

October 22, 2007

Andrew C. von Eschenbach, M.D.  
Acting FDA Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration (FDA)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Dear Dr. von Eschenbach:

The American Academy of Orthopaedic Surgeons (AAOS/Academy), and the American Association of Hip and Knee Surgeons (AAHKS) representing over 17,000 Board-certified orthopaedic surgeons, welcomes the opportunity to comment on the FDA's experimental evaluation on the impact of distraction on consumer understanding of risk and benefit information in direct-to-consumer prescription drug broadcast advertisements [Docket No. 2007N-0321].

The FDA has the difficult task of balancing First Amendment rights with the protection of public health. Currently, the United States and New Zealand are the only countries allowing direct-to-consumer (DTC) advertising and marketing of regulated medical products, as the number and breadth of marketed products continues to grow.

The AAOS/AAHKS have closely followed the actions of the FDA on consumer-directed advertising. To date, the FDA issued a draft guidance document in 1997 and a final guidance in 1999<sup>1</sup> on consumer-directed broadcast advertisements requiring that advertising for medical products must not be false, misleading, or lacking in material facts. Fair balance of risks and benefits must be presented in a brief summary of the adverse event profiles, contraindications, warnings, and precautions. In 2004, the FDA followed with guidance on the brief summary requirements, consumer-directed broadcast advertising of restricted devices, and help-seeking and disease awareness communications by drug or device firms.<sup>2</sup>

The AAOS/AAHKS continue to have concerns about the DTC advertising and marketing of restricted medical products. In 2004, AAOS appointed a Board of Directors level Task Force and issued a position statement on device and drug DTC advertising issues. The AAOS/AAHKS continue to examine DTC advertising and its subsequent effects on the physician-patient relationship and believe that the primacy of the physician-patient relationship is sacrosanct.

Physicians and patients are partners in health care and must reach informed decisions together. The AAOS/AAHKS will limit its comments to the following:

- AAOS/AAHKS support the efforts of the FDA to research communications of risk information in DTC advertising;
- DTC advertising and marketing may have positive consequences;
- Patient education is vital to public health;
- DTC advertising and marketing have negative consequences;
- The FDAAA will provide more resources for DDMAC;
- AAOS/AAHKS support the efforts of the FDA to refine their regulatory authority for DTC advertised medical products;
- AAOS/AAHKS support a prohibition on DTC advertising and marketing of restricted medical products to children; and
- AAOS/AAHKS support more research on the effects of DTC advertising and marketing of restricted medical products.

**AAOS/AAHKS SUPPORT THE EFFORTS OF THE FDA TO RESEARCH COMMUNICATIONS OF RISK INFORMATION IN DTC ADVERTISING**

The AAOS/AAHKS support the FDA's proposed study on the variations in communicating risk information in direct-to-consumer advertising. While the study is designed to collect information on a pharmaceutical drug, the AAOS/AAHKS encourage a similar study for prescription medical devices. This proposed study will assess the presentation of the "fair balance" of risk and benefit information in a DTC advertisement. Of note, FDA regulations require that advertisements make claims about medical products with a fair balance of benefit and risk information in terms of presentation and content.

It is necessary and appropriate to determine if compelling visual information about potential drug benefits interferes with viewers' processing and comprehension of risk information. As television advertising is a visual medium, it is essential to assess the different effects on cognition of compelling visuals versus aural cues such as voice-over, music, and dialogue. The study design employing three variables each for visual cues and consistency of disclosure of risk information should allow for the collection of necessary data.

**DTC ADVERTISING AND MARKETING MAY HAVE POSITIVE CONSEQUENCES**

The direct-to-consumer advertising and marketing of regulated medical products has the potential for both positive and negative consequences. DTC advertising

may encourage a patient to seek treatment subsequently; a patient may be diagnosed with a previously undiagnosed disease. Additionally, DTC advertising may facilitate earlier awareness of health conditions, create more informed patients, foster shared decision-making between patients and physicians, and de-stigmatize certain diseases or health conditions.<sup>3</sup>

### **PATIENT EDUCATION IS VITAL TO PUBLIC HEALTH**

“Help-seeking” advertising should be differentiated from product endorsement advertising and may provide patients with useful educational material. The AAOS/AAHKS hold patient education as one of its most important objectives. *Your Orthopaedic Connection* on the Academy’s home page is an objective information source for patients, containing diagrams, text, and brochures written specifically for patients. Additionally, the AAOS produced many patient education videos to generate a dialogue between patients and surgeons about what patients can anticipate during fracture care, joint replacement surgery, or during the treatment of soft tissue injuries.

The National Institutes of Health (NIH) consensus conferences on Total Knee Replacement (2003) and Total Hip Replacement (1994) found strong evidence of disparities between racial and ethnic groups in content knowledge and surgical rates, and that these underutilized therapies could greatly enhance the quality of life. The AAOS/AAHKS realize that there are significant health disparities in the U.S. and that education plays a vital role in bringing needed therapies to patients. “Help-seeking” advertising may aid in generating educational material and stimulate a patient to research their health condition and seek all available options with their health care practitioners.

### **DTC ADVERTISING AND MARKETING HAVE NEGATIVE CONSEQUENCES**

Even though the FDA requires a fair balance of risks and benefits in a brief summary, the guidance is ambiguous thereby leaving ample room for interpretation by manufacturers. Consequently, patients may have a limited understanding of the benefits, risks, and relative effectiveness of DTC advertised medical products.<sup>4</sup>

#### *Increased spending, utilization, and sales*

U.S. healthcare spending grew 7.4 percent in 2005 to exceed \$2 trillion dollars, much of that growth was attributable to increased drug spending. Increased drug spending is due to three factors: increased utilization, increased prices, and

the use of new, expensive medications.<sup>5</sup> DTC advertising is relegated to a concentrated subset of medications which tend to be the best selling drugs<sup>6</sup> with the top ten drugs accounting for 36 percent of all DTC advertising spending in 2001.<sup>7</sup> According to a 2002 Government Accountability Office report, DTC advertising increases prescription drug sales and utilization.<sup>8</sup> DTC advertising also increases the sales in the entire class of drugs. For example, prescription drugs used to treat allergies would all increase in sales in response to the DTC advertisement of one allergy medication.

In a time of necessary fiscal responsibility, David M. Walker, Comptroller General of the U.S., in testimony before the Budget Committee of the House of Representatives, listed health care expenditures as the biggest driver of the long-term fiscal challenge facing this nation.<sup>9</sup> In light of Medicare Part D benefits, the cost-effectiveness of pharmaceutical medications is particularly important for long-term fiscal considerations.

The AAOS/AAHKS believe that the DTC marketing of restricted medical products has the potential to create a distorted market. Therefore, the AAOS/AAHKS support greater restraint from industry and greater oversight from the FDA. The AAOS/AAHKS believe that DTC advertising may create an over-utilization of certain therapies and become problematic when a patient is insistent upon a specific drug or device when that therapy is not appropriate for the patient. This type of situation is injurious to the physician-patient relationship and is often not in the best interest of the patients who demand these treatments. Orthopaedic surgeons are aware of the entire spectrum of medical therapies and will recommend conservative treatments if they are warranted. Surgeons tend to be restrained in their approach to treatment and are trained to use surgical options when more conservative treatments have failed.

*Information is not comprehensible and unbalanced*

Many advertisements are incomprehensible to the American public, which studies have shown on average read at an eighth grade reading level.<sup>10</sup> Most information, particularly in print advertisements, is edited from the FDA approved labeling requirements targeted to health care professionals. Side effects and risk information are often formatted on the back of a print advertisement and are therefore, generally neglected by readers. Additionally, the font size of the print advertisement is significantly smaller when conveying risk information as opposed to the benefit information. Smaller font size is particularly difficult for seniors to read as their vision becomes less acute during the aging process.

The lack of fair balance in describing benefit and risk information in advertising is problematic. Potential benefit information is typically presented in layman's terms whereas risk information is downplayed by using medical jargon, using a very small font size, or increasing the speed of delivery of information in a voice-over announcement. Therefore, risk information is often not read, not comprehended, nor sometimes even reasonably visible.

#### *Physician pressure to prescribe DTC advertised drugs*

The AAOS/AAHKS are very concerned that there is undue pressure to prescribe a medical product merely because a patient has viewed the DTC advertisement. Although DTC advertising has the potential to foster shared decision-making between patients and physicians, it often creates an impediment. A randomized controlled trial found that patient requests for an advertised medication had a profound effect on physician prescribing.<sup>11</sup> Similarly, in a Kaiser Permanente study, patients who saw or heard a Cox II inhibitor advertisement were significantly more likely to be prescribed a Cox II inhibitor rather than a non-steroidal anti-inflammatory drug (NSAID).<sup>12</sup> DTC advertisements are creating tension in the physician-patient relationship, and physicians acknowledge a high level of expectation from patients to receive a prescription. Additionally, surgeons cite problems with DTC advertising including the time needed to correct misconceptions, requests for unnecessary drugs, and requests for a particular treatment when another treatment is equally effective, and may be less expensive. DTC advertising also tends to market new drugs and therapies which may have unrecognized long-term consequences unlike therapies with established long-term records of safety and efficacy.

#### *Device Marketing*

There are substantial differences between pharmaceuticals and medical devices, including: a significant price differential; the selection of a device requires a much higher level of judgment and skill than the choice of a branded vs. generic drug; and most importantly, the potential negative consequences to the patient and the surgeon are substantial if an inappropriate device is chosen for a particular patient or procedure. Unlike drugs, the choice of an implant cannot be easily substituted if the result of the surgery is undesirable.

DTC advertising of devices may not inform patients about the differences in product design, composition of materials, strength of the devices, or proper clinical indication. Potential patients may not have access to post-market surveillance data or understand issues relating to device performance and safety.

Surgeons choose devices to meet an individual patient's needs. For example, implant wear is a significant issue for orthopaedic surgeons. Patients may not be aware of the appropriateness of certain devices for their particular health conditions or health status.

Despite the potential benefits of DTC advertising of empowering patients with information regarding their health and encouraging patients to seek treatment, results from an orthopaedic study<sup>13</sup> suggest significant issues. The findings relate that 77 percent of surgeons felt that patients exposed to DTC advertising are confused or misinformed about the appropriate treatment for their orthopaedic condition; have unrealistic expectations regarding the benefits of a particular surgical technique or implant; are not aware of the additional costs, potential risks, and complications associated with a particular implant or surgical technique; and are less likely to pursue surgery as a result of viewing the advertisement. Furthermore, study results indicate that patient exposure to DTC advertising has the potential to create friction between doctors and patients and may increase the length of office visits which is costly to the healthcare system. Seventy-four percent of respondents believe that DTC advertising had an overall negative impact on their relationship with patients. The AAOS/AAHKS will include a copy of Dr. Bozic's et. al. research in our submission to the FDA docket.

#### **THE FDAAA WILL PROVIDE DDMAC WITH MORE RESOURCES**

In testimony before the Senate Special Committee on Aging, Rachel Berman, MD, MPH, stated that the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the FDA received 52,800 materials for promotional review in 2004 and employ a staff of forty.<sup>14</sup> While we commend the hardworking staff at DDMAC, we are concerned that they may be operating with fewer resources than would be optimal. As the Food and Drug Administration Amendments (FDAAA) of 2007 was signed into law on September 27, 2007, in fiscal year 2008 DDMAC will receive over six million dollars in fees from industry for the voluntary pre-review of prescription drug advertising. Previously many violative ads completed their promotional runs before the FDA had proceeded with an enforcement action. The AAOS/AAHKS encourage the adoption of the Pharmaceutical Research and Manufacturer's of America (PhRMA) guiding principles which provide for the submission of broadcast advertisements prior to their airdates and allows for communication with DDMAC staff about the content of the advertising.

Nonetheless, AAOS/AAHKS understand that DDMAC does not oversee device marketing, rather a small number of reviewers are employed within the Center for Devices and Radiological Health (CDRH). As medical device marketing continues to grow, it would seem appropriate for the FDA to provide the necessary resources toward the review of device marketing and advertising directed to consumers. Currently in the U.S., the majority of those devices are orthopaedic and dermatological in nature.

**AAOS/AAHKS SUPPORT THE EFFORTS OF THE FDA TO THEIR REFINE REGULATORY AUTHORITY FOR DTC ADVERTISED MEDICAL PRODUCTS**

As mentioned previously, the AAOS/AAHKS strongly support the prior FDA review of new broadcast advertisements. While we realize this action is currently voluntary for manufacturers, the AAOS/AAHKS support increased regulatory authority in this area. The FDA must have greater authority to protect the public from false and misleading advertising claims. During hearings and negotiations on the FDAAA of 2007, many Representatives called for a voluntary moratorium on DTC advertising of two years following the approval of a new pharmaceutical drug. While phase III clinical drug trials are large by device trial standards, greater scientific knowledge is always acquired after the drug, device, or biologic has been used by millions of patients.

Patient safety must be the foremost concern of the FDA. Current regulations do not require sufficient disclosure to consumers of the health risks of prescription medications. The AAOS/AAHKS support a more comprehensible way to disclose important risk information. Broadcast advertisements should deliver risk information at the same speed as benefit information and print advertising should use the same font size for both risk and benefit information. A size ten font or larger should be used in print advertising. The AAOS/AAHKS are aware that the FDA is drafting a guidance document on the presentation of risk information of DTC advertising for industry. We encourage the continued development of the guidance and look forward to reviewing it during the public comment period.

**AAOS/AAHKS SUPPORT A PROHIBITION ON DTC ADVERTISING AND MARKETING OF RESTRICTED MEDICAL PRODUCTS TO CHILDREN**

The DTC advertising and marketing of restricted medical products to children is completely inappropriate and should be expressly prohibited by the FDA. Advertisements for an acne medication, Differin (adapalene), were broadcast on

MTV and the Internet and directed teenagers to receive free music downloads for varying levels of cooperation. Larger downloads (of up to ten free music downloads) were available for teens who successfully refilled their Differin prescription. Teens must have the cooperation of their parents and a physician to acquire the prescription legally. Nevertheless, Differin is readily available on the Internet and can be acquired from a pharmacy in Canada, which may be suspect to its authenticity, according to previous FDA investigations. This example highlights the interference that DTC advertising has on the physician-patient relationship. Moreover, it also highlights a more egregious affront to the principles of informed consent by advertising and marketing directly to children without the counsel or approval of their parents. This practice should be terminated immediately.

#### **AAOS/AAHKS SUPPORT MORE RESEARCH ON THE EFFECTS OF DTC ADVERTISING AND MARKETING OF RESTRICTED MEDICAL PRODUCTS**

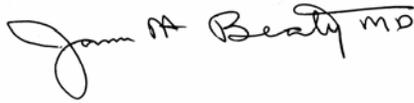
The AAOS/AAHKS support continued research on physician and public opinions of DTC advertising and the effects on the physician-patient relationship. More research is needed in a variety of areas on DTC advertising and marketing. In particular, more research is needed on the patient perceptions of medical device advertising and marketing. While a significant body of research is accruing on the effects of DTC drug advertising, DTC medical device advertising research is lacking.

Additional research is also needed on cognitive behaviors, information processing, and psychological reasoning. Findings from such research should be utilized in the design of future advertisements, such as grouping material together, or “chunking,” and decreasing the speed of delivery of risk information at the end of broadcast advertisements.

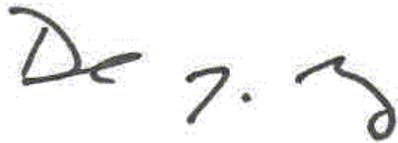
#### **CONCLUSION**

The AAOS/AAHKS encourage patients and their families to obtain and understand evidence-based health information and services. Further, we encourage patients to work with health care practitioners to develop shared decision-making for treatments that promote cost-effective health care. To that end, the AAOS/AAHKS look forward to working with the FDA in its efforts to regulate safe and effective medical therapies and their promotions.

Sincerely,



James H. Beaty, MD  
AAOS President



Daniel J. Berry, MD  
AAHKS President

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<sup>1</sup> Food and Drug Administration. Guidance for Industry: Consumer Directed Broadcast Advertisements. Division of Drug Marketing, Advertising and Communications, Aug.1999. Available at: <http://www.fda.gov/cder/guidance/1804fnl.htm>.

<sup>2</sup> Food and Drug Administration. Guidance for Industry: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements, Consumer-Directed Broadcast Advertising of Restricted Devices, "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms, Division of Drug Marketing, Advertising and Communications, Feb. 2004. Available at: <http://www.fda.gov/cder/ddmac/lawsregs.htm>

<sup>3</sup> Weissman JS, Blumenthal D, Silk AJ, Newman M, Zapert K, Leitman R, Feilbermann S. Physicians Report on Patient Encounters Involving Direct-To-Consumer Advertising. Health Affairs; April 2004: W4-219-233.

<sup>4</sup> Aikin KJ, Swasy JL, Braman AC. Food and Drug Administration. Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs- Summary of FDA Survey Research Results. Center for Drug Evaluation and Research, Nov. 2004. Available at: <http://fda.gov/cder/ddmac/Final%20Report/DTCsurvey%20Materialsb2.pdf>

<sup>5</sup> U.S. General Accounting Office. Prescription Drugs- FDA Oversight of Direct-to-Consumer Has Limitations. GAO-03-177, Oct. 2002.

<sup>6</sup> Ma, J, Stafford, RS, Cockburn, IM, Finkelstein, SN. A Statistical Analysis of the Magnitude and Composition of Drug Promotion in the United States in 1998. Clinical Therapeutics 25(5):1503-17, 2003.

<sup>7</sup> Impact of Direct-to-Consumer Advertising on Prescription Drug Spending. Kaiser Family Foundation. June 2003.

<sup>8</sup> Ibid, GAO-03-177.

<sup>9</sup> U.S. Government Accountability Office. 21<sup>st</sup> Century Addressing Long-Term Fiscal Challenges Must Include a Re-examination of Mandatory Spending. GAO-06-456T, Feb. 15, 2006.

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<sup>10</sup> Kutner, M, Greenberg, E, Jin, Y, Boyle, B, Hsu, Y, Dunleavy, E. Literacy in Everyday Life: Results from the 2003 National Assessment of Adult Literacy. April 2007. US Department of Education, NCES 2007-480.

<sup>11</sup> Kravitz RL, Epstein RM, Feldman MD, et.al. Influence of patient's requests for direct-to-consumer advertised antidepressants: a randomized controlled trial. *Journal of the American Medical Association* 2005;293:1995-2002.

<sup>12</sup> Spence MM, Teleki SS, Cheetham TC, Schweitzer SO, Millares M. Direct-to-Consumer Advertising of COX-2 Inhibitors: Effect on Appropriateness of Prescribing. *Medical Care Research and Review*. Vol.62 Oct. 2005, 544-559.

<sup>13</sup> Bozic, KJ, Smith, AR, Hariri, S, Adeoye, S, Gourville, J, Maloney, WJ, Parsley, B, Rubash, HE: The 2007 ABJS Marshall Urist Award: The Impact of Direct-to-Consumer Advertising in Orthopaedics. *Clinical Orthopaedics and Related Research*, May 2007;458:202-19.

<sup>14</sup> Department of Health & Human Services. Statement of Rachel E. Berman, MD, MPH before the Special Committee on Aging, US Senate, Sept. 29, 2005.