"To Do No Harm" Survey of NMA Physicians Regarding Perceptions on DTC Advertisements

Sharon D. Allison-Ottey, MD, Karen Ruffin, BA, and Kimberly B. Allison, BS

HISTORICAL MANIFESTO OF THE NATIONAL MEDICAL ASSOCIATION

> "Conceived in no spirit of racial exclusiveness, fostering no ethnic antagonism, but born of the exigencies of the American environment, the National Medical Association has for its object the banding together for mutual cooperation and helpfulness, the men and women of African descent who are legally and honorably engaged in the practice of the cognate professions of medicine, surgery, pharmacy and dentistry."
>
> *C.V. Roman, M.D.*
> *NMA Founding Member and First Editor of the Journal of the National Medical Association, 1908*

The National Medical Association (NMA) is the nation's oldest and largest association of physicians of color. The NMA was founded in 1895 and is intent on fulfilling its mission of promoting the science and art of medicine to the betterment of public health. The mission born in 1895 still guides the organization today and the NMA continues to be the nation's leading advocate for the elimination of health disparities and optimal health practices affecting African Americans and other underserved populations. The NMA represents the collective interests of over 25,000 physicians of African descent. In order to address our mission, the NMA must diligently investigate any perceived benefits and potential threats to the health of minority populations.

As the leading healthcare advocate for minority patients, the NMA has observed the ever-increasing presence of Direct to Consumer (DTC) advertisements over the last five years. The NMA has yet to issue an official policy statement regarding its position on the impact of DTC advertisements. As we reviewed the vast amount of literature that has been generated in both the private, public and federal sector, we noted that the clear voice of the African American (AA) physician and patient has yet to be heard. There were no substantial studies that specifically queried this group of physicians. Given our position in healthcare, our duty to address the needs and concerns of our membership and the patients that we serve, the NMA began to investigate the impact of DTC ads within our membership. The NMA specifically queried the "experts" in African American health, our vast membership, which represents varied demographic distributions, practice types, years in practice, medical specialties, and experience. According to our research, this survey is the largest and most encompassing survey of AA physicians published to date on DTC advertisements. The organization seeks to further explore the issues surrounding this controversial topic and anticipates developing our official policy based on the collective expertise of our membership and governing bodies. We plan to continue to collaborate with other private, public and government entities to address

this issue and to be the voice for the AA physicians and patients that we serve.

BACKGROUND

Direct to Consumer advertising, for the purposes of this article, refers to any advertisement developed by the pharmaceutical industry including radio, print and/or television of prescription medication that targets the consumers. The NMA generally does not refer to the target of the advertisements as "consumers" but rather they represent our actual or potential "patients." Therefore, we have a vested interest in how, when and where they will receive any and all health information. It is our historical and current policy that the healthcare of patients is entrusted to the physician and this is particularly important as it relates to the prescription medications. The NMA is acutely aware of the economic impact and the phenomenal increase in the amount of spending of DTC advertisements in the United States.

It is of interest to note that the only industrialized nations that allow DTC advertisements are the United States and New Zealand.[1] The FDA has an increasing presence in the monitoring and regulation of DTC advertisements and has ongoing physician and consumer studies. The first DTC advertisements appeared in the United States in the early 1980s and since their very inception, the FDA has been diligent in attempting to monitor and protect the interests of the consumer/patient. In fact, taken somewhat off guard in the early 80s with no regulations in place, the FDA requested that the pharmaceutical industry suspend the advertisements until it conducted a study to review perceived impact. Initial studies, although limited, indicated no adverse effect on patients and actually showed a slightly positive effect on increased awareness of disease states. The advertisements resumed in 1985 and the FDA exerted its role in overseeing DTC ads and mandated certain requirements. Ironically, the FDA's revised guidelines in 1997 allowed for the increase in television advertisements. With these revisions, we have witnessed a tremendous increase in DTC advertisement spending that continues to grow at a phenomenal rate. The FDA issued guidelines of 1997 were issued with the intent of providing patients a fair balance of risk versus benefits as it relates to the prescription medications featured in the advertisements. Although these guidelines called for a fair balance, they were generally thought to help the pharmaceutical industry reach their target populations without being unjustly restrictive. The FDA has continued to closely monitor DTC advertisements and attempt to protect public interests. *The agency publishes Guidance for Industry; Consumer-Directed Broadcast Advertisements,* which serves to steer the pharmaceutical industry in the path of balanced promotion of products.

The most recent "*Guidance for Industry*" was published in August 1999 and provides for the following:

> The prescription drug advertising regulations (21 CFR 202.1) distinguish between print and broadcast advertisements. Print advertisements must include the brief summary, which generally contains each of the risk concepts from the product's approved package labeling. Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the *major statement.* This guidance does not address the major statement requirement.
>
> Sponsors of broadcast advertisements are also required to present a brief summary or, alternatively, may make "adequate provision. . .for dissemination of the approved or permitted package labeling in connection with the broadcast presentation" (21 CFR 202.1 (e)(1)). This is referred to as the *adequate provision* requirement. The regulations thus specify that the major statement, together with adequate provision for dissemination of the product's approved labeling, can provide the information disclosure required for broadcast advertisements.
>
> The purpose of this guidance is to describe an approach that FDA believes can fulfill the requirement for *adequate provision* in connection with consumer-directed broadcast advertisements for prescription drug and biological products. The approach presumes that such advertisements:

- Are not false or misleading in any respect. For a prescription drug, this would include communicating that the advertised product is available only by prescription and that only a prescribing healthcare professional can decide whether the product is appropriate for a patient.
- Present a fair balance between information about effectiveness and information about risk.
- Include a thorough *major statement* conveying all of the product's most important risk information in consumer-friendly language.
- Communicate all information relevant to the product's indication (including limitations to use) in consumer-friendly language.[2]

The guidelines are observed by the pharmaceutical industry and the FDA has the authority to regulate any false or misleading advertisements. However, even with the guidelines the controversy rages over the impact of DTC advertisements on the patient/consumer. Both opponents and supporters of DTC advertisements cite multiple studies to defend their position.

Supporters of DTC advertisements cite the following:

- Prompting patients to seek medical care that might not otherwise visit the healthcare provider by increasing the awareness of specific symptoms, disease states and treatment options.
- Early diagnosis of disease/illness due to increased patient awareness.
- Improving the physician-patient relationship and promotion of the healthcare team. In theory, the ads increase the conversation between the physician and patient and allow for open dialogue as opposed to the physician dictating to the patient and allow for patients a more direct role in their individual treatment regimens.
- Supposition of increased compliance with treatment regimens because of their direct input into the decision making process.
- Increased competition generated by the DTC ads will drive down the cost of the medications.

Opponents of DTC advertisements cite the following:

- The ads tend to promote the "magic bullet" effect of a pill curing all of your ailments without an individualized approach to the patient.
- Provides misleading information by failing to fully communicate risk information.
- Usurping the autonomy of the physician-patient interaction by introducing an invisible "medical advisor" into the dyad.
- Patients may attempt to either self-medicate, or dictate the terms of specific treatments that they see advertised, which may not be the best option.
- Increased demands on physicians to address the advertisements as opposed to the patients' specific health status.
- Increased costs of prescription medications to cover the increased cost of advertisements.

As a national organization, we are keenly aware of the FDA's inherent interest in DTC advertisements and support their ongoing research and monitoring. Physicians have noted a shift from marketing of prescription medication through traditional methods (i.e. direct mail, print ads in medical journals and office pharmaceutical representatives) to advertising directly to their patients. The literature regarding DTC advertising is at best equivocal to slightly positive as it relates to physicians' perceptions regarding impact on patient care. The NMA, a physician driven organization, is committed to addressing the concerns and needs of our membership and the patients whom we serve and we believe that we can add value to the ongoing monitoring of the advertisements, given our unique mission. This study was developed out of a need to assess the perception of AA physicians and to provide the necessary support for development of an official position on DTC advertisements that was both comprehensive and fair to all interested parties but with particular scrutiny as it relates to minority patients.

In general, studies have indicated that pa-

tients are more favorable towards DTC advertisements than physicians. Several studies have been performed with retrospective, randomized patient surveys that indicate that the ads do play a role in educating the public about health conditions and treatment options, encourage patients to seek treatment, additional information and/or speak with their doctor. Further, a recently published study by The Henry J. Kaiser Foundation revealed that viewers of the ads were much more aware of the serious nature of the side effects associated with the medication than those that did not see the ad.[3] In efforts to begin to ascertain any ethnic differences, the DTC Monitor 2000 reported that minority respondents to their national survey were more affected by DTC advertisements than the majority population. Specifically cited were more minorities stating that the ads provided new information about treatments and that more minorities contacted their doctor as a result of the ads. This data is very general and this population requires more extensive study to formulate concrete conclusions.

The NMA is naturally very interested in the perceptions of other physicians in regards to DTC advertisements. The Scott-Levin DTC Advertising Audit[4] performed one of the more comprehensive studies on DTC ads and physician perceptions in 2000. This group reported a decrease in physician resistance to DTC advertisements with 55% of the 3,000 physicians surveyed being positive or neutral to the ads, as opposed to previous studies. Additionally, they reported several variables including specialty type, practice type and number of prescriptions written affecting the physicians' perceptions of DTC advertisements.

The data is lacking specifically as it relates to the perceptions of a large cohort of African-American physicians. Based on review of the published data and the need for the NMA to address the issue of DTC advertisements; we developed the physician survey with the following objectives:

1. Evaluate the general perception of DTC ads by AA physicians
2. Evaluate the physician's perception of a patient benefit
3. Evaluate the physician's perception of a physician benefit
4. To determine if patients are seeking advice from their physician based on the Ads
5. To determine the perceived educational benefit to patients and effect on compliance with medical treatment regimens

METHODS

The survey instrument was developed through a literature review, examination of published survey instruments and discussions with physicians representing multiple specialties and practice types. The research team developed a 26-item survey that was distributed to the Board of Trustees and the Scientific Section Chairs of the NMA that served as the pilot group. The survey was distributed via email and fax to this group of approximately 75 physicians that were located throughout the US representing multiple specialties and practice types. The physicians' were asked to complete the survey independently and to return with comments to the principal investigator. This pilot group's surveys were analyzed and the final instrument was modified based on the information and comments from the pilot respondents.

The final survey instrument consisted of 16 demographic/epidemiological questions related to practice type and patient population, 15 questions specifically about DTC advertisements, and an open query for general comments. The survey consisted of 3 pages and was self-administered in both phases of the distribution. Physicians were offered the incentive of being entered into a raffle for completion of the surveys.

Phase 1: Individual distribution at the 2001 Annual Convention and Scientific Assembly of the NMA held in Nashville Tennessee. *This*

event is the largest yearly gathering of African Americans physicians in the United States.

Phase 2: Within 30 days post the NMA convention, the survey was mailed via U.S. First Class to the members with specific instructions to complete only if they did not complete at the Annual Convention and Scientific Assembly. The survey instrument was also posted on the organization's website and the respondents returned via U.S. First Class Mail or by fax to the organization's headquarters.

STATISTICAL ANALYSIS

Upon receipt of the completed surveys, they were assigned an identifying number and entered into a Microsoft Excel database. Only fully completed surveys were entered, there was no duplication of surveys and in the case of multiple responses from a physician, the first survey received was entered. The data was entered as the surveys were received with the respondents. Categorical variables were analyzed by the chi-square or Fisher's exact test, and continuous data were analyzed by the unpaired Student's T-test to analyze significance between baseline characteristics. A two-tailed P value of less than .05 was considered statistically significant only the data with P = <.5 are reported. Other standard statistical analyses were performed, including Bonferroni correction for multiple comparisons, however for the purposes of the reporting of this study we have limited our reporting to percentile and frequency data. All analyses were performed using the SAS statistical package for Windows, version 6.12 (Carey, NC). The data was evaluated within several subgroups such as age, gender, specialty type, years in practice, use of the Internet, type of practice, ethnic makeup of practice, insurance status of patients, and educational level of patients within the practice.

RESULTS

Demographics

A total of 1,098 physicians responded to the survey, 212 of the surveys were disqualified because of incomplete responses and/or duplication of respondents. The final number of surveys analyzed for this project was 886 (Table 1). The majority (54%) of the respondents returned their survey during Phase 1 of the project, with (46 %) submitting via fax, mail or email. The majority of the respondents were either in solo practice or private group practice (50%). Eighty-nine percent of the respondents reported having an email address and used the Internet with 78% reporting use of email at least once per week. The majority of the physicians surveyed indicated that they saw a majority of black/AA patients, with females constituting the majority of their practice (Table 3). There was no clear majority in reference to patient educational level and there was incon-

Table 1. Demographics

Variable	Frequency	
Gender	Female: 50%	
	Male: 49.8%	
Age Group	20s: 5%	
	30s: 19%	
	40s: 33%	
	50s: 23%	
	60s: 12%	
	70s: 8%	
Degree	MD: 98.3%	
	DO: 2.7%	
	*Required MD or DO, several respondents had multiple degrees (i.e. MD/PhD, MD/MPH, etc. . .)	
Number of Years in Practice	Median: 16.5	
Specialty	Internal Medicine	16%
	Family Practice	15%
	Obstetrics/Gynecology	12%
	Pediatric Medicine	11%
	Surgical Specialty	09%
	Psychiatry	05%
	Anesthesiology	03%
	General Surgery	03%
	Emergency Medicine	03%
	Dermatology	02%
	Geriatric Medicine	>1%
	Medical Administrator	01%
	Other	11%

P = <.05

Table 2. Primary practice type

Solo Practice	30%
Private Group Practice	20%
Academic Practice w/Teaching Responsibilities	14%
Resident / Fellow Physician	08%*
Managed Care Practice	04%
Administrative Position w/Clinical Responsibilities	04%
Administrative Position w/No Clinical Responsibilities	04%
Hospitalist	03%
Active Military Practice	<1%
Medical Student Physician	01%*
Research Practice with Clinical Responsibilities	01%
Research Practice w/No Clinical Responsibilities	01%
Retired MD	03%
Other	06%

**Medical Students and Resident/Fellow Physicians were individually evaluated and not part of the general statistical analysis.*
P = <.05

Table 3. Patient demographics

Variable	Frequency
Gender	Male: 39% Female: 61%
Ethnicity	Black/African American: 55% White/ Caucasian: 33% Hispanic/Latino/Mexican: 09% Asian: 02% Other: 01%

P = <.05

sistency in reporting from respondents, therefore this data could not be analyzed with confidence. However, we assume that given the vast geographical distribution, practice types and specialties that we surveyed physicians with an adequate cross section of educational levels.

Exposure and Perceptions

Of the physicians surveyed, 98 % had seen or heard a DTC ad with 2% indicating that they had not been exposed to the ads (Q1). The authors evaluated each individual specialty, practice type and other subdivided groups. Further, we compared primary care physicians, (Internal Medicine, Family Practice and Ob/Gyn) versus other specialists (Surgery, Emergency Medicine, Psychiatry, et al) and their responses as a group to each question. There are no statistically significant differences in the means with comparison by specialty, gender years in practice, therefore only aggregate data is presented (Table 4). The respondents overwhelmingly (79%) felt that pharmaceutical companies had the most to gain from the ads followed by patients (20 %) and that physicians (42%) had the least to gain, followed by patients (23 %). The respondents gave various comments at the end of the survey in the discussion area that was reflective and varied within the survey group. A summation of the comments is listed in Table 5 and provides general information but was not analyzed or weighted, therefore all comments were included unless there was duplication in content.

LIMITATIONS

This study has a few limitations, which may or may not have been overcome. The sample size could have been increased in efforts to strengthen the validity of the conclusions. However, our survey size with diverse demographics is indicative of the proportional membership of the National Medical Association. The geographic distribution of the survey closely mimicked the distribution of the membership of the organization with the highest response rates on the east coast and from the state of California, there were only a few states with no respondents (Alaska, Oregon, and Idaho), but this is also representative of the population of African American physicians in those states. The number of questions was a limitation and thus was not able to ascertain perceptions on some specific aspects of DTC ads. We intentionally limited the survey so that we would not inhibit busy physicians from participation in the survey. Further, Phase 1 of the distribution is felt to be both strength and a limitation in that there was the opportunity to discuss the surveys with colleagues vs. sitting in your home

Table 4. Physician perception of DTC ads

Question	Frequency (%)		
	Yes	No	Unsure
2. Do you feel that there is a POSITIVE benefit to the ads for:			
a. Patients	55	25	20
b. Physicians	42	44	14
c. Managed Care Organizations	23	47	30
d. Government Health Organizations	24	49	27
e. Insurance Companies	34	42	24
f. Pharmaceutical Companies	75	11	14
3. Do not feel that there is a POSITIVE benefit to anyone	7		
4. Do you feel that there is a NEGATIVE effect to the ads for:			
a. Patients	52	30	18
b. Physicians	51	33	16
c. Managed Care Organizations	37	33	30
d. Government Health Organizations	33	30	37
e. Insurance Companies	37	36	27
f. Pharmaceutical Companies	15	64	21
5. Do not feel that there is a NEGATIVE effect on anyone	15		
6. Have patients come into your office SOLELY because of the ads?	36	64	
7. Have patients asked you for your opinion because of the ads?	90	10	
8. Have patients asked you for a specific treatment or medications based SOLELY on the ads?	72	28	
9. Do you feel that the ads promote increased communication between You (MD) and the patient?	48	33	19
10. Do you feel that the ads promote patient education regarding disease states?	53	34	13
11. Do you feel that patients that view the ads are more compliant?	17	56	27
12. As a result of the Ads have you changed your prescribing habits?	9	89	2
13. Do you feel additional pressure to justify your prescriptions?	38	61	1
14. Are the Ads beneficial as educational tools for patients with learning disabilities or difficulty comprehending medical information?	41	44	15
15. Are the Ads more beneficial to minority patients?	16	67	17

or office completing the survey. However, the authors feel that distribution at the NMA's Annual Conference encouraged participation in this NMA sponsored survey. Other limitations that are inherent in any questionnaire are that of bias. There is the possibility of selection bias in that we selected physicians that have chosen to affiliate with the National Medical Association, and thus may theoretically have similar views. However, the encompassing scope of the membership of the NMA is a true representation of the diversity of AA physicians in the U.S. Another possible bias is found in the physician that feels very strongly about DTC advertisements would be more likely to complete the survey and give comments versus those that are ambivalent.

DISCUSSION

While the controversy around DTC advertising continues, with the completion of this survey, we have begun to answer the questions related to the perceptions of the AA physician. It is of note that our results are not vastly out of line with the perceptions of our non-AA colleagues, however, there are some striking dif-

Table 5. Representative comments

- (The) ads make patients more alert to their medical problems.
- Patients' expectations far outweigh the actual results promised by the ads.
- Keeps practioners on his/her Ps and Qs about medications.
- A little knowledge can be a dangerous thing.
- The ads have increased my new patient self referrals.
- The ads help destigmatize sensitive health issues like depression, erectile dysfunction and HIV/AIDS.
- The ads need to be more representative of the population, there are very few AA depicted in the television commercials and magazines.
- I do not feel that the ads take control away from my decision-making capacity with my patient.
- When patients ask about a specific medication and I agree to prescribe the medication, often they are more compliant because they feel that they have helped make the decision.
- I feel that I have to defend my prescriptions, especially when patients are on a different medication in the same class and ask to switch.
- Patients have often asked for a medication that I had already prescribed for them but used the trade name.
- The ads have caused some of my patients to stop taking the medication that I had prescribed because they were afraid of all of the side effects that they saw on TV.
- In Psychiatry, I think that the ads have benefited the specialty tremendously because people are able to see themselves in the commercial and seek help without feeling isolated.
- The ads further drive up the cost of prescription medications, why not spend the money on true patient education without mentioning a drug.
- Patients need education on disease states, not the pill to take for it. Education is key.
- (The ads) stimulate patients to ask MDs questions about diseases, providing an excellent jumping off point for patient education.
- I think that the ads may be especially beneficial to my patients that cannot read and have no other means of learning about medications or health issues other than the radio or TV. However, more emphasis should be on increasing the awareness about the disease with the drug being secondary.
- It is funny, my patients usually are very negative about the commercials and wonder why they would take something that has so many side effects.
- I don't think that the ads particularly benefit my patients but I don't think that they harm my patients. I would much rather we focus on deleting cigarette and alcohol ads vs. addressing the pharmaceutical company advertisements.

ferences. For example, the Scott-Levin DTC Advertising Audit for the 2nd Quarter of 2000 reported that 26 % of physicians perceived compliance as a benefit of DTC ads versus our study in which only 17% answered yes; 56% no and 27% stated that they were unsure. Further, as reported by Market Measures Interactive, DTC ads were thought to be an effective means of providing important healthcare information to minority and low-income populations, including at risk populations. However, only 16% of NMA respondents found any additional benefit for the minority patient versus all patients.

As physicians one of our major credos is to "Do No Harm." It is evident from the input of the physicians of the National Medical Association that we perceive that the ads indeed "Do No Harm" and actually may have a role in patient education, increased awareness, and communication between the physician and the patient. The following are valid statements regarding the AA physician's perception of DTC advertisements as supported by this survey:

- The majority (90%) of physicians have been asked their medical opinion by patients because of the ads.
- The majority (72%) has been asked for a specific treatment based solely on the ads.
- The majority (48%) of respondents believe that DTC ads promote increased communication between physicians and patients.
- The majority (53%) believes that DTC ads do have a benefit to patients, particularly as it relates to education regarding disease states.
- The majority of the respondents (56%) do not believe that the ads make the patient more compliant with medications and/or treatment.

- Overwhelming physicians (89%) deny having changed their prescribing habits because of the ads.
- A significant number of physicians (38%) feel additional pressure to justify their prescribing habits, while the majority (61 %) does not feel such pressure.
- Only 16% of AA physicians feel that the ads are more beneficial to the minority patient versus 67% that see no additional benefit.
- It remains unclear as to whether the ads are beneficial or are an educational tool for patients with learning disabilities or difficulty comprehending medical information.

Based on these results, the authors recommend the following:

- The NMA issues a Position Paper supporting the current efforts of the FDA to continue to monitor DTC advertisements and assure patient safety and balance in the information presented.
- The NMA provides continued input and expertise to the FDA and other governmental agencies in reference to DTC advertisements and the interests of the AA physician and patient.
- The NMA convenes a consensus panel on DTC advertisements and the impact on the AA community.
- The NMA assigns a committee to monitor the effects of DTC advertisements on AA physicians and their patients.
- The NMA recognizes that there is an educational benefit of DTC advertisements, however we will advocate for increasing the awareness of the disease states in such advertisements.
- The NMA encourages cultural diversity and sensitivity in any ads produced by the pharmaceutical industry.
- The NMA commits to partner with the pharmaceutical industry in assuring the input of AA physicians and patients as it relates to DTC advertisements.
- The NMA seeks to increase the presence of such advertisements in traditionally AA media outlets to reflect an equivocal presence as seen in the mass media.
- The pharmaceutical industry should provide information to physicians and other healthcare providers prior to any new marketing or promotional campaign directed to the patients. This is especially significant in the AA population.
- The individual physician continues to increase their knowledge base and investigate medications utilizing traditional scientific methodology. However, the physician should be aware of the information that is being presented to their patients and assure that he/she would be able to enter into productive dialogue if questioned as a result of the advertisements.
- The physician must be open to alternative methods of communicating health information such as DTC advertisements as long as the information is balanced and outlines the risks versus benefits of any products.

ACKNOWLEDGEMENTS

The authors thank the respondents and our colleagues who made this research possible. We would like to also acknowledge the in-kind and logistical contributions of the COSHAR Medical and the COSHAR Foundation's staff. We would like to further thank C. Denise Stiney for her administrative assistance and C.E. Smith for statistical analysis. We would like to thank the members and staff of the National Medical Association; Rudolph Williams, Executive Director and M'Lita Carr of the Membership Services Division for your assistance as well as the oversight of the Board of Trustees of the National Medical Association. This project was made possible through an unrestricted educational support grant issued by Pfizer Pharmeuticals Inc. We particularly would like to thank Cliff Thumma and Jucinda Fenn-Hodson for their ongoing support from Pfizer.

REFERENCES

1. Martin, Sean. Drug company spending or direct to consumer advertising rocketed 39 % last year and experts predict its not going to slow down. WebMD Medical News. April 4, 2001. my.webmd.com/content/article/1691.51055.

2. Guidance for Industry; Consumer-Directed Broadcast Advertisements, August 1999. Food and Drug Administration.

3. Understanding the Effects of Direct to Consumer Prescription Drug Advertising. November 2001. The Henry J. Kaiser Foundation.

4. Scott-Levin 2000 Direct-to-Consumer Advertising Audit.