Self-Regulation in the Pharmaceutical Industry: The Exposure of Children and Adolescents to Erectile Dysfunction Commercials

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Abstract

Context: Spending on direct-to-consumer advertising (DTCA) for prescription pharmaceuticals has risen to record levels, five times as much as in 1996 in inflation-adjusted dollars. Major health care provider organizations have called for additional regulation of DTCA. These organizations argue that the negative impact of such advertising outweighs the informational value claimed by the pharmaceutical industry. The industry maintains that further restrictions on DTCA are not warranted because it is successfully self-regulating via "guiding principles" for DTCA as certified by firm executives.

Methods: The authors measured recent industry spending on DTCA and used regression models of Nielsen Monitor-Plus data to assess pharmaceutical firm self-regulation after the public disclosure of noncompliance with industry self-regulatory principles, specifically regarding the exposure of children and adolescents to broadcast advertisements for erectile dysfunction drugs.

Findings: Public disclosure of noncompliance with self-regulatory DTCA standards did not bring advertising into compliance. Results demonstrate that firms failed to meet the industry standard during every quarter of the six-year period of this study.

Conclusions: Results support previous research findings that pharmaceutical self-regulation is a deceptive blocking strategy rather than a means for the industry to police itself. Policy recommendations include broadcast restrictions on adult content and deincentivizing DTCA via tax reform.

Keywords direct-to-consumer advertising, self-regulation, blocking strategy, children and adolescents, pharmaceutical industry

Direct-to-consumer advertising (DTCA), ubiquitous in the United States, has received increased criticism since a 1997 US Food and Drug Administration (FDA) rule change effectively permitted television commercials

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for prescription pharmaceutical advertising (Pines 1999). Recently, the American Medical Association (AMA) and the American Society of Health-System Pharmacists (ASHP) have called for a ban on DTCA due to its negative impacts (AMA 2015; ASHP 2016). In response to criticism, the pharmaceutical industry has persistently maintained that new limitations or regulations of DTCA are not needed because it is self-regulating via the Pharmaceutical Research and Manufacturers of America's (PhRMA) "guiding principles" for DTCA (PhRMA 2008). Executives of leading pharmaceutical companies have pledged in writing that their firms are in compliance with these self-regulatory principles (PhRMA 2017). If the pharmaceutical industry can reduce the negative impacts of DTCA via self-regulation, then additional federal regulation may be perceived as unnecessary. If, on the other hand, the pharmaceutical industry is unsuccessful at self-regulating and DTCA is increasing, then there is a stronger case to be made for governmental regulatory measures.

Erectile dysfunction (ED) commercial advertising provides a particularly useful means of assessing the pharmaceutical industry's capacity to self-regulate, for several reasons. First, ED drugs have been consistently advertised since before the industry's guiding principles for DTCA were put in place. Second, as we document below, ED drugs have been among the most heavily advertised drugs in terms of both occurrences and spending. Third, ED commercials have been widely criticized by a variety of interested parties. Fourth, the exposure of children to ED advertisements is specifically regulated by the guiding principles. Finally, because we have access to data on all of the ED commercial broadcasts during the period of our study, it possible to provide a complete assessment of firm performance in this regard.

In this study we examined recent DTCA spending trends. We also sought to determine whether firm self-regulation improved after the public disclosure of noncompliance with self-regulatory principles by specifically focusing on the exposure of children and adolescents to ED broadcast advertisements (see hypotheses below). We present empirical evidence concerning these issues to advance understanding of the ability and willingness of firms to meet standards of DTCA self-regulation, to which they have attested to being in compliance, after initial noncompliance has been publicly disclosed. We conclude with policy recommendations.

Background

In 1997 the FDA introduced relaxed guidance for pharmaceutical marketing, effectively permitting broadcast advertisement of prescription

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medication. Advocates of DTCA argue that it is an appropriate means of educating consumers about diseases and appropriate treatments (Calfee 2002; Holmer 1999, 2002; PhRMA 2004, 2008). As DTCA grew in volume, public criticism mounted, resulting in a variety of governmental responses, including demands for additional restrictions on DTCA and calls for greater FDA oversight (for a chronology, see table 1). Scholars sympathetic to the educational mission of DTCA have found that "the pharmaceutical industry is not fulfilling its stated goal of patient education and empowerment" (Perry, Cox, and Cox 2013: 777). Epstein (2006) argued that too much regulation stifles pharmaceutical innovation. However, his analysis did not extend to DTCA, as he found that "misleading direct-to-consumer advertising" can "oversell the safety and efficacy of the product in question" (169). He used Merck's advertising of Vioxx to illustrate the common criticism that DTCA can be "false or misleading" (169).

The sexually explicit broadcast advertising of ED drugs during times when children and adolescents were known to be viewers have been particularly controversial. All ED television advertisements are sexually themed and mention sexual side effects, including erections lasting longer than 4 hours. Exposure to sexual content in the media has been linked to higher rates of sexual activity among adolescents (Brown et al. 2006; Collins et al. 2004) and teen pregnancy and sexual transmitted infections (Abma and Sonenstein 2001; Alves et al. 2014; Chandra et al. 2008; Devlin et al. 2007). As a result, ED advertising has been criticized by the American Academy of Pediatricians (AAP), which found that "ads for ED drugs give children and teens inappropriate messages about sex and sexuality at a time when they are not being taught well in school sex education programs" (Strasburger 2006: 2565).[1] AAP recommends that ED ads be broadcast only after 10:00 p.m. (Fuld et al. 2013). The Families for ED Advertising Decency Act would have restricted ED advertising to between 10:00 p.m. and 6:00 a.m. In 2005 PhRMA announced that it would self-regulate DTCA via its own guiding principles in an effort to obviate the need for new federal regulation (Pear 2005; Saul 2005). Specific legislation regarding ED advertising was allowed to die in subcommittee after industry

1. The AAP also states, "New research is showing that teenagers' exposure to sexual content in the media may be responsible for earlier onset of sexual intercourse or other sexual activities. What is increasingly apparent is the discrepancy between the abundance of advertising of products for erectile dysfunction . . . and the lack of advertising for birth control products or emergency contraceptives on the major TV networks" (Strasburger 2006: 2565). This policy was reaffirmed in November 2017 (AAP 2018).

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Table 1 Chronology of Key Events in the History of Direct-to-Consumer Advertising

Date	Action
August 1997	FDA published "Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements"
August 1999	FDA published "Guidance for Industry: Consumer-Directed Broadcast Advertisements"
December 4, 2002	US Government Accountability Office published "FDA Oversight of Direct-to-Consumer Advertising Has Limitations"
July 22, 2003	Senate Special Committee on Aging hearings: "Direct-to-Consumer Advertising of Prescription Drugs: What Are the Consequences?"
March 17, 2005	Families for ED Advertising Decency Act (H.R. 1420) introduced in the 109th Congress
August 2, 2005	PhRMA announces "guiding principles"
September 29, 2005	Senate Special Committee on Aging hearings: "The Impact of Direct-to-Consumer Drug Advertising on Seniors' Health and Health Care Costs"
January 1, 2006	Guiding principles go into effect; adult content must target audiences ≥80% adult
November 16, 2006	Government Accountability Office publishes "Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising"
December 1, 2006	American Academy of Pediatrics recommends restricting ED advertising to after 10:00 p.m.
December 2008	PhRMA announces revised guiding principles
April 29, 2009	H.R. 2175: Families for ED Advertising Decency Act introduced in the 111th Congress
March 2, 2009	Revised guiding principles go into effect; adult content must target audiences ≥90% adult
February 11, 2013	Noncompliance with guiding principles by ED advertisers disclosed

Notes: ED, erectile dysfunction; FDA, US Food and Drug Administration; PhRMA, Pharmaceutical Research and Manufacturers of America.

leaders pledged to modify these campaigns voluntarily via the PhRMA guiding principles (Moran 2005, 2009).

PhRMA's guiding principles restrict the programming during which ED drugs can be advertised. Because all ED ads are sexually explicit, these standards require that ED advertisements be broadcast only to audiences that are at least 90 percent adult (≥18 years of age) (PhRMA 2008). Since

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March 2, 2009, the guiding principles have required pharmaceutical firms to establish internal processes to assure compliance with the principles and require the chief executive officer and chief compliance officer of the firms utilizing DTCA to provide annual certifications of compliance. With respect to those firms that manufacture or market ED drugs in the United States, Pfizer last certified compliance with the guiding principles on March 20, 2017, and Eli Lily on April 27, 2017. GlaxoSmithKline most recently certified compliance on December 16, 2013, Bayer on April 18, 2013, and Merck on March 21, 2017 (PhRMA 2017).

In a previous study, Arnold and Oakley (2013) demonstrated that broadcast advertising campaigns for ED drugs systematically violate PhRMA's guiding principles. Over a 4-year period, eight of nine principles studied were systematically violated in ED DTCA, with each company represented in the study failing to comply with most of the principles over the study period. In particular, that study found that for no quarter during the 4-year period did any ED brand meet the audience composition standard required by the principles (Arnold and Oakley 2013: 527–32). These results were covered in the media and acknowledged by individual firms and PhRMA (Arnold 2013; Roehr 2013).

Hypotheses

If an industry is genuinely attempting to self-regulate consistent with its public pronouncements and certifications, then public disclosure of noncompliance should lead firms to modify their processes and practices to meet relevant standards. However, previous research has shown that industry self-regulation is ineffective in the absence of sanctions against firms that violate the self-regulatory norms (Arnold and Oakley 2013; King and Lenox 2000; Nash, Howard, and Ehrenfeld 2000; Short and Toffel 2010). PhRMA does not sanction firms for violating its guiding principles, and government regulators have not penalized firms for misrepresenting their compliance with these standards.

Self-regulation without genuine oversight and explicit sanctions for noncompliance fails to provide firms with adequate incentives for compliance when noncompliance is perceived to be advantageous (Arnold and Oakley 2013; King and Lenox 2000; Nash, Howard, and Ehrenfeld 2000; Short and Toffel 2010). In such cases, external commitments are decoupled from internal controls. Decoupling takes place when firms adapt formal policies but fail to implement the internal controls necessary to implement those policies (Elsbach and Sutton 1992; Westphal and Zajac 2001).

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Instead, the formal commitment constitutes a means of placating stakeholders without significantly altering firm behavior. The advantage to firms is that stakeholders accept the attestations to improved behavior and reduce pressure on the firms to alter their behavior.

Since there are no sanctions for violating the guiding principles, we would not expect the public disclosure of noncompliance to significantly alter future firm behavior absent intervention from a social control agent (Greve, Palmer, and Pozner 2010). Instead, firms can be anticipated to engage in a blocking strategy whereby they represent themselves as meeting social expectations regarding their behavior but do not implement the internal measures necessary to achieve implementation of the stated policy (Arnold and Oakley 2013). Thus, our primary hypothesis is that the disclosure event did not alter brand advertising behavior. We developed the following specific hypotheses: in the absence of penalties for noncompliance, public disclosure of firm noncompliance will not significantly alter firm compliance measured as (H1) percentage of television occurrences in violation of target audience guidelines, (H2) number of impressions generated to audience members under the age of 18, or (H3) number of advertisements placed.

Methods

Data

To determine spending on DTCA, we obtained data from Kantar Media that tracks local and national advertising campaigns covering television, print, radio, and online advertising. We obtained data specifically for the ED category, the individual drugs within this category, and overall spending data for the entire prescription pharmaceutical industry. The data from Kantar Media (2017) covered all instances of advertising during the period of the study.

To test our hypotheses, we purchased Monitor-Plus data from Nielsen (2016). The Nielsen Monitor-Plus data set offers the ability to estimate the number of viewers by age for each advertising occurrence. There are approximately 120 million television households in the United States, and Nielsen provides estimates for viewership based on a panel of 40,300 households that report their viewing patterns on a daily basis. These viewership data are compared to the population household data to determine the number of viewers at a particular point in time, along with their demographic information, for each advertising occurrence. The Nielsen

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Monitor-Plus data set reports gross rating points for national, cable, broadcast, and syndication occurrences of all television advertisements. Specifically, the report identified all occurrences of Viagra, Cialis, and Levitra television spots, along with audience composition as measured by Nielsen (2016).

Analysis

The three hypotheses (H1–H3) were tested using regression models employing a dummy variable representing the time periods pre- and post-disclosure of noncompliance, defined as the publication of Arnold and Oakley 2013 (all statistical analysis conducted with SPSS v25). With the disclosure occurring on February 11, 2013 (midway through first quarter 2013), the time from first quarter 2010 to first quarter 2013 represents the predisclosure period, and from second quarter 2013 to fourth quarter 2015 represents the postdisclosure period. Testing for the presence of an impact from this disclosure involved creating a regression model for the dependent variable associated with each hypothesis (Hawton et al. 2009; Wagner et al. 2002). The independent variables under analysis were time as a continuous variable and a dummy variable (disclosure) assigned as 0 for predisclosure and 1 for postdisclosure. The progressive analysis then involved the addition of an interaction term (time × dummy) to measure independent variable main effects as well as the interactive effects of time postdisclosure, with the following basic design:

$$Y = \beta_0 + (\beta_1 \times \text{time}) + (\beta_2 \times \text{disclosure}) + (\beta_3 \times \text{time postdisclosure}) + e$$

If the firms under analysis were to respond to the disclosure of noncompliance, we would expect all three dependent variables to show a negative trend postdisclosure. For example, a response to disclosure of noncompliance should lead to a lower percentage of television occurrences in violation of target audience guidelines. Such a response would indicate that the pharmaceutical firm actively engaging in behavior to bring its advertising into compliance with PhRMA guidelines. Similarly, such a response would be expected to result in fewer impressions generated to audience members under the age of 18, and should likely also result in fewer advertisements placed as the firms do a better job of complying with the PhRMA guidelines for audience composition. To summarize the expected results of the regression models if the firms under analysis were to respond to the disclosure event, β_1 (time) is not hypothesized to have a

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specific effect or direction, and both β_2 (disclosure) and β_3 (time postdisclosure) will be negative and significant. The three hypotheses, however, anticipate the opposite.

Results

Spending

The pharmaceutical industry spent $985 million on DTCA in 1996, or $1.218 billion in 2016 dollars adjusting for inflation using the gross domestic product deflator. Twenty years later, DTCA spending had risen to $6.083 billion (see table 2), or five times as much as 1996 in inflation-adjusted dollars. The ED drugs sildenafil citrate, manufactured and marketed as Viagra in the United States by Pfizer; tadalafil, manufactured and marketed as Cialis in the United States by Eli Lilly; and vardenafil, manufactured by Bayer Healthcare and jointly marketed as Levitra in the United States by GlaxoSmithKline, Bayer Healthcare, and Merck, were typically ranked in the top 10 for DTCA annual spending (see table 3 and figure 1). DTCA marketing for Levitra effectively ceased in 2010.

Occurrences in Violation of Target Audience

With respect to our first specific hypothesis (H1), figure 2 illustrates the percentage of advertising occurrences where the audience composition for the brand failed to meet the PhRMA principle. Arnold and Oakley 2013 provided analysis of the data from first quarter 2006 to fourth quarter 2009. None of the brands was in full compliance with the PhRMA standard during this period despite each firm's attestation of compliance. In 2009, when the standard moved from 80 percent to 90 percent adult audience, the percentage of broadcast advertisements in noncompliance exceeded 72% for Levitra, 64% for Viagra, and 55% for Cialis. Analysis of the data from 2010 to 2015 showed that the two brands that continued broadcast advertising, Viagra and Cialis, improved compliance compared with 2009 but still remained in substantial noncompliance for every quarter of the six-year period analyzed in this study.

Public disclosure of noncompliance with the audience composition principle took place in Q1 2013, and a qualitative assessment of figure 2 indicates that the disclosure event did not result in firms altering their behavior to bring broadcast advertisements into compliance with the guiding principles. There is no lag needed to assess compliance, as changes

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Table 2 Direct-to-Consumer Media Spending for All Prescription Pharmaceuticals (in US$ millions), 1996–2017

Year	Direct-to-consumer spending
1996	$985
1997	$1301
1998	$1578
1999	$2166
2000	$2798
2001	$2954
2002	$2864
2003	$3478
2004	$4160
2005	$4237
2006	$4741
2007	$4838
2008	$4416
2009	$4716
2010	**$4328**
2011	**$4254**
2012	**$3713**
2013	**$4106**
2014	**$4792**
2015	**$5755**
2016	**$6125**
2017	**$5843**
Total	**$84,148**

Source: Kantar Media 2017.

Notes: Boldface rows indicate new data compiled for this study, 1996–2009 data was previously communicated in Arnold and Oakley (2013).

to the placement of advertisements can take place almost immediately.[2] During the postdisclosure period, broadcast advertisements for Viagra hovered around 20% violation for most quarters, including a 23.2% violation in Q2 2013 and a 22.7% violation rate in Q2 2015. Broadcast advertisements for Cialis had lower rates of violation, generally remaining below 10%, peaking at 11% in Q4 2010 (predisclosure) and 9.6% in Q2 2013 (postdisclosure).

2. We interviewed two former pharmaceutical industry account executives who confirmed that it is routine to acquire and utilize Nielsen data to confirm audience composition and that changes in the placement of advertisements can be made within 24 hours by switching advertising placement with other advertising space already purchased. Permanent changes to the placement of advertisements can be made within a week.

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Table 3 Direct-to-Consumer Media Spending for Erectile Dysfunction Category and the Three Brands (in US$ millions): 2010–17

		Brands		
Year	Entire category	Viagra[a]	Cialis[a]	Levitra[b]
2010	$324.3	$101.7 (9)	$217.2 (2)	$5.4
2011	$324.5	$132.3 (5)	$192.1 (3)	$0.1
2012	$518.0	$177.9 (6)	$340.1 (2)	$0.0
2013	$686.7	$289.5 (4)	$397.1 (2)	$0.1
2014	$814.2	$400.1 (4)	$414.1 (1)	$0.0
2015	$435.5	$225.5 (3)	$209.9 (4)	$0.1
2016	$383.1	$257.4 (6)	$125.9 (8)	$0.0
2017	$321.5	$208.9[c]	$112.6[c]	$0.0

Source: Kantar Media 2017.

Notes: [a] Number in parentheses represents rank among prescription drug brands in direct-to-consumer spending, 2010–2016.

[b] Levitra ceased extensive marketing efforts in early 2010.

[c] Rank among prescription drug brands for 2017 not yet published.

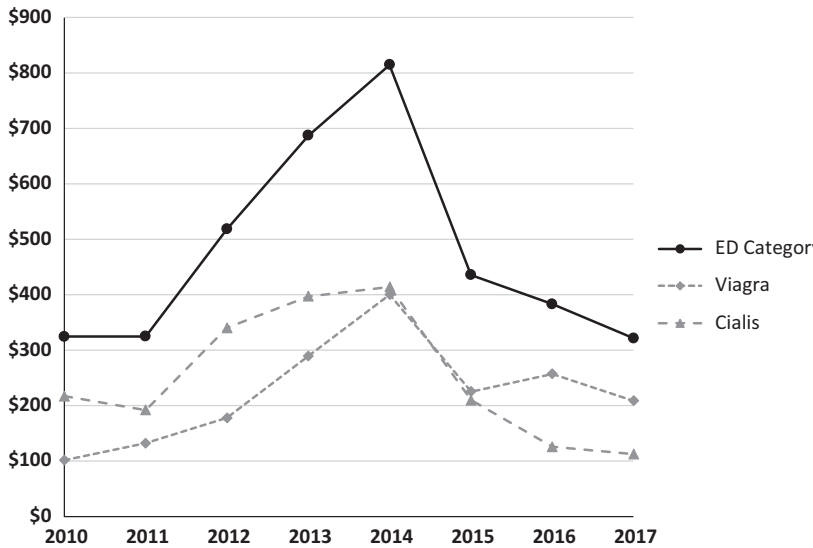

Figure 1 Direct-to-consumer media spending for erectile dysfunction (ED) category and Viagra and Cialis brands (in US$ millions): 2010–17.

Source: Kantar Media 2017.

Notes: Levitra ceased extensive marketing efforts in early 2010 and is thus not represented on this chart. Beginning in 2015, both Viagra and Cialis started to prepare for the end of their patents with reduced advertising budgets.

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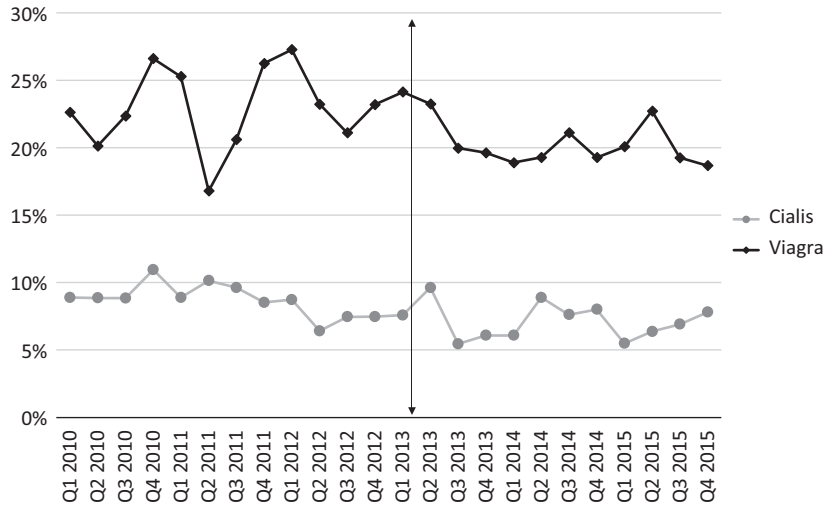

Figure 2 Percentage of television occurrences in violation of target audience (age 18+) for ED category and individual brands, first quarter 2010 through fourth quarter 2015.

Source: Nielsen (2016) Monitor-Plus.

Notes: The line at Q1 2013 represents the publication of Arnold and Oakley 2013, disclosing noncompliance by the brands in question regarding audience composition.

While figure 2 does not indicate the presence of a shock following the disclosure of DTCA noncompliance with audience composition guidelines (Q1 2013), further statistical analysis allowed us to determine if any change is actually present postdisclosure. Utilizing the model described in the methods section, testing for the presence of an impact from this disclosure involved the creation of a regression model with the percentage of television occurrences in violation of target audience guidelines as the dependent variable (model 1). The independent variables under analysis were time as a continuous variable and a dummy variable assigned as 0 for predisclosure time periods and 1 for postdisclosure time periods. An interaction term (time × dummy) was added to the model to allow for the measurement of independent variable main effects, as well as the interactive effects of time postdisclosure.

For H1, two analyses for model 1 tested unique dependent variables—Cialis and Viagra—while employing the same set of independent variables (time and disclosure dummy) to measure the percentage of television occurrences in violation of target audience guidelines for each brand individually. Thus, for each analysis, the only change is in the dependent variable (Y). The results for model 1 are presented in table 4. Both

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Table 4 Results for Regression Models

Factor	Model 1: Percentage of television occurrences in violation of target audience guidelines		Model 2: Number of impressions		Model 3: Number of advertisements	
	Cialis	Viagra	Cialis	Viagra	Cialis	Viagra
Constant	0.098*	0.223*	81376526.9*	72983652.6*	1391.5*	1887.9*
	(0.006)	(0.009)	(5.348)	(4.727)	(4.405)	(5.768)
Time	–0.941*	0.318	0.336	0.426	0.430	0.869*
	(0.001)	(0.002)	(0.845)	(1.302)	(1.727)	(3.009)
Disclosure	–0.675	0.037	0.071	0.251	0.417	–0.148
	(0.022)	(0.045)	(0.180)	(0.766)	(1.674)	(0.514)
Time postdisclosure[a]	0.992	–0.859	—	—	—	—
	(0.001)	(0.003)				
R^2	0.417	0.300	0.159	0.429	0.669	0.555
Adjusted R^2	0.330	0.195	0.079	0.375	0.638	0.512
Observations	24	24	24	24	24	24

Notes: Data are standardized coefficients presented for independent variables with standard errors in parentheses.

[a]Time postdisclosure is excluded from the analysis for models 2 and 3, given the scale of the dependent variables and the recommendation of the statistical software (SPSS v25, IBM).

* $p < 0.05$.

analyses showed a reasonable fit to the data, with adjusted R^2 values ranging from 0.195 to 0.330, indicating that the models explain 19.5–33.0% of the variance in the dependent variable under analysis (percentage of television occurrences in violation of target audience guidelines).

The analyses for the individual drugs indicate that the disclosure event was not a significant factor for either Cialis or Viagra. For Cialis, the time factor is significant and negative, indicating that from first quarter 2010 to fourth quarter 2015 Cialis lowered the percentage of ads in violation of the target audience guidelines. However, the disclosure event itself had no significant impact on this general trend. For Viagra, none of the factors included in model 1 was significant—the overall interpretation is that the average percentage of television occurrences in violation of target audience guidelines for Viagra was generally consistent over the time period under study, with a constant value hovering around 22%.

The overall interpretation of these models is that for the individual drugs there was no significant impact of the disclosure of noncompliance in first quarter 2013. Therefore, these results strongly suggest that the disclosure event had no discernable impact on the placement of television advertisements in regard to audience composition for either Cialis or Viagra after the first quarter 2013 disclosure event, supporting our first specific hypothesis (H1).

Audience Impressions

With respect to our second hypothesis, figure 3 displays the number of impressions generated to audience members under the age of 18 from first quarter 2010 to fourth quarter 2015. In total, Viagra and Cialis ran over 141,000 advertisements during this time: Cialis ran 63,644 ads while Viagra ran 77,497 ads. This resulted in a total of 5.2 billion impressions among children and adolescents under the age of 18: Cialis was responsible for 2.5 billion such impressions, and Viagra generated 2.7 billion. Thus, an average advertising occurrence resulted in approximately 39,000 child impressions for Cialis and 35,000 child impressions for Viagra.

Notably, while Cialis ran fewer television advertisements during the time period under analysis and the compliance levels for Cialis were significantly better than its competitor, the total number of impressions for both brands is very similar. Cialis typically targeted advertising placements with larger audiences, generating a similar number of child and adolescent impressions while engaging in better formal compliance and running

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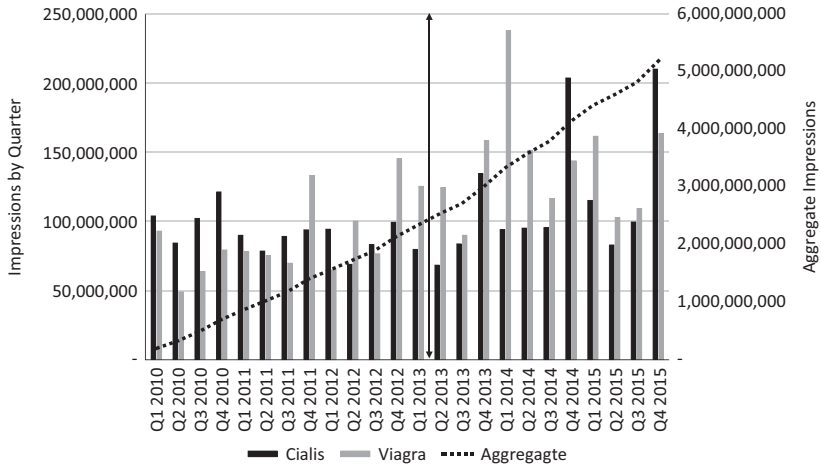

Figure 3 Number of impressions for audience members under 18 years of age, first quarter 2010 through fourth quarter 2015.

Source: Nielsen (2016) Monitor-Plus.

Notes: The line at Q1 2013 represents the publication of Arnold and Oakley 2013, disclosing noncompliance by the brands in question regarding audience composition.

fewer ads. Overall, Cialis averaged 103 million impressions per quarter to those under 18, and Viagra averaged 113 million, with a high for Cialis of 210 million in fourth quarter 2015 and for Viagra of 238 million in first quarter 2014. The trend line in figure 3 appears linear, and the peak quarters for impressions to those under 18 occur after disclosure of noncompliance.

We tested the hypothesis for audience impressions (H2) statistically using regression model 2 (see table 4). The analysis results for Cialis impressions are not actually significant, nor are the two independent variables (time and disclosure). The results for Cialis indicate that the actual distribution of impressions for Cialis over the time period under study is not linear and, more important, that the disclosure of noncompliance had no significant impact on the number of audience impressions under the age of 18 for Cialis. The analysis results for Viagra are significant (the distribution of Viagra impressions is more linear), though neither independent variable in the model is itself significant, again indicating that the disclosure of noncompliance did not have a significant impact on the number of audience impressions under the age of 18 for Viagra. These results provide support for our second specific hypothesis (H2).

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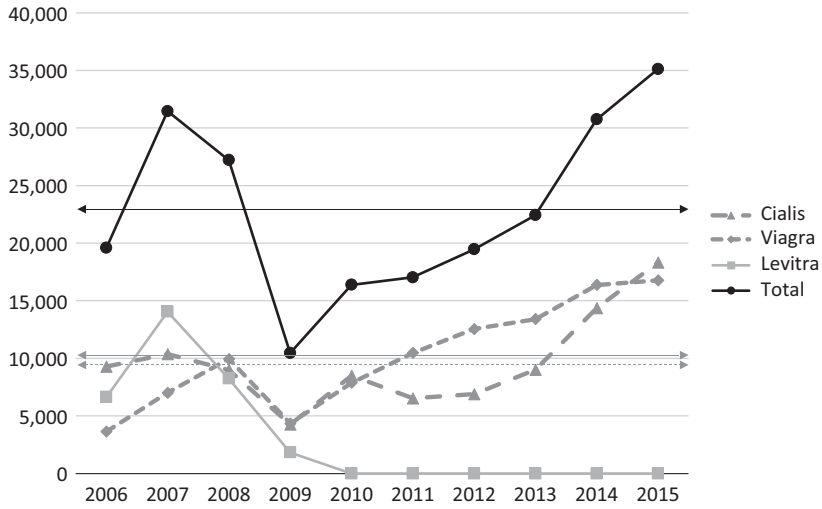

Figure 4 Number of advertisements placed per year for erectile dysfunction category and individual brands, 2006–2015.

Source: Nielsen (2016) Monitor-Plus.

Notes: The double-ended arrows represent the average number of advertisements for the category (22,986), and for each brand (Viagra, 10,248; Cialis, 9,661).

Number of Advertisements

Figure 4 presents the total number of advertisements placed per year for the ED category in aggregate and for each of the three brands in the category. The chart covers both the time period specifically for the present study (2010–15) and the period covered in Arnold and Oakley 2013 (2006–9). The brands did not reduce the number of ads placed after the guidelines changed in 2009 (though 2009 itself was an anomaly as the entire category struggled to adapt to the new guidelines), nor did they reduce the number of ads placed after the disclosure of noncompliance in first quarter 2013. Rather, the number of ads placed for the category and for each of the brands still engaged with television advertising increased consistently from 2010 to 2015, offering qualitative support for our third specific hypothesis (H3).

We tested this hypothesis statistically using regression model 3 (see table 4) covering 2010–15, with first quarter 2013 as the disclosure event of interest. For both Cialis and Viagra, the results were significant, supporting the qualitative assessment of figure 4 that the brands increased the number of advertisements over time, both pre- and postdisclosure. For Cialis, neither independent variable was significant, and for Viagra, the disclosure variable again was not significant—both analyses provided support for

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H3, that the disclosure of noncompliance did not lead the brands under analysis to alter their advertising behavior. And, while the level of advertising is likely to decline as the patents expire for these drugs, such declines were not evident during the time period studied here.

Limitations

This is the first study of which we are aware to assess industry self-regulation in light of the public disclosure of previous firm noncompliance with the same standard. Our analysis benefits from utilizing all available data on actual DTCA spending rather than projected or estimated spending. Our analysis also benefits from utilizing data on all ED broadcast advertisements during the period of study. This study is limited by its focus on compliance with one self-regulatory principle, and one category of drugs, although our findings are consistent with findings of other studies of pharmaceutical industry self-regulation that firms routinely fail to meet self-regulatory guidelines (Alves et al. 2014; Arnold and Oakley 2013; Devlin et al. 2007; Zetterqvist and Mulinari 2013). Other drug classes found to violate self-regulatory standards include treatments for reactive airways disease, gastroesophageal reflux, dyslipidemia, and pain (nonsteroidal anti-inflammatory drugs; Devlin et al. 2007) and psychiatric disorders (antipsychotics and antidepressants; Zetterqvist and Mulinari 2013). This study is also limited by its focus on the time period after the introduction of self-regulatory standards, that is, the analysis does not include data from before the launch of PhRMA's original guiding principles in January 2006.

Discussion

Prescription drug advertising is big business. In 2015, pharmaceutical industry spending on DTCA was more than double the $2.36 billion spent by the US film industry on marketing (Rainey 2016). In 2016, DTCA spending reached its highest level ever, at over $6 billion. Research has shown that the more money pharmaceutical firms spend on consumer marketing relative to research and development, the less likely the firm is to produce pioneering new drugs (Arnold and Troyer 2016).

The advertising of prescription pharmaceuticals is prolific, with the ED category of pharmaceuticals alone accounting for over 25,000 advertising occurrences per year from 2010 to 2015. This translates to approximately 68 advertisements per day, every day, for either Viagra or Cialis. On average there were 35,000–40,000 ED advertising impressions on children and adolescents daily, totaling over 5 billion impressions, between January

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1, 2010, and December 31, 2015. Parents can limit exposure to some sexually themed media content by filtering Internet access and restricting the television programs and films to which children and adolescents are exposed. However, when sexually themed advertisements are broadcast during family-orientated television programming, such as sports or news programs, parents and other care providers have limited ability to prevent adolescents and children from being exposed to sexually explicit messages. Exposure to ED advertisements can provoke questions by children at inappropriate developmental stages regarding erections and sexual activity, and at times when adults are ill prepared to have such conversations.

Notwithstanding firm attestations of compliance, noncompliance with the PhRMA standard regarding the exposure of children and adolescents to adult content was found to be the norm. Public disclosure of noncompliance did not result in individual firms altering the placement of advertisements to bring the firms into compliance. No firm was in full compliance with the standard for any quarter of any year during the full 10-year period analyzed across two studies (2006–9, Arnold and Oakley 2013; 2010–16, present study). Pharmaceutical firms could choose to stipulate in contracts with marketing agencies that DTCA campaigns adhere to the guiding principles and cease to do business with noncompliant agencies. Instead, firm executives have tolerated routine and substantial violation of the principle.

Because there are no sanctions for firms that violate pharmaceutical industry self-regulatory standards, there is little incentive for firms to create and maintain the internal processes and policies needed to achieve compliance, despite written assurances of chief executive officers and chief compliance officers that their firms are in adherence with the principles. It is noteworthy that the industry trade association made no publicly reported effort to improve firm performance after public disclosure of noncompliance. With respect to the marketing campaigns described in this study, formal commitments by firms to voluntarily alter their behavior are consistent with a collective blocking strategy (Arnold and Oakley 2013) whereby firms within an industry utilize false public commitments to meet trade association standards to help prevent unwanted regulations in pursuit of their strategic aims.

Policy Recommendations

In *The Future of Drug Safety* (Baciu, Stratton, and Burke 2007: 166), the Institute of Medicine's Committee on the Assessment of the US Drug Safety System found, with respect to pharmaceutical communications,

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that the "FDA's authority is built on an aging regulatory framework [and] that FDA's largely all-or-nothing regulatory tools limit its ability to regulate effectively after approval." It called for new FDA regulatory authority, including "a new way to address DTC advertising" and "improved enforcement tools to ensure that regulatory requirements imposed at or after approval are fulfilled" (167). However, at the same time, the committee found PhRMA's guiding principles an "important action" consonant with its goals of improving the quality of communications regarding pharmaceuticals (163–64). Implicit in this assessment is the faulty presumption that firms would actually adhere to the industry's own guiding principles. Firm self-regulation is an unreliable means of reducing or eliminating the negative impacts of DTCA identified by the AAP, AMA, ASHP, and other critics (Frosch et al. 2007; Gagnon 2013). Despite attestations of compliance by firm executives, noncompliance remains the norm. This study demonstrates that noncompliance among major firms is routine. Congress could convert the principles into statutory requirements enforceable by the FDA and thereby provide firms with an incentive for compliance.

With respect to ED advertising in particular, restricting advertisements to between 10:00 p.m. and 6:00 a.m. consistent with the AAP recommendation and the 2009 Families for ED Advertising Decency Act (H.R. 2175) would facilitate compliance with the audience composition principle. H.R. 2175 would limit the broadcast times of only "medication for the treatment of erectile dysfunction or for male enhancement." Broadening the legislation to apply to any drugs that utilize sexually explicit language not appropriate for children or adolescents would be more balanced, consistent with AAP guidelines, and would likely better withstand legal challenge.[3] Deincentivizing DTCA would also reduce its value as a source of revenue to pharmaceutical firms. Currently the Internal Revenue Code permits the deduction of most drug marketing expenses by pharmaceutical companies, including DTCA. The Say No to Drug Ads Act (H.R. 722)

3. While an outright ban on DTCA may not stand constitutional challenges to commercial speech (Shuchman 2007), limitations on DTCA have firm legal grounding in the Supreme Court's decision in *Central Hudson Gas and Electric Corp. v. Public Service Commission* (447 U.S. 557 [1980]). In *Central Hudson* the court found that commercial speech that "does not accurately inform the public" or is "more likely to deceive the public than to inform it" has no grounds for constitutional protection. Given the widespread deception in pharmaceutical marketing revealed by the Department of Justice and states' attorneys general (Arnold et al. 2016; Gagnon 2013) and identified in previous research (Alves et al. 2014; Arnold and Oakley 2013; Devlin et al. 2007; Zetterqvist and Mulinari 2013), restrictions in the public interest appear justified. In cases where deception is not present, the government may nonetheless regulate speech when there is a substantial public interest and when it is not more extensive than necessary to protect those interests.

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introduced in the 112th Congress would have eliminated the tax deduction for DTCA, but it was not enacted. Passing similar legislation would decrease the value of DTCA to pharmaceutical organizations and is likely to result in reduced DTCA, mitigating the negative impacts that have been identified (AMA 2015; Arnold 2009; Arnold and Troyer 2016; ASHP 2016; Friedman and Gould 2007; Frosch et al. 2007; Gagnon 2013; Royne and Myers 2008). In addition, taxing DTCA, as well as other pharmaceutical marketing (Arnold and Troyer 2016; Frosch et al. 2007), would discourage the practice. These new revenues could be directed to the FDA to better ensure the scientific accuracy, truthfulness, balance of risk and benefits, and appropriate audience for DTCA.

Conclusion

DTCA expenditures have grown steadily in recent years, reaching the highest level yet in 2016. The pharmaceutical industry's failure to effectively self-regulate DTCA calls into question the willingness or ability of the pharmaceutical industry to police itself, even when firm noncompliance with industry standards is publicly disclosed. Our results indicate that policy changes regarding DTCA at the federal level are warranted. Such regulation would include the adoption of versions of the guiding principles as regulations, restricted broadcast times for advertisements with sexually oriented content, the elimination of tax incentives for DTCA, and taxes on DTCA intended to support the FDA.

■ ■ ■

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