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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signed to maximize market share, and doctors are one of their main
targets. 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. 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. 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. 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.

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. Under an educa-
tional guise, paid and highly trained sales representatives en-

Drugs, 357 NEW ENGL. J. MED. 673, 675 (2007) (estimating $29.9 billion in marketing expendi-
tures 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 (esti-
mating $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 market-
ing 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 represen-
tatives 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
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. For decades, the pharmaceutical industry made no pretense about showering doctors with lavish, nonmedical gifts. Despite recent attempts at reform, however, medical marketing remains a common practice. 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. But the drug and device industries are not only big; they are also highly profitable, returning some fifteen percent on investments—an “extraordinary” amount. Accordingly, to maintain a dominant market position, drug and device companies engage in a number of marketing activities that financially entangle doctors, com-


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.

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.”).
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. Indeed, “[d]rug companies spend billions wooing doctors—more than they spend on research or consumer advertising.” 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.”

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. 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.).


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.


See Ernst R. Berndt et al., Information, Marketing, and Pricing in the U.S. Antiulcer 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. PRACT. 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 illness\textsuperscript{34}\—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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{39}

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

\begin{itemize}
\item Wazana, supra note 27, at 378.
\item Id.
\item Id.
\item 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.”).
\item Id.
\item 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).
\end{itemize}
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

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).
48 Id. at 99.
percent more likely to consider the advertised product than those who had not seen the ads.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{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.\textsuperscript{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 devicedetailers have a clear impact on medical decisionmaking.\textsuperscript{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.\textsuperscript{54} By contrast, the twice-daily generic version, monocycline, costs $109 a month, or $1308 per year.\textsuperscript{55} Similarly, “[c]linical studies show that 95 percent of the population with arthritis—those not at risk for side effects—could take generic

\textsuperscript{49} Id. at 101–02.
\textsuperscript{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, \textit{Adios, Allegra Pens; Farewell, Flonase Mugs}, STAR TRIB., Jan. 18, 2008, at A10.
\textsuperscript{52} See, e.g., James P. Orlowski & Leon Wateska, \textit{The Effects of Pharmaceutical Firm En- ticements on Physician Prescribing Patterns: There’s No Such Thing as a Free Lunch}, 102 \textit{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).
\textsuperscript{53} \textit{See supra} Part I.B.
\textsuperscript{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.


59 See supra text accompanying note 16.


61 Id. (emphasis added).

11% of drug expenditures.”

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. Medical schools, industry organizations, state legislatures, and Congress 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 California and New Hampshire, 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.
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).
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 state\textsuperscript{71} and federal\textsuperscript{72}—relies on Justice Brandeis’s ad-
monition that “sunlight is the best disinfectant”\textsuperscript{73} by requiring regular
disclosure of various marketing expenditures.\textsuperscript{74} Disclosure schemes
are designed to “outlaw particular conduct by bringing legal or moral
pressure to bear upon those engaging in it.”\textsuperscript{75}
Disclosure-based regulations fall short as a means of eliminating
the pernicious effect detailers have on medical decisionmaking be-
cause disclosure laws, although admirable in theory, “do not restrict
conduct beyond requiring that certain information be provided.”\textsuperscript{76}
Therefore, disclosure alone does little to counteract the effects detail-
ers have on medical decisionmaking. Even though doctors claim that
gifts do not affect their medical judgment,\textsuperscript{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.\textsuperscript{78}
Moreover, disclosure is an empty gesture because patients cannot
adequately use disclosed information to adjust their approaches to

\textsuperscript{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.

\textsuperscript{71} See supra note 67.

\textsuperscript{72} See supra note 68.

\textsuperscript{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.”).

\textsuperscript{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.”).

\textsuperscript{75} STEPHEN G. BREYER, REGULATION AND ITS REFORM 162 (1982).

\textsuperscript{76} Id. at 163.

\textsuperscript{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,

\textsuperscript{78} See, e.g., Katz et al., supra note 10, at 39 (“Considerable evidence from the social sci-
cences 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

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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. 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. In Minnesota, payment data has never been publicly available. “Indeed, the disclosure forms submitted have literally sat in boxes for up to a decade, gathering dust and never being analyzed.” 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. 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”). The codes proffered by both AMA and PhRMA represent respectable attempts at curbing many of medical marketing’s most troubling aspects, including free meals, complimentary entertainment and recreation, funds for continuing medical education, questionable consultancy agreements, inflated speaking fees, and even gifts.
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

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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).

Although the aforementioned state disclosure statutes will be preempted as of January 1, 2012, by the Patient Protection and Affordable Care Act, the new federal statute itself includes its own exception for gifts and payments valued under $10. Even the PhRMA Code expressly permits gifts that “advance disease or treatment education” as well as meals that are both “modest as judged by local standards” and “provided in a manner conducive to informational communication.” 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. Cheap trinkets and modest meals trigger the norm of reciprocity, ultimately contributing to overspending on prescription drugs and medical devices. 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.” 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.” 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-
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. Traditionally used to “protect the exchange of ideas and political, social, scientific, or artistic expression,” the Supreme Court has expanded the First Amendment’s reach to also include commercial speech. 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. 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. 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. In so holding, the First Circuit concluded that the challenged restrictions on medical marketing regulated con-

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117 Ayotte, 550 F.3d at 45.
duct and not protected speech. The court also held that, in the alternative, the contested regulations were permissible restrictions on protected speech if marketing did indeed qualify as speech.

Because parties have invoked the First Amendment in other aspects of advertising regulations generally and pharmaceutical marketing specifically—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. 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.” 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. Here, detailing by drug and device companies meets all three criteria. Medical marketing is concededly a marketing activity, detailers push specific prod-

\[\text{118 Id.}\]
\[\text{119 Id.}\]
\[\text{120 See, e.g., Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512, 520–21 (W.D. Ky. 2010).}\]
\[\text{123 Wash. Legal Found., 13 F. Supp. 2d at 59; see also Harris, supra note 18.}\]
\[\text{124 Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 66–67 (1983) (holding that each factor alone was not dispositive as to the status of speech, but that “[t]he combination of all these characteristics . . . provides strong support for . . . [concluding] that the [advertisements] are properly characterized as commercial speech”).}\]
\[\text{125 See PhRMA Code, supra note 66, at 2 (stating that the industry’s guidelines are aimed}\]
ucts,\textsuperscript{126} and detailing is motivated by the economic interests of the speaker.\textsuperscript{127} As such, medical marketing qualifies as commercial speech under \textit{Bolger}.

Second, in \textit{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.”\textsuperscript{128} The practice of detailing is similar. Even though medical marketing is superficially educational, medical marketers are chiefly concerned with increasing product sales.\textsuperscript{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.\textsuperscript{130} Thus, because detailers “propose[] a commercial transaction,”\textsuperscript{131} medical marketing constitutes commercial speech.

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\textsuperscript{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)).
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\textsuperscript{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, \textit{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”).
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\textsuperscript{129} See supra Part I.A.
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\textsuperscript{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.”).
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\textsuperscript{131} Fox, 492 U.S. at 473.
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The test for regulating commercial speech comes from *Central Hudson Gas & Electric Corp. v. Public Service Commission*. 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.”

While Congress and a number of states have enacted statutes aimed at regulating medical marketing, no case challenging such a statute has contested restrictions on medical marketing as it is discussed here. 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.” Moreover, “[t]he prescription drug costs incurred by some 850,000 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.”

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

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.
137 Id.; see also notes 57–63 and accompanying text.
substantial government interest. Likewise, the district court in IMS Health Inc. v. Sorrell relied on Ayotte to conclude that “Vermont’s interest[ ] in cost containment . . . [is] substantial.” 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.”

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.

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. 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. 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.

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138 Ayotte, 550 F.3d at 55.
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.”).
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.”


[^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).


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.” 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.” Here, by contrast, the evidence demonstrates the effect that marketing has on medical decisionmaking and the economic toll those decisions can have. Simply put, “past detailing affects current prescription behavior.”

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. 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. Not only does the empirical and anecdotal evidence here match the breadth and depth of the evidence offered in *Went For It, Inc.*, 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. 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. Similarly here, the extensive body of evidence documenting the link between medical marketing and doctors’ decisionmaking supports the claim that marketing causes overspending and limiting physician exposure to in-

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150 Id. at 771.
151 Id.
152 See supra Part I.B.
153 See supra Part I.C.
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.
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. 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.”

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.” 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.

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

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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.”).
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.\textsuperscript{165}

In other words, “this standard requires the restriction to be ‘in reasonable proportion to the interest served.’”\textsuperscript{166} This aspect of the commercial speech test is the most treacherous.\textsuperscript{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.\textsuperscript{168} In Thompson v. Western States Medical Center, the Court overturned a ban on the advertisement and promotion of certain compounded medicines.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.”\textsuperscript{172} The Court found the statute’s broad reach indicated a fa-

\textsuperscript{165} Id. (internal quotation marks and citations omitted).
\textsuperscript{166} IMS Health Inc. v. Ayotte, 550 F.3d 42, 59 (1st Cir. 2008) (quoting Edenfield v. Fane, 507 U.S. 761, 767 (1993)).
\textsuperscript{167} Cent. Hudson Gas & Etc. Corp., 447 U.S. at 569 (referring to the fourth prong as “the critical inquiry”).
\textsuperscript{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).
\textsuperscript{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).
\textsuperscript{170} Id. at 371–73, 376.
\textsuperscript{171} See id. at 377.
\textsuperscript{172} Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 561–62 (2001) (observing that the cumula-
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.

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173 Id. at 563.
174 Id. at 564.
175 Id. at 562–63.
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 samples—\(^{177}\) 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—


\(^{178}\) 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
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.\textsuperscript{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,\textsuperscript{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,\textsuperscript{184} defiant 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 flexibility\textsuperscript{185} and

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

\textsuperscript{182} See \textit{supra} note 52.

\textsuperscript{183} See, \textit{e.g.}, Patient Protection Act § 6022, 124 Stat. at 691.

\textsuperscript{184} See \textit{supra} note 22 and accompanying text.

\textsuperscript{185} See Lisa Schultz Bressman, \textit{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, \textit{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.”

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, 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. Assuming drug and medical device detailing qualifies as commercial speech, 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. 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.

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 requirement because it carefully proscribes only marketing conduct that is particularly likely to cause wasteful prescribing—namely, gifts and meals. By carving out narrow exceptions for those forms of industry marketing with the most educational potential, 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. 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.

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. 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.” 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.”).
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.