An Examination of Consumer Perceptions of Direct to Consumer Prescription Drug Advertisements

And Implications for Current Food and Drug Administration Oversight of Direct to Consumer Advertisement Regulations

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Abstract
The debate over the effects of marketing prescription drugs to consumers is a rich and complex one. Proponents of direct to consumer (DTC) advertising of prescription drugs claim that advertisements provide consumers with powerful information about their health that they otherwise would not have had. Opponents claim that prescription drug advertisements market more expensive medications, leading consumers to request advertised medications and ignore lower priced alternatives and that consumers do not receive full disclosure of the risks and benefits of medications. Using a study of DTC advertising conducted by the Harvard Medical School in 2002, this article examines consumer perceptions regarding information presented in prescription drug advertisements to investigate how consumers interpreted information contained in drug advertisements. Results of this examination suggest that the education level of the respondent affects how the information in the advertisement is interpreted. Implications from this analysis, and reports that false and misleading DTC advertisements are reaching the public, suggest that the Food and Drug Administration (FDA) must be more vigilant and provide more timely oversight of DTC prescription drug advertisements to prevent false and misleading claims from reaching the public.

Background

In recent times, a noticeable increase of prescription drug advertisements has appeared in television commercials and magazines around the United States. While these advertisements now seem as normal as commercials for laundry detergent, these advertisements traditionally were not a component of mainstream advertising. Before 1980, the information consumers received from pharmaceutical companies about prescription drugs was through patient package inserts (PPI). These inserts were purely informational and focused on how to correctly use the prescription. In 1968, the Food and Drug Administration (FDA) required that PPIs be dispensed to the patient with the medication. Advertisements regarding prescription drugs during this time period were directed at health care professionals. Pharmaceutical representatives would usually visit with doctors to discuss new medications or send them information through the mail and print advertisements were restricted to medical journals (Pines, 1999).

In the 1980s, pharmaceutical companies began to experiment with DTC advertising beginning with two drugs: Rufen (an ibuprofen product) and a pneumonia vaccine called Pneumovax. The FDA had mixed reactions to these advertisements. The Pneumovax advertisement was viewed positively by the FDA, who felt it would raise awareness of vaccinations. However, the FDA felt that the Rufen advertisement was inappropriate. Between 1982 and 1985, the FDA imposed a moratorium on DTC advertising for prescription drugs. During the moratorium, the FDA conducted a study which found consumers wanted more information about their prescription drugs and would welcome DTC advertising (Pines, 1999).

In late 1985, the FDA lifted the moratorium on DTC prescription drug advertisements and set forth guidelines to regulate these advertisements, which were considered very stringent. Detailed information regarding the risks, known as the major statement, had to be included in radio and television advertisements. In addition to the major statement, companies were required to give television viewers access to full prescribing information, which made for a lengthy commercial. Pharmaceutical companies found it too costly to produce advertisements that adequately followed FDA guidelines. To circumvent the guidelines, drug advertisements either discussed that a treatment existed for a condition but did not mention the drug in the advertisement, or the advertisement named the drug to advertise the brand but did not mention what the drug treated. Consumers

found the resulting advertisements confusing. In many cases, it was hard to determine that the advertisement was for a health product (Rosenthal, Berndt, Donohue, Frank & Epstein, 2002, p.498; Calfee, 2002, p.174).

In 1997, the FDA re-evaluated its regulations on DTC prescription drug advertising. No regulations were actually changed; the FDA interpreted its guidelines in a new way. The main change between the 1985 guidelines and the 1997 re-interpretation was that the required information regarding risks in an advertisement could be simplified. Broadcast advertisements could now use a voice-over to provide brief summaries of side effects and include sources such as toll free phone numbers and websites where the consumer could receive more information (Calfee, 2002, p. 175).

Since the inception of DTC prescription drugs advertisements, there has been much controversy over their use. Proponents of DTC advertising insist that advertisements empower consumers with information. Opponents charge that advertised drugs are simply more expensive forms of medicines that perform similarly and that consumers really do not receive full disclosure of necessary information (Lexchin & Mintzes, 2002; Rosenthal et al., 2002). Much of the FDA's uneasiness in 1982 stemmed from the fact that drugs up until the 1980's were marketed to health professionals who had the medical knowledge to evaluate claims in professional drug advertisements. Fueling the current debate is Merck's recent recall of Vioxx, which is not only one of Merck's top selling drugs, but was also one of Merck's most heavily promoted drugs via DTC advertising. Prior to this development, an increasing amount of legislation had been proposed which would heavily fine pharmaceutical companies that knowingly produce false and/or misleading advertisements and strengthen enforcement of FDA advertising guidelines.

Data and Methodology

The data used in this analysis was obtained from the Inter-university Consortium for Political and Social Research (ICPSR, 2003). The original study, conducted by researchers at Harvard Medical School, looked at whether DTC advertising lead patients to discuss information presented in advertisements with their physicians. The study took place between July 2001 and January 2002. Data was collected through telephone surveys conducted by Harris Interactive. The typical interview length was 20 minutes. Respondents were chosen using a stratified sampling technique to produce a representative sample of households with telephones in the continental United States. A total of 3,000 respondents were interviewed. The key questions this ICPSR study sought to answer were:

- What sorts of conditions or problems are discussed during physician visits that include a discussion about a Direct to Consumer (DTC) advertising drug?
- What actions are taken by physicians, including additional tests and treatments, as a result of these visits?
- Do outcomes of care differ according to whether the patient takes the DTC advertising drug that was discussed during the visit or some other drug?

Survey questions fell under five main categories: 1) health status and utilization, 2) experience with DTC advertising, 3) visits to the doctor to discuss information, 4) outcomes of doctor visits to discuss information, and 5) health insurance coverage. Respondents had to be at least 18 years of age and had to have seen or heard at least one prescription drug advertisement in the past 12 months.

Statistical Analysis

The ICPSR survey respondents' answers pertaining to their perceptions of DTC prescription drug advertisements were analyzed using descriptive statistics. The main comparisons were information regarding respondent demographics and health behaviors against respondent opinions on information presented in prescription drug advertisements they had viewed. Trends between consumer perceptions of advertisements and consumer behaviors and demographics were sought using cross-tabulations and frequencies. Respondent answers to sets of statements regarding DTC prescription drug advertisements were analyzed by comparing various demographic factors in the sample set.

Results

Incidence of Routine Doctor Visits and Sources of Health Information

Respondents were asked to identify the sources from which they received health information. To determine if there was a relationship between the types of health information received by respondents and the likelihood that the respondent would visit their doctor annually, result from both questions were cross-tabulated. Results from this analysis are summarized in Table 1.

Table 1: Cross-tabulation Results of Media Information Sources and Frequency of Doctor Visits

Get health care information from: television or radio, not including advertisements

Time since last doctor visit	Often	Sometimes	Hardly Ever	Never
Within the last 12 months	79.56%	80.43%	80.18%	76.93%
More than 12 months ago	20.44%	19.78%	19.82%	23.07%

Get health care information from: Internet websites

Time since last doctor visit	Often	Sometimes	Hardly Ever	Never
Within the last 12 months	83.40%	78.81%	79.28%	78.64%
More than 12 months ago	16.60%	21.19%	20.72%	21.36%

Get health care information from: advertisements on TV, radio, newspapers and/or magazines

Time since last doctor visit	Often	Sometimes	Hardly Ever	Never
Within the last 12 months	79.35%	78.75%	80.35%	78.30%
More than 12 months ago	20.65%	21.25%	19.65%	21.70%

As illustrated in the table above, there does not appear to be a relationship between the amount of time since the respondent's last doctor visit and the types of information sources used. In addition to media sources, respondents were also asked how often they consulted health care professionals for health information. Respondents who visited their physician within the last twelve months were more likely to consult a health professional for further medical information in much higher proportions than respondents whose last doctor visit was over a year ago. Results are summarized in Table 2.

Table 2: Cross-tabulation Results of Professional Health Information Sources and Frequency of Doctor Visits

	Get health care information from: a pharmacist			
Time since last doctor visit	Often	Sometimes	Hardly Ever	Never
Within the last 12 months	87.99%	83.63%	80.40%	72.08%
More than 12 months ago	12.01%	16.37%	19.60%	27.92%

	Get health care information from: pamphlets in a doctor's office or waiting room			
Time since last doctor visit	Often	Sometimes	Hardly Ever	Never
Within the last 12 months	87.34%	81.90%	76.85%	73.36%
More than 12 months ago	12.66%	18.10%	23.15%	26.64%

	Get health care information from: a doctor			
Time since last doctor visit	Often	Sometimes	Hardly Ever	Never
Within the last 12 months	91.50%	82.36%	67.42%	55.66%
More than 12 months ago	8.50%	17.64%	32.58%	44.34%

Respondents whose last doctor visit occurred over a year ago were less likely to have consulted professional health sources for health information. If not for the previous analysis, it would appear that respondents who had not visited their doctor recently would be more prone to obtain health information from other non-professional sources. However, because the proportions in each of the frequency categories for obtaining information from media sources was similar across all categories, the trend shown in Table 2 is most likely explained by time. Those who visit the doctor more often have a higher exposure to health care professionals; therefore one would expect to see higher incidences of health care information obtained from professionals by those respondents who visit their physicians more often.

Respondent Perceptions of DTC Prescription Drug Advertisements

Respondents were also asked to indicate how strongly they agree or disagree with a series of statements regarding prescription drug advertisements. One main charge that opponents of drug advertisements have lodged is that drug advertisements contain asymmetrical information that misleads consumers as to the true function of the drug. Again, proponents claim that advertisements empower consumers with information. To investigate this claim, respondent opinions regarding prescription drug advertisements were cross-tabulated with the education level of respondents. Cross-tabulation results of this analysis are displayed in Table 3.

Table 3: Summary of Results for Cross-Tabulations of Respondent Opinions on Prescription Drug Advertisements and Respondent's Educational Level

	Prescription drug ads: Made me aware of treatments that I did not know about			
Level of Education	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
Less than HS education	6.57%	4.29%	6.27%	5.11%
HS or some college	57.01%	52.60%	48.04%	44.03%
College graduate	36.42%	43.11%	45.69%	50.85%

	Prescription drug ads: Did not provide information on risks and benefits in a balanced manner			
Level of Education	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
Less than HS education	4.45%	5.78%	5.19%	5.81%
HS or some college	48.74%	51.54%	51.34%	58.51%
College graduate	46.81%	42.67%	43.47%	35.68%

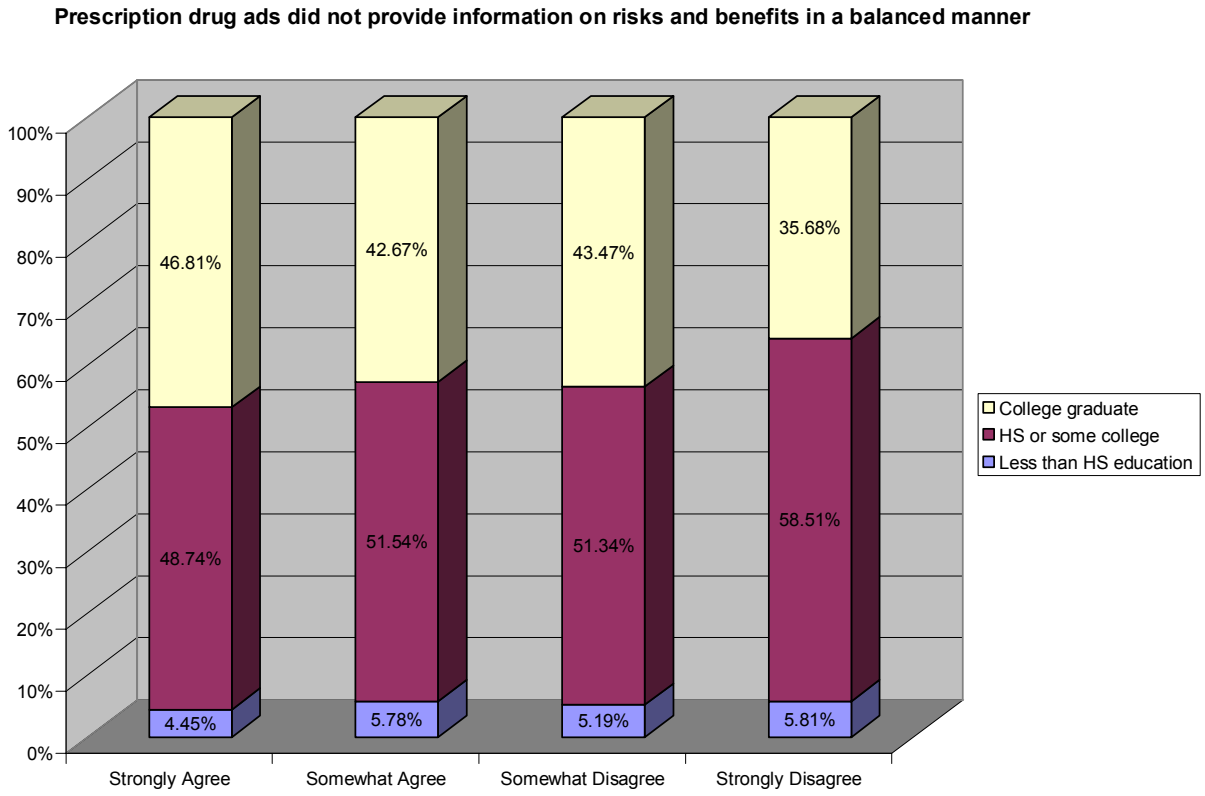
	Prescription drug ads: Made me less confident in my doctor's judgement			
Level of Education	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
Less than HS education	10.87%	6.33%	5.96%	4.29%
HS or some college	57.97%	64.24%	55.46%	46.96%
College graduate	31.16%	29.43%	38.58%	48.75%

	Prescription drug ads: Helped me to have better discussions about my health with a health professional			
Level of Education	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
Less than HS education	8.39%	4.46%	4.18%	4.55%
HS or some college	60.60%	52.97%	47.33%	44.01%
College graduate	31.01%	42.57%	48.49%	51.45%

	Prescription drug ads: Reminded me to follow directions or advice from my doctor			
Level of Education	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
Less than HS education	6.09%	5.24%	4.41%	4.26%
HS or some college	58.18%	50.32%	51.53%	41.85%
College graduate	35.73%	44.44%	44.07%	53.88%

Overall, respondents with less than a high school education had similar proportions of agreement and disagreement for all five statements, showing no particular trend. However, respondents with a high school degree or some college tended to agree with positive statements about prescription drug advertisements and disagree with negative statements about prescription drug advertisements. College graduates had a trend that ran almost counter to the respondents with high school or some college. College graduates tended to agree with negative statements regarding prescription drug advertisements and disagree with positive statements. To better illustrate the trend, two of the statements are illustrated below using stacked bar charts.

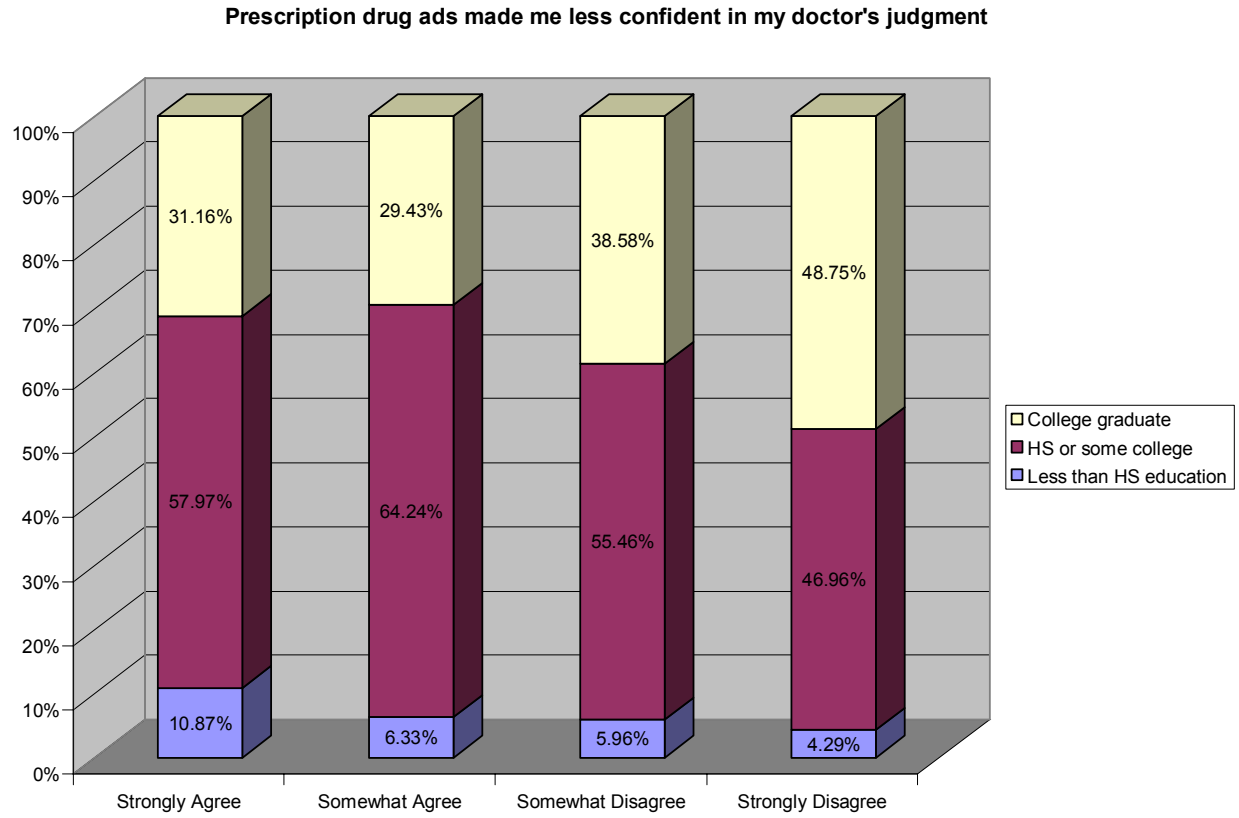
Figure 1: Respondent Opinions on Risks and Benefits in Prescription Drug Advertisements vs. Respondent's Educational Level



When asked about whether or not prescription drug advertisements present risks and benefits in a balanced manner, the proportion of college graduates agreeing that the advertisements did not present risks and benefits in a balanced manner was proportionally higher than respondents with a high school degree or some college. Those with a high school degree or some college tended to disagree with the statement in much higher proportions than college graduates.

The gap between respondent perceptions regarding prescription drug advertisements and education level became clearer when examining the statement "Prescription drug advertisements made me less confident in my doctor's judgment."

Figure 2: Respondent Opinions on Doctor's Judgment after viewing Prescription Drug Advertisements vs. Respondent's Educational Level

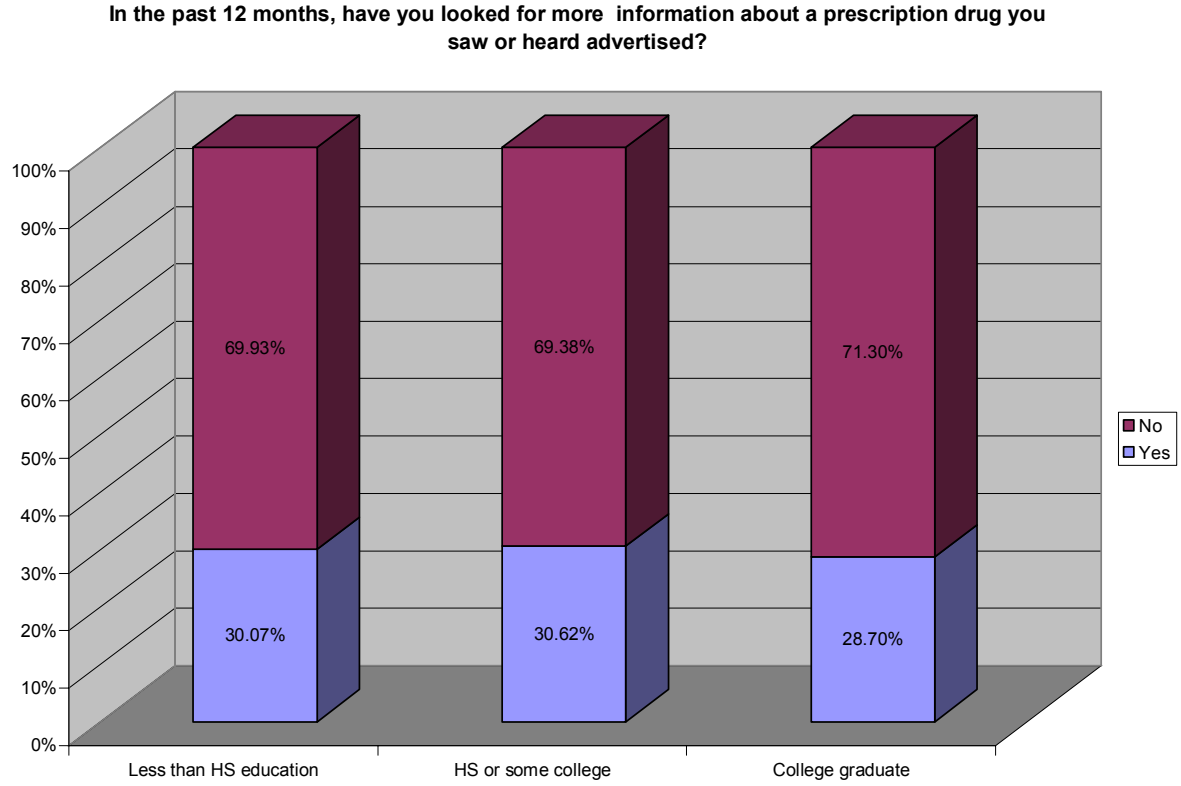


Again, we see that the responses of high school graduates run contrary to responses of college graduates. High school graduates were more likely to agree that they felt less confident in their doctor's judgment about their health based on information received in prescription drug advertisements. College graduates disagreed with this statement in much higher proportions than high school graduates.

Likelihood of seeking further information

Whether or not a respondent would seek out additional information regarding a prescription drug advertisement was examined next. In the survey, respondents were asked "In the past 12 months, have you looked for more information about a prescription drug you saw or heard advertised." Results from this question were cross-tabulated against respondent educational level. The analysis is illustrated in Figure 3.

Figure 3: Likelihood of Seeking Further Information as a Result of DTC Prescription Drug Advertisements



College graduates were no more likely to seek further information about a drug after viewing or hearing a prescription drug advertisement than high school graduates and those with less than a high school education.

These sets of analyses imply that college graduates are more skeptical of information presented in prescription drug advertisements while high school graduates or those with some college but no degree are more likely to take claims presented in prescription drugs advertisements at face value. As mentioned earlier, when prescription drugs were marketed to health professionals, there was not an air of uneasiness because the target market consisted of people with a medical education who had the knowledge to effectively evaluate information presented in drug advertisements. With consumer drug advertisements, the population at large is exposed to the information, and given the diversity of education in the United States, both in actual amount of schooling and subjects studied, it is hard to determine whether the population at large has adequate information to critically evaluate the information contained in the advertisements. The above analysis illustrates the disparity of the reaction to information presented regarding prescription drug advertisements among the American population. This suggests that action needs to continue to be taken to further ensure that the population receives accurate and complete information about prescription drugs.

Current FDA oversight

Before examining possible policy alternatives, it would be useful to review current FDA oversight regarding false or misleading prescription drug claims. According to the latest report by the General Accounting Office (GAO), *Prescription Drugs: FDA Oversight of Direct to Consumer Advertising has Limitations* released in October 2002, when an advertisement appears to have false and/or misleading claims or does not present a balanced representation of risks and benefits, the FDA sends a letter to the pharmaceutical company to cease the dissemination of the information in question. According to the GAO report, the FDA reported that pharmaceutical companies had complied with every FDA request to cease the distribution of misleading information. The FDA has the power to initiate legal action through the Department of Justice (DOJ) to seize

prescription drugs that are being marketed with false or misleading claims. Alternately, the FDA may also seek court orders to force a pharmaceutical company to run a campaign correcting false and/or misleading claims made in advertisements. The GAO explains that the FDA has yet to use such measures because the FDA did not want to remove from the market a drug that could be useful for many people.

The GAO concluded that the FDA was effective in halting the distribution of misleading advertisements already in circulation. However, the GAO also concluded that cease and desist letters have not stopped companies from producing further false and misleading claims in advertisements. Since the 1997 re-interpretation, several pharmaceutical companies have received multiple letters from the FDA regarding information presented in advertisements. Sometimes the letters are directed towards advertisements for a different drug and sometimes subsequent advertisements that the companies release are just as misleading as the original advertisement cited by the FDA. According to the GAO report, in 2001 the FDA sent letters to eleven different pharmaceutical companies because information in prescription drug advertisements overstated the effectiveness of the drug, implied the drug could be used for purposes other than what it had been approved for, or gave minimal information regarding risks associated with the drug.

Although the FDA states that misstatements made by pharmaceutical companies are rectified, there is a delay between the time the FDA identifies a false claim in an advertisement and the time the company receives a regulatory letter. In some cases, the lifespan of the advertising campaign ends before the FDA ever had a chance to send out a regulatory letter identifying the advertising violation. The GAO identified two factors that contribute to the delay. The first factor is the occasional failure by pharmaceutical companies to notify the FDA of a forthcoming drug advertisement. The FDA contracts out with a private company that searches television channels for advertisements not reported to the FDA. This service monitors major cable and non-cable networks as well as local New York City network affiliates. However, DTC advertisements broadcast on many local television channels and small cable channels are not identified in the monitoring process because they are ignored by this service. The second factor is a change in policy by the Department of Health and Human Services (HHS) mandating that the FDA Office of the Chief Counsel (OCC) must review regulatory letters before they are sent to the companies in question. This policy was implemented late in 2001 to ensure that violations cited by the FDA had sufficient legal grounding. Prior to this policy, the Division of Drug Marketing, Advertising, and Communications (DDMAC), which is the arm of the FDA responsible for implementing DTC regulations, sent out regulatory letters within days of identifying advertisements as false or misleading. Under the current policy, the OCC has up to 45 working days to review regulatory letters.

Policy Alternatives

Proponents of DTC advertising would argue that no action needs to be taken regarding current regulations/ guidelines on direct to consumer advertising of prescription drugs. However, given the above analysis, consumers appear to be affected by claims made in prescription drug advertisements. Information in the GAO report demonstrates that pharmaceutical companies have consistently violated FDA policies on consumer prescription drug advertisements, allowing misleading information to filter through to the public. This lends support to claims that consumers receive asymmetrical information regarding prescription drug advertisements.

The statistical analysis discussed above illustrates a gap between consumer perceptions between college graduates and high school graduates. This indicates that college graduates, through their education, have developed skills that aid them in evaluating information contained in advertisements. Implementing a program to educate the public on how to analyze information presented in drug advertisements could be a viable solution to bridge the gap between the way college graduates and high school graduates perceive advertisements. Such information could be presented as part of a high school curriculum during health and/or physical education classes. High school students could be given instruction on frequently used marketing tactics and could practice analyzing information given in advertisements by learning of sources they can consult to learn more about the drug in question. Pamphlets summarizing information on prescription drug advertisements and additional sources to consult could also be placed in health offices at schools. In addition, health professionals could also present this information during workshops at community centers, such as libraries or senior centers. Although improving consumer education on how to evaluate information in drug advertisements could be feasibly implemented, it does not address the underlying problem, which is that false and misleading advertisements are released to the public. Policy recommendations should place more responsibility on pharmaceutical companies to produce advertisements containing a better balance of risks and benefits information in advertisements.

Policy Recommendation

Prior to 1997, prescription drug advertisements were hardly plentiful. It was much easier for the FDA to enforce violations of advertisement regulations. Since the 1997 re-interpretation of guidelines for prescription drug advertisements, each subsequent year has seen an increase in spending for prescription drug advertisements in mainstream media sources over the previous year (Rosenthal et al., 2002, p. 500). This, coupled with the analysis of consumer perceptions and educational level suggests that action should be taken to prevent false and misleading advertisements. Stricter guidelines by the FDA could help ease the problems experienced thus far by allowing pharmaceutical companies to market to consumers. Reverting back to pre-1997 guidelines is not the answer, as that resulted in advertisements that were confusing to consumers. However, post-1997 guidelines have proven to be too lax. Somewhere between the strict pre-1997 guidelines and the more lenient post-1997 guidelines is a middle ground containing compromises where prescription drug advertisements could still be affordable to air, and more accountability could be placed on companies to produce advertisements that give consumers a clearer picture of the efficacy of the drug as well as the risks and benefits associated with the drug.

As previously mentioned, the pre-1997 era required a major statement of risks and benefits to be included in the advertisement, resulting in lengthy advertisements that were impractical for companies to air. The post-1997 guidelines reduced the major statement to include an "adequate provision" that quickly summarized risks and benefits and could be communicated as long as consumers were given additional sources to consult for more information. However, many television commercials use constantly changing scenes that potentially distract viewers from the audio portion of the commercial. The FDA has identified this as a problem, described in a regulatory letter sent in 2001 to the makers of Differin, citing that the commercial contained many visual distractions which decreased the viewer's ability to focus on the audio voiceover (GAO, 2002). Without increasing the length of the commercial, advertisements could be required to emphasize the risks associated with the drug by requiring a voice over and a visual statement of risks during the last 5-7 seconds of the commercial. Having an audio and visual component draws all the attention to risks of taking the advertised drug.

Another possible guideline change is that advertisements must receive FDA approval for the advertisement prior to the advertisement being aired or published. While companies are currently required to forward forthcoming advertisements to the FDA, advertisements are not always reviewed by the FDA before they are shown to the public. The DDMAC primarily focuses its review on broadcast advertisements due to their potential to reach more people than print advertisements. While the DDMAC reviews advertisements at the beginning of the broadcast cycle, violations of guidelines are not quickly communicated to pharmaceutical companies.

Congressional Proposals

Proposed legislation aims to punish pharmaceutical companies who produce advertisements with false and/or misleading claims. The Fair Balance Prescription Drug Advertisement Act of 2003 proposes to amend the Internal Revenue Service Act of 1986 to disallow deductions on any business expenses related to prescription drug advertisements that have been identified by the FDA as containing false and/or misleading claims, misbrands the drug, or fails to present information in a balanced manner. Other bills proposed by Congress also contain this provision, although most other acts focus on ways to make prescription drugs more affordable. The Direct to Consumer Prescription Drug Advertising Act of 2004 proposes to assess civil penalties on pharmaceutical companies that produce advertisements deemed deceptive. Proposed fines start at $500,000, and depending on the situation, these fines could go as high as $10,000,000. This act would also seek to shorten the time taken by the FDA to send regulatory letters to violators and prohibit further policies that would slow FDA enforcement on violations. Additionally, it would require the Secretary of HHS to prepare an annual report for Congress regarding prescription drug advertisements that aired during the past year. House bill 5252 introduced in October 2004 proposes releasing a greater amount of information regarding clinical trials of drugs to the public to give the public access to balanced information regarding prescription drugs.

While the DTC Act of 2004 is more prescriptive in enforcing regulations of FDA guidelines, both acts focus more on punishment of violations rather than preventing deceptive advertisements from reaching the public in the first place. One could argue that amending the IRS code would be effective in making companies stick to FDA guidelines on prescription drug advertisements because it would affect their finances. However, it could also be argued that any such amendment would tempt pharmaceutical companies to find ways to hide expenses related to questionable advertisements.

Limits of Analysis

To better understand the breadth of the issue, it would be helpful if future studies focusing on consumer perceptions of advertisements had more information on the extent of exposure to prescription drug advertisements by respondents. The current study on which this analysis is based upon only asked respondents if they had seen or heard at least one prescription drug advertisement in the past 12 months. It would also be helpful to know from which media source respondents received the most exposure. Did they mostly view prescription drug advertisements on television or did most of their exposure to advertisements come from magazines? This is important given that the DDMAC places more scrutiny on television advertisements than print advertisements. The data used in this analysis was collected in 2001. Events during 2004, such as the Vioxx recall, could affect respondent opinions on drug advertisements. Conducting and analyzing a new survey examining respondent opinions on DTC advertisements would be helpful to future consideration of this subject.

Conclusion

The analysis presented here shows that the differing educational levels of respondents in the sample set affected how respondents evaluated information presented in prescription drug advertisements. The situation would not be problematic if only accurate information was presented in advertisements. Research into FDA oversight of DTC prescription drug advertisements shows that pharmaceutical companies do produce advertisements with false and misleading claims, and that policies within the FDA have limited the effectiveness of the FDA's ability to stop false and misleading claims from reaching the public. At the local level, community programs could be implemented to empower consumers with skills on how to evaluate information in advertisements. However, to tackle the problem at the source, policy recommendations should focus on preventing misleading advertisements from reaching the public.

Future debate over the issue is not likely to subside anytime soon. The amount of proposed legislation over prescription drug advertisements as well as the information received by the public about prescription drug advertisements is likely to increase given the 2004 recall of Vioxx. Policies on DTC advertising have come under intense scrutiny in recent years as Canada and the European Union examine the experience in the United States to decide if DTC advertising bans should be lifted in these nations. All of these factors will intensify the debate over whether or not the market for prescription drugs has become an issue of marketing over prescribing.

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