

Family Medicine Updates



From the American Academy
of Family Physicians

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AAFP SUPPORTS IMPROVEMENT, NOT BAN, ON DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADS

The media were abuzz in recent months about a study on direct-to-consumer advertising that appeared in the January/February 2007 issue of *Annals of Family Medicine*.

The study, "Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising" by Dominick Frosch, PhD, of the Department of Medicine at the University of California, Los Angeles, et al., examined TV commercials that directly targeted consumers regarding prescription medications. Among its conclusions: "The ads have limited educational value and may oversell the benefits of drugs in ways that might conflict with promoting population health." The authors based the study on advertisements that aired over 4 consecutive weeks in 2004.

So what's the problem? The 2004 ads were "old school" by the time the study was published in 2007. The study's conclusions don't reflect DTC advertising today.

In 2005, the Pharmaceutical Research and Manufacturers of America (PhRMA) issued its guiding principles on direct-to-consumer ads. The voluntary principles went into effect in January 2006.

Because the Frosch study was based on old advertisements, it reached conclusions that are now outdated. For example: "No ads mentioned lifestyle change as an alternative to products," the article concluded. However, the new guiding principles state that ads should include information about "other options such as diet and lifestyle changes where appropriate for the advertised condition."

The study also said the ads provided limited information about causes of a disease or who may be at risk. The guidelines now encourage companies to promote health and disease awareness as part of their DTC advertising.

The Frosch study did not call for banning DTC ads. Neither did the lead author in ensuing media

coverage, including a story in the February 11, 2007, *Atlanta Journal-Constitution*. In that story, Frosch was quoted as saying that the ads should be changed to include "more open acknowledgement of other treatment options, and talk about lifestyle options. There's room for a lot of improvement."

Yet such a ban is being discussed in the media and elsewhere. It's interesting to note that the Frosch study criticized DTC ads for preying on consumers' emotions. But the call for a ban sometimes appeals to emotion, too.

The First Amendment protects free speech, including commercial speech. "Commercial speech is protected from unwarranted government regulation," the U.S. Supreme Court has held. Even if Congress were to impose such a ban, it would be unlikely to pass Constitutional muster.

In 2006 the AAFP Congress of Delegates reviewed the Academy's policy on DTC advertising. The report to the Congress included an extensive review of the scientific evidence on the impact of DTC advertising on patient care, cost and safety as well as physician and patient behavior.¹ More than 75 reference sources were examined. The report demonstrated that there are at least 2 sides to the issue of DTC, and many gray areas in between. While there is concern that some DTC advertisements "oversell the benefits of medications while underselling the risks," to quote the report, there was also evidence that DTC advertising "improves patient care and safety by educating patients about new treatments and raising awareness of conditions that are often underdiagnosed and undertreated."

This doesn't mean that there are no remaining problems with DTC advertising. But progress is being made. FDA officials have made public statements indicating that DTC ads have tended to be more educational and informative since the principles took effect, and that companies are indeed submitting new DTC television ads to the FDA for review before broadcast.

The industry intends to be held accountable for improvements in the advertisements. The principles call for an independent review panel, whose members were announced in April 2006, and for periodic public reports on compliance.

PhRMA also has asked the AAFP to review the guiding principles and offer suggestions for improvement. This will give the Academy the perfect opportunity to encourage PhRMA to follow the AAFP's own policy on DTC advertising—a policy that does not call for a ban on DTC ads. That policy, which was reaf-

firmed by the AAFP Congress of Delegates last year, reads as follows:

The AAFP supports efforts by manufacturers of prescription pharmaceuticals, nonprescription medications, health care devices and health-related products and services to provide general health information to the public. At the same time, the AAFP urges that any direct-to-consumer advertising of prescription drugs by pharmaceutical companies be based on disease state only, without mention of a specific drug by name. AAFP believes direct-to-consumer advertising of these products and services is acceptable when the following conditions are met:

- Advertisements must conform to applicable laws, including FDA and/or FTC guidelines.
- Advertisements should be labeled as such.
- Information should be accurate, balanced, objective, and complete, not false or misleading, and should not promote unhealthy or unsafe practices.
 - If specific properties or indications are mentioned, then negative or adverse reactions and effects should likewise be mentioned, in a manner that is easily accessible and understood by the consumer.
 - Advertisements should not promote the use of products that have addictive or abuse potential.
 - If advertisements direct the consumer to a physician, referral should be to the consumer's family or personal physician. The AAFP considers it inappropriate and unethical for an advertiser to act as a referring agent, due to the consumer's lack of awareness of any potential conflict of interest associated with such a referral.

I should acknowledge here that the AAFP receives money from the pharmaceutical industry, including publication advertising revenue and support for AAFP meetings. The percentage of revenue coming from pharmaceutical firms has decreased over the past five years, caused in part by the AAFP's decision to cultivate other sources of revenue.

Finally, the AAFP supports the editorial independence of the *Annals of Family Medicine* in deciding to run the Frosch study. The *Annals* needs to be free of organizational or political pressure from its parent organizations in choosing what to publish and to let those decisions be based solely on the quality of the science, the rigor of external peer review, and editorial judgment. Clearly, editors saw value in the study—and there is great value in examining the health messages Americans receive via DTC ads.

In fact, here's hoping that researchers will conduct additional studies of DTC commercials—looking this time at ads created in the current advertising environment and under the industry's own guidelines. Further research and discussion can only benefit all parties in the effort to educate consumers responsibly.

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Reference

1. American Academy of Family Physicians Congress of Delegates. Board of Directors Report R to the 2006 AAFP Congress of Delegates. 2006; 99-103. Available at: <http://www.aafp.org/online/en/home/aboutus/theaafp/congress/transact06.mem.html>.



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MAINTENANCE OF CERTIFICATION UPDATE

The ABFM is pleased to announce as of December 31, 2006, over 9,000 of the Diplomates who certified or recertified in 2003 successfully met the deadline of completing their Stage 1 requirements for Maintenance of Certification for Family Physicians (MC-FP). By completing these requirements, these Diplomates are eligible to remain on track for the 3-year extension of their current certificate, creating a 10-year certificate. The 2003 Diplomates are the first to complete Stage 1 and set an important precedent for the next several groups of Diplomates. The first 3-year stage of the MC-FP process includes completing either 3 Part II Modules (SAMs), or 2 Part II Modules and 1 Part IV Module (PPM or approved alternate).

Stage 2 requirements, which the 2003 cohort must complete by December 31, 2009, includes 2 Part II Modules (SAMs) and 1 Part IV Module (PPM or approved alternate). After successfully completing these requirements, Diplomates will earn the 3-year extension to their 7-year certificate. These requirements may be completed anytime prior to the deadline; however, the 10-year certificate will not be mailed to the Diplomates until the end of Stage 2 (December 31, 2009). For those Diplomates who have completed their Stage 2 requirements, the ABFM Web site will immediately indicate the 3-year extension on their certificate upon completion.

The Diplomates who certified or recertified in 2004, and who began MC-FP in 2005, must complete their Stage 1 requirements by December 31, 2007. To date, over 7,500 of the 2004 cohort have completed at least 1 SAM. As with the 2003 cohort, the Stage 1 requirements are the same: either 3 Part II Modules (SAMs), or 2 Part II Modules and 1 Part IV Module (PPM or approved alternate).

Diplomates who certified or recertified in 2005 have until December 31, 2008 to complete Stage 1 requirements. For this, and all subsequent groups of