American Academy of Orthopaedic Surgeons®

AAOS American Association of Orthopaedic Surgeons®

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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), representing over 19,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the open public hearing "Consumer-Directed Promotion of Regulated Medical Products" [Docket No. 2005N-0354]. The Academy appreciates the efforts of the FDA to facilitate the hearing in a transparent manner in which stakeholders were invited to present their perspectives in a public forum.

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

The AAOS has 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 To date, the FDA issued a draft guidance document in 1997 and a final guidance in 1999[1] on consumer-directed broadcast advertisements requiring that advertising for medical products must not be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.[2]

The Academy continues 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. An AAOS Fellow is currently assessing data from a survey on DTC advertising in the orthopaedic community; the Academy eagerly awaits the results as there is no published literature on the impact of DTC on orthopaedics to date.

The Academy supports the FDA's investigation into regulatory interpretations of DTC promotions in their efforts to protect the public health. The AAOS continues to examine DTC and its subsequent effects on the physician-patient relationship and believes 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 Academy will limit its comments to the following:

- DTC advertising and marketing may have positive consequences;
- Patient education is vital to public health;
- DTC advertising and marketing have negative consequences;
- AAOS encourages the FDA to reorganize their internal processes and structure;
- AAOS supports the efforts of the FDA to refine their regulatory authority for DTC advertised medical products;
- AAOS supports a prohibition on DTC advertising and marketing of restricted medical products to children; and
- AAOS supports more research on the effects of DTC advertising and marketing of restricted medical products.

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.[3]

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 holds 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 eleven 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 ethic groups in content knowledge and surgical rates, and that these underutilized therapies could greatly enhance the quality of life. The Academy realizes 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 willing 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.[4]

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.[5] DTC advertising is relegated to a concentrated subset of medications which tend to be the best selling drugs[6] with the top ten drugs accounting for 36 percent of all DTC advertising spending in 2001.[7] According to a 2002 Government Accountability Office report, DTC advertising increases prescription drug sales and utilization.[8] 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 Budget Committee of the House of Representatives, listed health care expenditures as the biggest driver of the long-term fiscal challenge facing this nation.[9] In light of Medicare Part D benefits, the cost-effectiveness of pharmaceutical medications is particularly important for long-term fiscal considerations.

The AAOS believes that the DTC marketing of restricted medical products is creating a distorted market and supports greater restraint from industry and greater oversight from the FDA. The Academy believes that DTC 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 are restrained in their approach to treatment and only use a surgical option when more conservative treatments have failed.

Information is not comprehensible and unbalanced

Many advertisements are incomprehensible to the American public which typically reads at an eighth grade reading level. 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 is 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.[10] 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).[11] 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 potential benefits of DTC advertising of empowering patients with information regarding their health and encouraging patients to seek treatment,

preliminary results from the unpublished orthopaedic study suggest significant issues. Preliminary findings relate that almost 90 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 increased the length of office visits and created friction between doctors and patients. Over 80 percent of respondents believed that DTC advertising had an overall negative impact on their practice and their relationship with patients. The AAOS will submit the findings of this orthopaedic study when they become publicly available.

AAOS ENCOURAGES THE FDA TO REORGANIZE THEIR INTERNAL PROCESSES AND STRUCTURE

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.[12] While we commend the hardworking staff at DDMAC, it is obvious that they are operating with inadequate resources. The Academy encourages greater staff allocations to DDMAC for review and oversight of promotional materials. Furthermore, since the FDA does not review the content of advertising prior to marketing, many violative ads have completed their promotional runs before the FDA has proceeded with an enforcement action.

The AAOS acknowledges that the DDMAC prioritizes broadcast advertisements as their most urgent review. Given that the potential for harm is significantly greater for this type of advertising, the Academy encourages the FDA to add more review staff for broadcast advertisements. Furthermore, the AAOS requests that the FDA consider regulatory amendments to increase their authority to include the review of new broadcast advertisements prior to their airdates. The Academy encourages 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.

The AAOS strongly encourages the FDA to streamline their internal processes. While it is important to provide a solid legal foundation for regulatory actions, the FDA has become encumbered in its legal review of documents. Internal processes should be more efficient with only the most important matters designated for the review of Chief Counsel. Regulatory enforcement actions, guidance document development, and rulemaking are all hampered by lengthy legal review.

AAOS SUPPORTS THE EFFORTS OF THE FDA TO THEIR REFINE REGULATORY AUTHORITY FOR DTC ADVERTISED MEDICAL PRODUCTS

As mentioned previously, the AAOS strongly supports the prior FDA review of new broadcast advertisements. While we realize this action is currently voluntary for manufacturers, the Academy supports increased regulatory authority in this area. The FDA must have greater authority to protect the public from false and misleading advertising claims. U.S. Senate Majority Leader Bill Frist, M.D. 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 acquired after the drug is marketed to 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 Academy supports 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 is 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 SUPPORTS 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 SUPPORTS MORE RESEARCH ON THE EFFECTS OF DTC ADVERTISING AND MARKETING OF RESTRICTED MEDICAL PRODUCTS

The AAOS supports 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. Additional research is 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 encourages 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 looks forward to working with the FDA in its efforts to regulate safe and effective medical therapies and their promotions.

Sincerely,

Stuart L. Weinstein, MD
AAOS President

[1] 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.

[2] 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

[3] 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.

[4] 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

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

[6] 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.

[7] Impact of Direct-to-Consumer Advertising on Prescription Drug Spending. Kaiser Family Foundation. June 2003.

[8] Ibid, GAO-03-177.

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

[10] 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.

[11] 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.

[12] Department of Health & Human Services. Statement of Rachel E. Berman, MD, MPH before the Special Committee on Aging, US Senate, Sept. 29, 2005.