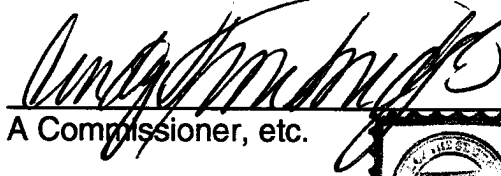
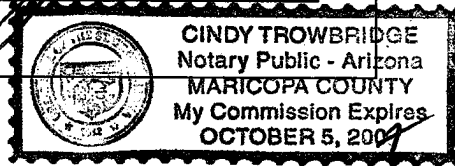


This is **Exhibit "J"** referred to in the Affidavit of  
**Dr. Richard Dolinar** sworn before me this  
23<sup>rd</sup> day of July, 2007.



A Commissioner, etc.



# “For the Good of the Patient,” Survey of the Physicians of the National Medical Association Regarding Perceptions of DTC Advertising, Part II, 2006

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**Background:** Since the advent of direct-to-consumer (DTC) advertising in the 1980s, there have been numerous studies and surveys on the topic, addressing issues as varied as its impact on patient understanding of health conditions to its repercussions for drug spending. However, until 2001, there was a dearth of research on DTC advertising's impact on minority populations, specifically the African-American community. The National Medical Association (NMA) remedied that in 2001 by undertaking a landmark study that gauged African-American physicians' perceptions of DTC advertising, its impact on the doctor-patient relationship and, perhaps most importantly, its role in educating underserved populations about critical health issues and potential treatments. In 2006, the NMA decided to once again poll its members on this critical issue to gauge not only current perceptions but how the community's understanding of DTC advertising has changed since 2001.

**Results:** The 2006 survey revealed several clear trends: NMA physicians are more positive toward DTC advertising now than they were in 2001; African-American physicians see DTC advertising as providing substantial educational benefits; physicians believe that DTC advertising helps rather than hurts the doctor-patient relationship; and African-American physicians see the benefits of DTC advertising outweighing its drawbacks. It must be noted that NMA physicians also had clear concerns about DTC advertising that point to potential areas of improvement for pharmaceutical companies.

**Key words:** advertising ■ African Americans ■ drugs

© 2007. From NW Indiana Dialysis, Gary, IN Center (Gadson); Department of Radiology at the University of Tennessee for Health Sciences, Memphis, TN (Morris, associate clinical professor); and North General Hospital, New York, NY (Burroughs). Send correspondence and reprint requests for *J Natl Med Assoc.* 2007;99:287-293 to: Dr. Sandra Lynn Gadson, NW Indiana Dialysis Center, 569 Tyler St., Gary, IN 46402-1829; phone: (219) 885-3300; fax: (219) 885-3306; e-mail: sandragadson@comcast.net

## INTRODUCTION

As the nation's oldest and largest association of physicians of color, the National Medical Association (NMA) has established as its mission the promotion of the science and art of medicine to the betterment of public health. Now, more than a century after the organization's founding, this goal remains vibrant. In particular, the NMA has taken on the roles of advocate for the elimination of health disparities and champion of optimal health practices affecting African Americans and other underserved populations. Representing more than 25,000 physicians of African descent, the NMA continues to investigate any perceived benefits and potential threats to the health of minority populations.

It was in this spirit that the NMA first undertook a survey of its members on the issue of direct-to-consumer (DTC) advertising in 2001. In response to the ever-increasing presence of DTC advertising since a regulatory change in 1997, the NMA critically examined the body of literature around the issue. Noting the lack of research focusing on the African-American community, the NMA set out to investigate the impact of DTC ads as perceived by its members. As part of that undertaking, the NMA also committed to collaborating with other private, public and government entities to address this issue and to be the voice for the African-American physicians and patients that the NMA serves.

Half a decade later, it seemed appropriate that we revisit our survey, both to determine our members' current perceptions of DTC advertising and to better inform our national policy on this significant issue. In the 2006 survey, we not only replicated the questions from our landmark 2001 poll, but we also included select questions from a 2002 Food and Drug Administration (FDA) study of office visit behavior regarding DTC advertising among African-American patients and their physicians (the initial 2001 NMA survey was published in the *Journal of the National Medical Association*, and the 2002 FDA survey was cited in that article).

## BACKGROUND

DTC advertising, for the purposes of this article, refers to any pharmaceutical industry advertisement of a prescription medication that targets consumers or, in the eyes of the NMA, patients, through radio, print and/or television media. Since all physicians have a vested interest in how, why and when our patients receive health information, this topic is of particular interest to us. It is the NMA's policy that the healthcare of patients is entrusted to physicians, which is of particular significance in the case of prescription medicines.

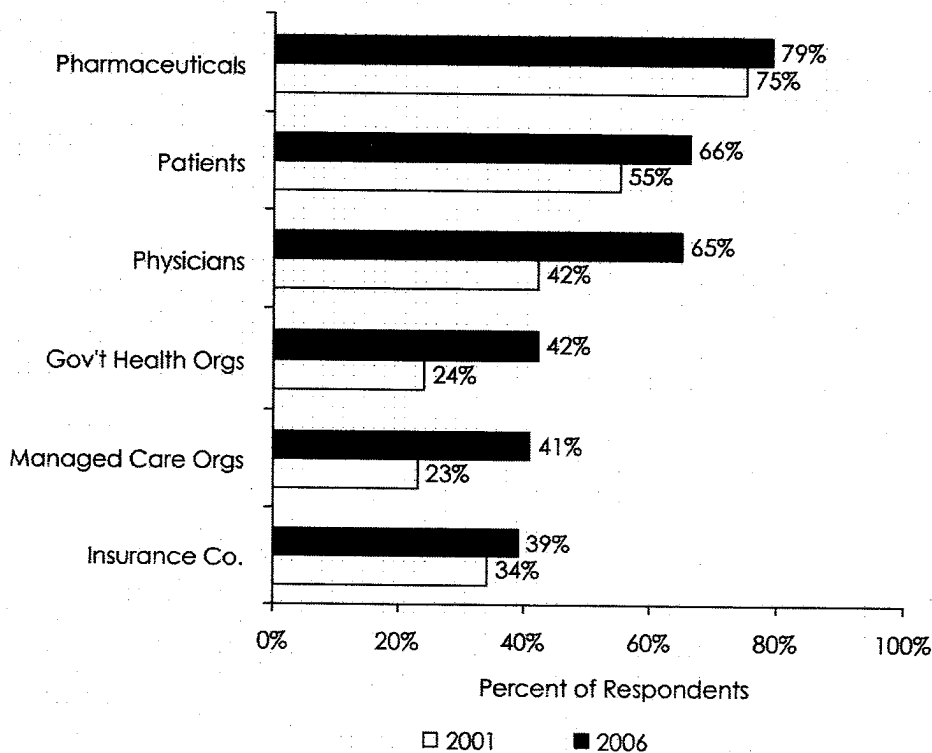
As this is written, only two industrialized nations allow DTC advertising of prescription medicines: the United States and New Zealand. In the United States, the FDA bears primary responsibility for the regulation and monitoring of DTC advertisements. Pharmaceutical companies first began advertising prescription medicines to the public in the 1980s. This foray into a new consumer communication channel prompted the FDA to enact a brief moratorium on prescription medicine advertising to consumers while it examined the manifold impacts on patients. These preliminary assessments indicated that DTC advertising had no negative effect on patients. Further, the research revealed that DTC advertising actually increased awareness of disease states among consumers, which was, and is considered one of the benefits of DTC advertising.

Armed with this knowledge, the FDA allowed the pharmaceutical industry to resume consumer advertising in 1985. Then, in 1997, the FDA revised its DTC advertising regulations, prompting an increase in television advertisements for prescription medicines. Both print and television spots have proliferated in the ensuing years, raising a host of new questions regarding their impact on both patients and the broader healthcare system. While the FDA guidelines were written to ensure that patients receive a fair and balanced portrait of the risks and benefits of a given medicine, they also gave the pharmaceutical industry greater flexibility in communicating this information. In the wake of this landmark change, the FDA and the pharmaceutical industry have remained in constant dialogue regarding the appropriate application of these regulatory guidelines.

The FDA issued its seminal communication on this matter in 1999: *Guidance for Industry; Consumer-Directed Broadcast Advertisements*.<sup>1</sup> Broadly, this mandates that all consumer-focused prescription medicine advertisements are accurate and not misleading; only make claims that are supported by substantial evidence; reflect balance between risks and benefits; and are consistent with the FDA-approved labeling. The FDA regularly reviews product ads to ensure that they are in compliance with these regulatory guidelines.

It was in this environment that we launched our 2001

**Figure 1. Ranking of positive beneficiaries of direct-to-consumer ads, 2006 and 2001**



survey on DTC advertising. Member responses indicated that DTC advertising educates patients, increases awareness of newer products on the market and spurs communication between the physician and patient. It can also exert pressure on doctors to justify their prescription choices. Specifically, the 2001 survey found that:

- The majority (90%) of physicians had been asked their medical opinion by patients because of the ads.
- The majority (72%) of physicians had been asked for a specific treatment based solely on the ads.
- Almost half (48%) of respondents believed that DTC ads promote increased communication between physicians and patients.
- The majority (53%) of physicians believed that DTC ads do have a benefit to patients, particularly as they relate to education regarding disease states.
- The majority of the respondents (56%) did not believe that the ads made the patient more compliant with medications and/or treatment.
- Overwhelmingly, physicians (89%) denied having changed their prescribing habits because of the ads.
- A significant number of physicians (38%) felt additional pressure to justify their prescribing habits, while the majority (61%) did not feel such pressure.
- Only 16% of physicians felt that the ads were more beneficial to the minority patient versus 67% that see no additional benefit.
- It remained unclear as to whether the ads were beneficial or were an educational tool for patients with learning disabilities or difficulty comprehending medical information.<sup>2</sup>

Since that time, the pharmaceutical industry has taken measures to reinforce the doctor-patient relationship and address the other concerns voiced by critics. In

2006, the industry took the initiative to issue its own voluntary guidelines to improve DTC advertising. Building on the FDA's regulations, these principles aim to increase the public health benefits of DTC advertising and support the doctor-patient relationship. Specifically, these guidelines:

- Reinforce compliance with all FDA regulations and require prior submission of all TV advertisements to the FDA;
- Require that ads for a medicine contain information about the medicine, its major risks and benefits and the condition it treats;
- Reiterate the importance of the doctor-patient relationship;
- Require an education period for physicians prior to the commencement of consumer advertising;

**Table 1. Respondent demographics**

*1.1 Gender*

- Female = 57%
- Male = 43%

*1.2 Percent in Each Age Group*

- 20s: 7%
- 30s: 13%
- 40s: 32%
- 50s: 31%
- 60s: 12%
- 70s: 5%

*1.3 Median Years in Practice: 19*

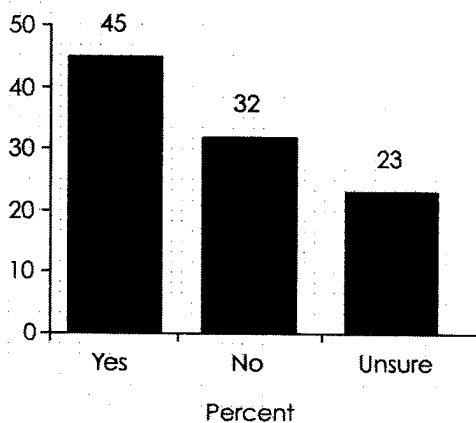
*1.4 Areas of Specialty*

- Internal Medicine: 20%
- Family Practice: 11%
- Ob/Gyn: 11%
- Peds: 12%
- Emergency medicine: 8%
- Surgical Specialty: 5%
- Other: 33%

*1.5 Practice Type*

Solo practice	23%
Private practice group	23
Academic practice w/ teaching responsibilities	18
Resident/fellow physician	6
Managed care practice	5
Admin. position w/clinical responsibilities	3
Admin. position w/no clinical responsibilities	3
Hospitalist	1
Active military practice	1
Medical student physician	1
Research practice w/clinical responsibilities	1
Research practice w/no clinical responsibilities	1
Retired MD	1
Other	12

**Figure 2. Are the ads beneficial as educational tools for patients in underserved communities and groups?**



- Encourage the inclusion of information about additional treatment options;
- Call for respectful advertising that is age-appropriate;
- Highlight the importance of health and disease awareness advertising; and,
- Underscore the need for information about help for the uninsured and underinsured in all advertising.<sup>3</sup>

In addition, several pharmaceutical companies issued their own statements echoing and expanding upon the above voluntary measures.

Despite the active engagement of both government and industry, the issue of DTC advertising continues to be an inflammatory one in the healthcare community. The preponderance of research on the topic only fuels the debate, with both sides citing studies to reinforce their position.

The following benefits are cited in support of DTC advertising:

- Increased consumer awareness of disease states, specific symptoms and treatment options;
- Increased consumer motivation to contact a physician and engage in a dialogue about health concerns;
- Increased consumer motivation to seek out other sources for additional information on the condition or medication;
- Enriched doctor-patient dialogues resulting from empowered consumers;
- Increased likelihood of patients receiving appropriate care for underdiagnosed and undertreated medical conditions;

- Increased awareness of the risks and benefits of prescription medications; and
- Increased compliance with prescription medicine treatment regimens.

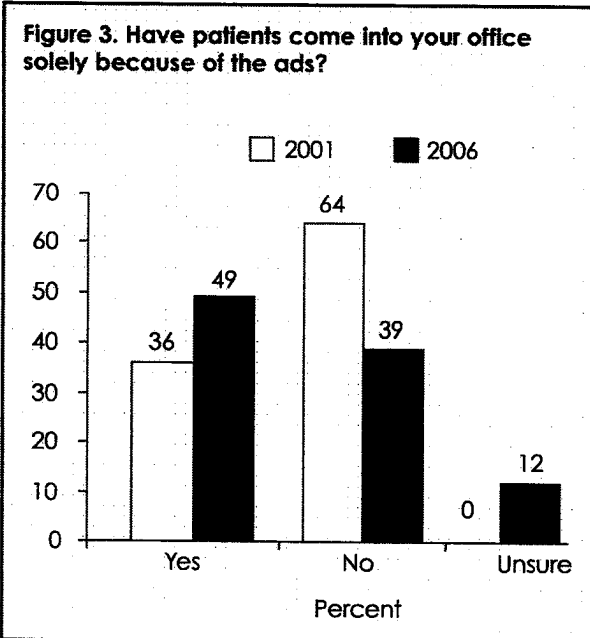
The following concerns are expressed regarding DTC advertising:

- Increased demand for “magic bullet” cures rather than individualized treatment programs;
- Incomplete communication of risk information;
- Infringement on the autonomy of the doctor-patient relationship;
- Trend toward self-medication or patients dictating treatments to physicians;
- Increased pressure on doctors to address specific medication issues rather than the patient’s health;
- Increased inappropriate use of prescription medicines leading to overall increased healthcare spending; and,
- Increased costs of prescription medicines fueled by marketing spending.

At the same time, both the House of Representatives and Senate have considered measures to further regulate and limit DTC advertising due to both safety and cost concerns. In September 2006, the Institute of Medicine issued a report that strongly advocated a DTC advertising moratorium to address patient safety concerns regarding new medicines. This recommendation is based on the assumption that DTC advertising drives increased utilization of new medicines, for which all side effects may not yet be known. However, a December 2006 report by the Government Accountability Office (GAO) concluded that DTC advertising is just one of many factors that have contributed to increased utilization of prescription medicines.

This GAO report to Congress focused on the trends in DTC advertising as well as the FDA’s regulation and oversight of this advertising. It noted that DTC advertising has both positive and potentially negative effects on consumers. For example, one cited study found that DTC advertising for antidepressant medications was associated with an increase in those diagnosed with depression, those treated with an antidepressant and those who received the appropriate duration of therapy. However, another study showed that consumers who requested a pain medication as a result of DTC advertising were more likely to get the requested medicine than another treatment that may be more appropriate.<sup>4</sup>

The recent Medicare reform has prompted increased scrutiny of the government’s spending on prescription medicines and the impact DTC advertising has on that spending. Even as this is written, Congress, the FDA and pharmaceutical companies are engaged in a debate over the terms of the reauthorization of the Prescription



Drug User Fee Act, which stipulates the terms of the FDA's industry funding for prescription drug advertisement reviews.

In light of both the industry changes and the increased government involvement in the issue, the NMA felt it would be appropriate and informative to once again poll our members to gauge their perceptions on the state of DTC advertising and its role in today's healthcare system, particularly in regards to the African-American population. This new data informs our evolving position on DTC advertisements, ensuring that it is dynamic and responsive to the changing marketplace.

As in 2001, our 2006 survey had the following objectives:

1. To evaluate the general perception of DTC ads by African-American physicians;
2. To evaluate the physician's perception of a patient benefit;
3. To evaluate the physician's perception of a physician benefit;
4. To determine whether patients are seeking advice from their physician as a result of the ads; and,
5. To determine the perceived educational benefit to patients and the effect on compliance with medical treatment regimens.

## METHODS

At the 2006 NMA Annual Convention in Dallas, TX, attendees were invited to respond to a written survey about DTC advertising. Of the 3,200 attendees, 322 completed surveys. The questionnaire comprised 20 questions about DTC advertisements, exploring respondents' opinions regarding the impact of DTC advertising as well as their personal experience of it in their in-office patient relationships. All surveys were distributed, completed and returned on site. Members were offered the incentive of being entered into a raffle for completion of the survey. Demographic information, including age, gender, practice specialty and type of practice is captured in Table 1.

As noted, the 2006 survey included the same questions as the 2001 survey so that the NMA could establish trend data. In addition, the association included a number of questions from the 2002 FDA survey for comparison.<sup>5</sup>

It is worth noting that the 2006 survey had a lower response rate than the 2001 survey. This is attributable, in part, to the fact that the 2001 survey was distributed and collected through more channels than the 2006 survey; in 2001, the survey was distributed at the convention, by mail to all members and online through the organization's website. Respondents were able to return the survey at the convention or by mail or fax.

Given the difference in sample sizes between the two surveys, the margin of error for comparison between

them is  $\pm 7\%$ . While findings from the current study are limited in terms of representation of both the NMA and African-American physicians in general due to the size of the sample, they remain suggestive of the actual perceptions of African-American physicians as a whole with regard to DTC advertising.

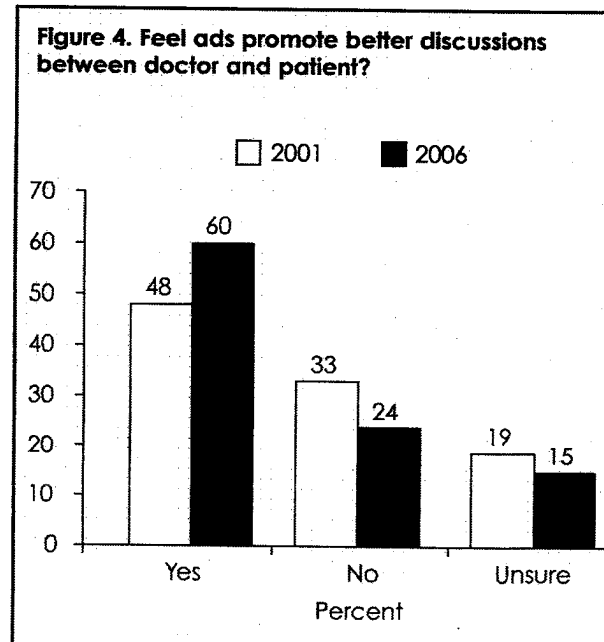
## Data Analysis

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, and there was no duplication of completed surveys. The data were entered as the surveys were received from the respondents. Categorical variables were analyzed by the Chi-squared 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  $<0.05$  was considered statistically significant and only the data with  $P \leq 0.05$  are reported. Due to the sample size of this study we have limited our reporting to percentile and frequency data. All analyses were performed using the WinCross™ statistical package for Windows,® version 5.0 (Scottsdale, AZ). The data were evaluated within several subgroups such as age, gender, specialty type, years in practice and type of practice.

## RESULTS

### Demographics

The final number of surveys analyzed for this project was 322. The majority (56%) of the respondents were either in solo practice or private group practice. The respondents were distributed across age groups, with the greatest representation in their 40s (32%) and 50s



(31%) and across genders, with a slightly higher number of women responding (57%).

## Perceptions

In regards to DTC advertisements, responding NMA members overwhelmingly perceived the benefits as outweighing any negative impact. Further, NMA physicians were more positive towards DTC advertising now than they were in 2001. Specifically, the majority of respondents cited a positive benefit for patients, physicians, managed care organizations, government health organizations and pharmaceutical companies (Figure 1). In each of these cases, the percentage of those who perceived a positive benefit was greater in 2006 than it was in 2001, with the most significant jumps in percentage for patients (from 55% to 66%) and physicians (from 42% to 65%).

Further, NMA physicians surveyed believed that DTC advertising provides notable educational benefits. An overwhelming majority of those surveyed (80%) felt that DTC advertising helps make people aware of treatment options, while almost two-thirds (64%) stated that DTC advertising makes people aware of problems earlier, and a solid majority (58%) said that DTC advertising promotes better patient education regarding disease states. Of particular importance for the NMA is the fact that nearly half (45%) agreed that DTC ads are a beneficial educational tool for patients in underserved communities (only 32% disagreed with that statement; Figure 2). In addition to disease state awareness, doctors saw other benefits to DTC advertising: 64% felt that DTC advertising makes their patients more aware of the side effects of a medicine, while nearly one-fifth (19%) noted increased compliance with their treatment programs.

NMA members' responses to several questions strongly support the idea that DTC advertising enriches, rather than undermines, the critical doctor-patient relationship. Physicians noted that DTC ads encourage patients to speak with their doctors; in fact, 80% said that patients sought their opinions because of seeing a DTC ad. Further, nearly half (49%) said that patients have come into their office solely because of an ad they saw, 13% more than observed that phenomenon in 2001 (Figure 3). The majority (60%) said that DTC ads promote better discussions in an office visit—a 12-percentage-point jump from 2001 (Figure 4). In addition, nearly three-quarters (73%) reported that their patients asked thoughtful questions as a result of seeing DTC ads. Finally, 63% of physicians said that patients inquiring about particular medications did have the condition that the advertised medicine treats. Also worth noting: only 15% of physicians reported that a patient mentioning an ad during the visit created a problem.

While all of the above results point to the net benefits NMA physicians attributed to DTC advertising, they did report downsides as well. Approximately half

of the respondents felt that patients are negatively impacted by DTC advertising, on par with the percentage who felt that way in 2001. However, the percentage who felt that DTC advertising does not negatively impact patients has increased by 11 percentage points since 2001 to 41%. Approximately four in 10 (39%) said that physicians are negatively impacted by DTC advertising, a drop of 12 percentage points from 2001.

Among other concerns voiced by the respondents: 76% indicated that DTC advertising makes people think that medicines work better than they do; three-quarters (76%) said that DTC advertising confuses people about the relative risks and benefits of a medication; two-thirds (65%) noted that DTC advertising can increase patient second-guessing of a diagnosis; 42% felt that DTC advertising may create tension between a doctor and a patient; and while nearly half (48%) felt that they are not at all pressured to prescribe a specific medication because of DTC advertising, 7% said they feel very pressured.

## Limitations

This study has a few limitations. The sample size could have been increased in efforts to strengthen the validity of the conclusions. However, as noted earlier, the population remains representative of the NMA membership. Further, while the number of questions limited the amount and detail of information we could gather about DTC advertising, increasing the survey length may have further compromised the sample size by discouraging busy physicians from participating.

There is the possibility of a selection bias in that we selected physicians that have chosen to affiliate with NMA and thus, theoretically, have similar views. However, the broad scope of the membership reflects the diversity among African-American physicians in the United States. Another possible bias is that physicians who feel strongly about DTC advertisements—whether positively or negatively—may have been more likely to complete the survey than those who are ambivalent.

## Recommendations

As the pharmaceutical, physician, consumer and legislative communities continue to debate the role of DTC advertising in America's healthcare system, we now have a clearer picture of its impact on the African-American population. Of note is the fact that while prominent medical groups have recently voiced opposition to DTC advertising, our survey reveals that it has a positive impact on both African-American physicians and patients and, notably, underserved populations. In addition, that net benefit has increased since 2001, indicating a positive trend.

In particular, we were pleased to see that DTC advertising continues to drive patients to visit their doctors. This is very important within the African-American pop-

ulation given that both the 2003 and 2004 National Health Disparities Reports noted that blacks tend to have a lower use of routine care and higher rates of avoidable admissions to both emergency departments and hospitals.<sup>6</sup> With this in mind, we recommend the following:

1. 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. Specifically, the NMA will call upon the pharmaceutical industry to increase DTC advertising promotions around disease states that significantly impact minority communities.
2. The NMA will support efforts that ensure DTC advertisements reinforce the importance of the relationship between physicians and patients and that DTC advertising continues to inform patients in underserved communities about medical conditions and potential treatment options. Furthermore, we assert that 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 African-American population.
3. The NMA will request that pharmaceutical companies commit to publicizing their prescription payment assistance programs to minority communities in DTC advertising.
4. The NMA will provide continued input and expertise to the FDA and other governmental agencies in reference to DTC advertisements and the interests of the African-American physician and patient.
5. The NMA will commit to partnering with the pharmaceutical industry in assuring the input of African-American physicians and patients as it relates to DTC advertisements.
6. The NMA will seek to increase the presence of such advertisements in traditionally African-American media outlets to reflect an equivalent presence as seen in the mass media.
7. The NMA encourages cultural diversity and sensitivity in any ads produced by the pharmaceutical industry.
8. The NMA encourages pharmaceutical companies to design DTC advertisements to reach and communicate with patients with low health literacy. The NMA notes that low health literacy is prevalent in the United States, affecting an estimated 90 million Americans, including minority populations.
9. The NMA encourages the individual physician to continue to increase his/her 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.

10. The NMA asserts that 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 to the consumer of any products.

## Suggestions for Future Research

The current survey shows that NMA members' perceptions of the positive benefits of DTC advertisements far outweigh their negative perceptions. Further, these positive perceptions have increased significantly since the 2001 survey. Additional qualitative research would provide a more focused view of the nuances of these perceptions. Among the questions to be considered:

- How could the pharmaceutical industry change DTC advertising in order to increase patient medicine compliance?
- How can the pharmaceutical industry strengthen the educational benefits of DTC advertising for patients in underserved communities?
- Does DTC advertising cause patients to become more involved in their healthcare?

## ACKNOWLEDGEMENTS

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