

FDA Finds More Promotion Violations in 2009

The FDA sent 41 enforcement letters to drug companies in 2009, almost doubling the number (21) of enforcement letters sent in 2008 to address drug promotion violations. (Note that 2009 was the first year of the Obama Administration.) And the agency kept that pace with eight violation letters in January 2010.

Tom Abrams, director of FDA's Division of Drug Marketing, Advertising and Communication (DDMAC), told Reuters, "We're trying to get the point across to industry that we want them to comply with the law because it affects public health. If you don't comply with the law, we are going to take action. We are not going to tolerate having consumers or healthcare professionals misled."

Among the 41 violation letters, 24 addressed consumer promotional materials that were disseminated in 2009. The others addressed promotional materials intended for healthcare professionals, or other violations. In March 2009, DDMAC issued 14 violation letters related to sponsored links that appear with search-engine results. This action led to a special public hearing, held in November, at which the agency asked for comments from industry about social media and online promotion. Abrams also noted in the Reuters interview that the agency has streamlined its procedures as a way to issue violation letters more quickly.



More Dollars Earmarked for New Media Channels



A recent survey of leading advertisers found that marketers are likely to continue shifting their budgets to newer digital media options over the next few years. According to the Forrester Research/Association of National Advertisers survey, the beneficiaries of this shift will be social media, Web advertising and search. Among the respondents, 77 percent indicated they planned to shift TV dollars to social media this year, 73 percent are planning to move funds to online ads and 59 percent expect to spend more on search-engine marketing. At the same time, only 15 percent of the respondents could foresee shifting budget to such traditional media as radio, outdoor, magazines or newspapers.

The data covered 104 U.S. advertisers with almost \$14 billion in measured media spending (companies such as GlaxoSmithKline, Kraft and State Farm). The silver lining in the findings for television is that the percentage of budget that marketers have earmarked for TV in 2010 held steady at 41 percent of the overall budget, the same percentage as the prior year. However, almost two of three respondents said they viewed television advertising as becoming less effective because of ad clutter. Interestingly, 82 percent of respondents said they are interested in ratings for individual commercials, according to a Media Post report of the survey's findings.

Internet Health-info Searchers Opt for Video

Almost one-half of all consumers who use the Internet to search for pharmaceutical information are including online health videos in their search, according to a study by Manhattan Research. In addition, the study found that online health video drives action among this segment, with almost three-quarters of consumers doing additional research after watching an online health video. These findings are in the firm's ePharma Consumer v9.0 study.

"The growing health video audience represents a strong opportunity for DTC marketers, particularly because this media format leads to considerable post-visit action," Monique Levy, a senior director of research at Manhattan Research, said. "Understanding what kind of health videos to develop, and which Web sites or online channels to put them on, however, is critical to success."



Finally, Some Good News — Five Blockbusters on the Horizon



Barrons.com, in collaboration with doctors and industry experts, has identified five potential blockbuster drugs coming in 2010: Victoza, Provenge, Qnexa, Prolia and Xarelto. Victoza and Prolia were selected for the 2009 list, but “hit snags” with FDA approval, Barron’s reported. (New drugs often are the lifeblood of the advertising business, as marketers seek to build awareness with new consumer advertising and education efforts – so a raft of new drugs could be a boon to the industry.)

Victoza, a Novo Nordisk diabetes treatment, could reach \$2 billion in annual sales by 2015, according to Mehta Partners. Experts anticipate Victoza’s success because, unlike insulin and other older diabetes drugs, it helps patients lose weight and avoid hypoglycemia. Provenge is Dendreon’s prostate cancer treatment that is produced to create an individualized vaccine, Barron’s reported. Decision Resources estimated annual sales of \$1 billion-plus by 2018.

Obesity treatment Qnexa, manufactured by Vivus, has shown the most success among the experimental weight-loss drugs, with patients losing an average of 15 percent of body mass. Despite safety concerns, clinical trials haven’t detected major problems. Sales could top \$1.1 billion by 2015, according to Jefferies & Co. FDA rejected Xarelto last year and Johnson & Johnson and Bayer must resubmit the application. The blood thinner is predicted to reach sales of \$1.5 billion or \$2.3 billion by 2015, according to Mehta Partners and Barclays Capital, respectively. Xarelto, which is said to rival Coumadin, also is being tested on atrial fibrillation, acute coronary syndrome and patients with a history of blood clots.

Amgen has submitted more information, as requested by FDA, for Prolia, a twice-yearly osteoporosis injection. An FDA advisory panel has suggested limited uses for Prolia, which is currently viewed as a preventative and treatment for postmenopausal osteoporosis and bone loss in prostate and breast-cancer patients undergoing hormone therapy. Mehta Partners predicts sales potentially totaling \$4.5 billion by 2017.

Judges Select Winners, Finalists in DTC National Ad Awards

A panel of five judges convened at the DTC Perspectives’ offices in mid-winter to review the entries in the 2010 DTC National Advertising Awards competition. The judges discussed, debated and determined the top three finishers in categories such as integrated marketing, point-of-care and disease education campaign, and they selected the 10 finalists in the branded print and branded television categories. (Delegates at the DTC National will vote on the 10 finalists in the branded print, TV categories, as they have in past years.) The DTC National Ad Awards dinner will be held April 8, as part of the DTC National, April 7-9, at the J.W. Marriott in Washington, D.C.



The judges in the 2010 DTC National Ad Awards are (from left) Frank Chipman of Millward Brown, Fred Church of IPSOS Vantis, Mark Einhorn of MVRG, Fariba Zamaniyan of Nielsen IAG and Marc Jaffe of VMS.