REFLECTION

It's Time to Shine the Light on Direct-to-Consumer Advertising

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ABSTRACT

Pharmaceutical marketing is undergoing a transition as the business, delivery, and consumption of health care have increasingly become part of a growing digital landscape. Changes in pharmaceutical promotion also coincide with federal "sunshine" regulations newly implemented under the Affordable Care Act that require disclosure of certain marketing and industry payments to physicians. Collectively, these trends could lead to fundamental shifts in physician-directed and direct-to-consumer advertising (DTCA) that have yet to be adequately identified or explored. In response, we advocate for greater DTCA transparency, especially in the emerging digital forms of DTCA, to complement forthcoming sunshine transparency data. This will allow more robust study and understanding of changes in overall pharmaceutical marketing trends and their impact on health care consumption and behavior. This can also lead to more targeted state and federal policy interventions leveraging existing federal transparency regulations to ensure appropriate marketing, sales, and consumption of pharmaceutical products.

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BACKGROUND

Over the past few decades, US pharmaceutical marketing has evolved in new and unexpected ways, as the business of health care has become part of a growing "eHealth" landscape. Increasingly, patients and other consumers, clinicians, and the industry have started to embrace emerging forms of digital technology (eg, the "health Internet," mobile health applications, self-tracking devices, and social media) that can influence health care information sourcing, consumption, and delivery. As an indication of this shift to "all things digital," the Pew Research Internet Project reports that 72% of surveyed US adults looked for health information online within the past year, 69% track at least 1 health indicator such as weight, exercise, symptoms, blood pressure, or sleeping patterns (with 21% of respondents using a form of technology to do so), and 52% of smartphone users use their devices to search for medical/health information.[1]

With consumers increasingly using information technology to deal with health issues, and with pharmaceutical manufacturers using direct-to-consumer advertising (DTCA) on the Internet, in social media, and through mobile applications (collectively "eDTCA"),[3-6] traditionally dominant forms of pharmaceutical marketing, which include physician-directed promotion and advertising in traditional media (eg, television, radio, print, and outdoor advertisements) might also be changing.

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RISE, DECLINE, AND LACK OF TRANSPARENCY OF PHARMACEUTICAL MARKETING

DTCA, a phenomenon legally permissible only in the United States and New Zealand among developed countries,[2] experienced rapid growth

in the United States when the US Food and Drug Administration (FDA) first liberalized its use in the 1980s and 1990s.[7] An estimated 330% rise in DTCA spending from 1996 to 2005 coincided with a wave of new FDA drug approvals, including approvals of "blockbuster" drugs such as Lipitor, Nexium, and Vioxx.[8] This led to a proliferation of drug advertisements on TV and in print to which the vast majority of Americans were exposed, likely prompting patients to request a promoted drug from their physician.[9,10] After hitting a peak of $5.89 billion in 2006, DTCA began to decline, with spending estimated to be $4.37 billion in 2010. This decrease has largely been attributed to dwindling drug pipelines, blockbuster patent expirations, and the recent global economic slowdown,[11-13] although certain subcategories (eg, television) are experiencing sharper declines than others (eg, the Internet).[11]

Proponents emphasize DTCA's potential to educate consumers, while critics argue that DTCA leads to overemphasis on benefits vs risks, inappropriate prescribing, and increased national drug expenditures.[8-10] Some have called for a complete ban on DTCA, while others have called for a temporary moratorium on new drug approvals, pointing out that many blockbuster drugs aggressively marketed through DTCA were later discovered to have adverse or harmful effects—some severe enough to result in their withdrawal, as in the case of Vioxx.[8,10,14]

Though DTCA has been the subject of debate, one inconvenient fact has made it difficult for researchers and policy makers to assess its economic and health impact: lack of transparency and public reporting of DTCA data. Though attempts have been made to quantify overall pharmaceutical promotion accurately, issues regarding its proprietary nature, the need to source information from third-party marketing firms and data analysis firms rather than directly from advertisers, and the lack of regulation requiring public reporting and transparency have all limited evidence-based assessment.[15] This specifically includes DTCA expenditure data (notably for eDTCA), with information available almost exclusively from proprietary and fee-based marketing firms that differ in reported estimates. These firms generally conduct surveys and monitor promotion from samples of national media data sources for data collection.

SHINING THE LIGHT ON PHYSICIAN-DIRECTED PROMOTION, BUT NOT DTCA?

The "Transparency Reports and Reporting of Physician Ownership or Investment Interests" section of the US Affordable Care Act, commonly called "The Sunshine Act," which has given rise to the Centers for Medicare & Medicaid Services (CMS) Open Payments system, will in 2014 expose a large category of pharmaceutical marketing expenditures to public scrutiny for the first time.[16] The law mandates that drug and device manufacturers now publicly report certain payments made to physicians and teaching hospitals (including entertainment, gifts, food, travel, consulting fees, honoraria, education or conference fees, and other forms of "transfers of value") annually, with monetary penalties for noncompliance.[16] This policy change, largely a response to concerns over physician-industry conflicts of interest, will provide detailed and validated data regarding important forms of national physician-directed promotion expenditures that will be public and freely available.[16]

Missing from this potentially groundbreaking legislation, however, are any requirements for transparency and reporting of DTCA expenditures by industry. Specifically, the regulations only cover certain forms of promotion directed to licensed physicians and teaching hospitals, *not* promotion directed to the consumer. Pharmaceutical DTCA is different from other forms of consumer marketing in that consumers do not directly purchase promoted pharmaceutical products as they do other consumer goods. Instead, pharmaceuticals require appropriate consultation and monitoring by healthcare professionals for use and dispensing; hence, DTCA content must be appropriately understood and regulated to ensure that it facilitates appropriate interactions between patients and physicians that balance the risks and benefits of treatment.[8]

The Sunshine Act is primarily aimed at curtailing gifts and favors to individual physicians, so it may have limited impact on certain forms of physician detailing, specifically those detailing encounters that do not involve a transfer of value or are nonreportable (e.g. involve a transfer of value less than $10, or $100 in the aggregate for a calendar year). Nor does it address drug sampling, which can also lead to physician-industry marketing encounters.[17] Further, the act will not prevent broader physician-directed marketing through medical journals, medical websites (eg, WebMD) and through advertising embedded into mobile apps such as Epocrates.[18] Hence, it is likely that physician-directed pharmaceutical marketing will simply shift to more subtle forms of promotion that are difficult to detect, not reportable, or emerging in new and largely unregulated media such as the Internet.

Changes in physician-directed promotion as a result of transparency requirements could also overlap with changes in DTCA strategies now focusing on meeting consumers where they predominantly search for and consume health information: online.[1] Innova-

Table 1: Proposed Public DTCA Disclosure Categories

DTCA Data Category	Description
Expenditure amount	Monetary value ($USD) for promotion for each marketing medium utilized
Category of DTCA	Product claims ad, reminder ad, help-seeking ad
Marketing medium	TV, radio, print, outdoor, Internet, Internet-social media, prescription drug coupon, etc.
Language	Language(s) utilized in DTCA
Location	Name of country/state DTCA is limited to/disseminated in
Time	Length (in days) of DTCA promotional campaign
Product class	Pharmaceutical, biological, medical device, etc.
Therapeutic category	Therapeutic category of DTCA product
Disease associated	Disease information associated with DTCA
Name of product	Branded or proprietary name of DTCA product

tive eDTCA tactics are being used more frequently—tactics such as offering electronic prescription drug coupons and marketing to consumers through patient-engagement Web portals.[6,19] So far, eDTCA is not regulated well by the FDA, which released draft guidance on the use of "interactive promotional media" by industry only recently, in early 2014, and the draft is subject to further comments and finalization.[20,21] The nature of the Internet means that eDTCA has the ability to cross country borders and spread globally, despite its prohibition in almost all countries.[4] Hence, increased use of eDTCA could have global public health consequences, especially if not well identified and regulated.

Without reliable and accessible data on DTCA and eDTCA promotional expenditure, it will be difficult to compare changing trends in physician-directed promotion with trends in DTCA spending. To get a clearer picture of the overall impact of pharmaceutical promotion in the changing digital health landscape, stakeholders should demand increased transparency of DTCA. We propose some initial DTCA disclosure requirements to meet these goals (Table 1). These data fields could be reported in a public online database similar to the CMS Open Payments system using a similar infrastructure to lower implementation costs.

Policy reform to mandate DTCA transparency could be pursued at the state and federal level. As has already happened in states such as Minnesota, Vermont, Maine, and West Virginia, state legislators eager to understand the health and economic impact of DTCA could enact state legislation requiring disclosure of DTCA expenditures targeted at their residents (a requirement not preempted by the Sunshine Act).[16,22] Another option is to seek clarification on whether the statutory language of the Sunshine Act permits CMS to add DTCA reporting as a new reportable category under existing regulations.[16]

Consumers, public health and health care professionals, and policy makers should collectively advocate for greater transparency of DTCA to better understand its influence on pharmaceutical and health care utilization and consumer behavior. Physicians play an important role in advocating for this change because their clinical practice and relationship with patients could be the most adversely affected and because of the heightened need for physicians to guide patients concerning DTCA claims. Hence, we believe this is an opportune time to leverage the Sunshine Act to finally shed light on DTCA.

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Key words: direct-to-consumer advertising; Sunshine Act; physician payments; conflicts of interest; health marketing and promotion; health policy; eHealth

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