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The Impact of Moving Pharmaceutical Products from Prescription Only to Over-the-Counter Status on Consumer Exposure to Advertising

Many pharmaceutical products are available through prescription (Rx) only status. As a result, access to physicians and insurance coverage play a key role in the use of these products, and therefore may affect the population to whom advertising is targeted at. The movement of pharmaceutical products from prescription (Rx) to Over-the-Counter (OTC), or Rx-to-OTC switch changes the cost of acquiring the drug and therefore may change the incentives manufacturers have at targeting particular population segments. This study examines whether Rx-to-OTC switch changes the frequency and the distribution of who is exposed to pharmaceutical advertising. Using an archive of pharmaceutical advertisements and National Consumer Survey, this study examines how individuals with particular demographic characteristics are exposed to pharmaceutical advertisements before and after drugs are moved from Rx to OTC. The results provide evidence that individual's advertising exposure increases after Rx-to-OTC switch. Moreover, the increase in advertising exposure is greater for the low socioeconomic status (SES) consumers which implies they may get more information about the disease, treatment and product after the Rx-to-OTC switch through advertising. If low SES consumers have more exposure to the advertising after products switched to OTC, then FDA policies regulating this switch should recognize the potential role of advertising providing access to health-related information.

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Consumers are taking a more active role in their health care these days. More and more consumers self-medicate and make decisions independently on health related purchases. Therefore, access to consumer health information is important for efficient decision making. When consumers self-medicate, prior experience, word-of-mouth from friends and family and pharmaceutical advertisements are the primary sources of information. Pharmaceutical advertisement that directly advertises to consumers rather than health care professionals in mass-media is called Direct-to-Consumer Advertising (DTCA). Some DTCA, especially advertisements in print may provide information on not only the existence of the product and how it is marketed, but also the symptoms associated with the illness and even the existence of the diseases and the availability of the treatment. Although controversial, empirical studies support the argument that DTCA works as a source of information to consumers. DTCA advocates suggest DTCA offers consumer information otherwise difficult to access, thus promotes better health care decisions, leads to more productive patient-physician relationships, and boosts patients' compliance with treatment (Calfee, 2002; Donohue, 2006; Hoek *et al*., 2011 Kelly, 2004; Meek, 2001; Myers *et al*., 2011). However, opponents argue that DTCA provides incomplete information that emphasizes the drug's benefit rather than risks and includes emotion-driven portrayals which lead consumers to be misinformed (Frosch *et al*., 2010; Hoek *et al*., 2011; Morris *et al*., 1986; Lexchin, 1999; Morris *et al*., 1985;

Toop *et al*., 2003).

In most countries, prescription (Rx) drugs cannot be advertised directly to consumers whereas Over-the-Counter (OTC) drugs are advertised directly to consumers. The U.S. is one of two countries in the world that allows prescription pharmaceutical products to be advertised directly to consumers. In the U.S., DTCA has been used as a promotion tool by pharmaceutical firms since the early 1980s. In 1997, the U.S. Food and Drug Administration (FDA), the agency that governs DTCA of prescription drugs reduced the burden of information disclosure for broadcast DTCA. Prior to 1997, DTCAs in both broadcast and print were required to include lengthy disclosure of the well-balanced risk and benefit information of the drug which made it costly to advertise especially on television. With the relaxation of this regulation, spending on and the number of DTCA appearing on television increased significantly. The disclosure requirement in print advertisements still remains. All prescription drug advertisements in print have at least one page of full information disclosure.

During this period of change in DTCA regulation, there were also several prominent switches of products from Rx only status to OTC status, known as Rx-to-OTC switch, across a number of therapeutic classes. When Rx-to-OTC switch happens, not only is there a change in where consumers can purchase the products but a change in the regulations that govern the advertising of these products. The Federal Trade Commission (FTC) which regulates OTC DTCA does not require extensive disclosures in print advertising that the FDA requires about the warnings of side effects and contraindications. Therefore, for print advertising, the reduced disclosure requirement by the FTC significantly reduces the cost of advertising of the same drug once it switches from Rx to OTC.

This research analyzes how Rx-to-OTC switch changes individual's exposure to print advertising for a set of pharmaceutical products that has been switched from Rx to OTC status. The focus of previous literature on drug issues has been on labeling, information disclosure and the impact of DTCA on demand for Rx drugs. The public policy and consumer issues on the association between DTCA and Rx-to-OTC switch are rarely studied. The focus is on the U.S. market since the U.S. allows DTCA of both Rx and OTC drugs. Many other countries only allow OTC drug advertising. Using the U.S. market as an example, I was able to observe the change in the distribution of advertising exposure before and after the switch.

There are several reasons to believe that this shift in regulatory status will result in changes in exposure to advertising. Since there is no need to see physicians to get prescription for OTC drugs, firms may re-target their advertisements to those who do not have health insurance coverage to explore new potential consumers. When a drug is prescription status only, it is likely that advertisements are targeted to consumers with access to the medical system, i.e. those with health insurance and those who can afford to see a physician to obtain a prescription. Once physician involvement is no longer necessary, it is likely that firms may target their products to a less advantageous group, i.e. low socioeconomic status (SES) group and those without health insurance. Firms may increase their advertisements in those magazines favored by the low SES group that can be characterized as those with low income, less education and without health insurance.

To test my hypotheses, I calculate advertising exposure based on a large consumer survey and an archive of pharmaceutical advertisements over a more than 10-year period. Drugs that have been switched to OTC during the study period are selected. The data used in this study allows me to observe the placement of DTCA for Rx-to-OTC switched products in over 6,500 issues from 26 nationally representative consumer magazines between 1994 and 2004. This data is then linked to a survey data that includes demographic information about the respondent and detailed information of the magazines read by each individual. Having information on which magazines individuals read along with what DTCA appear in these magazines allows us to develop a unique measure of advertising exposure. In addition, the availability of demographic information on these respondents allows us to

examine how advertising exposure varies by race, SES and how these relationships change by Rx-to-OTC switch.

The results provide evidence that when a drug is switched to OTC, individual consumer's advertising exposure increases. In addition the increase in advertising exposure is greater for low SES consumers which imply they may get more information about the disease, treatment and product after the Rx-to-OTC switch. These results have important public policy implications. The Rx-to-OTC switch may create changes in the amount and distribution of who is exposed to advertising thereby impacting the use of these products. If low SES group have more exposure to advertising after products switch to OTC, then FDA policies regulating this switch should recognize the potential role of DTCA providing access to health-related information.

DATA AND KEY VARIABLES

Data

Two data sets, a consumer survey and an archive of pharmaceutical advertisements, are used to generate the measure of advertising exposure. The archive of pharmaceutical advertisements comprises drug advertisements of Rx-to-OTC switched products from 26 consumer magazines between 1994 and 2004. These magazines were selected based on them being the most frequently read by individuals in each separate demographic group that is characterized by race, gender, income level, age, and education level in the U.S. The magazines selected are included in any of the top ten lists of most frequently read by each demographic group. These include *Reader's Digest, People, TV Guide, Better Homes and Gardens, Black Enterprise, National Geographic, Time, Family Circle, Women's Day, Newsweek, Good Housekeeping, Ebony, Jet, Essence, Sports Illustrated, U.S. News and World Report, Business Week, Playboy, McCalls, Modern Maturity, Money, Seventeen, Cosmopolitan, Rolling Stone, Glamour,* and *Vogue*. Using the magazine circulation data from three independent sources, I estimate that the 26 magazines used in this study account for between 30 to 57.7 percent of magazines circulating in the U.S.[1]

Once the number of advertisements for each pharmaceutical product is computed, I link these advertisements to individual survey respondents. The survey respondents come from the National Consumer Survey (NCS). The NCS is a repeated cross-section survey collected every year by the Simmons Marketing Research Bureau. It provides detailed information on consumer behavior and magazine readership. Survey questions on magazine reading allow me to link the data on which magazines advertisements are appearing in and attach these advertisements to individuals who report reading these magazines during the time in which the advertisements appeared. The NCS employs a multi-stage stratified probability sample that represents all adults living in households in the U.S. In order to minimize respondent fatigue, the data is collected in several phases. In the first part of phase one, interviewers collect demographic information and on the magazines respondents read. In NCS, each respondent is shown copies of the covers of magazines. If a respondent reports that he has read any portion of a magazine, he is asked a set of questions about readership. For each magazine, the respondent was asked whether he has read or looked into during the past six months, and if so, of the latest four issues on average, how many did the respondents read, including whether they read the whole magazine.

Key Variables

Following Avery *et al.* (2007b)'s routine for generating advertising exposure variable, advertising exposure is generated by merging all of the advertising data to each person in the NCS. The variable $Read_{im}$ is the fraction of issues of magazine *m* read by person *i*. For each magazine in the archive the NCS respondent reported, the fraction of the four issues one reads is multiplied by the number of advertisements that appeared in that magazine over

[1] According to the Magazine Publishers of America (MPA), magazines in our archive represent approximately 30 percent of total circulation of 580 U.S. magazines registered with the Audit Bureau of Circulations. The higher figure is estimated from readership data for the 182 magazines included in the NCS.

the previous twelve months. Note that, in doing so, I assume that an individual's reading habits over the four issues reflects his reading habits over the past year. Then this measure is summed up across all the magazines in the archive. As a result, this becomes the estimate of advertising exposure to each product to which a person was potentially exposed to by reading the magazines in the archive. Formulaically, measure of the advertising exposure of respondent t, $AdExp_i$, at one point of time is given by,

$$AdExp_i = \sum_{m=1}^{26} Ads_{im} \times \mathrm{Re}ad_{im}$$

where subscript m refers to each of the 26 magazines in the archive.

The key independent variable, Rx/OTC status was obtained from the list of *Ingredients and Dosages Transferred from Rx-to-OTC Status by the FDA since 1975* compiled by the Consumer Healthcare Product Association (CHPA).[2] CHPA list includes information on FDA's OTC switch approval date by each ingredient and product examples, adult dosage of that ingredient, and product category. Among the switched products in the CHPA list, not all of their advertisements showed up in my advertisement archive. This may be from the fact that the product itself was not advertised in the magazines I used during the time period.

Background of Products

For this study, nine products are selected based on the following criteria. Starting from the complete CHPA list, I choose brands that were switched to OTC during the study period, based on the availability of the NCS data 1994 to 2004, so that advertisements are observed before and after the switch to capture the change in the distribution of advertisement exposure.

The chosen products come from six different therapeutic classes. To briefly introduce each product used, Claritin is a second generation antihistamine for allergy treatment and was introduced in the market as a prescription-only drug in April 1993. Just before its patent expiry in December 2002, FDA approved Claritin switch to OTC in November 2002 (FDA, 2002). Prilosec and Zantac are acid reducers for treating heartburn. Most of the earlier generation of H_2 blockers for treating heartburn including Zantac were switched to OTC in the mid-1990s. Like Claritin, Zantac was also switched to OTC before its patent expiry. When it was switched to OTC in December 1995, Zantac changed its brand name to Zantac 75. Firms tend to consider switching when the patent expires because they can gain an additional three years of market exclusivity granted by the Waxman-Hatch Act of 1984 (Ling *et al.*, 2002). Prilosec is one of the latest generation of antiulcer drugs, namely Proton Pump Inhibitors (PPIs) and it was switched to OTC in the U.S. in June 2003. Nizoral is a shampoo to prevent dandruff and used to be a prescription drug before its switch to OTC in October 1997. Nicoderm CQ and Nicorette are Nicotine replacement products for smoking cessation. Both of them were switched to OTC in 1996. Rogaine, a drug used for the treatment of hair loss, was introduced as a prescription product in 1988. Since its introduction in the prescription market, Rogaine was heavily advertised in both print and broadcast media, which established high level of brand equity prior to its introduction in the OTC market in February 1996 (Creyer *et al.,* 2001). Lamisil and Vagistat 1 are antifungal products that were switched to OTC in 1999 and 1997 respectively. With the exceptions of Claritin and Prilosec, most of the products studied were switched to OTC during the mid to late 1990s, when there was a change in DTCA regulation.

Hypotheses and Methods

The hypotheses for this study are based on the differences in the cost of advertising for prescription drug and OTC drug and firms' motivation to change their advertising target population. The first hypothesis is that individual's advertising exposure increases after Rx-to-OTC switch. Since OTC advertising does not need to include an additional disclosure page, it might have a positive own-price effect since the cost of advertising is low without disclosure and thus increase firm's demand for advertising. However, as Avery and colleagues (2007a)

[2]Available at http://www.chpa-info.org/media/resources/r_4620.pdf

point out, a cross-price effect would decrease magazine advertising since relative cost of television advertising has decreased since 1997, firms may substitute to television advertising.

To test this hypothesis, individual's advertising exposure is modeled as a function of the product's marketing status – either Rx or OTC, and individual level demographic characteristics. OTC status indicates less regulated advertising environment when compared to prescription status. Socioeconomic variables include age, gender, race, education, marital status, family size, presence of children in the household, family income, and health insurance status. I also control for overall magazine reading, television watching and radio listening time. Moreover a set of magazine readership dummy variables for more than 180 magazines in the NCS are included as a magazine fixed effect to control any further unobserved individual's characteristics that are related to magazine readership, firm's targeting and thus advertising exposure.

To test the first hypothesis, equation (1) is specified to examine the coefficient on the OTC dummy variable for the products that I observe in both prescription and OTC versions during the time period.

$$AdExp_{ipt} = \beta_0 + \beta_1 OTC\ Status_{pt} + \beta_2 Demographic\ Characteristics_{it} + \beta_3 Year_t + \beta_4 Magazine_{it} + \varepsilon_{ipt} \quad (1)$$

OTC status$_{pt}$ variable indicates whether product *p* is available as OTC at time *t*. Based on the first hypothesis I expect β_1 to be positive.

The responsiveness to advertising is expected to depend on demographic characteristics. Hence the second hypothesis is that the impact of Rx-to-OTC switch on advertising exposure is greater for low SES consumers once a product moves from Rx to OTC. After Rx-to-OTC switch, not only the manufacturers increase the advertising but they may also target low SES and uninsured consumers because not only does the size of the market increases, but the responsiveness of the low SES consumers without health insurance may change after the Rx-to-OTC switch. Even if the advertising messages reach those without health insurance, it is difficult for them to translate the message into behavior because of the expense of seeing a physician to obtain a prescription. From the firm's side, when a product is prescription status firms should be less likely to target consumers who have less access to physicians. Once a product is OTC, low SES consumers represent a new group of potential consumers that may respond to advertising and thus firms are likely to target these consumers by placing more advertisements in magazines that are favored by low SES group.

To test this hypothesis, OTC status variable is interacted with the demographic characteristics as shown in equation (2). Based on the second hypothesis, I expect the coefficients on the interaction terms of the OTC variable with the demographic characteristics that reflect low socio-economic status to be positive.

$$AdExp_{ipt} = \gamma_0 + \gamma_1 OTC\ Status_{pt} + \gamma_2 Demographic\ Characteristics_{it} + \gamma_3 Demographic\ Characteristics_{it} * OTC\ Status_{pt} + \gamma_4 Year_t + \gamma_5 Magazine_{it} + \varepsilon_{ipt} \quad (2)$$

To investigate the general effect of Rx-to-OTC switch, all the product advertising exposures are stacked to make a single data set of each individual respondent having several observations of advertising exposure by product. In the previous data for product level analysis, each individual had nine different variables of advertising exposures and OTC status by product respectively. For all products stacked-up analysis, I create a data set with a rectangular structure that each individual's demographic information is merged with another data set that has one variable of advertising exposure that has nine records of advertising exposure for each individual. This results in each respondent in the data having nine different records of advertising exposures and OTC status. Since this results in the repetition of individual's demographic information nine times, the regression models are clustered by individual. Each model includes product fixed effect to control for product specific effect of OTC switch and a set of dummy variables of magazine readership of all the magazines included in the NCS. Advertising exposure for each person at time t is used as a dependent variable.

$$AdExp_{it} = \delta_0 + \delta_1 OTC\ Status_{pt} + \delta_2 \text{Demographic Characteristics}_{it} + \delta_3 Demographic\ Characteristics_{it} * OTC\ Status_{pt} + \delta_4 Year_t + \delta_5 Magazine_{it} + \delta_6 Product_{pt} + \varepsilon_{ipt} \quad (3)$$

RESULTS

Descriptive Statistics

Table 1 presents descriptive statistics of the variables used for the analyses. The highest mean advertising exposure is 6.07 for Prilosec followed by 5.44 for Claritin, 4.32 for Nicorette, 2.51 for Lamisil, 2.34 for Nicoderm CQ, 1.31 for Rogaine, 0.58 for Nizoral, and 0.38 for Vagistat 1. 46.7 percent of respondents are female. Our respondents are adults over 18 years old. The average age is 44.5. The majority, about 78 percent, is White, whereas 7 percent is Black, 12 percent is Hispanic and 3 percent is from other ethnic group. About 10 percent of the respondents did not complete high school, 28 percent graduated

Table 1. *Descriptive Statistics (N=193,928)*

Variable	Mean	St.d.	Min.	Max.
Advertising exposure				
Prilosec	6.07	7.72	0.00	74.00
Claritin	5.44	7.13	0.00	77.50
Lamisil	2.51	3.77	0.00	43.00
NicodermCQ	2.35	3.42	0.00	36.50
Nizoral	0.58	1.71	0.00	23.00
Nicorette	4.32	5.72	0.00	53.00
Rogaine	1.31	2.71	0.00	46.25
Zantac75	2.52	6.17	0.00	75.00
Vagistat1	0.38	1.14	0.00	18.00
Demographic characteristics				
%Female	46.67			
Age	44.49	15.42	18.00	77.00
%White	78.14			
%Black	6.96			
%Hispanic	11.73			
%Asian and other	3.17			
%High school drop out	9.97			
%High school graduates	27.92			
%Some college	29.56			
%College or more	32.55			
Yearly family income	68144.51	60646.16	2500.00	341984.60
Family size	2.88	1.55	1.00	15.00
%Have children	53.76			
%Unemployed	3.95			
Health Insurance				
%Private	60.43			
%Medicare	13.77			
%Medicaid	1.75			
%No insurance	24.05			
Media habits				
Radio hours per week	2.43	4.18	0.00	72.00
TV hours per week	15.76	15.94	0.00	157.55
Magazine issues read/year	5.75	6.06	0.00	155.38

high school, and 33 percent have graduated college or have more advanced degrees. The average yearly family income is 68,144 dollars. Average family size is three with more than half responding that they have children. About 4 percent is unemployed. 60.4 percent of respondents have employer-provided or private health insurance, 13.8 percent has Medicare, 1.8 percent has Medicaid and 24 percent of respondents are uninsured. On average, a respondent reads 5.8 issues of magazines a year and watches 15.8 hours of television in an average week.

Product Level Analysis

Table 2 presents selected OLS estimates of advertising exposure of products that switched to OTC. Although not showing in the table, all specifications include rich set of control variables such as age, age squared, female, race, education level, marital status, family size, number of children, employment status, family income, type of health insurance, television viewing, magazine readership, radio listening, time trend and dummy variables of readership of more than 180 magazines included in the NCS as magazine fixed effect. Table 2 report only the findings for OTC status and its interaction with key demographic variables. Model (1) controls for OTC status of each product, and model (2) adds interactions of OTC with demographic variables.

In seven out of nine products, the coefficients of OTC are positive and statistically significant in model (1) which indicates that for these products, advertising exposure increases after Rx-to-OTC switch. However, for Lamisil and Rogaine, when these products were switched to OTC, advertising exposure of each individual decreased. This could be due to the fact that these products were already heavily promoted even before the switch and the promotion decreased gradually after the switch. So for example, Rogaine was heavily advertised upon its introduction in the market thus building a high level of brand equity and awareness among consumers prior to its OTC switch (Creyer *et al.,* 2001).

Results from model (2) somewhat vary by product, however for the majority of products, I find evidence that Rx-to-OTC switch positively affects advertising exposure especially for those with low income, less education and no health insurance. Specifically in seven out of nine products, the increase in advertising exposure is greater for those without health insurance and less education. In eight out of nine products, OTC switch has negative effect at the margin on advertising exposure for those in the highest income quintile group. In summary, at the product level advertising exposure, there is some evidence that advertising exposure increases after Rx-to-OTC switch and the marginal effect of OTC switch is positive for the low SES consumers.

All Products Stacked-up Analysis

To find a general effect of Rx-to-OTC switch on individual consumer's advertising exposure, each different product advertising exposure is stacked to make a data set that include one advertising exposure variable and one OTC status indicator variable. Model (1) only includes OTC dummy variable and model (2) includes OTC variable interacted with demographic variables. Both of the specifications control for a long list of individual characteristics variables and also magazine and product fixed effects.

In Table 3, the coefficient of OTC dummy variable in model (1) is positive and statistically significant which indicates when drugs are switched to OTC, individual's advertising exposure increases. The coefficients in model (2) also support the second hypothesis. I find the increase in advertising exposure is greater for low SES and uninsured consumers. Specifically when OTC variable is interacted with less education, the coefficient is positive and significant. Although not statistically significant the coefficients for higher education interacted with OTC are negative. This suggests advertising exposure increases for those with less education when the product switches to OTC. The coefficients of interaction with income suggest when the drug switches to OTC advertising exposure for lower income group increases whereas that of higher income group decreases. Compared to Whites, minority groups such as Hispanics and Black's advertising exposure increases after switch. Lastly when OTC variable is interacted with the uninsured is positive and statistically significant which suggests

Table 2. *Selected Coefficients: OLS Models of Advertising Exposure by Products (N=193,928)*

Variable	Claritin		Prilosec		Zantac 75		Nizoral		Nicoderm CQ	
	1	2	1	2	1	2	1	2	1	2
OTC	0.821***	2.104***	3.215***	4.512***	2.150***	4.534***	0.637***	1.016***	4.441***	3.086***
	(0.036)	(0.091)	(0.043)	(0.128)	(0.206)	(0.335)	(0.016)	(0.047)	(0.134)	(0.150)
OTC*Female		-0.438***		-0.133***		-0.767***		-0.452***		0.429***
		(0.038)		(0.054)		(0.130)		(0.020)		(0.035)
OTC*Age		-0.120***		-0.196***		-0.431***		-0.097***		0.264***
		(0.013)		(0.019)		(0.051)		(0.008)		(0.013)
OTC*Black		-0.183***		1.647***		-1.372***		0.764***		0.581***
		(0.086)		(0.152)		(0.259)		(0.045)		(0.077)
OTC*Hispanic		0.637***		0.331***		-0.713**		0.164***		0.153*
		(0.060)		(0.076)		(0.308)		(0.045)		(0.080)
OTC*Asian & other		-0.235*		-0.188		-0.391		0.194***		0.271***
		(0.126)		(0.185)		(0.304)		(0.068)		(0.082)
OTC*High school drop out		0.456***		0.024		0.433*		0.069		-0.217***
		(0.060)		(0.085)		(0.259)		(0.047)		(0.071)
OTC*Some college		-0.690***		-0.217***		-0.470***		0.034		0.256***
		(0.051)		(0.075)		(0.162)		(0.029)		(0.043)
OTC*College or more		-1.112***		-0.480***		-0.286*		0.189***		0.171***
		(0.051)		(0.073)		(0.168)		(0.028)		(0.044)
OTC*Income quintile 1		0.370***		-0.200**		0.761***		0.179***		-0.181***
		(0.056)		(0.084)		(0.184)		(0.033)		(0.050)
OTC*Income quintile 2		0.302***		-0.154*		0.373**		0.041		0.040
		(0.060)		(0.088)		(0.179)		(0.031)		(0.047)
OTC*Income quintile 4		-0.519***		-0.552***		-0.172		0.014		-0.310***
		(0.063)		(0.096)		(0.180)		(0.028)		(0.044)
OTC*Income quintile 5		-0.915***		-0.506***		-0.848***		0.099***		-0.256***
		(0.059)		(0.085)		(0.252)		(0.034)		(0.057)
OTC*Uninsured		0.362***		0.025		0.151		0.016		-0.038
		(0.046)		(0.065)		(0.155)		(0.025)		(0.042)
Year trend	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Magazine fixed effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
R^2	0.562	0.565	0.497	0.498	0.582	0.583	0.409	0.415	0.376	0.378

Robust standard errors in parentheses; *** p<0.01, ** p<0.05, * p<0.1

Table 2. *continued*

Variable	Nicorette		Rogaine		Lamisil		Vagistat	
	1	2	1	2	1	2	1	2
OTC	3.796***	3.398***	-1.389***	-1.894***	-4.563***	-4.150***	1.227***	1.290***
	(0.145)	(0.184)	(0.110)	(0.240)	(0.026)	(0.054)	(0.054)	(0.061)
OTC*Female		-0.047		0.321***		0.034		-0.201***
		(0.062)		(0.099)		(0.023)		(0.016)
OTC*Age		0.118***		0.155***		-0.107***		-0.017***
		(0.023)		(0.038)		(0.008)		(0.006)
OTC*Black		0.724***		-0.884***		0.349***		0.130***
		(0.115)		(0.210)		(0.045)		(0.032)
OTC*Hispanic		0.283**		-0.954***		0.909***		0.145***
		(0.133)		(0.256)		(0.043)		(0.037)
OTC*Asian & other		0.055		-0.387*		0.148**		0.060*
		(0.140)		(0.235)		(0.063)		(0.033)
OTC*High school drop out		-0.024		0.068		0.030		0.078**
		(0.111)		(0.218)		(0.042)		(0.033)
OTC*Some college		0.021		-0.265**		-0.070**		0.080***
		(0.070)		(0.127)		(0.030)		(0.020)
OTC*College or more		-0.068		0.281**		-0.064**		0.081***
		(0.074)		(0.129)		(0.030)		(0.020)
OTC*Income quintile 1		-0.190**		0.276*		-0.396***		0.030
		(0.081)		(0.143)		(0.036)		(0.022)
OTC*Income quintile 2		0.201***		0.150		0.008		0.038*
		(0.077)		(0.139)		(0.037)		(0.021)
OTC*Income quintile 4		-0.323***		-0.460***		0.162***		-0.079***
		(0.079)		(0.137)		(0.033)		(0.020)
OTC*Income quintile 5		-1.089***		-1.047***		-0.164***		-0.020
		(0.106)		(0.191)		(0.036)		(0.023)
OTC*Uninsured		0.328***		-0.096		0.114***		0.087***
		(0.068)		(0.127)		(0.027)		(0.018)
Year trend	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Magazine fixed effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
R^2	0.525	0.525	0.536	0.538	0.424	0.426	0.392	0.393

Robust standard errors in parentheses; *** p<0.01, ** p<0.05, * p<0.1

Table 3. *Selected Coefficients: OLS Models of Advertising Exposure (N=1,745,352)*

Variables	Model 1	Model 2
OTC	0.429***	1.961***
	(0.018)	(0.051)
OTC*Female		-0.911***
		(0.023)
OTC*Age		-0.191***
		(0.008)
OTC*Black		0.251***
		(0.049)
OTC*Hispanic		0.087*
		(0.045)
OTC*Asian & other		-0.901***
		(0.063)
OTC*High school drop out		0.275***
		(0.042)
OTC*Some college		-0.049
		(0.030)
OTC*College graduate		-0.001
		(0.030)
OTC*Income quintile 1		0.269***
		(0.035)
OTC*Income quintile 2		0.200***
		(0.036)
OTC*Income quintile 4		-0.798***
		(0.034)
OTC *Income quintile 5		-0.759***
		(0.037)
OTC*Uninsured		0.068**
		(0.027)
Year trend	Yes	Yes
Magazine fixed effects	Yes	Yes
Product fixed effects	Yes	Yes
R^2	0.28	0.37

Robust standard errors in parentheses; *** p<0.01, ** p<0.05, * p<0.1

advertising exposure of the uninsured increases after Rx-to-OTC switch. In summary, the results in table 4 support both of my hypotheses that when a drug switches to OTC, not only individual's advertising exposure increases but also the increase is greater for low SES consumers.

DISCUSSION AND CONCLUSIONS

One of the interesting aspects of the debate surrounding DTC print advertising is the abrupt shift in regulatory treatment for products that move from Rx to OTC status. When this transition occurs, the regulation of advertising shifts from an extremely regulated environment governed by strict FDA disclosure requirement to a less restrictive regulatory environment where the FTC treats OTC drug advertising under the general legal construct that applies to all advertising. There are no required disclosures though the FTC requires that advertising is substantiated and not false or misleading. This study examines how these changes in regulatory status impact on consumer exposure to DTCA for products that switched to OTC. The results suggest that Rx-to-OTC switch results in statistically significant increase in the advertising exposure. Moreover, the increase in the exposure is concentrated to those without insurance and among the low SES group of consumers.

The evidence that OTC status may create more advertising exposure for consumers, especially the low SES consumers, raises a host of intriguing regulatory issues. First, how should the FDA take this into account when considering a request by a manufacturer to shift a product from prescription to OTC status? If the switch enables more exposure to advertising and enhance more information flow to low SES consumers, restricting drugs to prescription status only may contribute and enhance disparity in health information among different socioeconomic status. If more information is available to low SES consumers, including those with less education, it is also important to make health information included in the advertisements easy to comprehend. Content analyses of advertisements consistently find that college-level reading ability is needed to read the average brief summary section of DTCA, and suggest eight-grade level of descriptions in DTCAs are recommended for the general public (Frosch *et al*., 2010; Kaphingst and DeJong, 2004).

Second, this study raises another question about the value of disclosure requirement in print advertising. If the elimination of the print disclosure is the reason that more consumers are exposed to DTCA once the product is OTC, then one could argue for the FDA to consider reducing this disclosure requirement for products that are currently still prescription status only. This is particularly relevant given the ironic fact that the required disclosure for prescription smoking cessation products is much more extensive than the disclosure requirements for print advertisements for cigarettes. Cigarette advertisements require a small warning label in the corner while prescription smoking cessation products require a full page disclosure of the risks of using these products.

Although this paper studies the U.S. market only, the results provide implications for other countries. In Korea, prescription drugs are not allowed to be advertised directly to consumers but when the drug is switched to OTC, it can be advertised in print and broadcast media to consumers. However, during the past ten years after the separation of dispensary from medical practice in 2000, almost no prescription drugs have been switched to OTC in Korea even though many of these drugs have been switched and are available as OTC in other countries (Korea Food and Drug Administration, 2011). According to the current Rx-to-OTC switch regulation in Korea, unless otherwise submitted for a review, examination for OTC switch happens every 15 years which is too long to adapt rapid pharmaceutical development efficiently. If access to health information by consumers is improved by advertising, from consumer's perspective it is necessary for this examination to OTC switch to occur more frequently. In addition, it is also important to monitor the amount of information included in the advertising and for it to be prepared in a clear, balanced and comprehensible way.

This study is exploratory since all the products that were switched to OTC are not covered. Because the NCS data is only available for a certain time period, I only focused on a few products that are switched to OTC during this period. Moreover, the advertisement archive includes pharmaceutical advertisements that appeared in 26 magazines during this time period. Even if some products were switched to OTC, not all of them are advertised in consumer magazines or not all of the relevant advertisements are appeared in 26 consumer magazines I used. Because of this, a full range of therapeutic classes and products within a class are not available. Differential effect of OTC switch on advertising exposure for different types of drugs is expected depending on the targeted potential users.

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