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Awareness of FDA's Bad Ad Program and Education Regarding Pharmaceutical Advertising: A National Survey of Prescribers in Ambulatory Care Settings

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Abstract

The Food and Drug Administration's (FDA's) Bad Ad program educates healthcare professionals about false or misleading advertising and marketing and provides a pathway to report suspect materials. To assess familiarity with this program and the extent of training about pharmaceutical marketing, a sample of 2,008 healthcare professionals, weighted to be nationally representative, responded to an online survey. Approximately equal numbers of primary care physicians, specialists, physician assistants, and nurse practitioners answered questions concerning Bad Ad program awareness and its usefulness, as well as their likelihood of reporting false or misleading advertising, confidence in identifying such advertising, and training about pharmaceutical marketing. Results showed that fewer than a quarter reported any awareness of the Bad Ad program. Nonetheless, a substantial percentage (43%) thought it seemed useful and 50% reported being at least somewhat likely to report false or misleading advertising in the future. Nurse practitioners and physician assistants expressed more openness to the program and reported receiving more training about pharmaceutical marketing. Bad Ad program awareness is low but opportunity exists to solicit assistance from healthcare professionals and to help healthcare professionals recognize false and misleading advertising. Nurse practitioners and physician assistants are perhaps the most likely contributors to the program.

Pharmaceutical marketing has grown considerably in the United States in recent decades (Ross & Kravitz, 2013). Academic literature on the topic tends to focus on the documentation of sales-effort prevalence or the influence of such efforts (Kaphingst, DeJong, Rudd, & Daltroy, 2004; Kornfield, Donohue, Berndt, & Alexander, 2013; Rosenthal, Ernst, Donohue, Frank, & Epstein, 2002). Little research addresses how national programs can assist healthcare professionals navigate the flood of contemporary prescription drug information available and help them identify false or misleading advertising.

At least one body of research, for example, has focused on the influence of pharmaceutical promotion on medical students, residents, and physicians (Brotzman & Mark, 1993; McCormick, Tomlinson, Brill-Edwards, & Detsky, 2001; Mintzes, 2014; Sierles et al., 2005; Wilkes & Hoffman, 2001). Starting as early as the 1950s, researchers have surveyed practitioners about their reactions to interactions with pharmaceutical sales representatives

(Vinson, McCandless, & Hosokawa, 1993; Zipkin & Steinmann, 2005). Some authors have bemoaned the dearth of proper ethics teaching in schools and the lack of proper development of skepticism (Hafferty & Franks, 1994). Over the course of the last decade, overt persuasion techniques, such as dinners, lunches, free gifts, travel, and other promotional techniques, have declined based in part on Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines (PhRMA, 2009). However, pharmaceutical representatives continue to visit physicians and other healthcare professionals and, in many cases, provide gifts and meals that are ostensibly discouraged in the guidelines (Austed et al., 2013). In some case, healthcare professionals report that they tolerate interaction with representatives in order to obtain the free drug samples that many providers believe increase medication adherence (Austed et al., 2013). Others suggest that they learn valuable information about new drugs from pharmaceutical representatives (Tardif, Bailey, Bussieres, Lebel, & Soucy, 2009). Almost all healthcare professionals deny that they themselves are susceptible to questionable influence when learning about these new drugs (Austed et al., 2013). Thus, despite many changes in professionally-directed pharmaceutical promotion over the years, it is unlikely to completely disappear.

Although previous research focused on avoiding pharmaceutical promotion entirely (Mansfield et al., 2006), no existing literature has focused on improving healthcare professionals' ability to accurately assess promotional claims sales representatives make. The U.S. Food and Drug Administration's (FDA's) Bad Ad program, which provides information to providers on how to recognize false or misleading claims and a pathway to report suspect advertising (Food and Drug Administration, 2014c), is designed to foster this ability. Launched in 2010, this program began by educating physicians, pharmacists, nurse practitioners, nurses, and physician assistants at professional conferences and through printed materials. The Bad Ad website has had 231,841 hits and, most recently, FDA developed a Continuing Medical Education (CME) course, which has had 5243 views. As of April 2014, FDA had received 772 complaints through the Bad Ad program, 366 of which were related to prescription drug promotion as opposed to the promotion of other products such as homeopathic remedies. FDA has sent sponsors nine untitled or warning letters based on complaints that originated through this program (Food and Drug Administration, 2014b).

The Bad Ad program is one of the strategies FDA has used to monitor prescription drug advertising. As part of its mission, FDA's Office of Prescription Drug Promotion (OPDP) maintains a program of surveillance, enforcement, and education. Over 87,000 pieces of promotion were processed in 2013 (Food and Drug Administration, 2014a) by fewer than 70 employees. The Bad Ad program helps the office with the education of healthcare providers, assistance with surveillance from healthcare providers, and the development of enforcement actions when violative advertising is discovered.

The purpose of the current study is to explore healthcare professional awareness and knowledge of the Bad Ad program. We also explore the extent of reported formal and informal education regarding pharmaceutical advertising as further evidence relevant to the question of how prepared healthcare professionals are to negotiate the prescription drug promotion landscape they face regularly.

Methods

Respondents and Setting

Respondents were recruited from a national panel of healthcare professionals, the Physician Consulting Network (PCN), which is primarily based on the American Medical Association Masterfile and supplemented for this study with additional nurse practitioners and physician assistants. Approximately 500 healthcare professionals from each of four fields (primary care physicians, specialists, nurse practitioners, and physician assistants) participated in the study, for a total sample size of 2,008. Eligibility included direct patient care at least 50% of the time, authority to prescribe medicine, and not being hospital-based. We limited eligible specialties to those for which there were advertised drugs during the duration of the data collection, which occurred from June to August of 2013. These specialties included: allergy or pulmonology, psychiatry, endocrinology, dermatology, rheumatology, cardiology, otolaryngology, urology, neurology, oncology, pain management, and OB/GYN.

Response rates ranged from 1.4% to 12.8% depending on whether respondents were original PCN members or were recruited for this study. We conducted two nonresponse bias analyses, first with the whole sample on available variables of gender and region. No difference appeared by region, but respondents were more likely to be male. We also conducted additional analysis with the original PCN sample because we had access to information on gender, region, age, and graduation year. This analysis showed that respondents were more likely to be female, younger, and have graduated after the year 2000. Again, there were no differences by region. Although the findings show significant differences for gender, age, and years of practice, weighting was used to adjust for deviations between the sample and population distributions (Table 1). These variables were included as the adjustment cells for the post-stratification weight adjustment to minimize nonresponse bias. For example, although respondents tended to be younger than nonrespondents, the survey estimates were weighted to be representative of the actual population. Therefore, the responses for younger providers were weighted down slightly and the responses for older providers were weighted up. This resulted in a slight increase in variance, but a reduction in bias due to differences in the type of providers who responded to the survey.

A cooperation rate is the extent to which contacted individuals complete a survey (AAPOR, 2009). Unlike response rates, the number of contacted individuals who complete the survey is compared to those who were ever contacted, not all of the possible individuals who may have been contacted. In this study, cooperation rate ranged from 91.9% to 100% depending on whether respondents were original PCN members or were recruited for this study.

Measurements

We invited respondents to complete a 42-item survey via the Internet containing questions about direct-to-consumer advertising, interactions with patients, attitudes toward (and experience with) training regarding pharmaceutical marketing, knowledge of the Bad Ad program, online activities, and demographic characteristics. Fielded over eight weeks during the summer of 2013, the median length of time to complete the survey was 15 minutes. The

data reported here represent only the Bad Ad program and training findings. We provided respondents with a detailed consent form and, after agreeing to participate, they accessed a link to the survey, which took approximately 15 minutes to complete.

To assess familiarity with the Bad Ad program, we asked respondents if they had ever heard of the Bad Ad program (*yes/no/unsure*). After a brief description of the program, respondents indicated how useful they thought the program would be (1 = *very useful*, 4 = *not at all useful*). We asked whether they had ever reported false or misleading advertising (*yes/no/don't remember*) and how likely they are to report false or misleading advertising in the future (1 = *very unlikely*, 7 = *very likely*). We asked those who indicated that they were unlikely to report false or misleading advertising an open-ended question about what makes them unlikely to do so. We also asked respondents how confident they were that they could identify false or misleading advertising (1 = *very unsure*, 7 = *very sure*).

Additionally, we asked respondents whether they received any formal (e.g., lectures, presentations) or informal (e.g., advice from colleagues) training in two separate questions (*yes/no/don't remember*). We also asked how useful it would be for new healthcare professionals to receive formal training regarding pharmaceutical marketing (1 = *not at all useful*, 5 = *extremely useful*).

This study was granted an exemption by the FDA's Research Involving Human Subjects Committee and RTI International's Institutional Review Board.

Analyses

For the Likert scale items (e.g., 1 = *very unlikely*, 7 = *very likely*), we initially conducted *t*-tests to assess mean differences. However, because in most cases variable means tended to cluster around the neutral point on the scale, we opted to compare variable distributions in a different way. To account for response categories with only a few responses and to better interpret the results, we collapsed all Likert scale items into three categories, such as *unlikely*, *neutral*, and *likely*. We then used chi-square analyses to detect patterns of overall difference between healthcare professional subgroups. For items with significant chi-square results, we then conducted pairwise comparisons on the frequencies to determine which subgroups differed on which response options. These analyses used a Bonferroni-adjusted *p*-value of .0028 (.05/18) to account for multiple comparisons.

Reported frequencies may in some cases total more than 100% due to rounding.

Results

Bad Ad Program

Five percent of respondents had heard of the Bad Ad program and 14% were not sure if they had or not, leaving 81% who reported no awareness of the program. There were no significant differences in awareness between types of healthcare professionals. Of those who had heard of the program, 1% had actually used it to report false or misleading advertising.

After reading a description of the Bad Ad program, 72% of all healthcare professionals said the program seemed at least moderately useful. As shown in Figure 1, responses to this question differed by field ($\chi^2 [6, N = 2,007] = 4.90, p < .001, V = .03$). Primary care physicians and specialists were more likely to think that the Bad Ad program would not be useful (or only slightly useful) compared with physician assistants ($t[1,007] = 3.66, p < .001$ and $t[1,007] = 3.80, p < .001$, respectively) or nurse practitioners ($t[1,007] = 3.75, p < .001$ and $t[1,000] = 3.88, p < .001$, respectively).

Fifty percent of all healthcare professionals indicated that they were at least somewhat likely to report false or misleading drug advertising in the future. As shown in Figure 2, more than half of physician assistants and nurse practitioners indicated they would report “bad ads.” Results indicate a significant difference among fields ($\chi^2 [6, N = 1,997] = 4.70, p < .001, V = .03$) such that primary care physicians and specialists indicated they were less likely to report false or misleading prescription drug ads through the Bad Ad program, compared with nurse practitioners ($t[1,000] = 3.50, p < .001$ and $t[997] = 3.21, p < .001$, respectively). Physician assistants and nurse practitioners were more likely to indicate that they would be somewhat to very likely to report false or misleading ads, compared with primary care physicians ($t[1,000] = 3.61, p < .001$ and $t[1,000] = 3.71, p < .001$, respectively).

Seventy percent of healthcare professionals reported that they were somewhat to very sure that they could recognize false or misleading advertising of prescription drugs. There were no significant differences between types of healthcare professionals. However, auxiliary analyses revealed that receiving formal training on pharmaceutical marketing was associated with being more sure about being able to recognize false or misleading advertising ($\chi^2 [6, N = 1,856] = 7.46, p < .001, V = .04$).

Pharmaceutical Training

Overall, 13% of healthcare professionals reported having received formal training regarding pharmaceutical marketing, 80% reported not receiving formal training, and 7% could not remember. More healthcare professionals (27%) reported receiving informal training, with 65% reporting no informal training and 9% unable to remember.

As shown in Figure 3, training differed across fields. Pairwise comparisons revealed that primary care physicians were less likely to have had formal training than physician assistants ($t[1,008] = -4.86, p < .001$) and nurse practitioners ($t[1,007] = -3.46, p < .001$). Specialists were significantly less likely to have received formal training than physician assistants ($t[1,004] = -3.25, p < .001$). Similar to the results for formal training, primary care physicians and specialists were less likely to have had informal training than physician assistants (primary care physicians: $t[1,006] = -3.48, p < .001$; specialists: $t[997] = -3.92, p < .001$) or nurse practitioners (primary care physicians: $t[998] = -3.60, p < .001$; specialists: $t[889] = -4.03, p < .001$).

Thirty-five percent of all healthcare professionals thought it would be very to extremely useful for new healthcare professionals to receive formal training regarding pharmaceutical marketing for prescription drugs, whereas 38% thought it would not be useful or only slightly useful. As shown in Figure 4, results differed by field ($\chi^2 [6, N = 2,006] = 4.50, p$

$< .001$, $V = .03$). Nurse practitioners were less likely to report that training would be not at all or slightly useful compared with primary care physicians ($d[1,005] = -3.17$, $p < .01$) or specialists ($d[998] = -5.03$, $p < .001$).

Discussion

Results suggest two major themes. First, healthcare professional awareness is low with respect to the assistance available through the Bad Ad program to identify false or misleading advertising, indicating room for future growth in Bad Ad program exposure. Second, and perhaps more compelling for officials who hope to leverage healthcare professionals as partners in communication with consumers, is the greater openness to program participation expressed by some healthcare professionals in specific fields. We offer clear evidence regarding the potential for targeting healthcare professionals with future campaign efforts regarding false or misleading advertising. From the standpoint of these national survey results, nurse practitioners and physician assistants offer the most apparent promise for future engagement.

As expected, we found that very few healthcare professionals were aware of the Bad Ad program. Although the program has been in existence for almost 5 years, the outreach in initial years was limited to healthcare professional conferences and website development. Thus, a lack of national exposure helps to account for this low reported awareness. Although we have no measure of baseline awareness before the program was initiated, the current findings nonetheless provide comparison data for future examinations of the program, for example, after the online CME offering has become well established.

More important than the current levels of general awareness of the Bad Ad program, however, is the relative openness to the program by healthcare professionals in specific fields. Overall, 72% of healthcare professionals thought the program would be at least moderately useful; this reflects substantial interest in the program despite relatively low awareness. Moreover, our survey evidence provides useful information for future targeting of program efforts. Nurse practitioners and physician assistants tended to see the program as more useful than primary care physicians and specialists. They also reported a greater likelihood of reporting false or misleading advertising in the future. Related to these findings is the fact that nurse practitioners and physician assistants reported more formal and informal training regarding pharmaceutical marketing than primary care physicians and specialists.

Given that the two more traditional fields (physicians and specialists) were dominated by males with more years in practice and the two newer medical fields (nurse practitioners and physician assistants) were dominated by females with fewer years in practice, we checked to see if these factors were the basis of this finding. We found that, after controlling for gender and years in practice, differences between subgroups were still present. These results suggest that differences between provider subgroups on perceived usefulness and intention to use the Bad Ad program cannot be explained by the fact that nurse practitioners and physician assistants tend to be female, and have fewer years in practice. Instead, it may be the nature of the jobs that nurse practitioners and physician assistants hold that predispose them to be

more likely to report false or misleading advertising. This has implications for the dissemination of information about CME classes and perhaps the further refinement of CME offerings to capitalize on the receptiveness of individuals in these fields.

Consistent with previous research (Vinson, McCandless, & Hosokawa, 1993; Wilkes & Hoffman, 2001), we found that few healthcare professionals report receiving informal training regarding pharmaceutical marketing, such as conversations with mentors or colleagues. Even fewer receive formal training in the form of lectures, presentations, or computerized training. Although overall rates of any training were low, nurse practitioners and physician assistants reported more informal and formal training in pharmaceutical marketing than primary care physicians and specialists. Perhaps this accounts for a portion of the greater openness to the Bad Ad program reported by these professionals. It is also possible that nurse practitioners and physician assistants are more open, in general, to new programs or continuing education opportunities, which would make them more likely to take training and more likely to use a program such as the one discussed in this paper. These are fruitful areas for future research.

It is important to note that approximately 50% of healthcare professionals overall indicated they would be at least somewhat likely to report false or misleading advertising in the future. This number is likely to be attenuated by the reality of busy medical practices, but it demonstrates that a substantial part of this population may be interested in helping to ensure that pharmaceutical advertising is truthful and non-misleading. As the Bad Ad program becomes more established, it is possible that additional healthcare professionals will decide to participate. Because contact with pharmaceutical companies is an inevitable part of a field that involves providing pharmacological treatments to alleviate discomfort and solve medical problems, this additional education about what makes promotion truthful may help ameliorate some of the problems identified in previous research (Austed et al., 2013; Hafferty & Franks, 1994; Vinson, McCandless, & Hosokawa, 1993; Zipkin & Steinmann, 2005).

Perhaps also attenuating the percentage of healthcare professionals who claimed they would report to the Bad Ad program in the future was the finding that 70% of them were relatively sure they could identify false or misleading advertising on their own. This confidence was higher in those who participated in formal training and is consistent with prior findings that physicians and nurses often display substantial confidence in their decisions, especially after many years on the job (Baumann, Deber, & Thompson, 1991; Dawson et al., 1993; Yang & Thompson, 2010). The previous studies found, however, that there was no correlation between confidence and accuracy (Yang & Thompson, 2010). We did not measure healthcare professionals' actual accuracy in identifying false or misleading advertising; this is something that future research should assess. At this time, however, there is no precedent to suggest that they would necessarily be so able, despite their confidence. Programs like the Bad Ad program and healthcare professionals themselves may benefit from efforts to debunk assumptions of knowledge on their part. Future assessment of the program after the CME courses have been in existence for several years, for example, may shed light on the question of whether confidence and accuracy are related in this setting, unlike many other settings previously studied.

As with all research, ours has limitations. First, our response rate was relatively low, although our cooperation rate was high. Recall that the cooperation rate compares individuals who complete the survey to those who were ever contacted, rather than all of the possible individuals who may have been contacted, as the response rate does. We addressed the low response rate by weighting the data to be representative of the appropriate healthcare professional fields included in the study. Second, the numbers of individuals who had heard of the Bad Ad program and those who had actually reported false or misleading advertising were low, prohibiting us from gathering meaningful data with our open-ended questions. Third, the data were cross-sectional, prohibiting us from making conclusions about how awareness of the program has changed since inception. Finally, the survey did not include pharmacists, who dispense the medications and have an increasing role in medication management. Future research should address the awareness and receptivity of these individuals to the Bad Ad program.

Previous research has suggested that the influence pharmaceutical sales representatives have on healthcare professionals can lead to negative health outcomes, including overprescribing and increased healthcare costs (Wilkes & Hoffman, 2001). Despite calls for reduced interaction and the substantial changes that have resulted since the advent of PhRMA guidelines in 2009 (PhRMA, 2009), promotion by pharmaceutical sales representatives and the exposure of healthcare professionals to pharmaceutical advertising is unlikely to disappear entirely. Moreover, given the low numbers of respondents indicating any formal or informal training, it does not appear that educational strategies suggested in previous research (Vinson, McCandless, & Hosokawa, 1993; Wilkes & Hoffman, 2001) are gaining a foothold. Thus, FDA's Bad Ad program is designed to educate healthcare professionals about what to look for in terms of false or misleading advertising in interactions with pharmaceutical representatives, and media venues such as television and medical journals. Although this study demonstrated that few healthcare professionals are aware of the fledgling program, as the CME offering gains traction, the current and future assessments may determine what role the program has in facilitating truthful advertising. In the meantime, the current findings demonstrate openness to the program and suggest that nurse practitioners and physician assistants may be the front-line healthcare professionals who will be most likely to engage future national efforts to identify false or misleading advertising.

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Figure 1:

Usefulness of Bad Ad Program, by Healthcare Provider

Note: PCP = primary care physician; PA = physician assistant; NP = nurse practitioner; matching superscripts indicate at least one significant difference between provider pairs. Numbers may not add to 100 due to rounding.

Figure 2:

Likelihood of Reporting False or Misleading Drug Advertising to Bad Ad Program, by Healthcare Provider

Note: PCP = primary care physician; PA = physician assistant; NP = nurse practitioner; matching superscripts indicate at least one significant difference between provider pairs. Numbers may not add to 100 due to rounding.

Figure 3:

Formal and Informal Training, by Healthcare Provider

Note: PCP = primary care physician; PA = physician assistant; NP = nurse practitioner; matching superscripts indicate at least one significant difference between provider pairs.

Figure 4:

Usefulness of Formal Training in Marketing for Prescription Drugs, by Healthcare Provider

Note: PCP = primary care physician; PA = physician assistant; NP = nurse practitioner;

matching superscripts indicate at least one significant difference between provider pairs.

Numbers may not add to 100 due to rounding.

Table 1.

Healthcare provider demographics by subgroup.

Demographics	PCPs	Specialists	Pas	NPs	Total
Total number of respondents	507	500	501	500	2008
Age					
25-34	12 (2%)	34 (7%)	195 (39%)	48 (10%)	288 (14%)
35-44	150 (30%)	156 (31%)	145 (29%)	104 (21%)	555 (28%)
45-54	143 (28%)	127 (25%)	84 (17%)	150 (30%)	504 (25%)
55-64	134 (27%)	123 (25%)	65 (13%)	173 (35%)	495 (25%)
65+	67 (13%)	59 (12%)	11 (2%)	24 (5%)	161 (8%)
Gender					
Male	351 (69)	324 (65)	187 (37)	43 (9)	905 (45)
Female	155 (31)	176 (35)	313 (63)	457 (91)	1102 (55)
Mean years since graduation	22 (0.70)	21 (0.60)	11 (0.50)	12 (0.50)	17 (0.30)
Type of practice (multiple responses permitted)					
Family Practice	231 (46%)	0	227 (70%)	211 (70%)	669 (59%)
General Practice	75 (15%)	0	36 (11%)	29 (10%)	140 (12%)
Internal Medicine	182 (36%)	0	59 (18%)	42 (14%)	283 (25%)
OB/GYN	19 (4%)	0	4 (1%)	19 (7%)	42 (4%)
Level of prescribing authority (PAs and NPs only)					
Unrestricted	N/A	N/A	281 (56%)	296 (59%)	N/A
In conjunction with a medical doctor	N/A	N/A	204 (41%)	111 (22%)	N/A
As part of a CDM agreement	N/A	N/A	16 (3%)	93 (19%)	N/A
Average # patients seen/week	117 (3.4)	107 (3.3)	95 (2.4)	76 (2.1)	99 (1.5)
Average # prescriptions written/week	194 (9.4)	124 (5.8)	109 (4.5)	90 (4.8)	129 (3.4)

Note: All data are weighted. PCP = Primary care physician; NP = Nurse practitioner; PA = Physician assistant; CDM = Collaborative drug management.