Government is the nation's largest purchaser of prescription drugs," specious marketing should concern both Congress and taxpayers alike.¹⁶

To rein in overspending caused by medical marketing, Congress should pass stringent legislation banning the provision of gifts and free meals. This Note proposes the Medical Marketing Act for Congress's consideration and defends it against legal attack. A comprehensive ban on the drug and device industries' most troublesome marketing activities would lower spending on prescription drugs and medical devices by substantially reducing doctors' tendencies to prescribe more expensive and unnecessary branded drugs and medical devices.

This Note begins, in Part I, by describing how medical marketing impacts doctors' decisionmaking and how this shift affects drug and device spending. Part II examines the common shortcomings of the many medical marketing proposals put forth by industry organizations, state legislatures, and Congress. Part III responds to the most

ucts." *Under the Influence: Can We Provide Doctors an Alternative to Biased Drug Reviews?: Hearing Before the S. Spec. Comm. on Aging*, 110th Cong. 4 (2008) [hereinafter *Under the Influence*] (statement of Shahram Ahari, former sales representative, Eli Lilly). See generally *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the S. Spec. Comm. on Aging*, 110th Cong. 1 (2007) [hereinafter *Paid to Prescribe*].

¹² "Pharmaceutical 'detailing' is the term used to describe those sales visits in which drug reps go to doctors' offices to describe the benefits of a specific drug." Daniel Carlat, *Dr. Drug Rep*, N.Y. TIMES MAG., Nov. 25, 2007, at 64, 67.

¹³ Saul, *supra* note 8.

¹⁴ See *infra* Part I.B.

¹⁵ See *Under the Influence*, *supra* note 11, at 2 (statement of Sen. Herb Kohl, Chairman, S. Spec. Comm. on Aging) (discussing how Norvasc, a commonly prescribed blood pressure medication, costs between \$60 and \$70, whereas the generic costs around \$12).

¹⁶ *Id.*

likely challenge to the Medical Marketing Act—the accusation that restrictions on medical marketing impermissibly curtail commercial speech in violation of the First Amendment. Finally, Part IV proposes the Medical Marketing Act for Congress’s consideration.

I. THE EFFECT OF MEDICAL MARKETING ON DOCTORS’ DECISIONS AND THE COST OF HEALTH CARE

The relationship between doctors and medical manufacturers has long been subject to public scrutiny.¹⁷ For decades, the pharmaceutical industry made no pretense about showering doctors with lavish, nonmedical gifts.¹⁸ Despite recent attempts at reform,¹⁹ however, medical marketing remains a common practice.²⁰ This Part begins with an overview of pharmaceutical companies’ current marketing practices and explains the effect this marketing has on doctors’ decisionmaking. Finally, this Part illustrates the dramatic impact medical marketing has on the cost of medicine.

A. *Medical Marketing Is a Pervasive Practice in the United States*

Drug and medical device companies use their massive resources to engage in a variety of marketing activities. With approximately \$500 billion in annual sales, prescription drugs and medical devices are big business.²¹ But the drug and device industries are not only big; they are also highly profitable, returning some fifteen percent on investments—an “extraordinary” amount.²² Accordingly, to maintain a dominant market position, drug and device companies engage in a number of marketing activities that financially entangle doctors, com-

¹⁷ Howard Brody, *Pharmaceutical Industry Financial Support for Medical Education: Benefit, or Undue Influence?*, 37 J.L. MED. & ETHICS 451, 451 (2009) (“As early as the 1960s and 1970s, astute commentators began to call into question the degree of influence that the pharmaceutical industry was exercising over all aspects of medical research, education, and practice in the U.S.” (citing Charles D. May, *Selling Drugs by “Educating” Physicians*, 36 J. MED. EDUC. 1 (1961))); see also MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 308 (1974) (discussing the “problem” of drug detailers in the practice of medicine).

¹⁸ For example, when Dr. Arthur S. Levine, Dean of the University of Pittsburgh School of Medicine, graduated from medical school in 1964, “Eli Lilly gave him his first doctor’s bag, and Roche gave him an Omega watch for being valedictorian. He still has the watch.” Gardiner Harris, *Group Urges Ban on Medical Giveaways*, N.Y. TIMES, Apr. 28, 2008, at A15.

¹⁹ See *infra* Part II.

²⁰ See *supra* notes 7–9 and accompanying text.

²¹ See *supra* notes 2–3 and accompanying text.

²² *Paid to Prescribe*, *supra* note 11, at 2 (statement of Sen. Herb Kohl, Chairman, S. Spec. Comm. on Aging). “From 1995 to 2002, pharmaceutical manufacturers were the nation’s most profitable industry (profits as a percent of revenues). They ranked 3rd in profitability in 2003 and 2004, 5th in 2005, 2nd in 2006, and 3rd in 2007” Lundy, *supra* note 1, at 3.

promising patients' health and raising healthcare costs as a result. Drug and device companies call their activities educational,²³ but as one former sales representative made clear before the Senate Special Committee on Aging, "[a]mong the myriad of myths that the industry uses to justify the pharma-physician relationship, none is more dangerous than the notion that the drug rep provides valuable education to the doctor. As their formal title implies, pharmaceutical sales representatives are hired to sell. Period."²⁴

Armed with detailed prescriber data, medical sales representatives carefully tailor their approaches based on the personalities and prescribing habits of particular physicians.²⁵ Moreover, medical sales representatives receive extensive—albeit nonmedical—training to hone their craft.²⁶ On average, physicians meet with pharmaceutical sales representatives around four times a month.²⁷ One study found that the vast majority of "physicians (94%) reported some type of relationship with the pharmaceutical industry, and most of these relationships involved receiving food in the workplace (83%) or receiving drug samples (78%)."²⁸

In addition to showering physicians with free food and gifts, drug and medical device companies hire doctors as consultants and representatives, "offer[ing] lucrative consulting arrangements to top-notch teachers and even ghost-[writing] research papers for busy professors."²⁹ One researcher discovered that fifty-six percent of the doctors

²³ In response to a report by the Association of American Medical Colleges calling for a ban to most gifts, meals, and other medical marketing activities, chief executives Jeffrey B. Kindler of Pfizer and Sidney Taurel of Eli Lilly wrote that medical marketing programs "can be worthwhile educational activities." Harris, *supra* note 18.

²⁴ *Under the Influence*, *supra* note 11, at 4 (statement of Shahram Ahari, former sales representative, Eli Lilly).

²⁵ To better understand doctors' motivations, detailers receive "psychological profile training, beginning with [their] own psychological profile." *Id.* at 5. Understanding their own psychological profiles allows detailers to learn "to assess . . . doctors," how their "personality traits overlap with . . . physicians' traits, and how best to ingratiate" themselves with doctors they meet. *Id.* Moreover, detailers "seek out personal details from [their] encounters with the doctors and analyze them to determine what sales methods will be the most effective. This information gets recorded, compiled and shared company wide throughout the years, without doctors' consent, or often, even their awareness." *Id.*

²⁶ *Id.* at 4 ("Although drug reps learn a modicum of science, the fact is our science training is secondary to our ability to establish a friendship with [doctors], and we maximize every opportunity to befriend them.").

²⁷ Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 373 (2000).

²⁸ Campbell et al., *supra* note 7, at 1742.

²⁹ Harris, *supra* note 18.

Drug companies exert control by controlling drug trials and linking them to mar-

contributing to the diagnostic criteria of the widely used Diagnostic and Statistical Manual of Mental Disorders (“DSM”) had financial ties to the pharmaceutical industry.³⁰ Indeed, “[d]rug companies spend billions wooing doctors—more than they spend on research or consumer advertising.”³¹ And detailing works: as one judge described it, “[t]he fact that the pharmaceutical industry spends over \$4,000,000,000 annually on detailing bears loud witness to its efficacy.”³²

B. Medical Marketing Affects Doctors’ Decisions

Pharmaceutical marketing impacts the prescribing habits of doctors, causing them to prescribe expensive branded medications when cheaper or more effective alternatives are available.³³ Although medi-

keting efforts; nurturing key opinion leaders . . . to influence medical decisionmaking; providing money, travel, and publicity for community doctors when they agree to promote certain products; funding professorships and other academic needs of those who support company interests; using unrestricted grants to influence journals, societies, meetings, and Web sites; controlling speakers and presentation of [continuing medical education] courses and materials; and creating bogus expert panels to promote products and treatments.

Paid to Prescribe, *supra* note 11, at 12 (statement of Greg Rosenthal, M.D.).

³⁰ Lisa Cosgrove et al., *Financial Ties Between DSM-IV Panel Members and the Pharmaceutical Industry*, 75 PSYCHOTHERAPY & PSYCHOSOMATICS 154, 154 (2006). The DSM is “a medical guidebook and a cultural institution” that “helps doctors make a diagnosis and provides insurance companies with diagnostic codes.” Benedict Carey, *Psychiatry’s Struggle to Revise the Book of Human Troubles*, N.Y. TIMES, Dec. 18, 2008, at A1.

³¹ Harris, *supra* note 18. Based on spending figures disclosed in Minnesota, psychiatrists received payments ranging from \$51 to \$689,000. Gardiner Harris, *Psychiatrists Top List in Drug Maker Gifts*, N.Y. TIMES, June 27, 2007, at A14.

³² *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 56 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009).

³³ See Ernst R. Berndt et al., *Information, Marketing, and Pricing in the U.S. Ant ulcer Drug Market*, 85 AM. ECON. REV. 100, 104 (1995) (finding that detailing had a significant effect on prescription behavior and that the impact was greater than the effect had by journal ads, direct-to-consumer advertisements, and pricing); Anthony D. Bower & Gary L. Burkett, *Family Physicians and Generic Drugs: A Study of Recognition, Information Sources, Prescribing Attitudes, and Practice*, 24 J. FAM. PRAC. 612, 615–16 (1987) (finding that family physicians who relied the least on pharmaceutical marketers were most likely to prescribe generic drugs, and that those who relied “a great deal” on marketer information were substantially less likely to prescribe generic drugs); Mary-Margaret Chren & C. Seth Landefeld, *Physicians’ Behavior and Their Interactions with Drug Companies: A Controlled Study of Physicians Who Requested Additions to a Hospital Drug Formulary*, 271 JAMA 684, 684 (1994) (finding a strong and specific relationship between physician interactions with pharmaceutical companies and requests by physicians that drugs manufactured by those companies be added to hospital formularies); Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 MARKETING LETTERS 129, 138 (2004) (finding that pharmaceutical detailing impacts prescribing behavior); Natalie Mizik & Robert Jacobson, *Are Physicians “Easy Marks”? Quantifying the Effects of Detailing and Sampling on New*

cal marketing can impact patients positively—by, for instance, increasing a doctor's ability to identify treatment for a complicated illness³⁴—drug and device marketing engenders alarming negative effects as well. Studies demonstrate that medical marketing can impact doctors' abilities to recognize incorrect claims about medication and can change their attitudes and preferences regarding pharmaceutical representatives and their products.³⁵ Medical marketing also increases the likelihood that doctors will request that the advertised product be added to hospital formularies, even when the medicine lacks a significant advantage over existing products.³⁶

Most important, gifts need not be of any particular value to affect the recipient; even the pens, notepads, and plush toys that drug and medical device detailers give to doctors impact medical decisionmaking.³⁷ In one survey-based study, a team of researchers concluded that “the use of the information provided by pharmaceutical representatives . . . [was an] independent positive predictor[] of prescribing costs.”³⁸ In fact, the same study found that when doctors choose treatments, cost to the patient becomes less important the more doctors rely on promotional materials for information.³⁹

Medical marketing affects physician psychology in at least two ways: the norm of reciprocity and priming.⁴⁰ The norm of reciprocity suggests that “we should help those who help us . . . [and] is appar-

Prescriptions, 50 MGMT. SCI. 1704, 1714 (2004) (finding that past detailing affects current prescribing habits); Wazana, *supra* note 27, at 373 (analyzing twenty-nine studies of industry-physician relationships and concluding that “[t]he present extent of physician-industry interactions appears to affect prescribing and professional behavior”); Toshiaki Iizuka & Ginger Z. Jin, *The Effects of Direct-to-Consumer Advertising in the Prescription Drug Market* 22–23 (Univ. of Md., Working Paper, 2002), available at <http://www.cramton.umd.edu/workshop/papers/jin-direct-drug-advertising.pdf> (finding that direct-to-consumer advertising does not affect prescribing habits, but “that doctors’ decisions are highly influenced by promotional efforts by pharmaceutical salespersons”).

³⁴ Wazana, *supra* note 27, at 378.

³⁵ *Id.*

³⁶ *Id.*

³⁷ See Katz et al., *supra* note 10, at 39 (“Considerable evidence from the social sciences suggests that gifts of negligible value can influence the behavior of the recipient in ways the recipient does not always realize.”).

³⁸ T. Shawn Caudill et al., *Physicians, Pharmaceutical Sales Representatives, and the Cost of Prescribing*, 5 ARCHIVES FAM. MED. 201, 206 (1996).

³⁹ *Id.*

⁴⁰ For a study analyzing a number of other potential ways detailing affects physician behavior, see E. E. Roughead et al., *Commercial Detailing Techniques Used by Pharmaceutical Representatives to Influence Prescribing*, 28 AUSTL. & N.Z. J. MED. 306, 306 (1998).

ently a *very powerful* force in our social lives.”⁴¹ We regularly rely implicit on an expectation of reciprocity.⁴² “For example, when someone does us a favor, we are expected to return the favor at some point down the road. Hence, the phrase ‘much obliged’ is used as a synonym for ‘thank you.’”⁴³ In this respect, medical marketing is hardly different. The gifts, payments, and meals provided by drug and device companies create a significant, yet unconscious, desire to reciprocate among practitioners.⁴⁴ “While medical professionals might believe themselves to be ‘more rational and critical’ than the average person, the success of pharmaceutical marketing illustrates that physicians are as susceptible to target marketing as others.”⁴⁵

Medical marketing also affects the decisions of doctors through the effect of priming. Priming is a psychological phenomenon whereby prior exposure to information leading up to, and during, the making of a choice affects how brands are perceived and which brands are chosen.⁴⁶ In one experiment, researchers manipulated advertisements placed near fictional magazine articles being read by participants in a purported memory study.⁴⁷ At the end of the reading experiment, the participants were asked for additional input for a separate study relating to purchase activities.⁴⁸ On average, the individuals incidentally exposed to relevant product ads were over fifty

⁴¹ KENNETH S. BORDENS & IRWIN A. HOROWITZ, *SOCIAL PSYCHOLOGY* 257 (2001) (emphasis added).

⁴² See Robert B. Cialdini et al., *When Tactical Pronouncements of Change Become Real Change: The Case of Reciprocal Persuasion*, 63 J. PERSONALITY & PSYCHOL. 30, 30 (1992) (“There is good evidence that a rule for reciprocity governs much of human experience: We report liking those who report liking us; we cooperate with cooperators and compete with competitors; we self-disclose to those who have disclosed themselves to us; we try to harm those who have tried to harm us; in negotiations, we make concessions to those who have made concessions to us; and we provide gifts, favors, services, and aid to those who have provided us with these things.” (citations omitted)).

⁴³ Katz et al., *supra* note 10, at 41. The norm of reciprocity crops up in popular culture as well. In an episode of the television show *The Office*, one of the show’s main characters, Dwight Schrute (played by Rainn Wilson), brings bagels from New York City to his Scranton, Pennsylvania, office as a favor. *The Office: Double Date* (NBC television broadcast Nov. 5, 2009). Rather than providing breakfast out of goodwill, however, Dwight’s bagels are intended to leave his coworkers indebted for future favors. *Id.* As Dwight puts it, “Don’t mention it. You owe me one. You all owe me one.” *Id.*

⁴⁴ See *supra* note 33.

⁴⁵ Katz et al., *supra* note 10, at 40–41 (citations omitted).

⁴⁶ See Prakash Nedungadi, *Recall and Consumer Consideration Sets: Influencing Choice Without Altering Brand Evaluations*, 17 J. CONSUMER RES. 263, 273–74 (1990) (finding that relative brand name accessibility in an individual’s memory affects his or her choice).

⁴⁷ Stewart Shapiro et al., *The Effects of Incidental Ad Exposure on the Formation of Consideration Sets*, 24 J. CONSUMER RES. 94, 96–97 (1997).

⁴⁸ *Id.* at 99.

percent more likely to consider the advertised product than those who had not seen the ads.⁴⁹ Priming occurs by way of the logo-laden trinkets that drug and medical device companies litter throughout physicians' offices—gifts which the drug and device companies aptly refer to as “reminder items.”⁵⁰ By leaving calendars, clocks, foam toys, pens, and paper around a doctor's office, drug and device companies increase exposure to the company's brand and affect medical decisionmaking in subtle, yet important, ways.⁵¹

As a whole, gifts, meals, and interactions with detailers affect doctors' prescribing habits in wily ways because gifts work psychologically. That is, the undesirable effect of medical marketing occurs unconsciously upon the completion of the exchange.⁵² Invidious medical marketing is less about quid pro quo exchanges and more about subtle manipulation by companies with a financial incentive to encourage consumption of expensive medicines.

C. Medical Marketing Produces Significant Overspending Among Both Taxpayers and Insurance Policyholders

The assiduous efforts of drug and medical device detailers have a clear impact on medical decisionmaking.⁵³ In the aggregate, these efforts result in overspending on prescription drugs and medical devices due to the substantial price differences between branded and generic products. For example, once-a-day Solodyn (an acne medication) costs \$514 a month, or \$6168 per year.⁵⁴ By contrast, the twice-daily generic version, monocycline, costs \$109 a month, or \$1308 per year.⁵⁵ Similarly, “[c]linical studies show that 95 percent of the population with arthritis—those not at risk for side effects—could take generic

⁴⁹ *Id.* at 101–02.

⁵⁰ Katz et al., *supra* note 10, at 40. Reminder items are so prevalent that one network of hospitals in Minnesota collected more than 18,700 items—enough to fill twenty shopping carts—“including clocks, mugs, surgical caps, calculators, tape dispensers, and a stress-relieving squeeze toy made to look like a red blood cell.” Larry Oakes, *Adios, Allegra Pens; Farewell, Flonase Mugs*, STAR TRIB., Jan. 18, 2008, at A10.

⁵¹ James Jastifer & Sarah Roberts, *Patients' Awareness of and Attitudes Toward Gifts from Pharmaceutical Companies to Physicians*, 39 INT'L J. HEALTH SERVICES 405, 406 (2009).

⁵² See, e.g., James P. Orlowski & Leon Wateska, *The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There's No Such Thing as a Free Lunch*, 102 CHEST 270, 270 (1992) (finding that, despite self-predicting otherwise, physicians who attended all-expense-paid symposia at popular vacation sites used the drugs advertised at those symposia more often after attending).

⁵³ See *supra* Part I.B.

⁵⁴ Chana Joffe-Walt, *Drug Coupons Hide True Costs from Consumers*, NAT'L PUB. RADIO (Oct. 20, 2009), <http://www.npr.org/templates/story/story.php?storyId=113969968>.

⁵⁵ *Id.*

ibuprofen for pennies a day, compared with about \$1,000 annually for Vioxx.”⁵⁶ Moreover, “[n]ame-brand prices have risen even as prices of widely used generic drugs have fallen by about 9 percent in the last year . . . [and] name brands account for 78 percent of total prescription drug spending in this country.”⁵⁷

The higher price of branded medicines and the increasing frequency of their use in turn cause private insurance companies to raise premiums. And because “around half of all Americans get their health care courtesy of the government,”⁵⁸ taxpayers end up paying for much of that medical overspending.⁵⁹ The Government Accountability Office monitored the price of ninety-six prescription drugs from January 2000 to December 2004 and found that “retail prices for drugs frequently used by Medicare beneficiaries increased 24.0 percent—an average rate of 4.5 percent per year. In general, higher drug prices mean higher spending by consumers and health insurance sponsors, including employers and federal and state governments.”⁶⁰ The same report found that brand-name drug prices increased “*three times as fast* as generic drug prices.”⁶¹ In 2000 alone, “[i]f a generic had been substituted for all corresponding brand-name outpatient drugs,”⁶² the national savings would have topped \$8.8 billion, or “approximately

⁵⁶ Scott Serota, Letter to the Editor, *Drugs and Advertising*, N.Y. TIMES, Nov. 28, 2001, at A6. It should be noted that Merck, the maker of Vioxx, has since pulled the drug off the market, “citing its safety risks.” Barnaby J. Feder, *Merck’s Actions on Vioxx Face New Scrutiny*, N.Y. TIMES, Feb. 15, 2005, at C1. Vioxx nevertheless presents a useful example of price differentials between branded medicines and alternate treatment options. See generally *Under the Influence*, *supra* note 11.

⁵⁷ Wilson, *supra* note 2; see also STEPHEN R. MACHLIN & MARIELLE KRESS, AGENCY FOR HEALTHCARE RES. AND QUALITY, U.S. DEP’T OF HEALTH & HUMAN SERVS., TRENDS IN HEALTH CARE EXPENDITURES FOR ADULTS AGES 18–44: 2006 VERSUS 1996, at 2 (2009), http://www.meps.ahrq.gov/mepsweb/data_files/publications/st254/stat254.pdf (finding that, from 1996 to 2006, the average cost to purchase prescription medicine more than doubled, jumping from \$79 to \$161).

⁵⁸ *Back from the Dead*, ECONOMIST, Oct. 31, 2009, at 20; see also Christopher D. Zalesky, *Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests: Moving Beyond Regulation-Through-Litigation*, 39 J. HEALTH L. 235, 238 (2006) (noting that federal spending on Medicare, Medicaid, and other health programs amounted to approximately \$521.7 billion in 2005).

⁵⁹ See *supra* text accompanying note 16.

⁶⁰ U.S. GOV’T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS PRICE TRENDS FOR FREQUENTLY USED BRAND AND GENERIC DRUGS FROM 2000 TO 2004, at 2–3, 13 (2005), <http://www.gao.gov/new.items/d05779.pdf>.

⁶¹ *Id.* (emphasis added).

⁶² Jennifer S. Haas et al., *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997–2000*, 142 ANNALS INTERNAL MED. 891, 891 (2005).

11% of drug expenditures.”⁶³ Taken together, medical marketing and the price of brand name drugs dramatically increase already exorbitant healthcare costs by encouraging wasteful overspending.

II. ATTEMPTS AT REGULATING MEDICAL MARKETING

As medical marketing receives increased public attention, a growing group of doctors and other professionals has started to call for additional regulation of medical marketing.⁶⁴ Medical schools,⁶⁵ industry organizations,⁶⁶ state legislatures,⁶⁷ and Congress⁶⁸ have each attempted to regulate medical marketing; however, each venture has fallen short. This Part will discuss the most common shortcomings of these efforts.

A. Regulations that Require Disclosure

With the exceptions of California⁶⁹ and New Hampshire,⁷⁰ every statutory attempt at regulating the interactions between detailers and

⁶³ *Id.*

⁶⁴ See generally Gardiner Harris, *In Article, Doctors Back Ban on Drug Companies' Gifts*, N.Y. TIMES, Jan. 25, 2006, at A14.

⁶⁵ Harvard Medical School recently became the latest major medical school to institute restrictions on interactions between affiliated individuals and drug and medical device companies. See Duff Wilson, *Hospitals Connected to Harvard Cap Outside Pay to Top Officials*, N.Y. TIMES, Jan. 3, 2010, at A1.

⁶⁶ See, e.g., COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, AM. MED. ASS'N, CODE OF MEDICAL ETHICS (2010), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.shtml> [hereinafter AMA CODE OF MEDICAL ETHICS]; PHARM. RESEARCH & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS 5 (2008), available at <http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf> [hereinafter PhRMA CODE].

⁶⁷ See, e.g., CAL. HEALTH & SAFETY CODE § 119402 (West 2006); D.C. CODE § 48-833.03 (2009); ME. REV. STAT. ANN. tit. 22, § 2698-A (2004); MASS. GEN. LAWS ch. 111N, § 2 (2009); MINN. STAT. § 151.47(f) (2009); W. VA. CODE ANN. § 5A-3C-13 (LexisNexis 2006).

⁶⁸ The first attempt at regulating medical marketing on a federal level came in the form of the Drug and Medical Device Company Gift Disclosure Act, H.R. 3023, 110th Cong. (2007) [hereinafter Gift Disclosure Act]. This bill, introduced during a previous session of Congress, died in the Subcommittee on Health. As part of Congress's recent sweeping healthcare reform, Congress enacted a disclosure scheme requiring annual disclosures of most payments and exchanges of value worth over \$10. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6022, 124 Stat. 119, 696 (2010) [hereinafter Patient Protection Act]. This scheme largely incorporates an earlier bill, the Physician Payments Sunshine Act, S. 301, 111th Cong. (2009). The Patient Protection Act explicitly preempts state disclosure statutes as of January 1, 2012. Patient Protection Act § 6022, 124 Stat. at 694. Nonetheless, given the substantial similarities between the Patient Protection Act and state statutes on point—and the lessons learned through the states' experiences thus far—the analysis contained here remains relevant.

⁶⁹ California's law merely requires compliance with the Office of Inspector General's April 2003 *Compliance Program Guidance for Pharmaceutical Manufacturers*, a publication fo-

doctors—both state⁷¹ and federal⁷²—relies on Justice Brandeis’s admonition that “sunlight is the best disinfectant”⁷³ by requiring regular disclosure of various marketing expenditures.⁷⁴ Disclosure schemes are designed to “outlaw particular conduct by bringing legal or moral pressure to bear upon those engaging in it.”⁷⁵

Disclosure-based regulations fall short as a means of eliminating the pernicious effect detailers have on medical decisionmaking because disclosure laws, although admirable in theory, “do not restrict conduct beyond requiring that certain information be provided.”⁷⁶ Therefore, disclosure alone does little to counteract the effects detailers have on medical decisionmaking. Even though doctors claim that gifts do not affect their medical judgment,⁷⁷ the subconscious effect that gifts have on the behavior of doctors occurs upon receipt of the gift, regardless whether the gift is subsequently disclosed.⁷⁸

Moreover, disclosure is an empty gesture because patients cannot adequately use disclosed information to adjust their approaches to

cused more on avoiding quid pro quo remunerations and other potential violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (2006). See CAL. HEALTH & SAFETY CODE § 119402.

⁷⁰ New Hampshire’s law is far more limited in its reach. It only governs the release of prescription information to data companies (a business known as “data mining”), a controversial feature of pharmaceutical marketing beyond the scope of this Note. See N.H. REV. STAT. ANN. § 318:47-f (2006).

⁷¹ See *supra* note 67.

⁷² See *supra* note 68.

⁷³ 155 Cong. Rec. S788 (2009) (statement by Sen. Grassley) (quoting Justice Brandeis); accord LOUIS D. BRANDEIS, *OTHER PEOPLE’S MONEY* 92 (1914) (“Publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants; electric light the most efficient policeman.”).

⁷⁴ See, e.g., MINN. STAT. § 151.47(f) (2009) (“A wholesale drug distributor shall file with the board an annual report, in a form and on the date prescribed by the board, identifying all payments, honoraria, reimbursement or other compensation authorized under section 151.461, clauses (3) to (5), paid to practitioners in Minnesota during the preceding calendar year. The report shall identify the nature and value of any payments totaling \$100 or more, to a particular practitioner during the year, and shall identify the practitioner.”).

⁷⁵ STEPHEN G. BREYER, *REGULATION AND ITS REFORM* 162 (1982).

⁷⁶ *Id.* at 163.

⁷⁷ Doctors consistently self-report that gift giving does not impact their medical decisions. See, e.g., Robert V. Gibbons et al., 13 J. GEN. INTERNAL MED. 151, 153 (1998); Dennis Murray, *Gifts: What’s All the Fuss About?*, 79 MED. ECON. 119, 119 (2002).

⁷⁸ See, e.g., Katz et al., *supra* note 10, at 39 (“Considerable evidence from the social sciences suggests that gifts of negligible value can influence the behavior of the recipient in ways the recipient does not always realize. Policies and guidelines that rely on arbitrary value limits for gift-giving or receipt should be reevaluated.”); Nedungadi, *supra* note 46, at 274 (finding that the mental accessibility and cues associated with a brand name affect choice); Mark A. Whatley et al., *The Effect of a Favor on Public and Private Compliance: How Internalized Is the Norm of Reciprocity?*, 21 BASIC & APPLIED SOC. PSYCHOL. 251, 251 (1999) (finding that the presence of a favor or gift increases compliance and reciprocity).

seeking treatment. Even when information is accessible, patients often lack the knowledge to apply the information profitably. As one author described the perils of medical disclosure:

For disclosure to be effective, the recipient of advice must understand how the conflict of interest has influenced the advisor and must be able to correct for that biasing influence. In many important situations, however, this understanding and ability may be woefully lacking. For example, imagine a patient whose physician advises, "Your life is in danger unless you take medication X," but who also discloses, "The medication's manufacturer sponsors my research." Should the patient take the medication? If not, what other medication? How much should the patient be willing to pay to obtain a second opinion? How should the two opinions be weighed against each other? The typical patient may be hard-pressed to answer such questions.⁷⁹

Some evidence even suggests that disclosure can make matters worse. Disclosure can fail because "people generally do not discount advice from biased advisors as much as they should, even when advisors' conflicts of interest are disclosed . . . [and] disclosure can increase the bias in advice because it leads advisors to feel morally licensed and strategically encouraged to exaggerate their advice even further."⁸⁰

In addition to the conceptual difficulties faced by disclosure statutes, disclosure laws enacted thus far also fall victim to crippling practical defects. To have an effect, disclosed information must get "transmitted to the buyer in a simple and meaningful way."⁸¹ Without marketing data that is easy to find and use, patients cannot use disclosed information at all. Unfortunately, few medical marketing disclosure laws make the relevant information easy to obtain, let alone publicly available.⁸²

In his testimony before the Senate Special Committee on Aging, one doctor discussed how his attempts at obtaining disclosed data in Vermont and Minnesota "required much effort."⁸³ In Vermont, data could be accessed online, but the only information available consisted

⁷⁹ Daylian M. Cain et al., *The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest*, 34 J. LEGAL STUD. 1, 3–4 (2005).

⁸⁰ *Id.* at 1.

⁸¹ BREYER, *supra* note 75, at 163.

⁸² For instance, Minnesota's disclosure laws explicitly make disclosed information public, whereas Vermont publishes information disclosed by pharmaceutical companies online. *Paid to Prescribe*, *supra* note 11, at 20, 25 (statement of Peter Lurie, Deputy Dir., Public Citizen's Health Research Group).

⁸³ *See id.* at 26.

of aggregate reporting information, not physician-specific payment information that patients could actually use.⁸⁴ Obtaining physician-specific data in Vermont took a legal battle that lasted almost an entire year and still resulted in only partial disclosure due to much of the marketing data being labeled as trade secrets.⁸⁵ In Minnesota, payment data has never been publicly available.⁸⁶ “Indeed, the disclosure forms submitted have literally sat in boxes for up to a decade, gathering dust and never being analyzed.”⁸⁷ To obtain the records, researchers had to travel to the Minnesota Board of Pharmacy’s office in Minneapolis and photocopy each form at a cost of \$0.25 per page.⁸⁸ Unfortunately, attempts at curbing the effects of medical marketing through disclosure consistently fall short, both in theory and in practice. In light of problems such as these, any attempt at reducing the impact of medical marketing on doctors’ decisions should eschew disclosure in favor of restrictions delineating the limits of acceptable marketing behavior.

B. Voluntary Guidelines

Besides statutes proposed at the state and federal level, concerned industry groups have also attempted to address the pitfalls of medical marketing by issuing their own guidelines. Two organizations in particular have issued broad regulations pertaining to medical marketing: the American Medical Association (“AMA”) and the Pharmaceutical Research and Manufacturers of America (“PhRMA”).⁸⁹ The codes proffered by both AMA and PhRMA represent respectable attempts at curbing many of medical marketing’s most troubling aspects, including free meals,⁹⁰ complimentary entertainment and recreation,⁹¹ funds for continuing medical education,⁹² questionable consultancy agreements,⁹³ inflated speaking fees,⁹⁴ and even gifts.⁹⁵

⁸⁴ *See id.*

⁸⁵ *See id.* at 27 (noting that forty-four percent of companies that disclosed marketing information in Vermont “designated at least some of their payments as trade secret”).

⁸⁶ *See id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *See supra* note 66.

⁹⁰ *See* PhRMA CODE, *supra* note 66, at 4.

⁹¹ *See id.* at 5.

⁹² *See id.* at 6.

⁹³ *See id.* at 7–8.

⁹⁴ *See id.* at 9–10.

⁹⁵ *See id.* at 11.

However, both the *AMA Code of Medical Ethics* and the *PhRMA Code* are completely voluntary and, thus, invite noncompliance.⁹⁶

Despite purportedly admirable intentions, by issuing voluntary guidelines industry organizations are unlikely to actually affect medical marketing.⁹⁷ Especially in such a competitive business, companies will not voluntarily risk losing huge swaths of market share for the sake of a clean conscience. In fact, “due to their voluntary nature, [the AMA and PhRMA] guidelines are likely to be more effective at staving off legislation than reducing marketing excesses.”⁹⁸ Drug and medical device companies have a strong financial incentive to continue their current marketing activities.⁹⁹ Thus, to substantially reduce the overspending caused by medical marketing, any new attempt should use mandatory guidelines to ensure compliance.

C. *Low-Value Gift Exceptions*

Attempts at changing the doctor-detailer relationship also fall short because they contain exceptions that ultimately undermine the goal of reducing the impact of medical marketing on doctors’ decisionmaking. The most common impediment to regulatory progress comes from exceptions that allow gifts and meals so long as they remain under a certain dollar amount.

With one exception,¹⁰⁰ every effort at regulating medical marketing contains exceptions for gifts that are cumulatively valued below a certain dollar amount. For example, the District of Columbia’s disclosure statute exempts expenses worth under \$25 and “reasonable compensation and reimbursement” for clinical trials, as well as certain product samples and scholarships.¹⁰¹ Maine uses similar exceptions,¹⁰² and Minnesota’s law exempts payments and provisions valued under

⁹⁶ See *AMA CODE OF MEDICAL ETHICS*, *supra* note 66, at xvii (stating that the “[p]rinciples adopted by the [AMA] are not laws, but standards of conduct which define the essentials of honorable behavior for the physician”); *PhRMA CODE*, *supra* note 66, at 3 (describing the PhRMA Code as “voluntary”).

⁹⁷ See *Paid to Prescribe*, *supra* note 11, at 2 (statement of Sen. Herb Kohl, Chairman, S. Spec. Comm. on Aging) (“While there are voluntary guidelines already in place . . . it seems clear that they are not being sufficiently followed.”).

⁹⁸ *Id.* at 28 (statement of Peter Lurie, Deputy Dir., Public Citizen’s Health Research Group).

⁹⁹ See *supra* notes 2–3, 22 and accompanying text.

¹⁰⁰ Massachusetts’s medical disclosure legislation is the only legislation in effect that actually bans gifts to most medical professionals. MASS. GEN. LAWS ch. 111N, § 2 (2010).

¹⁰¹ D.C. CODE § 48-833.03(b) (2001).

¹⁰² ME. REV. STAT. ANN. tit. 22, § 2698-A(5) (2004).

\$100.¹⁰³ Although the aforementioned state disclosure statutes will be preempted as of January 1, 2012, by the Patient Protection and Affordable Care Act,¹⁰⁴ the new federal statute itself includes its own exception for gifts and payments valued under \$10.¹⁰⁵ Even the *PhRMA Code* expressly permits gifts that “advance disease or treatment education”¹⁰⁶ as well as meals that are both “modest as judged by local standards” and “provided in a manner conducive to informational communication.”¹⁰⁷ Exceptions like these allow detailers to continue giving doctors gifts and meals and, thus, ultimately undermine the effectiveness of any regulatory regime.

First, low-value gift exceptions frustrate attempts at regulation because *any* exchange of value affects medical decisionmaking.¹⁰⁸ Cheap trinkets and modest meals trigger the norm of reciprocity, ultimately contributing to overspending on prescription drugs and medical devices.¹⁰⁹ Moreover, drug companies do in fact “inundate prescribers with gifts, running from writing pads, pens, and coffee cups emblazoned with the name of a drug to free lunches.”¹¹⁰ Second, drug and device detailers can, and often do, take advantage of regulatory exceptions to further undermine reform. For instance, during his testimony before the Senate Special Committee on Aging, Shahram Ahari, a former Eli Lilly sales representative, dismissed the effects of the *PhRMA Code*’s requirements, observing that “in the past, as a sales rep, I would spend \$100 on a golf club for a physician allowing him/her to spend \$100 on a medical textbook. Today, I buy the book and he/she buys the golf club. *It is still a gift, still a perk, and still \$100.*”¹¹¹ Exceptions open the door for companies to circumvent regulations; eliminating the effect of medical marketing requires absolute provisions.

Although avoiding paternalistic approaches that unduly interfere with market forces is ideal, medical marketing has fostered an environment of overspending and unsustainable waste, making stringent regulations necessary. Effective regulation of medical marketing re-

¹⁰³ MINN. STAT. § 151.47(f) (2009).

¹⁰⁴ Patient Protection Act, Pub. L. No. 111-148, § 6022, 124 Stat. 119, 694 (2010).

¹⁰⁵ *Id.* at 696.

¹⁰⁶ PHRMA CODE, *supra* note 66, at 11.

¹⁰⁷ *Id.* at 4.

¹⁰⁸ *See supra* Part I.B.

¹⁰⁹ *See supra* notes 41–45 and accompanying text.

¹¹⁰ IMS Health Corp. v. Rowe, 532 F. Supp. 2d 153, 160 (D. Me. 2007).

¹¹¹ *Under the Influence*, *supra* note 11, at 12 (statement of Shahram Ahari, former sales representative, Eli Lilly) (emphasis added).

quires mandatory restrictions with clearly delineated limits. Any such proposal, however, must survive First Amendment scrutiny.

III. MEDICAL MARKETING AND COMMERCIAL SPEECH

The most common argument against restricting medical marketing is that such restrictions would violate the protections afforded by the First Amendment.¹¹² Traditionally used to “protect the exchange of ideas and political, social, scientific, or artistic expression,”¹¹³ the Supreme Court has expanded the First Amendment’s reach to also include commercial speech.¹¹⁴ This Part discusses the Court’s standard of review for commercial speech cases and considers whether the marketing practices previously discussed qualify as commercial speech and whether they can be constitutionally restricted.

A. *Does Medical Marketing Fall Within the First Amendment?*

The Supreme Court has not yet addressed whether drug and medical device detailing qualifies as speech warranting First Amendment protection. Drug and medical device companies are likely to argue that detailing qualifies as speech because the Court has treated solicitations and spending as speech in other areas, most notably in the area of political contributions.¹¹⁵ It is possible, however, that detailing does not constitute speech under *Citizens United v. FEC* because gifts to doctors do not involve “political expression” or the “discussion of governmental affairs” the way political contributions do.¹¹⁶ For example, in *IMS Health Inc. v. Ayotte*, the First Circuit upheld a New Hampshire statute limiting the pharmaceutical industry’s practice of data mining.¹¹⁷ In so holding, the First Circuit concluded that the challenged restrictions on medical marketing regulated con-

¹¹² See, e.g., *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009). The First Amendment protects freedom of speech by providing that “Congress shall make no law . . . abridging the freedom of speech . . .” U.S. CONST. amend. I.

¹¹³ Brienne Taylor Greiner, Note, *A Tough Pill to Swallow: Does the First Amendment Prohibit WV From Regulating Pharmaceutical Companies Advertising Expenses to Lower the Cost of Prescription Drugs?*, 109 W. VA. L. REV. 107, 122 (2006).

¹¹⁴ See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366–67 (2002). “Commercial speech is defined as expression related solely to the economic interests of the speaker and its audience or speech proposing a commercial transaction.” *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1143 (D.C. Cir. 2009) (internal quotation marks omitted).

¹¹⁵ See *Citizens United v. FEC*, 130 S. Ct. 876, 899–900 (2010) (listing cases extending First Amendment protection to corporations).

¹¹⁶ See *Buckley v. Valeo*, 424 U.S. 1, 14 (1976).

¹¹⁷ *Ayotte*, 550 F.3d at 45.

duct and not protected speech.¹¹⁸ The court also held that, in the alternative, the contested regulations were permissible restrictions on protected speech if marketing did indeed qualify as speech.¹¹⁹

Because parties have invoked the First Amendment in other aspects of advertising regulations generally¹²⁰ and pharmaceutical marketing specifically¹²¹—and because a challenge by pharmaceutical companies depends on marketing qualifying as speech deserving protection—this Note assumes that gifts and other payments count as speech under the First Amendment.

B. *Is Medical Marketing Pure Speech or Commercial Speech?*

The distinction between pure speech and commercial speech is more than just cosmetic. Pure speech receives the most exacting constitutional scrutiny, whereas commercial speech is afforded far less constitutional protection and is thus more easily regulated.¹²² Pharmaceutical companies and medical device manufacturers have argued that their marketing amounts to “scientific and academic speech, which is entitled to the highest level of First Amendment protection.”¹²³ Past precedent suggests, however, that medical marketing almost certainly constitutes mere commercial speech.

First, in *Bolger v. Youngs Drug Products Corp.*, the Supreme Court held that speech qualifies as commercial speech when the speech is an advertisement, references a specific product, *and* is motivated by the economic interests of the speaker.¹²⁴ Here, detailing by drug and device companies meets all three criteria. Medical marketing is concededly a marketing activity,¹²⁵ detailers push specific prod-

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *See, e.g.,* *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 520–21 (W.D. Ky. 2010).

¹²¹ *See, e.g.,* *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *vacated sub nom. Wash. Legal Found. v. Henney*, 202 F.3d 331, 337 (D.C. Cir. 2000); Complaint at 26, *Allegran, Inc. v. FDA* (D.D.C. Oct. 1, 2009) (No. 09-cv-01879), 2009 WL 3187592; Jacob Rogers, Essay, *Freedom of Speech and the FDA’s Regulation of Off-Label Drug Uses*, 76 GEO. WASH. L. REV. 1429, 1435 (2008).

¹²² *United States v. Edge Broad. Co.*, 509 U.S. 418, 426 (1993) (“The Constitution . . . affords a lesser protection to commercial speech than to other constitutionally guaranteed expression.”).

¹²³ *Wash. Legal Found.*, 13 F. Supp. 2d at 59; *see also* Harris, *supra* note 18.

¹²⁴ *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66–67 (1983) (holding that each factor alone was not dispositive as to the status of speech, but that “[t]he combination of *all* these characteristics . . . provides strong support for . . . [concluding] that the [advertisements] are properly characterized as commercial speech”).

¹²⁵ *See* PHRMA CODE, *supra* note 66, at 2 (stating that the industry’s guidelines are aimed

ucts,¹²⁶ and detailing is motivated by the economic interests of the speaker.¹²⁷ As such, medical marketing qualifies as commercial speech under *Bolger*.

Second, in *Board of Trustees v. Fox*, the Court upheld a ban on commercial demonstrations (in this case, Tupperware parties) within a state university dormitory because the speech fundamentally “propose[d] a commercial transaction,” despite the fact that the presentations also “touch[ed] on other subjects . . . such as how to be financially responsible and how to run an efficient home.”¹²⁸ The practice of detailing is similar. Even though medical marketing is superficially educational, medical marketers are chiefly concerned with increasing product sales.¹²⁹ Any educational information detailers provide serves only to encourage physicians to use the product advertised, whether or not it is a significant improvement over existing drugs.¹³⁰ Thus, because detailers “propose[] a commercial transaction,”¹³¹ medical marketing constitutes commercial speech.

at “interactions with healthcare professionals that relate to the *marketing* of [pharmaceutical] products” (emphasis added)); Saul, *supra* note 8 (quoting a PhRMA representative referring to detailers as “sales rep[s]”).

¹²⁶ See, e.g., *Schering Corp. v. Pfizer, Inc.*, 189 F.3d 218, 222 (2d Cir. 1999) (describing Pfizer’s promotion of Zyrtec as “us[ing] a method that is common in the pharmaceutical industry: [Pfizer] employed a team of approximately 1200 sales representatives to visit physicians across the nation and emphasize the product’s qualities in one-on-one informational meetings called ‘detailings’”); Carlat, *supra* note 12, at 67 (defining “detailing” as “the term used to describe those sales visits in which drug reps go to doctors’ offices to describe the benefits of a *specific* drug” (emphasis added)).

¹²⁷ See, e.g., *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 159 (D. Me. 2008) (discussing how “[t]he pharmaceutical industry employs a small army of sales representatives” who “regularly visit prescribers at their clinics and medical offices to persuade them to prescribe their product”); Tina Benitez, *A Primary Concern*, INCENTIVE, Feb. 2003, at 18, 19 (describing a program designed for pharmaceutical sales representatives that “awarded points for increased incremental sales throughout the year, which could later be redeemed for a variety of merchandise and travel award in a company catalog”).

¹²⁸ *Bd. of Trs. v. Fox*, 492 U.S. 469, 473–74 (1989) (quoting *Va. Pharm. Bd. v. Va. Citizens Consumer Council*, 425 U.S. 748, 762 (1976)).

¹²⁹ See *supra* Part I.A.

¹³⁰ See *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 46 (1st Cir. 2008) (“[T]he detailer attempts to gain access to the physician’s office, usually by presenting herself as a helpful purveyor of pharmaceutical information and research. The detailer comes to the physician’s office armed with handouts and offers to educate the physician and his staff about the latest pharmacological developments. In other words, detailers open doors by holding out the promise of a convenient and efficient means for receiving practice-related updates.”).

¹³¹ *Fox*, 492 U.S. at 473.

C. *Regulations on Medical Marketing Satisfy the Commercial Speech Test*

The test for regulating commercial speech comes from *Central Hudson Gas & Electric Corp. v. Public Service Commission*.¹³² If the speech subject to regulation “concerns an otherwise lawful activity and is not misleading—statutory regulation of that speech is constitutionally permissible only if the statute is enacted in the service of a substantial governmental interest, directly advances that interest, and restricts speech no more than is necessary to further that interest.”¹³³ While Congress and a number of states have enacted statutes aimed at regulating medical marketing,¹³⁴ no case challenging such a statute has contested restrictions on medical marketing as it is discussed here.¹³⁵ Accordingly, the analysis here relies on relevant and otherwise analogous caselaw to demonstrate that drug and medical device companies’ provisions of gifts and meals can be constitutionally restricted.

1. *Does Restricting Medical Marketing Advance a Substantial Government Interest?*

The government has an interest in restricting medical marketing in order to save taxpayers’ money and reduce consumer costs. In the realm of Social Security alone, “[t]he average price of drugs per prescription among older persons rose 48% between 1992 and 2000, and drug expenses now consume 14% of the average Social Security benefit, up from 8% in 1992.”¹³⁶ Moreover, “[t]he prescription drug costs incurred by some 850 000 [sic] older Americans who lack insurance that covers drugs are more than \$2000 per year. The increased cost of prescription drugs accounted for the largest share—44%—of the total increase in health care costs in 1999.”¹³⁷

The Supreme Court would likely find this interest substantial for two reasons: consumer and taxpayer savings have constituted a substantial government interest in other cases, and the Court frequently defers to legislative findings regarding the government’s substantial interest in legislation. In the context of regulating medical marketing, the First Circuit has already held that cost containment constitutes a

¹³² Cent. Hudson Gas & Elec. Corp. v. Pub. Servs. Comm’n, 447 U.S. 557, 566 (1980).

¹³³ *Ayotte*, 550 F.3d at 55.

¹³⁴ See *supra* notes 67–68.

¹³⁵ Caselaw on point primarily focuses on challenging restrictions on data mining rather than medical marketing, as discussed in this Note. See *supra* notes 70, 112.

¹³⁶ Frank Davidoff, Editorial, *The Heartbreak of Drug Pricing*, 134 ANNALS INTERNAL MED. 1068, 1068 (2001).

¹³⁷ *Id.*; see also notes 57–63 and accompanying text.

substantial government interest.¹³⁸ Likewise, the district court in *IMS Health Inc. v. Sorrell* relied on *Ayotte* to conclude that “Vermont’s interest[] in cost containment . . . [is] substantial.”¹³⁹ And the court in *IMS Health Corp. v. Rowe* discussed the fact that “the Maine Legislature found that the pharmaceutical companies use the prescription information to attempt to influence prescribers to prescribe higher priced drugs, thus increasing the market share and profitability of the manufacturers and driving up the cost of health care.”¹⁴⁰

Various federal courts have found that savings to consumers and taxpayers constitutes a substantial government interest in other contexts as well. In *Missouri v. American Blast Fax, Inc.*, the Eighth Circuit held that, in passing restrictions on unsolicited fax ads, Congress had a substantial interest in preventing the practice, even though the costs were low relative to the increased spending associated with medical marketing.¹⁴¹

The findings of state legislatures and Congress are also important because the Supreme Court frequently defers to legislative judgments when evaluating legislation, especially in commercial speech cases.¹⁴² In *Ayotte*, Judge Lipez wrote separately and provided an extensive list of both empirical and anecdotal evidence that had been submitted to the New Hampshire legislature to show that detailing affects medical decisionmaking.¹⁴³ To that end, Congress has already recognized the rising cost of prescription drugs, the pervasive marketing practices of drug and medical device companies, and the impact marketing has on prescribing habits and medical spending.¹⁴⁴

¹³⁸ *Ayotte*, 550 F.3d at 55.

¹³⁹ *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434, 450 (D. Vt. 2009).

¹⁴⁰ *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 160 (D. Me. 2008) (internal quotation marks omitted).

¹⁴¹ *Missouri v. Am. Blast Fax, Inc.*, 323 F.3d 649, 655 (8th Cir. 2003) (“There was evidence that unsolicited fax advertisements can shift to the recipient more than one hundred dollars per year in direct costs”); see also *Destination Ventures, Ltd. v. FCC*, 46 F.3d 54, 57 (9th Cir. 1995) (“Viewing the facts in the light most favorable to Destination, we conclude that Destination’s own figures do not rebut the admitted facts that unsolicited fax advertisements shift significant advertising costs to consumers.”).

¹⁴² See, e.g., *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 195–96 (1997) (noting multiple reasons for granting deference to congressional findings); *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 509 (1981) (granting deference); *N.Y. State Liquor Auth. v. Bellanca*, 452 U.S. 714, 718 (1981) (granting deference to a state legislature).

¹⁴³ *Ayotte*, 550 F.3d at 88–89 (Lipez, J., concurring and dissenting).

¹⁴⁴ See generally *Under the Influence*, *supra* note 11; *Paid to Prescribe*, *supra* note 11; *Surgeons for Sale: Conflicts and Consultant Payment in the Medical Device Industry: Hearing Before the S. Spec. Comm. on Aging*, 110th Cong. 1 (2008); 155 Cong. Rec. S788 (2009) (statement of Sen. Herb Kohl) (“It has been estimated that the drug industry spends \$19 billion annually on

2. *Is Medical Marketing Misleading and Does the Marketing Concern a Lawful Activity?*

Under *Central Hudson*, “there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.”¹⁴⁵ The lawfulness of medical marketing is a nonissue; the drug and device industries produce legal products.¹⁴⁶ Although allegations of misleading marketing do exist,¹⁴⁷ the drug and device industries more likely than not engage in sufficiently honest—albeit competitive—marketing.

3. *Is the Substantial Government Interest Advanced Directly?*

In commercial speech cases, “the State must demonstrate that the challenged regulation advances the Government’s interest in a direct and material way.”¹⁴⁸ The Supreme Court requires a direct and material effect because the government’s “burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.”¹⁴⁹ In this respect, specific restrictions on how medical marketers can interact with physicians will likely be found to directly and materially impact the government’s asserted interest in saving money and reducing costs.

The available body of empirical data would go a long way toward satisfying the Court’s “directly advanced” requirement because of the Court’s deferential treatment of empirical evidence in commercial speech cases. For example, in *Edenfield v. Fane*, the Court struck

marketing to physicians in the form of gifts, lunches, drug samples and sponsorship of education programs. Americans pay the price as through unnecessarily high drug costs and skyrocketing health insurance premiums. Rising drug prices hurt us all by undermining our private and public health systems, including Medicare and Medicaid.”).

¹⁴⁵ Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n, 447 U.S. 557, 563 (1980).

¹⁴⁶ Cf. Vill. of Hoffman Estates v. Flipside, 455 U.S. 489, 504–05 (1982) (holding that the government could regulate advertisements relating to the sale of marijuana pipes because the government can regulate or ban entirely speech that proposes an illegal transaction).

¹⁴⁷ See, e.g., *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 105 (E.D.N.Y. 2008) (detailing allegations of misleading marketing); *Gordon v. Pfizer, Inc.*, No. CV-06-RRA-703-E, 2006 WL 2337002, at *4 (N.D. Ala. May 22, 2006) (referring to “affidavits from several physicians stating that the pharmaceutical representatives had made misrepresentations to them”); Michael G. Ziegler et al., *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 JAMA 1296, 1296 (1995) (surveying 106 statements made by pharmaceutical marketers during thirteen presentations and finding that eleven percent of statements made were inaccurate).

¹⁴⁸ Fla. Bar v. Went For It, Inc., 515 U.S. 618, 625–26 (1995) (internal quotation marks omitted) (citing *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995)).

¹⁴⁹ *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993).

down Florida's ban on in-person solicitations in large part because the state board "present[ed] no studies that suggest personal solicitation of prospective business clients by [certified public accountants] creates the dangers of fraud, overreaching, or compromised independence that the Board claim[ed] to fear."¹⁵⁰ The Court noted in particular that "[t]he record [did] not disclose any anecdotal evidence, either from Florida or another State, that validate[d] the Board's suppositions."¹⁵¹ Here, by contrast, the evidence demonstrates the effect that marketing has on medical decisionmaking¹⁵² and the economic toll those decisions can have.¹⁵³ Simply put, "past detailing affects current prescription behavior."¹⁵⁴

Conversely, in *Florida Bar v. Went For It, Inc.*, the Court upheld a regulation on solicitations by lawyers in part because of the extensive empirical and anecdotal evidence that substantiated the state's claim.¹⁵⁵ Justice Kennedy, however, disagreed with the weight given to the empirical evidence offered because much of it was not published in peer-reviewed publications and little information was available on the data's methodologies.¹⁵⁶ Not only does the empirical and anecdotal evidence here match the breadth and depth of the evidence offered in *Went For It, Inc.*,¹⁵⁷ but it also satisfies Justice Kennedy's concerns because most of the studies cited here disclose their methodology and were published in peer-reviewed publications.¹⁵⁸ Moreover, in *Lorillard Tobacco Co. v. Reilly*, the Court accepted the findings of various studies presented by the government to conclude that limiting youth exposure to tobacco marketing would reduce underage tobacco use and held the *Central Hudson* test satisfied.¹⁵⁹ Similarly here, the extensive body of evidence documenting the link between medical marketing and doctors' decisionmaking supports the claim that marketing causes overspending¹⁶⁰ and limiting physician exposure to in-

¹⁵⁰ *Id.* at 771.

¹⁵¹ *Id.*

¹⁵² *See supra* Part I.B.

¹⁵³ *See supra* Part I.C.

¹⁵⁴ Puneet Manchanda & Elisabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL'Y L. & ETHICS 785, 802 (2005).

¹⁵⁵ Fla. Bar v. *Went For It, Inc.*, 515 U.S. 618, 626–29 (1995).

¹⁵⁶ *Id.* at 640–41 (Kennedy, J., dissenting).

¹⁵⁷ Compare *id.* at 626–29 (majority opinion), with *supra* note 33.

¹⁵⁸ *See supra* note 33.

¹⁵⁹ *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 560–61 (2001).

¹⁶⁰ *See generally supra* Part I.B–C.

dustry gifts will decrease the use of overpriced and unnecessary drugs and medical devices.

Pharmaceutical companies and medical device manufacturers may contest the link between advertising (in the form of detailing) and consumption (in the form of prescribing) to argue that regulations would not directly advance the government's interest. However, the very size and scale of the medical marketing machine attests to the extent to which detailing directly boosts sales of expensive medicines; companies would not devote billions of dollars to detailing and doctors if marketing did not benefit business.¹⁶¹ Just as the Court made clear in *Central Hudson*, “[t]here is an immediate connection between advertising and demand . . . [Plaintiff] would not contest the advertising ban unless it believed that promotion would increase its sales. Thus, we find a direct link between the state interest in conservation and the Commission’s order.”¹⁶²

4. *Is the Regulation Narrowly Tailored to Serve the Government’s Interest?*

The fourth prong of the *Central Hudson* test is that restrictions must be “no more extensive than necessary to further the State’s interest.”¹⁶³ The Court qualified this part of the test in *Fox*, where Justice Scalia wrote that the language “not more extensive than necessary” is less demanding than a least-restrictive-means standard.¹⁶⁴

What our decisions require is a “fit” between the legislature’s ends and the means chosen to accomplish those ends—a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective. Within those bounds [the Court] leave[s] it to governmental

¹⁶¹ See *supra* text accompanying note 32.

¹⁶² *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 569 (1980). Other courts have also used the magnitude of marketing initiatives to satisfy the direct advancement prong of the *Central Hudson* test. See, e.g., *Dunagin v. City of Oxford*, 718 F.2d 738, 749 (5th Cir. 1983) (“It is beyond [the court’s] ability to understand why huge sums of money would be devoted to the promotion of sales of liquor without expected results, or continue without realized results . . . [D]ollars go into advertising only if they produce sales.”).

¹⁶³ *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 569–70.

¹⁶⁴ *Bd. of Trs. v. Fox*, 492 U.S. 469, 480 (1989) (noting that although restrictions must be narrowly tailored, they need not be the least restrictive means).

decisionmakers to judge what manner of regulation may best be employed.¹⁶⁵

In other words, “this standard requires the restriction to be ‘in reasonable proportion to the interest served.’”¹⁶⁶ This aspect of the commercial speech test is the most treacherous.¹⁶⁷ Regulations aimed at restricting medical marketing, however, should survive this element of judicial scrutiny so long as they are carefully crafted to avoid being impermissibly broad.

The Court, in assessing this prong of the test, balances the costs of the regulation, in terms of legal or useful speech banned, against the benefit likely to be realized—meaning the extent to which the regulation will further the government’s goal.¹⁶⁸ In *Thompson v. Western States Medical Center*, the Court overturned a ban on the advertisement and promotion of certain compounded medicines.¹⁶⁹ In addition to rejecting the government’s proffered justifications, the Court denounced the regulations under *Central Hudson* because of “the amount of beneficial speech prohibited” by the regulation in question.¹⁷⁰ The Court found the regulation lacking under the *Central Hudson* test because an absolute ban on promoting compounded drugs would prohibit a disproportionate amount of speech that is beneficial to patients.¹⁷¹ In other words, the legislature’s solution to a perceived problem was unreasonably broad because it prohibited too much speech.

Likewise, in *Lorillard Tobacco Co.*, the Court rejected a ban on outdoor advertisements for cigars and smokeless tobacco within 1000 feet of a school because the restriction would, in certain metropolitan areas, “constitute nearly a complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers.”¹⁷² The Court found the statute’s broad reach indicated a fa-

¹⁶⁵ *Id.* (internal quotation marks and citations omitted).

¹⁶⁶ *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 59 (1st Cir. 2008) (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993)).

¹⁶⁷ *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 569 (referring to the fourth prong as “the critical inquiry”).

¹⁶⁸ See *City of Cincinnati v. Discovery Network*, 507 U.S. 410, 417 (1993) (holding that the state must carefully calculate “the costs and benefits associated with the burden on speech imposed” by prohibitions on commercial speech).

¹⁶⁹ “Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient.” *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61, 376 (2002).

¹⁷⁰ *Id.* at 371–73, 376.

¹⁷¹ See *id.* at 377.

¹⁷² *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561–62 (2001) (observing that the cumula-

tal lack of tailoring.¹⁷³ The Court described the dilemma in terms also applicable to the regulation of medical marketing:

The State's interest . . . is substantial, and even compelling, but it is no less true that the sale and use of tobacco products by adults is a legal activity. We must consider that tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products.¹⁷⁴

Accordingly, medical marketing regulations could likely pass the Court's scrutiny so long as they do not effectively prohibit pharmaceutical companies and medical device manufacturers from communicating "truthful information" to physicians, either in marketing materials or through industry-sponsored educational activities.¹⁷⁵ Carefully tailoring regulations on drug and medical device detailing acknowledges that physician-industry relationships are not per se harmful. Indeed, pharmaceutical companies and medical device manufacturers ought to maintain contact with medical professionals in order to inform them about new and existing products. Given the Court's standard for evaluating restrictions on commercial speech, a carefully tailored statute restricting medical marketing would likely pass the Court's muster.

IV. THE MEDICAL MARKETING ACT

Although others in both the legal and medical community have lambasted medical marketing, few have offered concrete, detailed solutions.¹⁷⁶ This Part proposes statutory text for Congress to adopt, followed by a section-by-section analysis of this Note's solution: the Medical Marketing Act. Finally, this Part evaluates the Medical Marketing Act in light of the *Central Hudson* test and the First Amendment.

tive effect of zoning restrictions and the regulations at issue would effectively prohibit cigar and smokeless tobacco advertisements "in 87% to 91% of Boston, Worcester, and Springfield, Massachusetts").

¹⁷³ *Id.* at 563.

¹⁷⁴ *Id.* at 564.

¹⁷⁵ *Id.* at 562–63.

¹⁷⁶ See, e.g., Stephen A. Talmadge, *Influencing Physicians' Prescribing Behavior: Ethical Issues Related to Pharmaceutical Gifts*, 11 MICH. ST. J. MED. & L. 303, 318–20 (2007) (suggesting ways to avoid doctor-industry entanglements); Zalesky, *supra* note 58, at 260–64 (proposing characteristics for a framework of reform); Scott Velasquez, Note, *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, 580–81 (2008) (recommending the enactment of a federal gift disclosure law modeled on California and Vermont statutes).

A. *Proposed Text*

To reduce overspending on drugs and devices caused by medical marketing, Congress should amend section 353 of title 21 of the United States Code—the section of the United States Code that already contains regulations pertaining to drug sales and drug samples¹⁷⁷—to add the following language, which may be cited as “The Medical Marketing Act”¹⁷⁸:

(h)(1) A manufacturer or distributor of a drug or device may not—

(A) give a covered health entity a gift of any value, either directly or indirectly, or

(B) make a payment or transfer of value to a covered health entity, either directly or indirectly, except as provided in (h)(2).

(2) A manufacturer or distributor of a drug or of a device may make payments or transfers of value to a covered health entity for the following purposes, and subject to the following restrictions, notwithstanding (h)(1)(B):

(A) Consulting and Advisory Fees—

(i) Payments for consulting and advisory services may not exceed the reasonable fair market value for such services as determined by the Commissioner.

(ii) Token consulting or advisory arrangements are prohibited.

(iii) Covered health entities engaged in a bona fide consulting or advisory relationship may receive reasonable reimbursement for time, travel, lodging, and other out-of-pocket expenses.

(B) Continuing Medical Education and Third-Party Educational or Professional Meetings—A sponsorship of continuing medical education or independent medical education may be made if—

¹⁷⁷ See 21 U.S.C. § 353(c)–(d) (2006).

¹⁷⁸ The structure and language of this proposed legislation is borrowed in part from the Patient Protection Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), the Physician Payments Sunshine Act, S. 301, 111th Cong. (2009), the Gift Disclosure Act, H.R. 3023, 110th Cong. (2007), and the *PhRMA Code*, *supra* note 66. The Patient Protection Act is neither stricken nor expressly preempted by the Medical Marketing Act because both laws can peaceably coexist. The Medical Marketing Act may narrow the applicability of the Patient Protection Act by, for instance, banning many activities that would otherwise require disclosure. Nonetheless, the two Acts are not in direct conflict. The proposed statutory language begins at subsection (h) simply because section 353 of title 21 of the United States Code presently ends at subsection (g). See 21 U.S.C. § 353.

- (i) payment is made directly to the educational provider to reduce the participation cost for all attendees;
 - (ii) responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs exclusively to the organizers of the conferences or meetings in accordance with their guidelines; and
 - (iii) no payments for cost of travel, lodging, or otherwise are made directly to a covered health entity.
- (C) Speaking Arrangements and Training Meetings—
 - (i) A speaking arrangement or training meeting venue and accommodations must be modest and reasonable as determined by the Commissioner.
 - (ii) A paid speaker presenting or otherwise participating in the training event must have received substantial training regarding the relevant products or services.
 - (iii) A paid speaker presenting or otherwise participating in the training event must provide a valuable service to the relevant manufacturer or distributor of a drug or device.
- (3) A manufacturer or distributor of a drug or of a device is subject to a civil monetary penalty of not more than \$100,000 for each violation of this subsection.
- (4) Enforcement—
 - (A) The Commissioner shall investigate compliance with this subsection.
 - (B) If, after carrying out an investigation under subparagraph (A), the Commissioner has reasonable cause to believe that a gift, payment, or transfer of value has been made in violation of the provisions of this subsection, the Commissioner may petition the United States District Court in which the responsible party resides or transacts business for an order requiring such relief as the Court considers appropriate including but not limited to remedies listed under (h)(3).
- (5) For the purposes of this subsection:
 - (A) The term “covered health entity” means a person authorized to prescribe or dispense drugs or devices, including physicians, nurses, therapists, hospitals, nursing homes, pharmacists, and health benefit plan administrators.
 - (B) The term “gift” means any payment or transfer of any item or service of value, including meals, food other

than meals, travel, entertainment, recreation, and items of nominal value such as pens, stationary, coffee mugs, and the like. The term “gift” does not include free samples of drugs intended to be distributed to patients free of charge.

(C) The term “bona fide consulting or advisory relationship” means a relationship consisting of—

- (i) a written contract specifying the nature of the services to be provided and the basis of payment for those services;
- (ii) a legitimate need for the services specified in the contract under (h)(5)(C)(i); and
- (iii) a manufacturer, packer, or distributor of a drug or of a device not retaining more covered health entities than the number reasonably necessary for any particular purpose.

B. Section-by-Section Analysis

Subsection (h)(1) establishes the baseline mandatory ban on gifts and meals subject to the limited exceptions laid out in subsection (h)(2). To address some of the shortcomings of previous attempts at regulating marketing practices,¹⁷⁹ the Medical Marketing Act bans certain behavior outright instead of settling for disclosure or voluntary compliance.

Subsection (h)(2) sets out a limited number of exceptions to the Medical Marketing Act. These exceptions are intended to facilitate and otherwise leave, unaffected the beneficial aspects of the doctor-detailer relationship, while still drawing clear lines between acceptable and unacceptable marketing behavior.

Paragraph (h)(2)(A) addresses exceptions for consulting and advisory fees. These relationships can serve a useful function,¹⁸⁰ but they also require certain limits to ensure that they are not misused. Subsection (h)(2)(A)(i) is intended to limit the overall amount that medical providers can receive in such arrangements, while still giving a degree of flexibility for particularly prestigious doctors and others who might command higher fees in a fair market. Subsection (h)(2)(A)(ii) explicitly proscribes the type of token relationships that have occurred in the past,¹⁸¹ and subsection (h)(2)(A)(iii) limits the

¹⁷⁹ See *supra* Part II.

¹⁸⁰ See *supra* note 34 and accompanying text.

¹⁸¹ For example, medical device maker Medtronic had an arrangement with a prominent

types of expenses for which drug and device companies can reimburse physicians without running afoul of the Act.

Paragraph (h)(2)(B) seeks a middle ground, whereby drug and device companies can fund attendance at continuing medical education programs or other informational gatherings while eliminating the potential for reciprocity that can arise when a specific drug or device company pays for a particular physician's attendance by reducing the costs for all participants.¹⁸² Moreover, deference to the organizers of an educational event will help ensure that continuing medical education seminars take place at reasonable venues and focus on the educational aspect of the gathering.

Paragraph (h)(2)(C) attempts to place reasonable boundaries around speaking arrangements in a way similar to subsection (h)(2)(A). Subsection (h)(2)(C)(i) ensures that training events take place in modest locations, and subsections (h)(2)(C)(ii) and (h)(2)(C)(iii) help eliminate token arrangements by requiring that any speaker or presenter receive substantial training and provide a valuable service.

Subsection (h)(3) establishes a stringent civil penalty for noncompliance. Although other legislation includes provisions for fining noncompliant parties,¹⁸³ the Medical Marketing Act imposes particularly severe fines because lenient penalties provide almost no incentive to discontinue objectionable marketing practices. Given the extraordinary profits of the drug and medical device industries,¹⁸⁴ defendant companies might dismiss fines that are too low as the cost of doing business. Harsh fines send a message to the industry that improper marketing will not be tolerated.

Subsection (h)(4) establishes that the Commissioner of the Food and Drug Administration ("FDA") shall oversee compliance with the Medical Marketing Act. This delegation of responsibility gives the Medical Marketing Act considerable administrative flexibility¹⁸⁵ and

Wisconsin surgeon whereby the surgeon received \$400,000 under a consulting contract that only required eight days of work. See Harris, *supra* note 64.

¹⁸² See *supra* note 52.

¹⁸³ See, e.g., Patient Protection Act § 6022, 124 Stat. at 691.

¹⁸⁴ See *supra* note 22 and accompanying text.

¹⁸⁵ See Lisa Schultz Bressman, *Chevron's Mistake*, 58 DUKE L.J. 549, 568 (2009) ("Congress might aim to write just enough policy to receive a positive response for its action, while deflecting any negative attention for the burdensome details to the agency."); Victoria F. Nourse & Jane S. Schacter, *The Politics of Legislative Drafting: A Congressional Case Study*, 77 N.Y.U. L. REV. 575, 595 (2002) (discussing the use of "deliberate [legislative] ambiguity" and the perception of ambiguity "as justified by the felt need for action or the perceived threat that inflexible political positions would thwart passage of any bill at all").

makes sense given the FDA's historic role as the agency "responsible for the regulation and enforcement of law in the area of labeling, advertising, and promotion of prescription drug products."¹⁸⁶

Subsection (h)(5) provides definitions for some of the Medical Marketing Act's crucial terms. Subsection (h)(5)(A) defines "covered health entity" very broadly so as to apply to any professional who provides access to prescription drugs and medical devices. Subsection (h)(5)(B) also defines gift broadly so that the term includes everything from breakfast and coffee mugs to golf clubs and getaways. To avoid the problems of reciprocity that crop up with even the smallest gifts,¹⁸⁷ this subsection includes no exceptions based on the value of a gift. Finally, subsection (h)(5)(C) defines "bona fide consulting or advisory relationship" in such a way as to reduce the possibility of a token relationship. To do so, the Medical Marketing Act requires that drug and medical device companies specify, in writing, the services requested. This subsection also requires that drug and medical device companies employ physicians only where they have a legitimate need for the services and that no more consultants are employed than reasonably necessary. This reduces the possibility of token consultancy arrangements by linking employment to actual need.

C. *The Medical Marketing Act and Commercial Speech Jurisprudence*

In order to survive a First Amendment challenge, the Medical Marketing Act must satisfy the Supreme Court's commercial speech test.¹⁸⁸ Assuming drug and medical device detailing qualifies as commercial speech,¹⁸⁹ the Medical Marketing Act is aimed at advancing the government's interest in reducing costs and spending associated with prescription drugs and medical devices, a goal the Court will likely deem sufficiently substantial.¹⁹⁰ Also, considering the extent to which states, Congress, and academics have linked medical marketing with spending on drugs and devices, the Court will likely find that the Medical Marketing Act directly advances the government's substantial interest.¹⁹¹

¹⁸⁶ Zalesky, *supra* note 58, at 252.

¹⁸⁷ *See supra* Part II.

¹⁸⁸ *See supra* Part III.

¹⁸⁹ *See supra* Part III.A–B.

¹⁹⁰ *See supra* Part III.C.1.

¹⁹¹ *See supra* Part III.C.3.

Moreover, the Medical Marketing Act will likely meet the Court's tailoring requirement¹⁹² because it carefully proscribes only marketing conduct that is particularly likely to cause wasteful prescribing—namely, gifts and meals.¹⁹³ By carving out narrow exceptions for those forms of industry marketing with the most educational potential,¹⁹⁴ the Medical Marketing Act ardently attempts to address the growing problem of industry-induced overspending in a way that impinges on minimal amounts of beneficial speech.¹⁹⁵ Also, by requiring compliance, eliminating gift value exceptions, and eschewing disclosure, the Medical Marketing Act seeks to build upon lessons learned from other attempts at reducing the effect of detailing on medical decisionmaking.¹⁹⁶

The pharmaceutical and medical device industries would likely respond that any significant restriction on marketing activity will chill their ability to educate physicians on new and important medical developments.¹⁹⁷ This argument is unlikely to succeed, however, because the Medical Marketing Act does not prohibit sharing a meal, just paying for it; the same is true for gifts. If information is all detailers care to convey, pharmaceutical companies and medical device manufacturers remain free to pitch products to physicians under the regulations proposed here. The Medical Marketing Act is aimed solely at the meddling of financial interests through gifts and payments, not the underlying conversation between doctors and detailers. Because medical marketers are trying to sell a product, the likelihood of carefully crafted restrictions substantially limiting the marketer's business is minimal. Indeed, the Supreme Court has made abundantly clear that "the greater 'hardiness' of commercial speech, inspired as it is by the profit motive, likely diminishes the chilling effect that may attend its regulation."¹⁹⁸ For these reasons, the Medical Marketing Act would likely survive a First Amendment commercial speech challenge.

¹⁹² See *supra* Part III.C.4.

¹⁹³ See *supra* Part I.B–C.

¹⁹⁴ See *supra* Part IV.B.

¹⁹⁵ See *supra* Part III.C.4.

¹⁹⁶ See *supra* Part II.

¹⁹⁷ See, e.g., Saul, *supra* note 8 (quoting a PhRMA employee describing free meals as "a recognition that [healthcare providers] are extremely busy. They don't have time to talk. Perhaps the only time they do have time to talk is over lunch or dinner. So we thought it was appropriate for the sales rep to pay for that.").

¹⁹⁸ 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 499 (1996).

CONCLUSION

Medical marketing has become a widespread practice with pernicious effects on doctors' decisionmaking, which translate into unjustifiable overspending on prescription drugs and medical devices. Attempts thus far by industry groups, states, and Congress have failed to appropriately address the problem due to reliance on disclosure, voluntary guidelines, and regulations containing exceptions. As such, Congress should pass the Medical Marketing Act to limit permissible exchanges between doctors and detailers, thus reducing the wasteful overspending that ultimately affects every taxpayer.